CHAIRMAN RAND PAUL, M.D.

U.S. SENATE COMMITTEE ON HOMELAND SECURITY & GOVERNMENTAL AFFAIRS

PUBLIC RELEASE

THE READING ROOM

Records relating to the Committee's ongoing government-wide investigation into COVID-19 origins and taxpayer-funded life sciences research.

> The Committee is releasing these records to advance its investigation and the public's interest in government transparency and accountability. The records in this volume were produced to the Committee in the course of that investigation.

Released by Chairman Rand Paul

From: "Sanders, Ashley (NIH/OD) [E]" <[redacted]@nih.gov>
To: "Miller, David A. (NK) (FBI)" <[redacted]@fbi.gov>
Cc: "Stemmy, Erik (NIH/NIAID) [E]" <[redacted]@nih.gov>, "Shannon, Mike (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: FW: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Date: Fri, 22 May 2020 15:17:48 -0400
Importance: Normal
Attachments: SF_424_AI110964.docx

Hi David,

In preparation for our call on Tuesday, Erik (cc'd) has provided responses to your initial questions below (also attached).

Hope you have a great holiday weekend!
Ashley

Ashley M. Sanders, MPS
Senior Program Investigations Officer
NIH, OMA, Division Program Integrity
6011 Executive Blvd.
Rockville, Maryland 20852
Office: [redacted]
Cell: [redacted]
[redacted]@nih.gov

SF 424 AI110964-06 (received date 11/05/2018)
Both SF 424s seem to be describing "gain of function" experiments. On page 192 of SF 424 AI110964-06 (received date 11/05/2018) under P3CO Research, it indicates they are conducting gain of function of SARSr-CoV.

The funding pause on gain-of-function (GoF) experiments was in place from 2014-2017, and explicitly involved work reasonably anticipated to enhance the transmissibility or pathogenicity of influenza, MERS-CoV, or SARS-CoV. As such, that policy would not have applied to SARS-related coronaviruses (SARSr-CoV). The replacement policy, Potential Pandemic Pathogen Care and Oversight (P3CO), requires additional review and oversight of experiments that are anticipated to increase a potential pandemic pathogen's transmissibility or pathogenicity *in humans*. The viruses created under this award are chimeric bat viruses, which generally would not be anticipated to cause enhanced disease or transmission in people. When evaluating experiments for potential GoF or P3CO we determine the likelihood of altering one of these attributes compared to the wild-type or circulating viral strain.

Were they also conducting Seemless Cloining and Assembly? From a review of their experimental details, it looks as if they were generating recombinant DNA of the viruses using WIV1 as the backbone but I could not determine if they were using Seemless Cloning techniques.

I'm not aware of them using seamless cloning. Standard techniques for investigators in this field are to create cDNA molecular clones, which are then expressed in cull culture.

I could not determine exactly where they were conducting these gain of function experiments. I know UNC-Chapel Hill has done these but within the document, I could not determine where this was occurring. Do you know where this was occurring?

GoF experiments were not conducted as part of this award. While chimeric viruses were created via this award, they would not be considered GoF since the results did not confer attributes that were not already exhibited by the wild type versions of the viruses. For example, expressing the spike protein of SARS-CoV in the WIV-1 backbone did not increase the pathogenicity of WIV-1 beyond that of SARS-CoV. This award did not support work to manipulate CoV genomes or create chimeric viruses at Wuhan Institute of Virology; such work was performed at UNC-CH.

It then appears that the recombinant DNA of the virus was then injected into humanized mice. However, again I couldn't determine where this occurred or was to occur. On page 187 of the same SF 424 under **"Vertebrate Animals"** it indicates that work with vertebrate animals will be conducted at Wuhan University at the School of Medicine and UNC – CH. Then under **"Laboratory Mice"** it states that lab mice will be sourced commercially by Wuhan Center for Animal Experiment at Wuhan University and that humanized mice will be bread at University of Wuhan and UNC – CH. Furthermore, the mice will be inoculated with the virus.

Recombinant viral cDNA is not directly injected into humanized mice. Rather, these molecular clones are used to grow virus in culture to create an inoculum used in infectivity studies. Both WIV and UNC-CH performed studies with molecular clones, which included infecting mice with the resulting recombinant viruses.

Under **"UNC Facilities where selected agents to be used"** it continues with all mouse studies at UNC-CH will be performed…." However, on page 200 of the same SF 424 there is a letter from UNC – CH stating "The work to be performed by UNC-CH does not include animal and/or human research subjects." I know that was a lot of information but where exactly was the experimentation of injecting the humanized mice with the recombinant DNA occurring?

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On page 119 of AI110964-01 under "**C3d) Humanized mouse *in vivo* infection experiments"** it states that humanized mouse in vivo experiments in humanized mice was occurring at the Wuhan Institute of Virology. I did not see the location where these gain of function experiments were being done but if the injections were occurring at WIV then was the recombinant DNA also generated at WIV? Was Seemless Cloning also being done?

This is not GoF work. The humanized mouse experiments described in C3d refer to work with *wild type* viruses isolated from wild bats. Refer to the section stating: "We will passage isolated bat-CoVs in permissive cells twice…" This is a standard virological technique to create an inoculum to infect animals. In no portion of C3d do they describe any manipulation of isolated virus, therefore this does not describe any kind of gain-of-function studies, nor does it involve the creation of any recombinant DNA or viruses. Characterization of naturally occurring viruses was *explicitly excluded* from the GoF policy. Further, the USG P3CO Policy Guidance states that "Wild-type pathogens that are circulating in or have been recovered from nature are not enhanced PPPs, regardless of their pandemic potential."

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From: "Stemmy, Erik (NIH/NIAID) [E]" </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=585133D3FA194F06AA618678B2817C22-STEMMYEJ>
To: "Sanders, Ashley (NIH/OD) [E]" <[redacted]@nih.gov>, "Linde, Emily (NIH/NIAID) [E]" <[redacted]@mail.nih.gov>
Cc: "Shannon, Mike (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Date: Thu, 21 May 2020 17:49:51 -0400
Importance: Normal
Attachments: SF_424_AI110964.docx

Hi Ashley,
Since we'll only have a short time on Tuesday I thought it might be helpful to provide the agent my responses to the original questions. There may be some misunderstanding of gain-of-function experiments, so hopefully this will clarify some things or at least provide a framework for our discussion next week.

Thanks!
Erik

p.s. I've also pasted the response directly below in case there is an issue adding an attachment to an encrypted message.

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Sent: Thursday, May 21, 2020 3:04 PM
To: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>; Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Erik,

Thank you for providing this information. We would like to set up a call with the agent as they may need additional context or have other questions. Would you be available next Tuesday around 11:30AM? I'll set up a conference line for us and send an invite.

If that time doesn't work for you, please let me know alternative times you have available.

Thank you,
Ashley

From: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Thursday, May 21, 2020 11:22 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>; Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,
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Erik

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
5601 Fishers Lane, Room 8E18
Bethesda, MD 20892-9825
Phone: [redacted]
Email: [redacted]@nih.gov

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Sent: Thursday, May 21, 2020 6:17 AM
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Hi Ashley,

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The Program Official for this grant, Dr. Stemmy, who is copied on this email, would be the most appropriate POC for these questions.

Regards,

Emily

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Wednesday, May 20, 2020 1:00 PM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Good afternoon,

We are following up on a time-sensitive request for information from the FBI. Please let us know if you are able to accommodate their request or if you can recommend a POC to address the concerns.

Thank you,
Ashley

From: Sanders, Ashley (NIH/OD) [E]
Sent: Wednesday, May 13, 2020 11:59 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Good afternoon Emily,

OMA/DPI received questions related to an FBI inquiry for the following NIAID grants: 1R01AI110964-01 through 2R01AI110964-06. The agent is requesting clarification on the details of the study, where certain aspects were performed, and whether seamless cloning techniques were used. I note you were the last official to sign off on 4/27/20.

Would you be able to provide a response to the below-captured questions and/or be available for a joint call with our office and the agent? If not, who would be the best SME on this matter? I'm sure you understand, since this is a sensitive matter, we need to maintain confidentiality and limit the touch-points within NIH. I'm happy to discuss further if you have any questions.

Thank you,
Ashley

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From: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Sent: Thursday, May 21, 2020 6:17 AM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

The Program Official for this grant, Dr. Stemmy, who is copied on this email, would be the most appropriate POC for these questions.

Regards,

Emily

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Wednesday, May 20, 2020 1:00 PM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Released by Chairman Rand Paul

Good afternoon,

We are following up on a time-sensitive request for information from the FBI. Please let us know if you are able to accommodate their request or if you can recommend a POC to address the concerns.

Thank you,
Ashley

From: Sanders, Ashley (NIH/OD) [E]
Sent: Wednesday, May 13, 2020 11:59 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

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Would you be able to provide a response to the below-captured questions and/or be available for a joint call with our office and the agent? If not, who would be the best SME on this matter? I'm sure you understand, since this is a sensitive matter, we need to maintain confidentiality and limit the touch-points within NIH. I'm happy to discuss further if you have any questions.

Thank you,
Ashley

Ashley M. Sanders, MPS
Senior Program Investigations Officer
NIH, OMA, Division Program Integrity
6011 Executive Blvd.
Rockville, Maryland 20852
Office: [redacted]
[redacted]@nih.gov

FBI Questions:

SF 424 AI110964-06 (received date 11/05/2018)
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Released by Chairman Rand Paul

From: "Sanders, Ashley (NIH/OD) [E]" <[redacted]@nih.gov>
To: "Stemmy, Erik (NIH/NIAID) [E]" <[redacted]@nih.gov>, "Linde, Emily (NIH/NIAID) [E]" <[redacted]@mail.nih.gov>
Cc: "Shannon, Mike (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Date: Fri, 22 May 2020 11:05:47 -0400
Importance: Normal
Attachments: message_v2.rpmsg

Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov) has sent you a prot

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Microsoft Corporation, One Microsoft Way, Redmond, WA 98052

Released by Chairman Rand Paul

From: "Stemmy, Erik (NIH/NIAID) [E]" </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=585133D3FA194F06AA618678B2817C22-STEMMYEJ>
To: "Sanders, Ashley (NIH/OD) [E]" <[redacted]@nih.gov>, "Linde, Emily (NIH/NIAID) [E]" <[redacted]@mail.nih.gov>
Cc: "Shannon, Mike (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Date: Thu, 21 May 2020 17:49:51 -0400
Importance: Normal
Attachments: SF_424_AI110964.docx

Hi Ashley,
Since we'll only have a short time on Tuesday I thought it might be helpful to provide the agent my responses to the original questions. There may be some misunderstanding of gain-of-function experiments, so hopefully this will clarify some things or at least provide a framework for our discussion next week.

Thanks!
Erik

p.s. I've also pasted the response directly below in case there is an issue adding an attachment to an encrypted message.

SF 424 AI110964-06 (received date 11/05/2018)
Both SF 424s seem to be describing "gain of function" experiments. On page 192 of SF 424 AI110964-06 (received date 11/05/2018) under P3CO Research, it indicates they are conducting gain of function of SARSr-CoV.

The funding pause on gain-of-function (GoF) experiments was in place from 2014-2017, and explicitly involved work reasonably anticipated to enhance the transmissibility or pathogenicity of influenza, MERS-CoV, or SARS-CoV. As such, that policy would not have applied to SARS-related coronaviruses (SARSr-CoV). The replacement policy, Potential Pandemic Pathogen Care and Oversight (P3CO), requires additional review and oversight of experiments that are anticipated to increase a potential pandemic pathogen's transmissibility or pathogenicity *in humans*. The viruses created under this award are chimeric bat viruses, which generally would not be anticipated to cause enhanced disease or transmission in people. When evaluating experiments for potential GoF or P3CO we determine the likelihood of altering one of these attributes compared to the wild-type or circulating viral strain.

Were they also conducting Seemless Cloining and Assembly? From a review of their experimental details, it looks as if they were generating recombinant DNA of the viruses using WIV1 as the backbone but I could not determine if they were using Seemless Cloning techniques.

I'm not aware of them using seamless cloning. Standard techniques for investigators in this field are to create cDNA molecular clones, which are then expressed in cull culture.

I could not determine exactly where they were conducting these gain of function experiments. I know UNC-Chapel Hill has done these but within the document, I could not determine where this was occurring. Do you know where this was occurring?

GoF experiments were not conducted as part of this award. While chimeric viruses were created via this award, they would not be considered GoF since the results did not confer attributes that were not already exhibited by the wild type versions of the viruses. For example, expressing the spike protein of SARS-CoV in the WIV-1 backbone did not increase the

pathogenicity of WIV-1 beyond that of SARS-CoV. This award did not support work to manipulate CoV genomes or create chimeric viruses at Wuhan Institute of Virology; such work was performed at UNC-CH.

It then appears that the recombinant DNA of the virus was then injected into humanized mice. However, again I couldn't determine where this occurred or was to occur. On page 187 of the same SF 424 under **"Vertebrate Animals"** it indicates that work with vertebrate animals will be conducted at Wuhan University at the School of Medicine and UNC – CH. Then under **"Laboratory Mice"** it states that lab mice will be sourced commercially by Wuhan Center for Animal Experiment at Wuhan University and that humanized mice will be bread at University of Wuhan and UNC – CH. Furthermore, the mice will be inoculated with the virus.

Recombinant viral cDNA is not directly injected into humanized mice. Rather, these molecular clones are used to grow virus in culture to create an inoculum used in infectivity studies. Both WIV and UNC-CH performed studies with molecular clones, which included infecting mice with the resulting recombinant viruses.

Under **"UNC Facilities where selected agents to be used"** it continues with all mouse studies at UNC-CH will be performed…." However, on page 200 of the same SF 424 there is a letter from UNC – CH stating "The work to be performed by UNC-CH does not include animal and/or human research subjects." I know that was a lot of information but where exactly was the experimentation of injecting the humanized mice with the recombinant DNA occurring?

I believe this to be a typographical error on the part of UNC's business office. The application describes animal work at UNC. Budget justifications and the consortium agreement also include references to this work. I believe UNC mean to say that the work "… does not include human research subjects."

SF 424 AI110964-01 (received date 06/05/2013)
In this SF 424 Aim 3 seems indicative of gain of function experimentation (**C3a** and **C3b**) although it does not use that exact term.

The receipt date of this application was June of 2013, and the term "gain-of-function" was not widely used before the USG funding pause was announced in 2014. C3a and C3b describe work using pseudovirus assays, which would not have been considered GoF as they do not involve creating full replicating viruses.

On page 119 of AI110964-01 under "**C3d) Humanized mouse *in vivo* infection experiments"** it states that humanized mouse in vivo experiments in humanized mice was occurring at the Wuhan Institute of Virology. I did not see the location where these gain of function experiments were being done but if the injections were occurring at WIV then was the recombinant DNA also generated at WIV? Was Seemless Cloning also being done?

This is not GoF work. The humanized mouse experiments described in C3d refer to work with *wild type* viruses isolated from wild bats. Refer to the section stating: "We will passage isolated bat-CoVs in permissive cells twice…" This is a standard virological technique to create an inoculum to infect animals. In no portion of C3d do they describe any manipulation of isolated virus, therefore this does not describe any kind of gain-of-function studies, nor does it involve the creation of any recombinant DNA or viruses. Characterization of naturally occurring viruses was *explicitly excluded* from the GoF policy. Further, the USG P3CO Policy Guidance states that "Wild-type pathogens that are circulating in or have been recovered from nature are not enhanced PPPs, regardless of their pandemic potential."

RPPR (AI110964-05)
Finally, in the RPPR (6/1/2017-5/31/2018) on page 28 under "**In Vivo Infection of Human ACE2 Expressing Mice with SARSr-Cov S Protein variants",** it appears to be showing the results from their gain of function experiments as described in the SF 424. This is more of less the same as the question above, but do you know where this occurred?

These are not the results of GoF experiments. The figure you reference (Fig 35) shows weight loss and lung viral titers of chimeric viruses with bat CoV (wild type WIV-1, SHC014, WIV16, and 4231) spike proteins expressed on the WIV-1 backbone. Weight loss and viral titers were comparable across all chimeras when compared to the wild type (Fig 35a, red series; Fig 35b small box pattern). There are no statistical differences reported, so the chimeric viruses have not gained any function/attribute they did not already exhibit.

Released by Chairman Rand Paul

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Thursday, May 21, 2020 3:04 PM
To: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>; Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Erik,

Thank you for providing this information. We would like to set up a call with the agent as they may need additional context or have other questions. Would you be available next Tuesday around 11:30AM? I'll set up a conference line for us and send an invite.

If that time doesn't work for you, please let me know alternative times you have available.

Thank you,
Ashley

From: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Thursday, May 21, 2020 11:22 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>; Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,
I would be happy to answer questions related to this award. Would it be best if I just addressed the comments at the end of this email thread? I'll say generally that NIAID has an extensive review process for P3CO (and formerly for GoF) and that all of this work was formally evaluated by the respective committees and determined not to be gain-of-function, nor subject to P3CO oversight. We also continually monitored the progress (until the award was terminated) for evidence of unexpected increases in viral replication.

Erik

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
5601 Fishers Lane, Room 8E18
Bethesda, MD 20892-9825
Phone: [redacted]
Email: [redacted]@nih.gov

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Sent: Thursday, May 21, 2020 6:17 AM
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Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

Released by Chairman Rand Paul

The Program Official for this grant, Dr. Stemmy, who is copied on this email, would be the most appropriate POC for these questions.

Regards,

Emily

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Importance: High

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Office: [redacted]
[redacted]@nih.gov

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Released by Chairman Rand Paul

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Released by Chairman Rand Paul

From: "Bulls, Michelle G. (NIH/OD) [E]" <[redacted]@nih.gov>
To: "Lauer, Michael (NIH/OD) [E]" <[redacted]@nih.gov>
Cc: "Bulls, Michelle G. (NIH/OD) [E]" <[redacted]@nih.gov>, "Black, Jodi (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: FW: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Date: Thu, 10 Sep 2020 12:43:04 -0400
Importance: Normal

Hi Mike,

See way down below where OMA asks for information for the OIG and FBI regarding Eco Health Alliance. Emily referred them back to you, based on the nature of their questions. This is a sticky one—and from the beginning, NIAID were told to refer these detailed questions to you given the situation. Is it okay for us to provide her with a response to send that is accurate so that OMA does not have to translate? Or would you like for her to just respond and without context, that will be tricky for OMA and will cause more questions. Let me know…

Michelle

From: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Sent: Thursday, September 10, 2020 11:44 AM
To: Bulls, Michelle G. (NIH/OD) [E] [redacted]@nih.gov>; Dean, Diane (NIH/OD) [E] [redacted]@od31em1.od.nih.gov>
Subject: FW: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Good morning,

I wanted to alert you to this request. I referred them to Mike as we have discussed and just sent the following response to their latest inquiry and will let you know if I hear more.

Thanks,

Emily

From: Linde, Emily (NIH/NIAID) [E]
Sent: Thursday, September 10, 2020 11:40 AM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

For this award the most relevant and accurate source of information is Dr. Mike Lauer, Deputy Director for Extramural Research.

Thanks,

Emily

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Thursday, September 10, 2020 10:40 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>

Released by Chairman Rand Paul

Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Hi Emily,

These questions are specific to whether or not this particular NIAID grant was terminated early or ended as per a usual course of action. I'm not clear as to why I would need to go to the Deputy Director of NIH for OER for a response to a question on decisions and grant determinations made by NIAID.

OMA properly and routinely seeks and receives information from IC's on grants and grant activity in support of audits and investigations, in accordance with Manual Chapter 1754 and 1752, as we are responsible to fully coordinate responses to OIG/FBI/DOJ etc. to support ongoing investigations. I must ensure our response is from the most relevant and accurate source of information, and answered in a timely manner.

Is there a reason these inquiries are being directed outside of the IC?

Thanks for your help,
Ashley

From: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Sent: Wednesday, September 9, 2020 3:26 PM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

Questions for that nature on this award should be referred to Dr. Mike Lauer, Deputy Director for Extramural Research.

Thanks,

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Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

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Released by Chairman Rand Paul

3. What was communicated to the PI (Dr. Daszak) and/or Ecohealth?

Please let me know if you're able to provide this information.

Thank you,
Ashley

Ashley M. Sanders, MPS
Supervisor, DPI Program Investigations
NIH, OMA, Division Program Integrity
6011 Executive Blvd.
Rockville, Maryland 20852
Office: [redacted]
Cell: [redacted]
[redacted]@nih.gov

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Sent: Thursday, May 21, 2020 5:50 PM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>; Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

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Thanks!
Erik

p.s. I've also pasted the response directly below in case there is an issue adding an attachment to an encrypted message.

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Were they also conducting Seemless Cloining and Assembly? From a review of their experimental details, it looks as if they were generating recombinant DNA of the viruses using WIV1 as the backbone but I could not determine if they were using Seemless Cloning techniques.

I'm not aware of them using seamless cloning. Standard techniques for investigators in this field are to create cDNA molecular clones, which are then expressed in cull culture.

I could not determine exactly where they were conducting these gain of function experiments. I know UNC-Chapel Hill has done these but within the document, I could not determine where this was occurring. Do you know where this was occurring?

GoF experiments were not conducted as part of this award. While chimeric viruses were created via this award, they would not be considered GoF since the results did not confer attributes that were not already exhibited by the wild type versions of the viruses. For example, expressing the spike protein of SARS-CoV in the WIV-1 backbone did not increase the pathogenicity of WIV-1 beyond that of SARS-CoV. This award did not support work to manipulate CoV genomes or create chimeric viruses at Wuhan Institute of Virology; such work was performed at UNC-CH.

It then appears that the recombinant DNA of the virus was then injected into humanized mice. However, again I couldn't determine where this occurred or was to occur. On page 187 of the same SF 424 under **"Vertebrate Animals"** it indicates that work with vertebrate animals will be conducted at Wuhan University at the School of Medicine and UNC – CH. Then under **"Laboratory Mice"** it states that lab mice will be sourced commercially by Wuhan Center for Animal Experiment at Wuhan University and that humanized mice will be bread at University of Wuhan and UNC – CH. Furthermore, the mice will be inoculated with the virus.

Recombinant viral cDNA is not directly injected into humanized mice. Rather, these molecular clones are used to grow virus in culture to create an inoculum used in infectivity studies. Both WIV and UNC-CH performed studies with molecular clones, which included infecting mice with the resulting recombinant viruses.

Under **"UNC Facilities where selected agents to be used"** it continues with all mouse studies at UNC-CH will be performed…." However, on page 200 of the same SF 424 there is a letter from UNC – CH stating "The work to be performed by UNC-CH does not include animal and/or human research subjects." I know that was a lot of information but where exactly was the experimentation of injecting the humanized mice with the recombinant DNA occurring?

I believe this to be a typographical error on the part of UNC's business office. The application describes animal work at UNC. Budget justifications and the consortium agreement also include references to this work. I believe UNC mean to say that the work "… does not include human research subjects."

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In this SF 424 Aim 3 seems indicative of gain of function experimentation (**C3a** and **C3b**) although it does not use that exact term.

The receipt date of this application was June of 2013, and the term "gain-of-function" was not widely used before the USG funding pause was announced in 2014. C3a and C3b describe work using pseudovirus assays, which would not have been considered GoF as they do not involve creating full replicating viruses.

On page 119 of AI110964-01 under "**C3d) Humanized mouse *in vivo* infection experiments"** it states that humanized mouse in vivo experiments in humanized mice was occurring at the Wuhan Institute of Virology. I did not see the location where these gain of function experiments were being done but if the injections were occurring at WIV then was the recombinant DNA also generated at WIV? Was Seemless Cloning also being done?

This is not GoF work. The humanized mouse experiments described in C3d refer to work with *wild type* viruses isolated from wild bats. Refer to the section stating: "We will passage isolated bat-CoVs in permissive cells twice…" This is a standard virological technique to create an inoculum to infect animals. In no portion of C3d do they describe any manipulation of isolated virus, therefore this does not describe any kind of gain-of-function studies, nor does it involve the creation of any recombinant DNA or viruses. Characterization of naturally occurring viruses was *explicitly excluded* from the GoF policy. Further, the USG P3CO Policy Guidance states that "Wild-type pathogens that are circulating in or have been recovered from nature are not enhanced PPPs, regardless of their pandemic potential."

RPPR (AI110964-05)

Released by Chairman Rand Paul

Finally, in the RPPR (6/1/2017-5/31/2018) on page 28 under "**In Vivo Infection of Human ACE2 Expressing Mice with SARSr-Cov S Protein variants",** it appears to be showing the results from their gain of function experiments as described in the SF 424. This is more of less the same as the question above, but do you know where this occurred?

These are not the results of GoF experiments. The figure you reference (Fig 35) shows weight loss and lung viral titers of chimeric viruses with bat CoV (wild type WIV-1, SHC014, WIV16, and 4231) spike proteins expressed on the WIV-1 backbone. Weight loss and viral titers were comparable across all chimeras when compared to the wild type (Fig 35a, red series; Fig 35b small box pattern). There are no statistical differences reported, so the chimeric viruses have not gained any function/attribute they did not already exhibit.

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Thursday, May 21, 2020 3:04 PM
To: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>; Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Erik,

Thank you for providing this information. We would like to set up a call with the agent as they may need additional context or have other questions. Would you be available next Tuesday around 11:30AM? I'll set up a conference line for us and send an invite.

If that time doesn't work for you, please let me know alternative times you have available.

Thank you,
Ashley

From: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Thursday, May 21, 2020 11:22 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>; Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,
I would be happy to answer questions related to this award. Would it be best if I just addressed the comments at the end of this email thread? I'll say generally that NIAID has an extensive review process for P3CO (and formerly for GoF) and that all of this work was formally evaluated by the respective committees and determined not to be gain-of-function, nor subject to P3CO oversight. We also continually monitored the progress (until the award was terminated) for evidence of unexpected increases in viral replication.

Erik

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
5601 Fishers Lane, Room 8E18
Bethesda, MD 20892-9825
Phone: [redacted]
Email: [redacted]@nih.gov

Released by Chairman Rand Paul

From: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Sent: Thursday, May 21, 2020 6:17 AM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

The Program Official for this grant, Dr. Stemmy, who is copied on this email, would be the most appropriate POC for these questions.

Regards,

Emily

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Wednesday, May 20, 2020 1:00 PM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Good afternoon,

We are following up on a time-sensitive request for information from the FBI. Please let us know if you are able to accommodate their request or if you can recommend a POC to address the concerns.

Thank you,
Ashley

From: Sanders, Ashley (NIH/OD) [E]
Sent: Wednesday, May 13, 2020 11:59 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Good afternoon Emily,

OMA/DPI received questions related to an FBI inquiry for the following NIAID grants: 1R01AI110964-01 through 2R01AI110964-06. The agent is requesting clarification on the details of the study, where certain aspects were performed, and whether seamless cloning techniques were used. I note you were the last official to sign off on 4/27/20.

Would you be able to provide a response to the below-captured questions and/or be available for a joint call with our office and the agent? If not, who would be the best SME on this matter? I'm sure you understand, since this is a sensitive matter, we need to maintain confidentiality and limit the touch-points within NIH. I'm happy to discuss further if you have any questions.

Thank you,
Ashley

Released by Chairman Rand Paul

Ashley M. Sanders, MPS
Senior Program Investigations Officer
NIH, OMA, Division Program Integrity
6011 Executive Blvd.
Rockville, Maryland 20852
Office: [redacted]
[redacted]@nih.gov

FBI Questions:

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Released by Chairman Rand Paul

From: "Lauer, Michael (NIH/OD) [E]" <[redacted]@nih.gov>
To: "Bulls, Michelle G. (NIH/OD) [E]" <[redacted]@nih.gov>
Cc: "Black, Jodi (NIH/OD) [E]" <[redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: Re: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Date: Fri, 11 Sep 2020 04:36:36 -0400
Importance: Normal

Thanks Michelle – I agree with your plan we should handle this. We might also want to include OGC / Anna Jacobs in our conversations with OMA.

Best, Mike

Note: This conversation is restricted, so you might not be able to cut or copy from it. See the information above the To line for more details. Also, while the conversation is restricted, the conversation owner can send the message to other people.

From: "Bulls, Michelle G. (NIH/OD) [E]" [redacted]@nih.gov>
Date: Thursday, September 10, 2020 at 12:43 PM
To: "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>
Cc: "Bulls, Michelle G. (NIH/OD) [E]" [redacted]@nih.gov>, "Black, Jodi (NIH/OD) [E]" [redacted]@nih.gov>
Subject: FW: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Mike,

See way down below where OMA asks for information for the OIG and FBI regarding Eco Health Alliance. Emily referred them back to you, based on the nature of their questions. This is a sticky one—and from the beginning, NIAID were told to refer these detailed questions to you given the situation. Is it okay for us to provide her with a response to send that is accurate so that OMA does not have to translate? Or would you like for her to just respond and without context, that will be tricky for OMA and will cause more questions. Let me know…

Michelle

From: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Sent: Thursday, September 10, 2020 11:44 AM
To: Bulls, Michelle G. (NIH/OD) [E] [redacted]@nih.gov>; Dean, Diane (NIH/OD) [E] [redacted]@od31em1.od.nih.gov>
Subject: FW: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Good morning,

I wanted to alert you to this request. I referred them to Mike as we have discussed and just sent the following response to their latest inquiry and will let you know if I hear more.

Thanks,

Emily

From: Linde, Emily (NIH/NIAID) [E]
Sent: Thursday, September 10, 2020 11:40 AM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>

Released by Chairman Rand Paul

Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

For this award the most relevant and accurate source of information is Dr. Mike Lauer, Deputy Director for Extramural Research.

Thanks,

Emily

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Sent: Thursday, September 10, 2020 10:40 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
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Ashley M. Sanders, MPS
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Released by Chairman Rand Paul

On page 119 of AI110964-01 under "**C3d) Humanized mouse *in vivo* infection experiments"** it states that humanized mouse in vivo experiments in humanized mice was occurring at the Wuhan Institute of Virology. I did not see the location where these gain of function experiments were being done but if the injections were occurring at WIV then was the recombinant DNA also generated at WIV? Was Seemless Cloning also being done?

This is not GoF work. The humanized mouse experiments described in C3d refer to work with *wild type* viruses isolated from wild bats. Refer to the section stating: "We will passage isolated bat-CoVs in permissive cells twice…" This is a standard virological technique to create an inoculum to infect animals. In no portion of C3d do they describe any manipulation of isolated virus, therefore this does not describe any kind of gain-of-function studies, nor does it involve the creation of any recombinant DNA or viruses. Characterization of naturally occurring viruses was *explicitly excluded* from the GoF policy. Further, the USG P3CO Policy Guidance states that "Wild-type pathogens that are circulating in or have been recovered from nature are not enhanced PPPs, regardless of their pandemic potential."

RPPR (AI110964-05)
Finally, in the RPPR (6/1/2017-5/31/2018) on page 28 under "**In Vivo Infection of Human ACE2 Expressing Mice with SARSr-Cov S Protein variants",** it appears to be showing the results from their gain of function experiments as described in the SF 424. This is more of less the same as the question above, but do you know where this occurred?

These are not the results of GoF experiments. The figure you reference (Fig 35) shows weight loss and lung viral titers of chimeric viruses with bat CoV (wild type WIV-1, SHC014, WIV16, and 4231) spike proteins expressed on the WIV-1 backbone. Weight loss and viral titers were comparable across all chimeras when compared to the wild type (Fig 35a, red series; Fig 35b small box pattern). There are no statistical differences reported, so the chimeric viruses have not gained any function/attribute they did not already exhibit.

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Thursday, May 21, 2020 3:04 PM
To: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>; Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Erik,

Thank you for providing this information. We would like to set up a call with the agent as they may need additional context or have other questions. Would you be available next Tuesday around 11:30AM? I'll set up a conference line for us and send an invite.

If that time doesn't work for you, please let me know alternative times you have available.

Thank you,
Ashley

From: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Thursday, May 21, 2020 11:22 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>; Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,
I would be happy to answer questions related to this award. Would it be best if I just addressed the comments at the end of this email thread? I'll say generally that NIAID has an extensive review process for P3CO (and formerly for GoF) and that all of this work was formally evaluated by the respective committees and determined not to be gain-of-function, nor

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subject to P3CO oversight. We also continually monitored the progress (until the award was terminated) for evidence of unexpected increases in viral replication.

Erik

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
5601 Fishers Lane, Room 8E18
Bethesda, MD 20892-9825
Phone: [redacted]
Email: [redacted]@nih.gov

From: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Sent: Thursday, May 21, 2020 6:17 AM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

The Program Official for this grant, Dr. Stemmy, who is copied on this email, would be the most appropriate POC for these questions.

Regards,

Emily

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Wednesday, May 20, 2020 1:00 PM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Good afternoon,

We are following up on a time-sensitive request for information from the FBI. Please let us know if you are able to accommodate their request or if you can recommend a POC to address the concerns.

Thank you,
Ashley

From: Sanders, Ashley (NIH/OD) [E]
Sent: Wednesday, May 13, 2020 11:59 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

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Good afternoon Emily,

OMA/DPI received questions related to an FBI inquiry for the following NIAID grants: 1R01AI110964-01 through 2R01AI110964-06. The agent is requesting clarification on the details of the study, where certain aspects were performed, and whether seamless cloning techniques were used. I note you were the last official to sign off on 4/27/20.

Would you be able to provide a response to the below-captured questions and/or be available for a joint call with our office and the agent? If not, who would be the best SME on this matter? I'm sure you understand, since this is a sensitive matter, we need to maintain confidentiality and limit the touch-points within NIH. I'm happy to discuss further if you have any questions.

Thank you,
Ashley

Ashley M. Sanders, MPS
Senior Program Investigations Officer
NIH, OMA, Division Program Integrity
6011 Executive Blvd.
Rockville, Maryland 20852
Office: [redacted]
[redacted]@nih.gov

FBI Questions:

SF 424 AI110964-06 (received date 11/05/2018)
Both SF 424s seem to be describing "gain of function" experiments. On page 192 of SF 424 AI110964-06 (received date 11/05/2018) under P3CO Research, it indicates they are conducting gain of function of SARSr-CoV. Were they also conducting Seemless Cloining and Assembly? From a review of their experimental details, it looks as if they were generating recombinant DNA of the viruses using WIV1 as the backbone but I could not determine if they were using Seemless Cloning techniques. I could not determine exactly where they were conducting these gain of function experiments. I know UNC-Chapel Hill has done these but within the document, I could not determine where this was occurring. Do you know where this was occurring?
It then appears that the recombinant DNA of the virus was then injected into humanized mice. However, again I couldn't determine where this occurred or was to occur. On page 187 of the same SF 424 under **"Vertebrate Animals"** it indicates that work with vertebrate animals will be conducted at Wuhan University at the School of Medicine and UNC – CH. Then under **"Laboratory Mice"** it states that lab mice will be sourced commercially by Wuhan Center for Animal Experiment at Wuhan University and that humanized mice will be bread at University of Wuhan and UNC – CH. Furthermore, the mice will be inoculated with the virus. Under **"UNC Facilities where selected agents to be used"** it continues with all mouse studies at UNC-CH will be performed…." However, on page 200 of the same SF 424 there is a letter from UNC – CH stating "The work to be performed by UNC-CH does not include animal and/or human research subjects." I know that was a lot of information but where exactly was the experimentation of injecting the humanized mice with the recombinant DNA occurring?

SF 424 AI110964-01 (received date 06/05/2013)
In this SF 424 Aim 3 seems indicative of gain of function experimentation (**C3a** and **C3b**) although it does not use that exact term. On page 119 of AI110964-01 under "**C3d) Humanized mouse *in vivo* infection experiments"** it states that humanized mouse in vivo experiments in humanized mice was occurring at the Wuhan Institute of Virology. I did not see the location where these gain of function experiments were being done but if the injections were occurring at WIV then was the recombinant DNA also generated at WIV? Was Seemless Cloning also being done?

RPPR (AI110964-05)
Finally, in the RPPR (6/1/2017-5/31/2018) on page 28 under "**In Vivo Infection of Human ACE2 Expressing Mice with SARSr-Cov S Protein variants",** it appears to be showing the results from their gain of function experiments as described

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in the SF 424. This is more of less the same as the question above, but do you know where this occurred?

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From: "Lauer, Michael (NIH/OD) [E]" <[redacted]@nih.gov>
To: "Sanders, Ashley (NIH/OD) [E]" <[redacted]@nih.gov>
Cc: "Shannon, Mike (NIH/OD) [E]" <[redacted]@nih.gov>, "Kearse, Deborah (NIH/OD) [E]" <[redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: Re: OIG/FBI Inquiry - NIAID 1-R01AI110964-01 - 2-R01AI110964-06
Date: Fri, 11 Sep 2020 16:21:38 -0400
Importance: Normal

Hi Ashley – I'd be happy to speak with you over the phone to tell you the story – an atypical one. I could ask Melanie to find a time for us to talk next week. Another option – and feel free to ignore – would be to speak this Sunday; I'd be happy to do that.

After we review the story, I can then send you relevant materials.

OGC (mainly Anna Jacobs) has been engaged and it might be appropriate to include her as well at some point.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: [redacted]
Email: [redacted]@nih.gov

Note: This conversation is restricted, so you might not be able to cut or copy from it. See the information above the To line for more details. Also, while the conversation is restricted, the conversation owner can send the message to other people.

From: "Sanders, Ashley (NIH/OD) [E]" [redacted]@nih.gov>
Date: Friday, September 11, 2020 at 4:00 PM
To: "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>
Cc: "Shannon, Mike (NIH/OD) [E]" [redacted]@nih.gov>, "Kearse, Deborah (NIH/OD) [E]" [redacted]@nih.gov>
Subject: OIG/FBI Inquiry - NIAID 1-R01AI110964-01 - 2-R01AI110964-06

Good afternoon Dr. Lauer,

We are following-up on an ongoing case related to the above-captioned grant with NIAID awarded to Ecohealth Alliance. OIG has now joined FBI on a broader-scope investigation and have asked for clarity on the closure/termination of this grant. Since this is a sensitive matter, they are concerned that any action or communication from NIH could affect their investigation and they requested internal-coordination to ensure confidentiality and to maintain the integrity of the case.

The questions are highlighted below in the original email to NIAID. I looked through RMARS and did not see anything related to this company or PI that would suggest OER has been active with this case; however, Ms. Linde noted any inquiry was to be directed to you. I hate to send such trivial questions to your attention, but since this is a time-sensitive request, I want to make sure we get the most accurate information from the best source.

Please let me know the best method for getting these questions answered.

Thank you,

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Ashley

Ashley M. Sanders, MPS
Supervisor, DPI Program Investigations
NIH, OMA, Division Program Integrity
6011 Executive Blvd.
Rockville, Maryland 20852
Office: [redacted]
Cell: [redacted]
[redacted]@nih.gov

From: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Sent: Wednesday, September 9, 2020 3:26 PM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

Questions for that nature on this award should be referred to Dr. Mike Lauer, Deputy Director for Extramural Research.

Thanks,

Emily

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Wednesday, September 9, 2020 3:15 PM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Good afternoon Emily,

I'm following-up on this inquiry – originally the questions circled around the scientific terms of the grant and Erik Stemmy provided the context to the FBI. In a recent discussion with HHS OIG and the FBI, they noted they received information that the below-grant with Ecohealth Alliance was "suspended" or "terminated". I've reviewed QVR and do not see an indication of that action other than the attached "Closeout of Award" email stating the end of the grant was 4/24/20 with a request for the FFR and FRPPR. Was this just a typical end of term closeout, or was it terminated early? If terminated/suspended, the OIG has the following questions:

1. What information did NIH/NIAID receive, and from whom, that noted a concern for continuing to fund this research?
2. What was the reasoning for NIAID ending the grant and/or collaboration with Ecohealth Alliance?
3. What was communicated to the PI (Dr. Daszak) and/or Ecohealth?

Please let me know if you're able to provide this information.

Thank you,
Ashley

Ashley M. Sanders, MPS

Released by Chairman Rand Paul

Supervisor, DPI Program Investigations
NIH, OMA, Division Program Integrity
6011 Executive Blvd.
Rockville, Maryland 20852
Office: [redacted]
Cell: [redacted]
[redacted]@nih.gov

Released by Chairman Rand Paul

From: "Lauer, Michael (NIH/OD) [E]" <[redacted]@nih.gov>
To: "Bulls, Michelle G. (NIH/OD) [E]" <[redacted]@nih.gov>
Cc: "Black, Jodi (NIH/OD) [E]" <[redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: Re: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Date: Sun, 13 Sep 2020 13:23:53 -0400
Importance: Normal

Thanks Michelle for the update and good to hear that NIAID backed up Emily.

I'll be talking with Ashley Sanders (OMA) from 8:30 AM to 9:00 to tell her the story behind the case.

Best, Mike

Note: This conversation is restricted, so you might not be able to cut or copy from it. See the information above the To line for more details. Also, while the conversation is restricted, the conversation owner can send the message to other people.

From: "Bulls, Michelle G. (NIH/OD) [E]" [redacted]@nih.gov>
Date: Friday, September 11, 2020 at 9:23 AM
To: "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>
Cc: "Black, Jodi (NIH/OD) [E]" [redacted]@nih.gov>, "Bulls, Michelle G. (NIH/OD) [E]" [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Mike,
Just to provide you with an update on this one. Mike Shannon went to NIAIDs Deputy Director last evening to note that Emily was being "non-responsive" so the issue would be escalated. Emily said that as soon as the Deputy Director figured out which grant was involved, they knew that Emily had acted appropriately, and that OMA should be trusting her professional judgement. The Deputy Director is meeting with Mike Shannon today to discuss. You were not included in the emails from Mike Shannon at any point, not even as a FYI.

Really happy that NIAID leadership supported Emily—huge in this case. Just want you know what's going on in this space and the fact that Mike is meeting w/the Deputy Director today.

Thanks,
Michelle

From: Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
Sent: Friday, September 11, 2020 4:37 AM
To: Bulls, Michelle G. (NIH/OD) [E] [redacted]@nih.gov>
Cc: Black, Jodi (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
Subject: Re: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Thanks Michelle – I agree with your plan we should handle this. We might also want to include OGC / Anna Jacobs in our conversations with OMA.

Best, Mike

Note: This conversation is restricted, so you might not be able to cut or copy from it. See the information above the To line for more details. Also, while the conversation is restricted, the conversation owner can send the message to other people.

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From: "Bulls, Michelle G. (NIH/OD) [E]" <[redacted]@nih.gov>
Date: Thursday, September 10, 2020 at 12:43 PM
To: "Lauer, Michael (NIH/OD) [E]" <[redacted]@nih.gov>
Cc: "Bulls, Michelle G. (NIH/OD) [E]" <[redacted]@nih.gov>, "Black, Jodi (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: FW: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Mike,

See way down below where OMA asks for information for the OIG and FBI regarding Eco Health Alliance. Emily referred them back to you, based on the nature of their questions. This is a sticky one—and from the beginning, NIAID were told to refer these detailed questions to you given the situation. Is it okay for us to provide her with a response to send that is accurate so that OMA does not have to translate? Or would you like for her to just respond and without context, that will be tricky for OMA and will cause more questions. Let me know…

Michelle

From: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Sent: Thursday, September 10, 2020 11:44 AM
To: Bulls, Michelle G. (NIH/OD) [E] [redacted]@nih.gov>; Dean, Diane (NIH/OD) [E] [redacted]@od31em1.od.nih.gov>
Subject: FW: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Good morning,

I wanted to alert you to this request. I referred them to Mike as we have discussed and just sent the following response to their latest inquiry and will let you know if I hear more.

Thanks,

Emily

From: Linde, Emily (NIH/NIAID) [E]
Sent: Thursday, September 10, 2020 11:40 AM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

For this award the most relevant and accurate source of information is Dr. Mike Lauer, Deputy Director for Extramural Research.

Thanks,

Emily

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Thursday, September 10, 2020 10:40 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

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Hi Emily,

These questions are specific to whether or not this particular NIAID grant was terminated early or ended as per a usual course of action. I'm not clear as to why I would need to go to the Deputy Director of NIH for OER for a response to a question on decisions and grant determinations made by NIAID.

OMA properly and routinely seeks and receives information from IC's on grants and grant activity in support of audits and investigations, in accordance with Manual Chapter 1754 and 1752, as we are responsible to fully coordinate responses to OIG/FBI/DOJ etc. to support ongoing investigations. I must ensure our response is from the most relevant and accurate source of information, and answered in a timely manner.

Is there a reason these inquiries are being directed outside of the IC?

Thanks for your help,
Ashley

From: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Sent: Wednesday, September 9, 2020 3:26 PM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

Questions for that nature on this award should be referred to Dr. Mike Lauer, Deputy Director for Extramural Research.

Thanks,

Emily

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Wednesday, September 9, 2020 3:15 PM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Good afternoon Emily,

I'm following-up on this inquiry – originally the questions circled around the scientific terms of the grant and Erik Stemmy provided the context to the FBI. In a recent discussion with HHS OIG and the FBI, they noted they received information that the below-grant with Ecohealth Alliance was "suspended" or "terminated". I've reviewed QVR and do not see an indication of that action other than the attached "Closeout of Award" email stating the end of the grant was 4/24/20 with a request for the FFR and FRPPR. Was this just a typical end of term closeout, or was it terminated early? If terminated/suspended, the OIG has the following questions:

1. What information did NIH/NIAID receive, and from whom, that noted a concern for continuing to fund this research?
2. What was the reasoning for NIAID ending the grant and/or collaboration with Ecohealth Alliance?
3. What was communicated to the PI (Dr. Daszak) and/or Ecohealth?

Please let me know if you're able to provide this information.

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Thank you,
Ashley

Ashley M. Sanders, MPS
Supervisor, DPI Program Investigations
NIH, OMA, Division Program Integrity
6011 Executive Blvd.
Rockville, Maryland 20852
Office: [redacted]
Cell: [redacted]
[redacted]@nih.gov

From: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Thursday, May 21, 2020 5:50 PM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>; Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,
Since we'll only have a short time on Tuesday I thought it might be helpful to provide the agent my responses to the original questions. There may be some misunderstanding of gain-of-function experiments, so hopefully this will clarify some things or at least provide a framework for our discussion next week.

Thanks!
Erik

p.s. I've also pasted the response directly below in case there is an issue adding an attachment to an encrypted message.

SF 424 AI110964-06 (received date 11/05/2018)
Both SF 424s seem to be describing "gain of function" experiments. On page 192 of SF 424 AI110964-06 (received date 11/05/2018) under P3CO Research, it indicates they are conducting gain of function of SARSr-CoV.

The funding pause on gain-of-function (GoF) experiments was in place from 2014-2017, and explicitly involved work reasonably anticipated to enhance the transmissibility or pathogenicity of influenza, MERS-CoV, or SARS-CoV. As such, that policy would not have applied to SARS-related coronaviruses (SARSr-CoV). The replacement policy, Potential Pandemic Pathogen Care and Oversight (P3CO), requires additional review and oversight of experiments that are anticipated to increase a potential pandemic pathogen's transmissibility or pathogenicity *in humans*. The viruses created under this award are chimeric bat viruses, which generally would not be anticipated to cause enhanced disease or transmission in people. When evaluating experiments for potential GoF or P3CO we determine the likelihood of altering one of these attributes compared to the wild-type or circulating viral strain.

Were they also conducting Seemless Cloining and Assembly? From a review of their experimental details, it looks as if they were generating recombinant DNA of the viruses using WIV1 as the backbone but I could not determine if they were using Seemless Cloning techniques.

I'm not aware of them using seamless cloning. Standard techniques for investigators in this field are to create cDNA molecular clones, which are then expressed in cull culture.

I could not determine exactly where they were conducting these gain of function experiments. I know UNC-Chapel Hill has done these but within the document, I could not determine where this was occurring. Do you know where this was occurring?

GoF experiments were not conducted as part of this award. While chimeric viruses were created via this award, they would not be considered GoF since the results did not confer attributes that were not already exhibited by the wild type versions of the viruses. For example, expressing the spike protein of SARS-CoV in the WIV-1 backbone did not increase the pathogenicity of WIV-1 beyond that of SARS-CoV. This award did not support work to manipulate CoV genomes or create chimeric viruses at Wuhan Institute of Virology; such work was performed at UNC-CH.

It then appears that the recombinant DNA of the virus was then injected into humanized mice. However, again I couldn't determine where this occurred or was to occur. On page 187 of the same SF 424 under **"Vertebrate Animals"** it indicates that work with vertebrate animals will be conducted at Wuhan University at the School of Medicine and UNC – CH. Then under **"Laboratory Mice"** it states that lab mice will be sourced commercially by Wuhan Center for Animal Experiment at Wuhan University and that humanized mice will be bread at University of Wuhan and UNC – CH. Furthermore, the mice will be inoculated with the virus.

Recombinant viral cDNA is not directly injected into humanized mice. Rather, these molecular clones are used to grow virus in culture to create an inoculum used in infectivity studies. Both WIV and UNC-CH performed studies with molecular clones, which included infecting mice with the resulting recombinant viruses.

Under **"UNC Facilities where selected agents to be used"** it continues with all mouse studies at UNC-CH will be performed…." However, on page 200 of the same SF 424 there is a letter from UNC – CH stating "The work to be performed by UNC-CH does not include animal and/or human research subjects." I know that was a lot of information but where exactly was the experimentation of injecting the humanized mice with the recombinant DNA occurring?

I believe this to be a typographical error on the part of UNC's business office. The application describes animal work at UNC. Budget justifications and the consortium agreement also include references to this work. I believe UNC mean to say that the work "… does not include human research subjects."

SF 424 AI110964-01 (received date 06/05/2013)
In this SF 424 Aim 3 seems indicative of gain of function experimentation (**C3a** and **C3b**) although it does not use that exact term.

The receipt date of this application was June of 2013, and the term "gain-of-function" was not widely used before the USG funding pause was announced in 2014. C3a and C3b describe work using pseudovirus assays, which would not have been considered GoF as they do not involve creating full replicating viruses.

On page 119 of AI110964-01 under "**C3d) Humanized mouse *in vivo* infection experiments"** it states that humanized mouse in vivo experiments in humanized mice was occurring at the Wuhan Institute of Virology. I did not see the location where these gain of function experiments were being done but if the injections were occurring at WIV then was the recombinant DNA also generated at WIV? Was Seemless Cloning also being done?

This is not GoF work. The humanized mouse experiments described in C3d refer to work with *wild type* viruses isolated from wild bats. Refer to the section stating: "We will passage isolated bat-CoVs in permissive cells twice…" This is a standard virological technique to create an inoculum to infect animals. In no portion of C3d do they describe any manipulation of isolated virus, therefore this does not describe any kind of gain-of-function studies, nor does it involve the creation of any recombinant DNA or viruses. Characterization of naturally occurring viruses was *explicitly excluded* from the GoF policy. Further, the USG P3CO Policy Guidance states that "Wild-type pathogens that are circulating in or have been recovered from nature are not enhanced PPPs, regardless of their pandemic potential."

RPPR (AI110964-05)
Finally, in the RPPR (6/1/2017-5/31/2018) on page 28 under "**In Vivo Infection of Human ACE2 Expressing Mice with SARSr-Cov S Protein variants",** it appears to be showing the results from their gain of function experiments as described in the SF 424. This is more of less the same as the question above, but do you know where this occurred?

Released by Chairman Rand Paul

These are not the results of GoF experiments. The figure you reference (Fig 35) shows weight loss and lung viral titers of chimeric viruses with bat CoV (wild type WIV-1, SHC014, WIV16, and 4231) spike proteins expressed on the WIV-1 backbone. Weight loss and viral titers were comparable across all chimeras when compared to the wild type (Fig 35a, red series; Fig 35b small box pattern). There are no statistical differences reported, so the chimeric viruses have not gained any function/attribute they did not already exhibit.

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Thursday, May 21, 2020 3:04 PM
To: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>; Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Erik,

Thank you for providing this information. We would like to set up a call with the agent as they may need additional context or have other questions. Would you be available next Tuesday around 11:30AM? I'll set up a conference line for us and send an invite.

If that time doesn't work for you, please let me know alternative times you have available.

Thank you,
Ashley

From: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Thursday, May 21, 2020 11:22 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>; Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,
I would be happy to answer questions related to this award. Would it be best if I just addressed the comments at the end of this email thread? I'll say generally that NIAID has an extensive review process for P3CO (and formerly for GoF) and that all of this work was formally evaluated by the respective committees and determined not to be gain-of-function, nor subject to P3CO oversight. We also continually monitored the progress (until the award was terminated) for evidence of unexpected increases in viral replication.

Erik

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
5601 Fishers Lane, Room 8E18
Bethesda, MD 20892-9825
Phone: [redacted]
Email: [redacted]@nih.gov

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Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

The Program Official for this grant, Dr. Stemmy, who is copied on this email, would be the most appropriate POC for these questions.

Regards,

Emily

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Wednesday, May 20, 2020 1:00 PM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Good afternoon,

We are following up on a time-sensitive request for information from the FBI. Please let us know if you are able to accommodate their request or if you can recommend a POC to address the concerns.

Thank you,
Ashley

From: Sanders, Ashley (NIH/OD) [E]
Sent: Wednesday, May 13, 2020 11:59 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Good afternoon Emily,

OMA/DPI received questions related to an FBI inquiry for the following NIAID grants: 1R01AI110964-01 through 2R01AI110964-06. The agent is requesting clarification on the details of the study, where certain aspects were performed, and whether seamless cloning techniques were used. I note you were the last official to sign off on 4/27/20.

Would you be able to provide a response to the below-captured questions and/or be available for a joint call with our office and the agent? If not, who would be the best SME on this matter? I'm sure you understand, since this is a sensitive matter, we need to maintain confidentiality and limit the touch-points within NIH. I'm happy to discuss further if you have any questions.

Thank you,
Ashley

Ashley M. Sanders, MPS
Senior Program Investigations Officer
NIH, OMA, Division Program Integrity
6011 Executive Blvd.

Released by Chairman Rand Paul

Rockville, Maryland 20852
Office: [redacted]
[redacted]@nih.gov

FBI Questions:

SF 424 AI110964-06 (received date 11/05/2018)
Both SF 424s seem to be describing "gain of function" experiments. On page 192 of SF 424 AI110964-06 (received date 11/05/2018) under P3CO Research, it indicates they are conducting gain of function of SARSr-CoV. Were they also conducting Seemless Cloining and Assembly? From a review of their experimental details, it looks as if they were generating recombinant DNA of the viruses using WIV1 as the backbone but I could not determine if they were using Seemless Cloning techniques. I could not determine exactly where they were conducting these gain of function experiments. I know UNC-Chapel Hill has done these but within the document, I could not determine where this was occurring. Do you know where this was occurring?
It then appears that the recombinant DNA of the virus was then injected into humanized mice. However, again I couldn't determine where this occurred or was to occur. On page 187 of the same SF 424 under **"Vertebrate Animals"** it indicates that work with vertebrate animals will be conducted at Wuhan University at the School of Medicine and UNC – CH. Then under **"Laboratory Mice"** it states that lab mice will be sourced commercially by Wuhan Center for Animal Experiment at Wuhan University and that humanized mice will be bread at University of Wuhan and UNC – CH. Furthermore, the mice will be inoculated with the virus. Under **"UNC Facilities where selected agents to be used"** it continues with all mouse studies at UNC-CH will be performed…." However, on page 200 of the same SF 424 there is a letter from UNC – CH stating "The work to be performed by UNC-CH does not include animal and/or human research subjects." I know that was a lot of information but where exactly was the experimentation of injecting the humanized mice with the recombinant DNA occurring?

SF 424 AI110964-01 (received date 06/05/2013)
In this SF 424 Aim 3 seems indicative of gain of function experimentation (**C3a** and **C3b**) although it does not use that exact term. On page 119 of AI110964-01 under "**C3d) Humanized mouse *in vivo* infection experiments"** it states that humanized mouse in vivo experiments in humanized mice was occurring at the Wuhan Institute of Virology. I did not see the location where these gain of function experiments were being done but if the injections were occurring at WIV then was the recombinant DNA also generated at WIV? Was Seemless Cloning also being done?

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Finally, in the RPPR (6/1/2017-5/31/2018) on page 28 under "**In Vivo Infection of Human ACE2 Expressing Mice with SARSr-Cov S Protein variants",** it appears to be showing the results from their gain of function experiments as described in the SF 424. This is more of less the same as the question above, but do you know where this occurred?

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From: "Bulls, Michelle G. (NIH/OD) [E]" <[redacted]@nih.gov>
To: "Lauer, Michael (NIH/OD) [E]" <[redacted]@nih.gov>
Cc: "Black, Jodi (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Date: Mon, 14 Sep 2020 16:42:00 -0400
Importance: Normal

Perfect! Thanks so much, Mike.

From: Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
Sent: Sunday, September 13, 2020 1:24 PM
To: Bulls, Michelle G. (NIH/OD) [E] [redacted]@nih.gov>
Cc: Black, Jodi (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
Subject: Re: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Thanks Michelle for the update and good to hear that NIAID backed up Emily.

I'll be talking with Ashley Sanders (OMA) from 8:30 AM to 9:00 to tell her the story behind the case.

Best, Mike

Note: This conversation is restricted, so you might not be able to cut or copy from it. See the information above the To line for more details. Also, while the conversation is restricted, the conversation owner can send the message to other people.

From: "Bulls, Michelle G. (NIH/OD) [E]" <[redacted]@nih.gov>
Date: Friday, September 11, 2020 at 9:23 AM
To: "Lauer, Michael (NIH/OD) [E]" <[redacted]@nih.gov>
Cc: "Black, Jodi (NIH/OD) [E]" <[redacted]@nih.gov>, "Bulls, Michelle G. (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Mike,
Just to provide you with an update on this one. Mike Shannon went to NIAIDs Deputy Director last evening to note that Emily was being "non-responsive" so the issue would be escalated. Emily said that as soon as the Deputy Director figured out which grant was involved, they knew that Emily had acted appropriately, and that OMA should be trusting her professional judgement. The Deputy Director is meeting with Mike Shannon today to discuss. You were not included in the emails from Mike Shannon at any point, not even as a FYI.

Really happy that NIAID leadership supported Emily—huge in this case. Just want you know what's going on in this space and the fact that Mike is meeting w/the Deputy Director today.

Thanks,
Michelle

From: Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
Sent: Friday, September 11, 2020 4:37 AM
To: Bulls, Michelle G. (NIH/OD) [E] [redacted]@nih.gov>
Cc: Black, Jodi (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
Subject: Re: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

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Thanks Michelle – I agree with your plan we should handle this. We might also want to include OGC / Anna Jacobs in our conversations with OMA.

Best, Mike

Note: This conversation is restricted, so you might not be able to cut or copy from it. See the information above the To line for more details. Also, while the conversation is restricted, the conversation owner can send the message to other people.

From: "Bulls, Michelle G. (NIH/OD) [E]" <[redacted]@nih.gov>
Date: Thursday, September 10, 2020 at 12:43 PM
To: "Lauer, Michael (NIH/OD) [E]" <[redacted]@nih.gov>
Cc: "Bulls, Michelle G. (NIH/OD) [E]" <[redacted]@nih.gov>, "Black, Jodi (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: FW: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Mike,

See way down below where OMA asks for information for the OIG and FBI regarding Eco Health Alliance. Emily referred them back to you, based on the nature of their questions. This is a sticky one—and from the beginning, NIAID were told to refer these detailed questions to you given the situation. Is it okay for us to provide her with a response to send that is accurate so that OMA does not have to translate? Or would you like for her to just respond and without context, that will be tricky for OMA and will cause more questions. Let me know…

Michelle

From: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Sent: Thursday, September 10, 2020 11:44 AM
To: Bulls, Michelle G. (NIH/OD) [E] [redacted]@nih.gov>; Dean, Diane (NIH/OD) [E] [redacted]@od31em1.od.nih.gov>
Subject: FW: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Good morning,

I wanted to alert you to this request. I referred them to Mike as we have discussed and just sent the following response to their latest inquiry and will let you know if I hear more.

Thanks,

Emily

From: Linde, Emily (NIH/NIAID) [E]
Sent: Thursday, September 10, 2020 11:40 AM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

For this award the most relevant and accurate source of information is Dr. Mike Lauer, Deputy Director for Extramural Research.

Thanks,

Emily

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From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Thursday, September 10, 2020 10:40 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Hi Emily,

These questions are specific to whether or not this particular NIAID grant was terminated early or ended as per a usual course of action. I'm not clear as to why I would need to go to the Deputy Director of NIH for OER for a response to a question on decisions and grant determinations made by NIAID.

OMA properly and routinely seeks and receives information from IC's on grants and grant activity in support of audits and investigations, in accordance with Manual Chapter 1754 and 1752, as we are responsible to fully coordinate responses to OIG/FBI/DOJ etc. to support ongoing investigations. I must ensure our response is from the most relevant and accurate source of information, and answered in a timely manner.

Is there a reason these inquiries are being directed outside of the IC?

Thanks for your help,
Ashley

From: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Sent: Wednesday, September 9, 2020 3:26 PM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

Questions for that nature on this award should be referred to Dr. Mike Lauer, Deputy Director for Extramural Research.

Thanks,

Emily

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Wednesday, September 9, 2020 3:15 PM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Good afternoon Emily,

I'm following-up on this inquiry – originally the questions circled around the scientific terms of the grant and Erik Stemmy provided the context to the FBI. In a recent discussion with HHS OIG and the FBI, they noted they received information that the below-grant with Ecohealth Alliance was "suspended" or "terminated". I've reviewed QVR and do not see an indication of that action other than the attached "Closeout of Award" email stating the end of the grant was 4/24/20 with a request for the FFR and FRPPR. Was this just a typical end of term closeout, or was it terminated early? If terminated/suspended, the OIG has the following questions:

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1. What information did NIH/NIAID receive, and from whom, that noted a concern for continuing to fund this research?
2. What was the reasoning for NIAID ending the grant and/or collaboration with Ecohealth Alliance?
3. What was communicated to the PI (Dr. Daszak) and/or Ecohealth?

Please let me know if you're able to provide this information.

Thank you,
Ashley

Ashley M. Sanders, MPS
Supervisor, DPI Program Investigations
NIH, OMA, Division Program Integrity
6011 Executive Blvd.
Rockville, Maryland 20852
Office: [redacted]
Cell: [redacted]
[redacted]@nih.gov

From: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Thursday, May 21, 2020 5:50 PM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>; Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,
Since we'll only have a short time on Tuesday I thought it might be helpful to provide the agent my responses to the original questions. There may be some misunderstanding of gain-of-function experiments, so hopefully this will clarify some things or at least provide a framework for our discussion next week.

Thanks!
Erik

p.s. I've also pasted the response directly below in case there is an issue adding an attachment to an encrypted message.

SF 424 AI110964-06 (received date 11/05/2018)
Both SF 424s seem to be describing "gain of function" experiments. On page 192 of SF 424 AI110964-06 (received date 11/05/2018) under P3CO Research, it indicates they are conducting gain of function of SARSr-CoV.

The funding pause on gain-of-function (GoF) experiments was in place from 2014-2017, and explicitly involved work reasonably anticipated to enhance the transmissibility or pathogenicity of influenza, MERS-CoV, or SARS-CoV. As such, that policy would not have applied to SARS-related coronaviruses (SARSr-CoV). The replacement policy, Potential Pandemic Pathogen Care and Oversight (P3CO), requires additional review and oversight of experiments that are anticipated to increase a potential pandemic pathogen's transmissibility or pathogenicity *in humans*. The viruses created under this award are chimeric bat viruses, which generally would not be anticipated to cause enhanced disease or transmission in people. When evaluating experiments for potential GoF or P3CO we determine the likelihood of altering one of these attributes compared to the wild-type or circulating viral strain.

Were they also conducting Seemless Cloining and Assembly? From a review of their experimental details, it looks as if they were generating recombinant DNA of the viruses using WIV1 as the backbone but I could not determine if they were

using Seemless Cloning techniques.

I'm not aware of them using seamless cloning. Standard techniques for investigators in this field are to create cDNA molecular clones, which are then expressed in cull culture.

I could not determine exactly where they were conducting these gain of function experiments. I know UNC-Chapel Hill has done these but within the document, I could not determine where this was occurring. Do you know where this was occurring?

GoF experiments were not conducted as part of this award. While chimeric viruses were created via this award, they would not be considered GoF since the results did not confer attributes that were not already exhibited by the wild type versions of the viruses. For example, expressing the spike protein of SARS-CoV in the WIV-1 backbone did not increase the pathogenicity of WIV-1 beyond that of SARS-CoV. This award did not support work to manipulate CoV genomes or create chimeric viruses at Wuhan Institute of Virology; such work was performed at UNC-CH.

It then appears that the recombinant DNA of the virus was then injected into humanized mice. However, again I couldn't determine where this occurred or was to occur. On page 187 of the same SF 424 under **"Vertebrate Animals"** it indicates that work with vertebrate animals will be conducted at Wuhan University at the School of Medicine and UNC – CH. Then under **"Laboratory Mice"** it states that lab mice will be sourced commercially by Wuhan Center for Animal Experiment at Wuhan University and that humanized mice will be bread at University of Wuhan and UNC – CH. Furthermore, the mice will be inoculated with the virus.

Recombinant viral cDNA is not directly injected into humanized mice. Rather, these molecular clones are used to grow virus in culture to create an inoculum used in infectivity studies. Both WIV and UNC-CH performed studies with molecular clones, which included infecting mice with the resulting recombinant viruses.

Under **"UNC Facilities where selected agents to be used"** it continues with all mouse studies at UNC-CH will be performed…." However, on page 200 of the same SF 424 there is a letter from UNC – CH stating "The work to be performed by UNC-CH does not include animal and/or human research subjects." I know that was a lot of information but where exactly was the experimentation of injecting the humanized mice with the recombinant DNA occurring?

I believe this to be a typographical error on the part of UNC's business office. The application describes animal work at UNC. Budget justifications and the consortium agreement also include references to this work. I believe UNC mean to say that the work "… does not include human research subjects."

SF 424 AI110964-01 (received date 06/05/2013)
In this SF 424 Aim 3 seems indicative of gain of function experimentation (**C3a** and **C3b**) although it does not use that exact term.

The receipt date of this application was June of 2013, and the term "gain-of-function" was not widely used before the USG funding pause was announced in 2014. C3a and C3b describe work using pseudovirus assays, which would not have been considered GoF as they do not involve creating full replicating viruses.

On page 119 of AI110964-01 under "**C3d) Humanized mouse *in vivo* infection experiments"** it states that humanized mouse in vivo experiments in humanized mice was occurring at the Wuhan Institute of Virology. I did not see the location where these gain of function experiments were being done but if the injections were occurring at WIV then was the recombinant DNA also generated at WIV? Was Seemless Cloning also being done?

This is not GoF work. The humanized mouse experiments described in C3d refer to work with *wild type* viruses isolated from wild bats. Refer to the section stating: "We will passage isolated bat-CoVs in permissive cells twice…" This is a standard virological technique to create an inoculum to infect animals. In no portion of C3d do they describe any manipulation of isolated virus, therefore this does not describe any kind of gain-of-function studies, nor does it involve the creation of any recombinant DNA or viruses. Characterization of naturally occurring viruses was *explicitly excluded*

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from the GoF policy. Further, the USG P3CO Policy Guidance states that "Wild-type pathogens that are circulating in or have been recovered from nature are not enhanced PPPs, regardless of their pandemic potential."

RPPR (AI110964-05)
Finally, in the RPPR (6/1/2017-5/31/2018) on page 28 under "**In Vivo Infection of Human ACE2 Expressing Mice with SARSr-Cov S Protein variants",** it appears to be showing the results from their gain of function experiments as described in the SF 424. This is more of less the same as the question above, but do you know where this occurred?

These are not the results of GoF experiments. The figure you reference (Fig 35) shows weight loss and lung viral titers of chimeric viruses with bat CoV (wild type WIV-1, SHC014, WIV16, and 4231) spike proteins expressed on the WIV-1 backbone. Weight loss and viral titers were comparable across all chimeras when compared to the wild type (Fig 35a, red series; Fig 35b small box pattern). There are no statistical differences reported, so the chimeric viruses have not gained any function/attribute they did not already exhibit.

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Sent: Thursday, May 21, 2020 3:04 PM
To: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>; Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Erik,

Thank you for providing this information. We would like to set up a call with the agent as they may need additional context or have other questions. Would you be available next Tuesday around 11:30AM? I'll set up a conference line for us and send an invite.

If that time doesn't work for you, please let me know alternative times you have available.

Thank you,
Ashley

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Sent: Thursday, May 21, 2020 11:22 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>; Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
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Hi Ashley,
I would be happy to answer questions related to this award. Would it be best if I just addressed the comments at the end of this email thread? I'll say generally that NIAID has an extensive review process for P3CO (and formerly for GoF) and that all of this work was formally evaluated by the respective committees and determined not to be gain-of-function, nor subject to P3CO oversight. We also continually monitored the progress (until the award was terminated) for evidence of unexpected increases in viral replication.

Erik

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
5601 Fishers Lane, Room 8E18
Bethesda, MD 20892-9825

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Phone: [redacted]
Email: [redacted]@nih.gov

From: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Sent: Thursday, May 21, 2020 6:17 AM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

The Program Official for this grant, Dr. Stemmy, who is copied on this email, would be the most appropriate POC for these questions.

Regards,

Emily

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Wednesday, May 20, 2020 1:00 PM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Good afternoon,

We are following up on a time-sensitive request for information from the FBI. Please let us know if you are able to accommodate their request or if you can recommend a POC to address the concerns.

Thank you,
Ashley

From: Sanders, Ashley (NIH/OD) [E]
Sent: Wednesday, May 13, 2020 11:59 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Good afternoon Emily,

OMA/DPI received questions related to an FBI inquiry for the following NIAID grants: 1R01AI110964-01 through 2R01AI110964-06. The agent is requesting clarification on the details of the study, where certain aspects were performed, and whether seamless cloning techniques were used. I note you were the last official to sign off on 4/27/20.

Would you be able to provide a response to the below-captured questions and/or be available for a joint call with our office and the agent? If not, who would be the best SME on this matter? I'm sure you understand, since this is a sensitive matter, we need to maintain confidentiality and limit the touch-points within NIH. I'm happy to discuss further if you have any questions.

Released by Chairman Rand Paul

Thank you,
Ashley

Ashley M. Sanders, MPS
Senior Program Investigations Officer
NIH, OMA, Division Program Integrity
6011 Executive Blvd.
Rockville, Maryland 20852
Office: [redacted]
[redacted]@nih.gov

FBI Questions:

SF 424 AI110964-06 (received date 11/05/2018)
Both SF 424s seem to be describing "gain of function" experiments. On page 192 of SF 424 AI110964-06 (received date 11/05/2018) under P3CO Research, it indicates they are conducting gain of function of SARSr-CoV. Were they also conducting Seemless Cloining and Assembly? From a review of their experimental details, it looks as if they were generating recombinant DNA of the viruses using WIV1 as the backbone but I could not determine if they were using Seemless Cloning techniques. I could not determine exactly where they were conducting these gain of function experiments. I know UNC-Chapel Hill has done these but within the document, I could not determine where this was occurring. Do you know where this was occurring?
It then appears that the recombinant DNA of the virus was then injected into humanized mice. However, again I couldn't determine where this occurred or was to occur. On page 187 of the same SF 424 under **"Vertebrate Animals"** it indicates that work with vertebrate animals will be conducted at Wuhan University at the School of Medicine and UNC – CH. Then under **"Laboratory Mice"** it states that lab mice will be sourced commercially by Wuhan Center for Animal Experiment at Wuhan University and that humanized mice will be bread at University of Wuhan and UNC – CH. Furthermore, the mice will be inoculated with the virus. Under **"UNC Facilities where selected agents to be used"** it continues with all mouse studies at UNC-CH will be performed…." However, on page 200 of the same SF 424 there is a letter from UNC – CH stating "The work to be performed by UNC-CH does not include animal and/or human research subjects." I know that was a lot of information but where exactly was the experimentation of injecting the humanized mice with the recombinant DNA occurring?

SF 424 AI110964-01 (received date 06/05/2013)
In this SF 424 Aim 3 seems indicative of gain of function experimentation (**C3a** and **C3b**) although it does not use that exact term. On page 119 of AI110964-01 under "**C3d) Humanized mouse *in vivo* infection experiments"** it states that humanized mouse in vivo experiments in humanized mice was occurring at the Wuhan Institute of Virology. I did not see the location where these gain of function experiments were being done but if the injections were occurring at WIV then was the recombinant DNA also generated at WIV? Was Seemless Cloning also being done?

RPPR (AI110964-05)
Finally, in the RPPR (6/1/2017-5/31/2018) on page 28 under "**In Vivo Infection of Human ACE2 Expressing Mice with SARSr-Cov S Protein variants",** it appears to be showing the results from their gain of function experiments as described in the SF 424. This is more of less the same as the question above, but do you know where this occurred?

Released by Chairman Rand Paul

From: 胡犇 <[redacted]@wh.iov.cn>
Sent: Sunday, April 05, 2020 6:30 AM EDT
To: Alice Latinne <[redacted]@ecohealthalliance.org>
CC: Hongying Li <[redacted]@ecohealthalliance.org>; 石正丽 <[redacted]@wh.iov.cn>; Peter Daszak <[redacted]@ecohealthalliance.org>
Subject: Re: Re: Re: Re: China Maps used in the manuscript

Oh I see. It is named 4991 when submitted earlier as a partial sequence. We renamed it as RaTG13 when we publish as a full-length sequence.

So it would be OK. Only the deletion of "we" in the sentence will be enough.

Best

-----原始邮件-----
发件人:"Alice Latinne" <[redacted]@ecohealthalliance.org>
发送时间:2020-04-05 18:01:25 (星期日)
收件人: "胡犇" <[redacted]@wh.iov.cn>
抄送: "Hongying Li" <[redacted]@ecohealthalliance.org>, "石正丽" <[redacted]@wh.iov.cn>, "Peter Daszak" <[redacted]@ecohealthalliance.org>
主题: Re: Re: Re: China Maps used in the manuscript

Hi Ben,

1) RaTG13 is not included in the Figure 3. The closest sequence is a sequence from GenBank (KP876546) and published in 2016 in a paper from your lab:

Ge X-Y, Wang N, Zhang W, Hu B, Li B, Zhang Y-Z, Zhou J-H, Luo C-M, Yang X-L, Wu L-J, et al. (Ge2016 co-authors). 2016. Coexistence of multiple coronaviruses in several bat colonies in an abandoned mineshaft. Virologica Sinica 31:31-40.

This sequence is 100% identical to RaTG13, is it the same sample?

I'll delete the word "we" in the sentence.

2) I'll check and correct this as needed.

Cheers,
Alice

On Sun, Apr 5, 2020 at 4:24 PM 胡犇 <[redacted]@wh.iov.cn> wrote:

> Hi Alice,
>
> Thanks for the supplementary material.
>
> Now I have two more concerns regarding the manuscript:
>
> 1) In lines 48-49 in the PDF, you mentioned that "this emerging human virus is closely related to SARS-CoV, and also appears to have originated in horseshoe bats -- with its full genome 96% similar to a virus we discovered in Rhinolophus affinis".
> Here this virus refers to RaTG13. Could you please delete the word "we" in this sentence? Otherwise, some readers may think that RaTG13 was detected in our joint study (e.x.PREDICT) and we shared the sequence with EHA earlier. This may be used by some conspiracy theorists to make rumors.
>
> Actually, the sequence of RaTG13 was not included in the dataset I provided to you. It was not deposited into Genbank until this January. So I think it was not included in your dataset, and you used this sequence during the revision phase after COVID-19 outbreak.

[redacted]

Though not labeled clearly, RaTG13 is also shown in the phylogenetic tree in Figure 3 (the one most closely related to 2019-nCoV from Rhinolophus affinis in Yunnan). So could you please revise the figure legend of figure 3 as: Maximum clade credibility tree including 201 RdRp sequences from the *Sarbecovirus* lineage isolated in bats, including RaTG13 (Genbank accession numbers: MN996532) and two sequences of 2019-nCoV isolated in humans (GenBank accession numbers:MN908947 and MN975262).

This will mean that in your analysis you downloaded the sequence from public database, but it was not included in the original dataset of bat CoVs that I provided to you.

2) In lines 89-91 in the PDF. It says "Our geographic datasets included 694 α-CoV sequences from six zoogeographic regions (22 provinces) and 519 β-CoV sequences from five zoogeographic regions (21 provinces) .

The dataset contains some sequences detected from bats in Laos. Are the lao bat CoV sequences also counted in the 694 and 519 sequences? They are not from any Chinese province. If so,the numbers here needs to be corrected.

Besides, CAS now requires authors from CAS institutes to deposit coronavirus sequences not only in Genbank but also in the public database of China National Center for Bioinformation when we publish our researches. So I will submit the sequences which I submited to Genbank last year to the Chinese database next week.

If you have any questions please let me know.

Best

Ben

> -----原始邮件-----
> 发件人:"Alice Latinne" <[redacted]@ecohealthalliance.org>
> 发送时间:2020-04-04 22:26:44 (星期六)
> 收件人: "胡犇" <[redacted]@wh.iov.cn>
> 抄送: "Hongying Li" <[redacted]@ecohealthalliance.org>
> 主题: Re: Re: China Maps used in the manuscript
>
> Hi Ben,
>
> The supplementary material including Table S1 is attached. And yes it includes all the GenBank numbers you gave me (for the sequences you deposited in genbank by yourself) and all sequences already in GenBank from other studies. Please note that at this stage, I won't be able to modify the dataset, the analysis or the figures.
>
> Cheers,
> Alice
>
> On Wed, Apr 1, 2020 at 8:07 PM 胡犇 <[redacted]@wh.iov.cn> wrote:
>
> > Hi Alice,
> >
> > Can you please send me the Table S1 which shows the accession number of all sequences in the dataset used in the analysis? It includes both the sequences I share with you and the sequences you download from Genbank, right?
> >
> > Thank you!
> >
> > Ben
> >
> > > -----原始邮件-----
> > > 发件人:"Alice Latinne" <[redacted]@ecohealthalliance.org>
> > > 发送时间:2020-03-30 17:43:57 (星期一)
> > > 收件人: "胡犇" <[redacted]@wh.iov.cn>
> > > 抄送: "Hongying Li" <[redacted]@ecohealthalliance.org>
> > > 主题: Re: Re: Re: Re: Re: China Maps used in the manuscript

Released by Chairman Rand Paul

Great! :)

On Mon, Mar 30, 2020 at 4:43 PM 胡犇 <[redacted]@wh.iov.cn> wrote:

> Absolutely OK. Thanks a lot, Alice!
>
> -----原始邮件-----
> 发件人:"Alice Latinne" <[redacted]@ecohealthalliance.org>
> 发送时间:2020-03-30 17:38:25 (星期一)
> 收件人: "胡犇" <[redacted]@wh.iov.cn>
> 抄送: "Hongying Li" [redacted]@ecohealthalliance.org>
> 主题: Re: Re: Re: Re: China Maps used in the manuscript
>
> Hello,
>
> Here is the updated figure. I hope this is ok!
>
> Thanks,
> Alice
>
> On Sun, Mar 29, 2020 at 11:55 AM Alice Latinne <[redacted]@ecohealthalliance.org> wrote:
> > Hi all,
> >
> > I think using the new map from Hongying is too much work but I'll try. If not, I'll put two small China South Sea map on the figure
> >
> > On Sun, Mar 29, 2020 at 8:00 AM 胡犇 <[redacted]@wh.iov.cn> wrote:
> >
> > > Hi both!
> > >
> > > I think the map format that Hong Ying provided is even better. Thanks!
> > >
> > > -----原始邮件-----
> > > 发件人:"Hongying Li" <li@ecohealthalliance.org>
> > > 发送时间:2020-03-28 23:03:46 (星期六)
> > > 收件人: "胡犇" <[redacted]@wh.iov.cn>
> > > 抄送: "Alice Latinne" <[redacted]@ecohealthalliance.org>
> > > 主题: Re: Re: Re: China Maps used in the manuscript
> > >
> > > Hi Both!
> > >
> > > I think either the South China Sea label can be smaller so it can fit into Figure 6 in two maps; Or the attached format of the South China Sea can be considered, which will fit better into Figure 6 I guess, but requires some more editing. But I defer to whatever you decide.
> > >
> > > Hongying
> > >
> > > On Sat, Mar 28, 2020 at 9:16 AM 胡犇 <[redacted]@wh.iov.cn> wrote:
> > >
> > > > Yes I would like to suggest that it appears twice in both figure A and B. But it seems that the space is limited and the layout need to be adjusted?
> > > >
> > > > What do you think, Hongying?
> > > >
> > > > -----原始邮件-----
> > > > 发件人:"Alice Latinne" <[redacted]@ecohealthalliance.org>
> > > > 发送时间:2020-03-28 17:30:57 (星期六)
> > > > 收件人: "胡犇" <[redacted]@wh.iov.cn>
> > > > 抄送: "Hongying Li" <li@ecohealthalliance.org>, "博士石正丽" <[redacted]@wh.iov.cn>, "Peter Daszak"

Released by Chairman Rand Paul

<[redacted]@ecohealthalliance.org>
主题: Re: Re: China Maps used in the manuscript

Hi Ben,

Is the new Figure 6 ok? Or do I have to put the South China Sea 2 times?

Thanks,
Alice

On Sat, Mar 28, 2020 at 3:32 PM 胡犇 <[redacted]@wh.iov.cn> wrote:

> Thanks a lot Alice. The maps now seems perfect.
>
> Please note that the two maps in Figure 6 also need to be modified (that could be easier I think, as only South China Sea need to be added)
>
> Best wishes
>
> Ben
>
> -----原始邮件-----
> 发件人:"Alice Latinne" <[redacted]@ecohealthalliance.org>
> 发送时间:2020-03-24 22:08:46 (星期二)
> 收件人: "Hongying Li" <[redacted]@ecohealthalliance.org>
> 抄送: "胡犇" <[redacted]@wh.iov.cn>, "博士石正丽" <[redacted]@wh.iov.cn>, "Peter Daszak" <[redacted]@ecohealthalliance.org>
> 主题: Re: China Maps used in the manuscript
>
> Hi Hongying and Ben,
>
> Yes I can edit this map as needed, thank you!! I'll work on this when I have time.
>
> The revised and submitted version of the paper is attached. Let me know if there is anything else that is problematic (hopefully not too much!).
>
> Thanks,
> Alice
>
> On Mon, Mar 23, 2020 at 9:59 PM Hongying Li <[redacted]@ecohealthalliance.org> wrote:
>> Hi Alice,
>>
>> Does the attached editable PPT work for you? I colored Shanghai and Xizang in red, and copied pasted south China sea from Ben's template.
>>
>> Hongying
>>
>> On Mon, Mar 23, 2020 at 10:35 AM Alice Latinne <[redacted]@ecohealthalliance.org> wrote:
>>> Hi Ben,
>>>
>>> I totally understand your concerns and will correct these issues. Could you send me a correct map in **pdf format**? This would be really helpful. I really need a pdf where I can change the colour of each province. I can't do it with the pptx you sent me.
>>>
>>> I hope life in Wuhan is getting easier these days!
>>>
>>> Best wishes,
>>> Alice
>>>
>>> On Sun, Mar 22, 2020 at 9:50 PM 胡犇 <[redacted]@wh.iov.cn> wrote:
>>>> Dear Alice,
>>>>
>>>> How is going? I don't know where you are now but since almost every country is facing the threat of COVID-19, I hope everything is fine with you.
>>>>
>>>> I am happy to know that our paper on Chinese bat coronavirus is almost accepted. Thank you so much for the contribution to this joint work.

[redacted]

Today, when I re-checked the figures, I suddenly had a new concern about the paper. The problem is about the maps of China appearing in the figures. It is not a scientific issue, but we must be very careful about it, because in China some people are extremely strict about the territorial integrity and sovereignty shown in the map.

The problems I found include:

1) In figure 1, Shanghai is missing in the map. In the province of Tibet, the region called South Tibet (which is actually controlled by India) is not included.

2) In all three maps, South China Sea is not shown. For Chinese people, a complete map of China should clearly include the South China Sea with a focus on nine-dashed line (I attached a model in the PPT for you to know how it should look like).

I know it will take you some more time to correct the maps. but please understand this concern. If we don't correct the problems, people may judge that Zhengli, me and our Chinese colleagues are making political mistakes. We don't wish that the maps will become a target of attack from those people. You may know that at this every special and sensitive time when COVID-19 occurs, there are some rumors about the research cooperation on coronaviruses between our lab and the US. So we may have to be more careful than before.

After the maps are modified, please send them to me to have a look before they are finally submitted.

If you have any question, please contact me.

Thanks, and take care!

Ben

> -----原始邮件-----
> 发件人:"Alice Latinne" <[redacted]@ecohealthalliance.org>
> 发送时间:2019-10-08 00:08:10 (星期二)
> 收件人: "胡犇老师" <[redacted]@wh.iov.cn>, "朱光剑" <[redacted]@126.com>, zhanglb <[redacted]@gaibr.gd.cn>, "Carlos Zambrana-Torrelio" <[redacted]@ecohealthalliance.org>, "Kevin Olival, PhD" <[redacted]@ecohealthalliance.org>, "博士石正丽" <[redacted]@wh.iov.cn>, "Peter Daszak" <[redacted]@ecohealthalliance.org>, "李贝" <[redacted]@126.com>, "张玮" <[redacted]@wh.iov.cn>, "Hongying Li" <li@ecohealthalliance.org>, "Aleksei MacDurian" <[redacted]@ecohealthalliance.org>, "Hume Field" <[redacted]@ecohealthalliance.org>, "Jon Epstein" <[redacted]@ecohealthalliance.org>, "Wang Linfa" <linfa.wang@duke-nus.edu.sg>
> 抄送:
> 主题: China bat CoV paper submitted
>
> Dear Co-authors,
>
> I just wanted to let you know that I submitted our China bat CoV paper to Nature Communications yesterday. Thank you for all your comments and edits on previous versions of the paper, that was very helpful.
>
> Attached is the submitted version. I'll keep you updated. Finger's crossed...
>
> Best regards,
> Alice
>
> --
> **Alice Latinne, PhD**
>
> *Research Scientist*
> *PREDICT-2 Country Liaison, Thailand and Indonesia*
>
> EcoHealth Alliance
> 460 West 34th Street – 17th floor
> New York, NY 10001
>
> [redacted] (direct)

Released by Chairman Rand Paul

[redacted] (mobile)
www.ecohealthalliance.org

EcoHealth Alliance leads cutting-edge scientific research into the critical connections between human and wildlife health and delicate ecosystems. With this science, we develop solutions that prevent pandemics and promote conservation.

--
Alice Latinne, PhD

Research Scientist

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

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Alice Latinne, PhD

Research Scientist

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

[redacted] (mobile)

[redacted]

Released by Chairman Rand Paul

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Research Scientist

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--

Alice Latinne, PhD

Research Scientist

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New York, NY 10001

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--

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--

Alice Latinne, PhD

Research Scientist

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

[redacted] (mobile)
www.ecohealthalliance.org

[redacted]

Released by Chairman Rand Paul

> *EcoHealth Alliance leads cutting-edge scientific research into the critical connections between human and wildlife health and delicate ecosystems. With this science, we develop solutions that prevent pandemics and promote conservation.*

Released by Chairman Rand Paul

From: 胡犇 <[redacted]@wh.iov.cn>
Sent: Friday, April 10, 2020 11:24 AM EDT
To: Alice Latinne <[redacted]@ecohealthalliance.org>
CC: Hongying Li <[redacted]@ecohealthalliance.org>; 石正丽 <[redacted]@wh.iov.cn>; Peter Daszak <[redacted]@ecohealthalliance.org>; Kevin Olival <[redacted]@ecohealthalliance.org>
Subject: Re: Re: Re: Re: China Maps used in the manuscript

Hi Alice!

Just one more concern about the text. In the final version, please correct this expression in the Author contributions: "BH, GZ, LZ, HL, AAC and ZS provided samples or data".

Please write "BH, GZ, LZ, HL, AAC and ZS collected samples or provided data" instead. Otherwise, people may twisted the meaning and say that "WIV provided Chinese bat samples to a US lab".

Thank you!

Ben

> -----原始邮件-----
> **发件人:**"Alice Latinne" <[redacted]@ecohealthalliance.org>
> **发送时间:**2020-04-09 21:29:57 (星期四)
> **收件人:** "胡犇" <[redacted]@wh.iov.cn>
> **抄送:** "Hongying Li" <[redacted]@ecohealthalliance.org>, "石正丽" <[redacted]@wh.iov.cn>, "Peter Daszak" <[redacted]@ecohealthalliance.org>, "Kevin Olival" <[redacted]@ecohealthalliance.org>
> **主题:** Re: Re: Re: China Maps used in the manuscript
>
> Hi Ben,
>
> Hope all is well. Nat Comms requires that all sequences are publicly available in GenBank before they can formally accept our paper. So could you ask GenBank to release all sequences (MN312240 to MN312869) on April 15? I'll submit the revised final version to Nat Comms on the 13 or 14th.
>
> Thank you!
> Alice
>
> On Sun, Apr 5, 2020 at 5:01 PM Alice Latinne <[redacted]@ecohealthalliance.org> wrote:
>> Hi Ben,
>>
>> 1) RaTG13 is not included in the Figure 3. The closest sequence is a sequence from GenBank (KP876546) and published in 2016 in a paper from your lab:
>>
>> Ge X-Y, Wang N, Zhang W, Hu B, Li B, Zhang Y-Z, Zhou J-H, Luo C-M, Yang X-L, Wu L-J, et al. (Ge2016 co-authors). 2016. Coexistence of multiple coronaviruses in several bat colonies in an abandoned mineshaft. Virologica Sinica 31:31-40.
>>
>> This sequence is 100% identical to RaTG13, is it the same sample?
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>>
>> 2) I'll check and correct this as needed.
>>
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>> Alice
>>
>> On Sun, Apr 5, 2020 at 4:24 PM 胡犇 <[redacted]@wh.iov.cn> wrote:
>>> Hi Alice,
>>>
>>> Thanks for the supplementary material.

[redacted]

Released by Chairman Rand Paul

Now I have two more concerns regarding the manuscript:

1) In lines 48-49 in the PDF, you mentioned that "this emerging human virus is closely related to SARS-CoV, and also appears to have originated in horseshoe bats -- with its full genome 96% similar to a virus we discovered in Rhinolophus affinis".

Here this virus refers to RaTG13. Could you please delete the word "we" in this sentence? Otherwise, some readers may think that RaTG13 was detected in our joint study (e.x.PREDICT) and we shared the sequence with EHA earlier. This may be used by some conspiracy theorists to make rumors.

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Though not labeled clearly, RaTG13 is also shown in the phylogenetic tree in Figure 3 (the one most closely related to 2019-nCoV from Rhinolophus affinis in Yunnan). So could you please revise the figure legend of figure 3 as:
Maximum clade credibility tree including 201 RdRp sequences from the*Sarbecovirus* lineage isolated in bats, including RaTG13 (Genbank accession numbers: MN996532) and two sequences of 2019-nCoV isolated in humans (GenBank accession numbers:MN908947 and MN975262).

This will mean that in your analysis you downloaded the sequence from public database, but it was not included in the original dataset of bat CoVs that I provided to you.

2) In lines 89-91 in the PDF. It says 'Our geographic datasets included 694 α-CoV sequences from six zoogeographic regions (22 provinces) and 519 β-CoV sequences from five zoogeographic regions (21 provinces).

The dataset contains some sequences detected from bats in Laos. Are the lao bat CoV sequences also counted in the 694 and 519 sequences? They are not from any Chinese province. If so,the numbers here needs to be corrected.

Besides, CAS now requires authors from CAS institutes to deposit coronavirus sequences not only in Genbank but also in the public database of China National Center for Bioinformation when we publish our researches. So I will submit the sequences which I submited to Genbank last year to the Chinese database next week.

If you have any questions please let me know.

Best

Ben

-----原始邮件-----
发件人:"Alice Latinne" <[redacted]@ecohealthalliance.org>
发送时间:2020-04-04 22:26:44 (星期六)
收件人: "胡犇" <[redacted]@wh.iov.cn>
抄送: "Hongying Li" <[redacted]@ecohealthalliance.org>
主题: Re: Re: China Maps used in the manuscript

Hi Ben,

The supplementary material including Table S1 is attached. And yes it includes all the GenBank numbers you gave me (for the sequences you deposited in genbank by yourself) and all sequences already in GenBank from other studies. Please note that at this stage, I won't be able to modify the dataset, the analysis or the figures.

Cheers,
Alice

On Wed, Apr 1, 2020 at 8:07 PM 胡犇 <[redacted]@wh.iov.cn> wrote:

[redacted]

Released by Chairman Rand Paul

From: 胡犇 <[redacted]@wh.iov.cn>
Sent: Monday, April 13, 2020 10:45 PM EDT
To: Alice Latinne <[redacted]@ecohealthalliance.org>
CC: Hongying Li <[redacted]@ecohealthalliance.org>; 石正丽 <[redacted]@wh.iov.cn>; Peter Daszak <[redacted]@ecohealthalliance.org>; Kevin Olival <[redacted]@ecohealthalliance.org>
Subject: Re: Re: Re: Re: Re: China Maps used in the manuscript

Hi all,

I wrote to Genbank requesting the sequences be released on 15th April, but I have written another mail just now asking them to keep those sequences confidential until further notification.

Best

Ben

> -----原始邮件-----
> **发件人:**"Alice Latinne" <[redacted]@ecohealthalliance.org>
> **发送时间:**2020-04-14 10:34:00 (星期二)
> **收件人:** "胡犇" <[redacted]@wh.iov.cn>
> **抄送:** "Hongying Li" <[redacted]@ecohealthalliance.org>, "石正丽" <z[redacted]@wh.iov.cn>, "Peter Daszak" <[redacted]@ecohealthalliance.org>, "Kevin Olival" <[redacted]@ecohealthalliance.org>
> **主题:** Re: Re: Re: Re: China Maps used in the manuscript
>
> Hi Ben,
>
> I don't know if you wrote to GenBank already or not but as we have to delay the publication of the paper, we CAN'T release the sequences tomorrow (April 15). Could you please ask GenBank to release the sequences at a later date? I hope this is not too late.
>
> Thanks,
> Alice
>
> On Thu, Apr 9, 2020 at 9:37 PM 胡犇 <[redacted]@wh.iov.cn> wrote:
>
> > No problem, Alice. I will write to them tomorrow.
> >
> > Cheers
> >
> > Ben
> >
> > -----原始邮件-----
> > **发件人:**"Alice Latinne" <[redacted]@ecohealthalliance.org>
> > **发送时间:**2020-04-09 21:29:57 (星期四)
> > **收件人:** "胡犇" <[redacted]@wh.iov.cn>
> > **抄送:** "Hongying Li" <li@ecohealthalliance.org>, "石正丽" <[redacted]@wh.iov.cn>, "Peter Daszak" <[redacted]@ecohealthalliance.org>, "Kevin Olival" <[redacted]@ecohealthalliance.org>
> > **主题:** Re: Re: Re: China Maps used in the manuscript
> >
> > Hi Ben,
> >
> > Hope all is well. Nat Comms requires that all sequences are publicly available in GenBank before they can formally accept our paper. So could you ask GenBank to release all sequences (MN312240 to MN312869) on April 15? I'll submit the revised final version to Nat Comms on the 13 or 14th.

[redacted]

Released by Chairman Rand Paul

Thank you!
Alice

On Sun, Apr 5, 2020 at 5:01 PM Alice Latinne <[redacted]@ecohealthalliance.org> wrote:

> Hi Ben,
>
> 1) RaTG13 is not included in the Figure 3. The closest sequence is a sequence from GenBank (KP876546) and published in 2016 in a paper from your lab:
>
> Ge X-Y, Wang N, Zhang W, Hu B, Li B, Zhang Y-Z, Zhou J-H, Luo C-M, Yang X-L, Wu L-J, et al. (Ge2016 co-authors). 2016. Coexistence of multiple coronaviruses in several bat colonies in an abandoned mineshaft. Virologica Sinica 31:31-40.
>
> This sequence is 100% identical to RaTG13, is it the same sample?
>
> I'll delete the word "we" in the sentence.
>
> 2) I'll check and correct this as needed.
>
> Cheers,
> Alice
>
> On Sun, Apr 5, 2020 at 4:24 PM 胡犇 <[redacted]@wh.iov.cn> wrote:
>
> > Hi Alice,
> >
> > Thanks for the supplementary material.
> >
> > Now I have two more concerns regarding the manuscript:
> >
> > 1) In lines 48-49 in the PDF, you mentioned that "this emerging human virus is closely related to SARS-CoV, and also appears to have originated in horseshoe bats -- with its full genome 96% similar to a virus we discovered in Rhinolophus affinis".
> > Here this virus refers to RaTG13. Could you please delete the word "we" in this sentence? Otherwise, some readers may think that RaTG13 was detected in our joint study (e.x.PREDICT) and we shared the sequence with EHA earlier. This may be used by some conspiracy theorists to make rumors.
> >
> > Actually, the sequence of RaTG13 was not included in the dataset I provided to you. It was not deposited into Genbank until this January. So I think it was not included in your dataset, and you used this sequence during the revision phase after COVID-19 outbreak.
> >
> > Though not labeled clearly, RaTG13 is also shown in the phylogenetic tree in Figure 3 (the one most closely related to 2019-nCoV from Rhinolophus affinis in Yunnan). So could you please revise the figure legend of figure 3 as: Maximum clade credibility tree including 201 RdRp sequences from the*Sarbecovirus* lineage isolated in bats, including RaTG13 (Genbank accession numbers: MN996532) and two sequences of 2019-nCoV isolated in humans (GenBank accession numbers:MN908947 and MN975262).
> >
> > This will mean that in your analysis you downloaded the sequence from public database, but it was not included in the original dataset of bat CoVs that I provided to you.
> >
> > 2) In lines 89-91 in the PDF. It says 'Our geographic datasets included 694 α-CoV sequences from six zoogeographic regions (22 provinces) and 519 β-CoV sequences from five zoogeographic regions (21 provinces) .
> >
> > The dataset contains some sequences detected from bats in Laos. Are the lao bat CoV sequences also counted in the 694 and 519 sequences? They are not from any Chinese province. If so,the numbers here needs to be corrected.
> >
> > Besides, CAS now requires authors from CAS institutes to deposit coronavirus sequences not only in Genbank but also in the public database of China National Center for Bioinformation when we publish our researches. So I will submit the sequences which I submited to Genbank last year to the Chinese database next week.
> >
> > If you have any questions please let me know.

[redacted]

Released by Chairman Rand Paul

Best

Ben

-----原始邮件-----
发件人:"Alice Latinne" <[redacted]@ecohealthalliance.org>
发送时间:2020-04-04 22:26:44 (星期六)
收件人: "胡犇" <[redacted]@wh.iov.cn>
抄送: "Hongying Li"[redacted]@ecohealthalliance.org>
主题: Re: Re: China Maps used in the manuscript

Hi Ben,

The supplementary material including Table S1 is attached. And yes it includes all the GenBank numbers you gave me (for the sequences you deposited in genbank by yourself) and all sequences already in GenBank from other studies. Please note that at this stage, I won't be able to modify the dataset, the analysis or the figures.

Cheers,
Alice

On Wed, Apr 1, 2020 at 8:07 PM 胡犇 <[redacted]@wh.iov.cn> wrote:

Hi Alice,

Can you please send me the Table S1 which shows the accession number of all sequences in the dataset used in the analysis? It includes both the sequences I share with you and the sequences you download from Genbank, right?

Thank you!

Ben

-----原始邮件-----
发件人:"Alice Latinne" <[redacted]@ecohealthalliance.org>
发送时间:2020-03-30 17:43:57 (星期一)
收件人: "胡犇" <[redacted]@wh.iov.cn>
抄送: "Hongying Li"[redacted]@ecohealthalliance.org>
主题: Re: Re: Re: Re: Re: China Maps used in the manuscript

Great! :)

On Mon, Mar 30, 2020 at 4:43 PM 胡犇 <[redacted]@wh.iov.cn> wrote:

Absolutely OK. Thanks a lot, Alice!

-----原始邮件-----
发件人:"Alice Latinne" <[redacted]@ecohealthalliance.org>
发送时间:2020-03-30 17:38:25 (星期一)
收件人: "胡犇" <[redacted]@wh.iov.cn>
抄送: "Hongying Li" <[redacted]@ecohealthalliance.org>
主题: Re: Re: Re: Re: China Maps used in the manuscript

Hello,

Here is the updated figure. I hope this is ok!

Thanks,
Alice

[redacted]

Released by Chairman Rand Paul

On Sun, Mar 29, 2020 at 11:55 AM Alice Latinne <[redacted]@ecohealthalliance.org> wrote:

Hi all,

I think using the new map from Hongying is too much work but I'll try. If not, I'll put two small China South Sea map on the figure

On Sun, Mar 29, 2020 at 8:00 AM 胡犇 <[redacted]@wh.iov.cn> wrote:

> Hi both!
>
> I think the map format that Hong Ying provided is even better. Thanks!
>
> -----原始邮件-----
> 发件人:"Hongying Li" <li@ecohealthalliance.org>
> 发送时间:2020-03-28 23:03:46 (星期六)
> 收件人: "胡犇" <[redacted]@wh.iov.cn>
> 抄送: "Alice Latinne" <[redacted]@ecohealthalliance.org>
> 主题: Re: Re: Re: China Maps used in the manuscript
>
> Hi Both!
>
> I think either the South China Sea label can be smaller so it can fit into Figure 6 in two maps; Or the attached format of the South China Sea can be considered, which will fit better into Figure 6 I guess, but requires some more editing. But I defer to whatever you decide.
>
> Hongying
>
> On Sat, Mar 28, 2020 at 9:16 AM 胡犇 <[redacted]@wh.iov.cn> wrote:
>
> > Yes I would like to suggest that it appears twice in both figure A and B. But it seems that the space is limited and the layout need to be adjusted?
> >
> > What do you think, Hongying?
> >
> > -----原始邮件-----
> > 发件人:"Alice Latinne" <[redacted]@ecohealthalliance.org>
> > 发送时间:2020-03-28 17:30:57 (星期六)
> > 收件人: "胡犇" <[redacted]@wh.iov.cn>
> > 抄送: "Hongying Li" <[redacted]@ecohealthalliance.org>, "博士石正丽" <[redacted]@wh.iov.cn>, "Peter Daszak" <[redacted]@ecohealthalliance.org>
> > 主题: Re: Re: China Maps used in the manuscript
> >
> > Hi Ben,
> >
> > Is the new Figure 6 ok? Or do I have to put the South China Sea 2 times?
> >
> > Thanks,
> > Alice
> >
> > On Sat, Mar 28, 2020 at 3:32 PM 胡犇 <[redacted]@wh.iov.cn> wrote:
> >
> > > Thanks a lot Alice. The maps now seems perfect.
> > >
> > > Please note that the two maps in Figure 6 also need to be modified (that could be easier I think, as only South China Sea need to be added)
> > >
> > > Best wishes
> > >
> > > Ben

Released by Chairman Rand Paul

-----原始邮件-----
发件人:"Alice Latinne" <[redacted]@ecohealthalliance.org>
发送时间:2020-03-24 22:08:46 (星期二)
收件人: "Hongying Li" <[redacted]@ecohealthalliance.org>
抄送: "胡犇" <[redacted]@wh.iov.cn>, "博士石正丽" <[redacted]@wh.iov.cn>, "Peter Daszak" <[redacted]@ecohealthalliance.org>
主题: Re: China Maps used in the manuscript

Hi Hongying and Ben,

Yes I can edit this map as needed, thank you!! I'll work on this when I have time.

The revised and submitted version of the paper is attached. Let me know if there is anything else that is problematic (hopefully not too much!).

Thanks,
Alice

On Mon, Mar 23, 2020 at 9:59 PM Hongying Li <[redacted]@ecohealthalliance.org> wrote:

> Hi Alice,
>
> Does the attached editable PPT work for you? I colored Shanghai and Xizang in red, and copied pasted south China sea from Ben's template.
>
> Hongying
>
> On Mon, Mar 23, 2020 at 10:35 AM Alice Latinne <[redacted]@ecohealthalliance.org> wrote:
>
>> Hi Ben,
>>
>> I totally understand your concerns and will correct these issues. Could you send me a correct map in **pdf format**? This would be really helpful. I really need a pdf where I can change the colour of each province. I can't do it with the pptx you sent me.
>>
>> I hope life in Wuhan is getting easier these days!
>>
>> Best wishes,
>> Alice
>>
>> On Sun, Mar 22, 2020 at 9:50 PM 胡犇 <[redacted]@wh.iov.cn> wrote:
>>
>>> Dear Alice,
>>>
>>> How is going? I don't know where you are now but since almost every country is facing the threat of COVID-19, I hope everything is fine with you.
>>>
>>> I am happy to know that our paper on Chinese bat coronavirus is almost accepted. Thank you so much for the contribution to this joint work.
>>>
>>> Today, when I re-checked the figures, I suddenly had a new concern about the paper. The problem is about the maps of China appearing in the figures. It is not a scientific issue, but we must be very careful about it, because in China some people are extremely strict about the territorial integrity and sovereignty shown in the map.
>>>
>>> The problems I found include:
>>>
>>> 1) In figure 1, Shanghai is missing in the map. In the province of Tibet, the region called South Tibet (which is actually controlled by India) is not included.
>>>
>>> 2) In all three maps, South China Sea is not shown. For Chinese people, a complete map of China should clearly include the South China Sea with a focus on nine-dashed line (I attached a model in the PPT for you to know how it should look like).
>>>
>>> I know it will take you some more time to correct the maps. but please understand this concern. If we don't correct the problems, people may judge that Zhengli, me and our Chinese colleagues are making political mistakes. We don't wish that the maps will become a target of attack from those people. You may know that at this every special and sensitive time when COVID-19 occurs, there

[redacted]

Released by Chairman Rand Paul

are some rumors about the research cooperation on coronaviruses between our lab and the US. So we may have to be more careful than before.

After the maps are modified, please send them to me to have a look before they are finally submitted.

If you have any question, please contact me.

Thanks, and take care!

Ben

> -----原始邮件-----
> **发件人:**"Alice Latinne" <[redacted]@ecohealthalliance.org>
> **发送时间:**2019-10-08 00:08:10 (星期二)
> **收件人:** "胡犇老师" <[redacted]@wh.iov.cn>, "朱光剑" <[redacted]@126.com>, zhanglb <[redacted]@gaibr.gd.cn>, "Carlos Zambrana-Torrelio" <[redacted]@ecohealthalliance.org>, "Kevin Olival, PhD" <[redacted]@ecohealthalliance.org>, "博士石正丽" <[redacted]@wh.iov.cn>, "Peter Daszak" <[redacted]@ecohealthalliance.org>, "李贝" <[redacted]@126.com>, "张玮" <[redacted]@wh.iov.cn>, "Hongying Li" <[redacted]@ecohealthalliance.org>, "Aleksei MacDurian" <[redacted]@ecohealthalliance.org>, "Hume Field" <[redacted]@ecohealthalliance.org>, "Jon Epstein" <[redacted]@ecohealthalliance.org>, "Wang Linfa" <[redacted]@duke-nus.edu.sg>
> **抄送:**
> **主题:** China bat CoV paper submitted
>
> Dear Co-authors,
>
> I just wanted to let you know that I submitted our China bat CoV paper to Nature Communications yesterday. Thank you for all your comments and edits on previous versions of the paper, that was very helpful.
>
> Attached is the submitted version. I'll keep you updated. Finger's crossed...
>
> Best regards,
> Alice
>
> --
> **Alice Latinne, PhD**
>
> *Research Scientist*
> *PREDICT-2 Country Liaison, Thailand and Indonesia*
>
> EcoHealth Alliance
> 460 West 34th Street – 17th floor
> New York, NY 10001
>
> [redacted] (direct)
> [redacted] (mobile)
> www.ecohealthalliance.org
>
> ***EcoHealth Alliance leads cutting-edge scientific research into the critical connections between human and wildlife health and delicate ecosystems. With this science, we develop solutions that prevent pandemics and promote conservation.***

--
Alice Latinne, PhD

Research Scientist

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

[redacted] (mobile)

[redacted]

Released by Chairman Rand Paul

www.ecohealthalliance.org

EcoHealth Alliance leads cutting-edge scientific research into the critical connections between human and wildlife health and delicate ecosystems. With this science, we develop solutions that prevent pandemics and promote conservation.

--
Alice Latinne, PhD

Research Scientist

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

[redacted] (mobile)
www.ecohealthalliance.org

EcoHealth Alliance leads cutting-edge scientific research into the critical connections between human and wildlife health and delicate ecosystems. With this science, we develop solutions that prevent pandemics and promote conservation.

--
Alice Latinne, PhD

Research Scientist

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

[redacted] (mobile)
www.ecohealthalliance.org

EcoHealth Alliance leads cutting-edge scientific research into the critical connections between human and wildlife health and delicate ecosystems. With this science, we develop solutions that prevent pandemics and promote conservation.

--
Alice Latinne, PhD

Research Scientist

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

[redacted] (mobile)
www.ecohealthalliance.org

EcoHealth Alliance leads cutting-edge scientific research into the critical connections between human and wildlife health and delicate ecosystems. With this science, we develop solutions that prevent pandemics and promote conservation.

--
Alice Latinne, PhD

Research Scientist

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

[redacted] (mobile)
www.ecohealthalliance.org

[redacted]

Released by Chairman Rand Paul

> *EcoHealth Alliance leads cutting-edge scientific research into the critical connections between human and wildlife health and delicate ecosystems. With this science, we develop solutions that prevent pandemics and promote conservation.*

--
Alice Latinne, PhD

Research Scientist

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

[redacted] (mobile)
www.ecohealthalliance.org

> *EcoHealth Alliance leads cutting-edge scientific research into the critical connections between human and wildlife health and delicate ecosystems. With this science, we develop solutions that prevent pandemics and promote conservation.*

--
Alice Latinne, PhD

Research Scientist

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

[redacted] (mobile)
www.ecohealthalliance.org

> *EcoHealth Alliance leads cutting-edge scientific research into the critical connections between human and wildlife health and delicate ecosystems. With this science, we develop solutions that prevent pandemics and promote conservation.*

--
Alice Latinne, PhD

Research Scientist

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

[redacted] (mobile)
www.ecohealthalliance.org

> *EcoHealth Alliance leads cutting-edge scientific research into the critical connections between human and wildlife health and delicate ecosystems. With this science, we develop solutions that prevent pandemics and promote

[redacted]

Released by Chairman Rand Paul

> *conservationNo*
>
> N

--

Alice Latinne, PhD

Research Scientist

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

[redacted] (mobile)
www.ecohealthalliance.org

EcoHealth Alliance leads cutting-edge scientific research into the critical connections between human and wildlife health and delicate ecosystems. With this science, we develop solutions that prevent pandemics and promote conservation.

[redacted]

Released by Chairman Rand Paul

From: 石正丽 <[redacted]@wh.iov.cn>
Sent: Wednesday, August 11, 2021 11:22 PM EDT
To: Peter Daszak <[redacted]@ecohealthalliance.org>
CC: Alice Latinne <[redacted]@ecohealthalliance.org>; 胡犇 <[redacted]@wh.iov.cn>
Subject: Fw: Permission to adapt published figure

Dear Peter,

Have you received the request of the following email? I give my permission if you agree.

Best regards,

Zhengli,

-----原始邮件-----
发件人:"VANITHA MARIAPPAN" <[redacted]@ukm.edu.my>
发送时间:2021-08-12 11:07:45 (星期四)
收件人: [redacted]@wh.iov.cn
抄送:
主题: Permission to adapt published figure

Dear Zheng-Li Shi,

I'm Vanitha Mariappan, a researcher from Universiti Kebangsaan Malaysia, would like to seek your permission to adapt an image (Figure 4) published in your recent article 'Origin and cross-species transmission of bat coronaviruses in China' published in *Nat. Commun.* (2020) 11(1):4235.

My team and I are coming up with a book chapter on COVID-19 in our national language (Bahasa Melayu) and planning to incorporate the figure that you have published. The publisher will need to see written permission from the original author to allow us to adapt the figure in our book chapter.

Hence, I hope to hear from you favourably soon
Thank you and stay safe!
--
Best regards,
VM

Vanitha Mariappan, PhD
Center for Toxicology and Health Risk Studies (CORE),
Faculty of Health Sciences,
Universiti Kebangsaan Malaysia,
Jalan Raja Muda Abdul Aziz,
50300 Kuala Lumpur,
Malaysia
Tel: [redacted]

PENAFIAN: E-mel ini dan apa-apa fail yang dikepilkan bersamanya ("Mesej") adalah ditujukan hanya untuk kegunaan penerima(-penerima) yang termaklum di atas dan mungkin mengandungi maklumat sulit. Anda dengan ini dimaklumkan bahawa mengambil apa jua tindakan bersandarkan kepada, membuat penilaian, mengulang hantar, menghebah, mengedar, mencetak, atau menyalin Mesej ini atau sebahagian daripadanya oleh sesiapa selain daripada penerima(-penerima) yang termaklum di atas adalah dilarang. Jika anda telah menerima Mesej ini kerana kesilapan, anda mesti menghapuskan Mesej ini dengan segera dan memaklumkan kepada penghantar Mesej ini menerusi balasan e-mel. Pendapat, rumusan, dan sebarang maklumat lain di dalam Mesej ini yang tidak berkait dengan urusan rasmi Universiti Kebangsaan Malaysia (UKM) adalah difahami sebagai bukan dikeluar atau diperakui oleh mana-mana pihak yang disebut.

DISCLAIMER *: This e-mail and any files transmitted with it ("Message") is intended only for the use of the recipient(s) named above and may contain confidential information. You are hereby notified that the taking of any action in reliance upon, or any review, retransmission, dissemination, distribution, printing or copying of this Message or any part thereof by anyone other than the intended recipient(s) is strictly prohibited. If you have received this Message in error, you should delete this Message immediately and advise the sender by return e-mail. Opinions, conclusions and other information in this Message that do not relate to the official business of The National University of Malaysia (UKM) shall be understood as neither given nor endorsed by any of the aforementioned.*

Released by Chairman Rand Paul

From: 石正丽 <[redacted]@wh.iov.cn>
Sent: Saturday, April 30, 2022 8:44 AM EDT
To: Peter Daszak <[redacted]@ecohealthalliance.org>; 李泓萤 <[redacted]@ecohealthalliance.org>
CC: 周鹏 <[redacted]@wh.iov.cn>
Subject: Fw: RE: RE: Matters Arising regarding your Nature paper
Attachment(s): "Email to Nature.docx"

Dear Peter,

I hope you are doing well.

I forward a recent email from Clare Thomas. This is one of emails from Clare asked by some scientists regarding the RaTG13 sequence. I believe Jessie Bloom is the leading scientist among them. We prepared a draft to explain to Clare what Jessie Bloom has done for us. Can you please help us to edit and snapshot some of his comments on Chinese Scientist on his Twitter?

Best regards,

Zhengli,

> -----原始邮件-----
> **发件人:**"Clare Thomas" <[redacted]@nature.com>
> **发送时间:**2022-04-29 17:38:47 (星期五)
> **收件人:** "[redacted]@wh.iov.cn" <[redacted]@wh.iov.cn>
> **抄送:**
> **主题:** RE: RE: Matters Arising regarding your Nature paper
>
> Dear Zhengli,
>
> I hope you're well. We've been contacted again by several scientists regarding some of the methodological details that you clarified at the end of last year. Some of these scientists are asking the same questions as the correspondent who submitted the Matters Arising. I think this information needs to be provided publicly. We can either do a correction to the paper to add these details, or the person who originally wrote to us has provided some helpful suggestions below for how these methods details can be added to the relevant databases (please see the suggestions below). This would be our preference. Could you please add the information, as indicated, and let me know when you've done it so that I can let them know? Please let me know if you have any questions.
>
> Thanks in advance,
>
> Clare
>
> Second and most importantly, it seems that the information that was provided to me in your email and in the Word document prepared by the laboratory of Shi Zheng-Li has still not been shared publicly by the authors.
>
> For example, a few days ago I was asked by researcher Moreno Colaiacov about the RaTG13 sample that was "gone" and yet used later for 5'RACE. Unfortunately I could not answer him because you told me that this information was confidential.
>
> It would be really nice for this information that has been shared with me to be made public.
> For example, would it be possible for the authors to include the information as metadata in NCBI GenBank?
>
> For example:

[redacted]

1) Timeline information

"Year 2017: Amplification of full-length RdRp gene and ORF8 gene

Year 2018: NGS and gap filling of the genome sequence

September 2020: RACE for determination of the 5'end sequence"

and

"anal swab, not a fecal pellet, they used the High Pure Viral RNA kit for the RNA extraction"

"for the 5'race done in September 2020 they used the viral RNA previously extracted from that anal swab sample."

could go into the category called "description" for the Biosample accession of RaTG13 sample https://www.ncbi.nlm.nih.gov/biosample/?term=SAMN14082201, as in:

https://www.ncbi.nlm.nih.gov/biosample/SAMN02928182

2) The information about the "Method of genome sequence assembly" could go into the "Comment" section of the RaTG13 full sequence accession:

https://www.ncbi.nlm.nih.gov/nuccore/1916859392

3) the list of primers used for amplicons and the points related to the amplicon names could go into the "Strategy" section of the SRA Experiment accession:

https://www.ncbi.nlm.nih.gov/sra/SRX8357956 (see https://www.ncbi.nlm.nih.gov/sra/docs/submitmeta/ for details)

From: Clare Thomas
Sent: 29 November 2021 09:37
To: [redacted]@wh.iov.cn
Subject: RE: RE: Matters Arising regarding your Nature paper

Dear Zhengli,

Thank you very much.

All the best,

Clare

From: [redacted]@wh.iov.cn <[redacted]@wh.iov.cn>
Sent: 29 November 2021 09:07
To: Clare Thomas <[redacted]@nature.com>
Subject: Re: RE: Matters Arising regarding your Nature paper

[External - Use Caution]

Dear Clare,

[redacted]

Please see our answers as follows:

The reasons for the low bacterial reads in the raw sequencing data of RaTG13 could be:

1) The sample is anal swab, not a fecal pellet.

2) We used the High Pure Viral RNA Kit for the RNA extraction.

3) The sequencing depth was not high.

For the 5'race done in September 2020, we used the viral RNA previously extracted from that anal swab sample.

Best regards,

Zhengli,

[redacted]@wh.iov.cn

From: Clare Thomas

Date: 2021-11-24 19:51

To: [redacted]@wh.iov.cn

Subject: RE: Matters Arising regarding your Nature paper

Dear Zhengli,

Thanks again for providing very helpful responses to the Matters Arising. We do have an obligation to look into any comments about papers that we publish, particularly if they relate to concerns about insufficient methodological detail etc. I just wanted to ask you about a two more things, about the sample source, for the sake of completeness.

The Matters Arising author points to a preprint that claims the raw data contain lower levels of bacterial reads than would be expected from a fecal swab. I cannot see from the methods anywhere that the nature of the sample was described. Was it a fecal swab? If so, is there an explanation for the low bacterial reads, if indeed that claim is true?

And along the same lines, what was the sample used for the sequencing of the 5'end done in September 2020?

Thanks in advance for clarifying these details, which do seem pertinent to the methods described in our paper and therefore we do have to ask.

Once again I'm very sorry for having to trouble you on so many occasions with these queries.

With best wishes,

Clare

[redacted]

Released by Chairman Rand Paul

From: [redacted]@wh.iov.cn <[redacted]@wh.iov.cn>
Sent: 24 November 2021 09:10
To: Clare Thomas <[redacted]@nature.com>
Subject: Re: Matters Arising regarding your Nature paper

[External - Use Caution]

Dear Clare,

I'm sorry that you continue to recieve such emails. It's a pity that there are someone who is contining to doute and scruetine our work. This person has been interrupting me and my colleagues and want to find evidence to show that the SARS-CoV-2 is a lab leak. I don't think I should answer his unreasonable questions and crazy ideas. But for your refrence, I would like to send you more details although I think they are not whinth the duty of you and neither the scope of my publication in your journal.

Best regards,

Zhengli,

[redacted]@wh.iov.cn

From: Clare Thomas

Date: 2021-11-19 02:09

To: 石正丽

Subject: Matters Arising regarding your Nature paper

Dear Zhengli,

I hope you're well. I'm afraid we've been contacted by a scientist who has submitted a Matters Arising to the journal, regarding your 2020 Nature paper. I've attached the MA here.

One of the points raised is something we already discussed, which is why there is a difference in sequence identity between SARS-CoV and RaTG13 and SARS-CoV and the virus labelled Ra4991-Yunnan in the thesis which appeared online. You already responded to a journalist's query about this, and told us that the difference was due to different bioinformatics approaches.

The other concerns seem to be points that have not been raised with us before. The author notes that the original Nature paper did not contain any information about how the RaTG13 genome was assembled and has some concerns regarding the timeline of the sequencing and assembly as well as missing methods (e.g. primer sequences). The addendum touched on the timing of the sequencing, but not the methods, and the author has some concerns regarding the timeline and asks for further details to clarify how the full RaTG13 sequence was obtained.

Would you please be able to send us a response to these new concerns so that we can discuss how to proceed? If you could return a response within one week that would be greatly appreciated.

[redacted]

Released by Chairman Rand Paul

With best wishes,

Clare

Clare Thomas

Senior Editor

Nature

From: 石正丽 <[redacted]@wh.iov.cn>
Sent: 29 June 2021 00:13
To: Clare Thomas <[redacted]@nature.com>
Subject: Re: RE: RE: A question about the addendum to your Nature paper

[External - Use Caution]

Dear Clare,

Thank you for your information. I'm fine with the passing to the journalist on the information I told you.

Best regards,

Zhengli,

-----原始邮件-----
发件人:"Clare Thomas" <[redacted]@nature.com>
发送时间:2021-06-29 04:39:21 (星期二)
收件人: "[redacted]@wh.iov.cn" <[redacted]@wh.iov.cn>
抄送:
主题: RE: RE: A question about the addendum to your Nature paper

Dear Zhengli,

Thanks again for replying to my question about the discrepancy highlighted to us. We've received some queries about it from journalists. Conversations between editors and authors are confidential but I wanted to ask you if you would have any objection to our passing on the information that you have told us? Would you be willing for us to tell the journalists that you have told us that the bioinformatics approaches used to analyse the genome sequences in the Nature paper and the thesis were different? We are considering how to respond and wonder whether this might help dampen the speculation. Please could you let me know?

All the best,

Clare

[redacted]

Released by Chairman Rand Paul

From: [redacted]@wh.iov.cn <[redacted]@wh.iov.cn>
Sent: 27 June 2021 03:48
To: Clare Thomas <[redacted]@nature.com>
Subject: Re: RE: A question about the addendum to your Nature paper

[External - Use Caution]

Dear Clare,

I'm sorry for replying you late.

This kind of speculation by the anonymous person is damging the science. I thought it's not necessary to clarify the question when I received your email. But I did carefully check with my colleagues who did the sequence analyses. First, there is no doubt that the TG13 and 4991 are the same sample and also the only one we found in the past 17 years and show the closest relative to SARS-CoV-2. Second, the resason of the discrepancy come from different comparison strategy with different softwares. The data we published in Nature was produced by blastp in NCBI between TG13 and SARS-CoV Tor. The data in the thesis of our graduate student as indicated in the request email was produced by alignment of mutiple sequences using Mafft software followed by cauculation of identity by Bioedit.

In addition, the thesis of our graduate student is currently embargo becuase of knowledge property protection and we don't know why this thesis was uploded in the google drive and misused by the consparicy people.

I hope I clarify your concern.

Best regards,

Zhengli,

[redacted]@wh.iov.cn

From: Clare Thomas

Date: 2021-06-25 02:09

To: [redacted]@wh.iov.cn

Subject: RE: A question about the addendum to your Nature paper

Dear Zhengli,

I wonder whether you have had a chance to consider my email below? I am sorry to bug you about it, but

[redacted]

Released by Chairman Rand Paul

we do have an obligation to look into any queries that we receive about any Nature paper that we publish. I can imagine that you must be quite frustrated with these sorts of queries, but if there is an explanation for the apparent discrepancy highlighted to us then it would be great if you could please let us know.

Many thanks in advance and all the best,

Clare

From: Clare Thomas
Sent: 23 June 2021 17:07
To: [redacted]@wh.iov.cn' <[redacted]@wh.iov.cn>
Subject: A question about the addendum to your Nature paper

Dear Zhengli,

I hope you're well. We have been contacted by someone who claims that a thesis from the Wuhan Institute of Virology contains information that seemingly questions the relationship of RaTG13 to the sample originally named 4991. You can see the correspondence that we've received below. We have not clicked on these links, so have not looked at the thesis itself, but would you please be able to provide some clarification about these claims? I believe the concern is that if Ra4991 and RaTG13 are the same virus, as claimed in the addendum, then their identity to SARS-CoV should be the same and the table pasted below indicates that they differ to some extent in the spike gene.

Thanks in advance and best wishes,

Clare

Clare Thomas

Senior Editor

Nature

A Dissertation submitted to The University of Chinese Academy of Sciences in 2019 by Yu Ping at the Wuhan institute of Virology has recently surfaced online.

Original: https://drive.google.com/drive/folders/1cJBYAkjkZX9KbNfHCaeaaMhNDgff1elg

English
translation: https://docs.google.com/document/d/15U2uE7Eru0QxRbf8QVRPRMpssCoYhGvT/edit

The document has been uploaded by an anonymous user on Twitter, and contains potentially new information the RATG13 virus sequence and its relationship to bat sample 4991.

The RATG13 sequence was first mentioned in the article "A pneumonia outbreak associated with a new coronavirus of probable bat origin» published by Nature. In the addendum to this article, that was published November last year, the authors clarify that RATG13 sequence is the full virus sequence collected from bat sample 4991.

[redacted]

Released by Chairman Rand Paul

However, the newly uncovered thesis by Ping, raises new questions on the raw data in regards to the RATG13 sequence and its relationship to the 4991 sample. In the thesis the full sequence of bat sample 4991 is shown to be 75,4% identical in the spike gene compared to SARs-CoV Tor2.

Table 3.2 Comparison of ORF amino acid identities between bat SARSr-CoVs and human SARS-CoV Tor2.

CoV	ORF1a	S	ORF3	E	M	ORF6	ORF7	ORF8	N
LYRa11/Yunnan	95.8	89.2	90.8	98.6	97.7	95.2	94.2	15.4	97.8
WIV16/Yunnan	98.0	96.8	97.0	100.0	98.1	92.0	95.0	16.1	99.5
WIV1/Yunnan	97.9	92.1	96.7	100.0	98.1	93.6	95.0	16.9	99.7
Rs4084/Yunnan	97.9	89.8	97.0	98.6	98.1	96.8	95.9	85.9	99.5
Anlong-103/Guizhou	98.1	79.4	89.7	100.0	98.6	96.8	95.0	31.8	98.3
Rp3/Guangxi	96.5	78.5	83.5	100.0	97.2	92.0	95.0	15.4	97.8
HKU3-7/Guangdong	94.0	78.1	82.8	98.6	97.2	92.0	93.4	15.4	98.1
HKU3-1/Hong Kong	94.1	77.9	81.7	100.0	98.6	93.6	94.2	14.7	96.4
Rf1/Hubei	94.0	76.6	86.1	96.0	97.7	93.6	91.8	23.9	95.4
Jiyuan-84/Henan	94.0	76.8	86.8	96.0	97.7	92.0	94.2	25.3	96.2
Rp/Shaanxi	95.4	79.0	82.4	97.3	96.8	92.0	92.6	15.4	97.8
HeB2013/Hebei	94.1	76.8	87.2	96.0	97.7	93.6	93.4	25.3	96.2
JL2012/Jilin	93.2	74.6	86.1	97.3	97.2	87.3	90.1	NA	95.7
Ra4991_Yunnan	80.0	75.4	73.8	94.7	90.9	66.6	83.6	12.6	90.5
Rs5725_Yunnan	98.2	94.8	97.0	100.0	100.0	100.0	95.9	31.1	NC
Rs8561_Guangdong	80.4	75.2	70.5	94.7	89.6	68.2	83.6	12.6	92.8
Rs141456_Guangxi	96.1	78.6	83.5	98.6	98.6	88.8	94.2	16.3	98.1
BM48-31/Bulgaria	80.8	74.7	69.0	92.1	88.5	49.2	56.5	NP	87.2

NA, not available; NP, not present; NC, not complete.

This indicates that bat sample 4991 is not fully identical to RATG13 across the genome, as the RATG13 Spike is shown to be 76.59 percent identical to SARS-CoV Tor2 in the spike gene, thereby deviating by 1.1 percent.

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Registered Number: 00785998 England.

Released by Chairman Rand Paul

From: 石正丽 <[redacted]@wh.iov.cn>
Sent: Tuesday, September 07, 2021 9:36 PM EDT
To: Peter Daszak <[redacted]@ecohealthalliance.org>
CC: 周鹏 <[redacted]@wh.iov.cn>; Hongying Li <[redacted]@ecohealthalliance.org>
Subject: Re: IMPORTANT - FW: bat coronavirus genetic data

Dear Peter,

Thank you for your reminding. I'll do what you suggest if I receive the email from Jesse Bloom. He is obsessive of the conspiracy that China is not transparent regarding the origin of COVID-19. I believe he is a brilliant scientist but don't understand why he stands with the conspiracy makers.

We are trying to update our database in cyber security and scientific data and hope to reopen it in several months.

Take cares.

Best regards,

Zhengli,

> -----原始邮件-----
> **发件人:**"Peter Daszak" <[redacted]@ecohealthalliance.org>
> **发送时间:**2021-09-08 05:24:47 (星期三)
> **收件人:** "Zhengli Shi" <[redacted]@wh.iov.cn>, "周鹏" <[redacted]@wh.iov.cn>
> **抄送:** "Hongying Li" <[redacted]@ecohealthalliance.org>
> **主题:** IMPORTANT - FW: bat coronavirus genetic data
>
> Hello Zhengli and Peng – I hope everything is going well. I have a couple of things to catch up on. The first and most important is this very annoying request from Jesse Bloom. He is the geneticist/phylogeny person who recently caused trouble over the partial genomes of SARS-CoV-2 that were deleted from a database by a Chinese researcher and he claimed this was done for suspicious reasons.
>
> Now he is asking me for sequence data from our joint work on bat-CoVs. The reason for this is that NIH has been asked by journalists to release the full proposal for our China R01 grant. I've been fighting this for many months, and NIH has also been refusing to release the details. Now journalists took the NIH to court and a judge forced them to release our grant proposals and annual reports for the last 7 years. Jesse Bloom has read the proposal and saw that I promised to share sequence data after 6 months publicly. He is now asking for all the data.
>
> I am writing because I know you have spoken and emailed with him and I believe he is the sort of person who will also email you directly. Please do NOT share agree to this request! If he asks for this data from the NIH grant work, tell him that I am the Principal Investigator and he needs to ask permission from me.
>
> I will respond to him sometime in the next few days and explain to him that all of the bat SARSr-CoV sequences are now uploaded onto Genbank. He will probably write back and ask for the raw data. I will then ignore his requests.
>
> The truth is that EcoHealth Alliance has a policy on how we work in foreign countries. We do this in a way that is respectful of local laws, and of scientists from the countries. We form partnerships (our alliance), like we have with you that are based on trust and respect for the country of origin of samples. We believe that samples and data belong to the country that they were collected in, and we never publish data or share it publicly unless it has been approved by the country of origin. In this case, some has been published, and he can download the Genbank references and work with those. Additionally, our grant was terminated and is now suspended, so I believe this sort of request is not appropriate.
>
> Cheers,
>
> Peter

[redacted]

Released by Chairman Rand Paul

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: [redacted]
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

---

From: Bloom PhD, Jesse D [redacted]@fredhutch.org>
Sent: Tuesday, September 7, 2021 3:23 PM
To: [redacted]@ecohealthalliance.org; [redacted]@ecohealthalliance.org
Subject: bat coronavirus genetic data

Hi Peter and Kevin,

Hope all is well.

I'm writing because I was just reading the text of R01 AI110964, and noticed that the resource sharing section said that all viral genetic data (presumably the raw sequencing data) would be publicly released no later than 6 months after it was acquired.

I'm very interested in analyzing as much data as possible about coronavirus sequences that were collected in China to better understand the evolution of SARS-CoV-2. I know Peter has publicly discussed at various times in late 2019 and early 2020 the discovery of additional ACE2-utilizing coronaviruses not yet published. Given the grants resource sharing terms, I wanted to ask if you could share those data? I'd of course be happy to collaborate in any analyses.

Thanks,
Jesse

Jesse Bloom
Professor, Fred Hutch Cancer Research Center
Affiliate Professor, Genome Sciences & Microbiology, University of Washington
Investigator, Howard Hughes Medical Institute

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Released by Chairman Rand Paul

From: [redacted]@wh.iov.cn <[redacted]@wh.iov.cn>
Sent: Saturday, April 30, 2022 9:22 PM EDT
To: Peter Daszak <[redacted]@ecohealthalliance.org>
CC: zlshi <[redacted]@wh.iov.cn>; Hongying Li <[redacted]@ecohealthalliance.org>
Subject: Re: Matters Arising regarding your Nature paper

Thanks Peter, sorry to hear that. Maybe these constant attacks are also damaging the international effort on pathogen discovery, which will eventually hurt the preparedness of future pandemic. I don't think Nature is happy to see that.

---- 回复的原邮件 ----

发件人	Peter Daszak<[redacted]@ecohealthalliance.org>
日期	2022年05月01日 05:40
收件人	石正丽<z[redacted]@wh.iov.cn>、Hongying Li<[redacted]@ecohealthalliance.org>
抄送至	周鹏<[redacted]@wh.iov.cn>
主题	RE: RE: RE: Matters Arising regarding your Nature paper

Hi Zhengli and Peng,

Sorry to read this – looks like Nature are falling into the trap of responding to these demands for more and more information as if they are genuine scientific concerns.

I think the best way to deal with this is to write a strong letter (and I will help by editing it and inserting the references), but I think you should probably also make the additions to the database. The problem is that, whatever the reason for these people writing into Nature, the editor is now asking for you to either: 1) have a correction to the paper, or 2) make edits and additions to the database that give further details on the methodology used and timing of sequencing etc..
If you don't do the changes to the database, the editor might then force you to make a correction to the paper. I think your response to Nature should say that this is unnecessary and inappropriate, and it is not normal scientific practice for such detailed information to be demanded. However in the interests of helping Nature deal with the letters they are receiving, you will reluctantly further information in the database. You could make the additions to the database very short and simple, because these requests are not really to help anyone understand the issue better, they're largely designed to claim that you didn't provide full information.

We've had the same thing with our Nature Communications paper, and with the 'competing interests' statement on our lancet paper ("Statement of support for scientists in China"). The original Lancet paper said 'no competing interests', but the editor made me draft 380 word statement that was longer than the actual letter, mainly because people had written to him to complain. I think this is going to happen for many others papers in the past and in the future. Every time we publish work, the lab leak people get ready to attack and demand corrections/changes. We've also had to respond to so many political attacks here in the same way. For example, NIH has made us change the language in our subcontracts, even though we already had language that covered their concerns. They're doing it because some politicians who believe in the lab leak theory write to them and make the letters public. They cover themselves by showing politicians that they are making us do more than others to continue our work. It's awful, but our response is always like this: "We first would like to point out that we have already addressed this issue. However, because you insist on us changing the wording, we will of course do that". It's the same thing with this request from Nature.

Give me a couple of days to go through the background documents and I'll edit the so it says that you find these constant attacks on the credibility of your work unnecessary and inappropriate, and that these are part of a series of online attacks on you and other scientists from China. I'll also put in links like you suggest.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: [redacted]
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

[redacted]

Released by Chairman Rand Paul

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

From: 石正丽 <[redacted]@wh.iov.cn>
Sent: Saturday, April 30, 2022 8:45 AM
To: Peter Daszak <[redacted]@ecohealthalliance.org>; 李泓萤 <[redacted]@ecohealthalliance.org>
Cc: 周鹏 <[redacted]@wh.iov.cn>
Subject: Fw: RE: RE: Matters Arising regarding your Nature paper

Dear Peter,

I hope you are doing well.

I forward a recent email from Clare Thomas. This is one of emails from Clare asked by some scientists regarding the RaTG13 sequence. I believe Jessie Bloom is the leading scientist among them. We prepared a draft to explain to Clare what Jessie Bloom has done for us. Can you please help us to edit and snapshot some of his comments on Chinese Scientist on his Twitter?

Best regards,

Zhengli,

> -----原始邮件-----
> **发件人:**"Clare Thomas" <[redacted]@nature.com>
> **发送时间:**2022-04-29 17:38:47 (星期五)
> **收件人:** "[redacted]@wh.iov.cn" <[redacted]@wh.iov.cn>
> **抄送:**
> **主题:** RE: RE: Matters Arising regarding your Nature paper
>
> Dear Zhengli,
>
> Dear Zhengli,
>
> I hope you're well. We've been contacted again by several scientists regarding some of the methodological details that you clarified at the end of last year. Some of these scientists are asking the same questions as the correspondent who submitted the Matters Arising. I think this information needs to be provided publicly. We can either do a correction to the paper to add these details, or the person who originally wrote to us has provided some helpful suggestions below for how these methods details can be added to the relevant databases (please see the suggestions below). This would be our preference. Could you please add the information, as indicated, and let me know when you've done it so that I can let them know? Please let me know if you have any questions.
>
> Thanks in advance,
>
> Clare
>
> Second and most importantly, it seems that the information that was provided to me in your email and in the Word document prepared by the laboratory of Shi Zheng-Li has still not been shared publicly by the authors.
>
> For example, a few days ago I was asked by researcher Moreno Colaiacov about the RaTG13 sample that was "gone" and yet used later for 5'RACE. Unfortunately I could not answer him because you told me that this information was confidential.
>
> It would be really nice for this information that has been shared with me to be made public.
> For example, would it be possible for the authors to include the information as metadata in NCBI GenBank?
>
> For example:
>
> 1) Timeline information
>
> "Year 2017: Amplification of full-length RdRp gene and ORF8 gene
>
> Year 2018: NGS and gap filling of the genome sequence

[redacted]

September 2020: RACE for determination of the 5'end sequence"

and

"anal swab, not a fecal pellet, they used the High Pure Viral RNA kit for the RNA extraction"

"for the 5'race done in September 2020 they used the viral RNA previously extracted from that anal swab sample."

could go into the category called "description" for the Biosample accession of RaTG13 sample https://www.ncbi.nlm.nih.gov/biosample/?term=SAMN14082201, as in:

https://www.ncbi.nlm.nih.gov/biosample/SAMN02928182

2) The information about the "Method of genome sequence assembly" could go into the "Comment" section of the RaTG13 full sequence accession:

https://www.ncbi.nlm.nih.gov/nuccore/1916859392

3) the list of primers used for amplicons and the points related to the amplicon names could go into the "Strategy" section of the SRA Experiment accession:

https://www.ncbi.nlm.nih.gov/sra/SRX8357956 (see https://www.ncbi.nlm.nih.gov/sra/docs/submitmeta/ for details)

From: Clare Thomas
Sent: 29 November 2021 09:37
To: [redacted]@wh.iov.cn
Subject: RE: RE: Matters Arising regarding your Nature paper

Dear Zhengli,
Thank you very much.
All the best,
Clare

From: [redacted]@wh.iov.cn <[redacted]@wh.iov.cn>
Sent: 29 November 2021 09:07
To: Clare Thomas <[redacted]@nature.com>
Subject: Re: RE: Matters Arising regarding your Nature paper

[External - Use Caution]

Dear Clare,

Please see our answers as follows:
The reasons for the low bacterial reads in the raw sequencing data of RaTG13 could be:
1) The sample is anal swab, not a fecal pellet.
2) We used the High Pure Viral RNA Kit for the RNA extraction.
3) The sequencing depth was not high.

For the 5'race done in September 2020, we used the viral RNA previously extracted from that anal swab sample.

Best regards,
Zhengli,

[redacted]@wh.iov.cn

From: Clare Thomas
Date: 2021-11-24 19:51
To: [redacted]@wh.iov.cn
Subject: RE: Matters Arising regarding your Nature paper

[redacted]

Dear Zhengli,

Thanks again for providing very helpful responses to the Matters Arising. We do have an obligation to look into any comments about papers that we publish, particularly if they relate to concerns about insufficient methodological detail etc. I just wanted to ask you about a two more things, about the sample source, for the sake of completeness.

The Matters Arising author points to a preprint that claims the raw data contain lower levels of bacterial reads than would be expected from a fecal swab. I cannot see from the methods anywhere that the nature of the sample was described. Was it a fecal swab? If so, is there an explanation for the low bacterial reads, if indeed that claim is true?

And along the same lines, what was the sample used for the sequencing of the 5'end done in September 2020?

Thanks in advance for clarifying these details, which do seem pertinent to the methods described in our paper and therefore we do have to ask.

Once again I'm very sorry for having to trouble you on so many occasions with these queries.

With best wishes,

Clare

From: [redacted]@wh.iov.cn <[redacted]@wh.iov.cn>
Sent: 24 November 2021 09:10
To: Clare Thomas <[redacted]@nature.com>
Subject: Re: Matters Arising regarding your Nature paper

[External - Use Caution]

Dear Clare,

I'm sorry that you continue to recieve such emails. It's a pity that there are someone who is contining to doute and scru etine our work. This person has been interrupting me and my colleagues and want to find evidence to show that the SARS-CoV-2 is a lab leak. I don't think I should answer his unreasonable questions and crazy ideas. But for your refrence, I would like to send you more details although I think they are not whinth the duty of you and neither the scope of my publication in your journal.

Best regards,
Zhengli,

[redacted]@wh.iov.cn

From: Clare Thomas
Date: 2021-11-19 02:09
To: 石正丽
Subject: Matters Arising regarding your Nature paper

Dear Zhengli,

I hope you're well. I'm afraid we've been contacted by a scientist who has submitted a Matters Arising to the journal, regarding your 2020 Nature paper. I've attached the MA here.

One of the points raised is something we already discussed, which is why there is a difference in sequence identity between SARS-CoV and RaTG13 and SARS-CoV and the virus labelled Ra4991-Yunnan in the thesis which appeared online. You already responded to a journalist's query about this, and told us that the difference was due to different bioinformatics approaches.

The other concerns seem to be points that have not been raised with us before. The author notes that the original Nature paper did not contain any information about how the RaTG13 genome was assembled and has some concerns regarding the timeline of the sequencing and assembly as well as missing methods (e.g. primer sequences). The addendum touched on the timing of the sequencing, but not the methods, and the author has some concerns regarding the timeline and asks for further details to clarify how the full RaTG13 sequence was obtained.

Would you please be able to send us a response to these new concerns so that we can discuss how to proceed? If you could return a response within one week that would be greatly appreciated.

With best wishes,

[redacted]

Released by Chairman Rand Paul

Clare

Clare Thomas
Senior Editor
Nature

From: 石正丽 <[redacted]@wh.iov.cn>
Sent: 29 June 2021 00:13
To: Clare Thomas <[redacted]@nature.com>
Subject: Re: RE: RE: A question about the addendum to your Nature paper

[External - Use Caution]

Dear Clare,

Thank you for your information. I'm fine with the passing to the journalist on the information I told you.

Best regards,

Zhengli,

-----原始邮件-----
发件人:"Clare Thomas" <[redacted]@nature.com>
发送时间:2021-06-29 04:39:21 (星期二)
收件人: "[redacted]@wh.iov.cn" <[redacted]@wh.iov.cn>
抄送:
主题: RE: RE: A question about the addendum to your Nature paper
Dear Zhengli,

Thanks again for replying to my question about the discrepancy highlighted to us. We've received some queries about it from journalists. Conversations between editors and authors are confidential but I wanted to ask you if you would have any objection to our passing on the information that you have told us? Would you be willing for us to tell the journalists that you have told us that the bioinformatics approaches used to analyse the genome sequences in the Nature paper and the thesis were different? We are considering how to respond and wonder whether this might help dampen the speculation. Please could you let me know?

All the best,

Clare

From: [redacted]@wh.iov.cn <[redacted]@wh.iov.cn>
Sent: 27 June 2021 03:48
To: Clare Thomas <[redacted]@nature.com>
Subject: Re: RE: A question about the addendum to your Nature paper

[External - Use Caution]

Dear Clare,

I'm sorry for replying you late.

This kind of speculation by the anonymous person is damging the science. I thought it's not necessary to clarify the question when I received your email. But I did carefully check with my colleagues who did the sequence analyses. First, there is no doubt that the TG13 and 4991 are the same sample and also the only one we found in the past 17 years and show the closest relative to SARS-CoV-2. Second, the resason of the discrepancy come from different comparison strategy with different softwares. The data we published in Nature was produced by blastp in NCBI between TG13 and SARS-CoV Tor. The data in the thesis of our graduate student as indicated in the request email was produced by alignment of mutiple sequences using Mafft software followed by cauculation of identity by Bioedit.

[redacted]

Released by Chairman Rand Paul

In addition, the thesis of our graduate student is currently embargo becuase of knowledge property protection and we don't know why this thesis was uploded in the google drive and misused by the consparicy people.

I hope I clarify your concern.

Best regards,
Zhengli,

[redacted]@wh.iov.cn

From: Clare Thomas
Date: 2021-06-25 02:09
To: [redacted]@wh.iov.cn
Subject: RE: A question about the addendum to your Nature paper

Dear Zhengli,

I wonder whether you have had a chance to consider my email below? I am sorry to bug you about it, but we do have an obligation to look into any queries that we receive about any Nature paper that we publish. I can imagine that you must be quite frustrated with these sorts of queries, but if there is an explanation for the apparent discrepancy highlighted to us then it would be great if you could please let us know.

Many thanks in advance and all the best,

Clare

From: Clare Thomas
Sent: 23 June 2021 17:07
To: [redacted]@wh.iov.cn' <[redacted]@wh.iov.cn>
Subject: A question about the addendum to your Nature paper

Dear Zhengli,

I hope you're well. We have been contacted by someone who claims that a thesis from the Wuhan Institute of Virology contains information that seemingly questions the relationship of RaTG13 to the sample originally named 4991. You can see the correspondence that we've received below. We have not clicked on these links, so have not looked at the thesis itself, but would you please be able to provide some clarification about these claims? I believe the concern is that if Ra4991 and RaTG13 are the same virus, as claimed in the addendum, then their identity to SARS-CoV should be the same and the table pasted below indicates that they differ to some extent in the spike gene.

Thanks in advance and best wishes,

Clare

Clare Thomas
Senior Editor
Nature

A Dissertation submitted to The University of Chinese Academy of Sciences in 2019 by Yu Ping at the Wuhan institute of Virology has recently surfaced online.

Original: https://drive.google.com/drive/folders/1cJBYAkjkZX9KbNfHCaeaaMhNDgff1elg

English translation: https://docs.google.com/document/d/15U2uE7Eru0QxRbf8QVRPRMpssCoYhGvT/edit

The document has been uploaded by an anonymous user on Twitter, and contains potentially new information the RATG13 virus sequence and its relationship to bat sample 4991.

The RATG13 sequence was first mentioned in the article "A pneumonia outbreak associated with a new coronavirus of probable bat origin» published by Nature. In the addendum to this article, that was published

[redacted]

Released by Chairman Rand Paul

November last year, the authors clarify that RATG13 sequence is the full virus sequence collected from bat sample 4991.

However, the newly uncovered thesis by Ping, raises new questions on the raw data in regards to the RATG13 sequence and its relationship to the 4991 sample. In the thesis the full sequence of bat sample 4991 is shown to be 75,4% identical in the spike gene compared to SARs-CoV Tor2.

Table 3.2 Comparison of ORF amino acid identities between bat SARSr-CoVs and human SARS-CoV Tor2.

CoV	ORF1a	S	ORF3	E	M	ORF6	ORF7	ORF8	N
LYRa11/Yunnan	95.8	89.2	90.8	98.6	97.7	95.2	94.2	15.4	97.8
WIV16/Yunnan	98.0	96.8	97.0	100.0	98.1	92.0	95.0	16.1	99.5
WIV1/Yunnan	97.9	92.1	96.7	100.0	98.1	93.6	95.0	16.9	99.7
Rs4084/Yunnan	97.9	89.8	97.0	98.6	98.1	96.8	95.9	85.9	99.5
Anlong-103/Guizhou	98.1	79.4	89.7	100.0	98.6	96.8	95.0	31.8	98.3
Rp3/Guangxi	96.5	78.5	83.5	100.0	97.2	92.0	95.0	15.4	97.8
HKU3-7/Guangdong	94.0	78.1	82.8	98.6	97.2	92.0	93.4	15.4	98.1
HKU3-1/Hong Kong	94.1	77.9	81.7	100.0	98.6	93.6	94.2	14.7	96.4
Rf1/Hubei	94.0	76.6	86.1	96.0	97.7	93.6	91.8	23.9	95.4
Jiyuan-84/Henan	94.0	76.8	86.8	96.0	97.7	92.0	94.2	25.3	96.2
Rp/Shaanxi	95.4	79.0	82.4	97.3	96.8	92.0	92.6	15.4	97.8
HeB2013/Hebei	94.1	76.8	87.2	96.0	97.7	93.6	93.4	25.3	96.2
JL2012/Jilin	93.2	74.6	86.1	97.3	97.2	87.3	90.1	NA	95.7
Ra4991_Yunnan	80.0	75.4	73.8	94.7	90.9	66.6	83.6	12.6	90.5
Rs5725_Yunnan	98.2	94.8	97.0	100.0	100.0	100.0	95.9	31.1	NC
Rs8561_Guangdong	80.4	75.2	70.5	94.7	89.6	68.2	83.6	12.6	92.8
Rs141456_Guangxi	96.1	78.6	83.5	98.6	98.6	88.8	94.2	16.3	98.1
BM48-31/Bulgaria	80.8	74.7	69.0	92.1	88.5	49.2	56.5	NP	87.2

NA, not available; NP, not present; NC, not complete.

This indicates that bat sample 4991 is not fully identical to RATG13 across the genome, as the RATG13 Spike is shown to be 76.59 percent identical to SARS-CoV Tor2 in the spike gene, thereby deviating by 1.1 percent.

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Released by Chairman Rand Paul

From: [redacted]@wh.iov.cn <[redacted]@wh.iov.cn>
Sent: Monday, March 14, 2022 12:53 AM EDT
To: Peter Daszak <[redacted]@ecohealthalliance.org>
CC: zlshi <[redacted]@wh.iov.cn>; huben <[redacted]@wh.iov.cn>; Hongying Li <[redacted]@ecohealthalliance.org>; Aleksei Chmura <[redacted]@ecohealthalliance.org>
Subject: Re: RaTG13 sequence?

Thanks Peter, our true friend !

---- 回复的原邮件 ----

发件人	Peter Daszak<[redacted]@ecohealthalliance.org>
日期	2022年03月14日 10:07
收件人	石正丽<[redacted]@wh.iov.cn>
抄送至	胡犇<[redacted]@wh.iov.cn>、周鹏<p[redacted]@wh.iov.cn>、Hongying Li<[redacted]@ecohealthalliance.org>、Aleksei Chmura<[redacted]@ecohealthalliance.org>
主题	RE: Re: RaTG13 sequence?

I don’t know him personally, and don’t know if he’s a good scientist or not, but anyone who looks at the evidence on whether COVID-19 came from a lab or from the wildlife markets, and still thinks it came from the lab, cannot be a good, logical scientist.

Additionally, some of his comments online suggest that he holds a deep-seated view that Chinese scientists do not have the same standards as Western scientists. I find that to be racist, and unacceptable.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: [redacted]
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

From: 石正丽 <[redacted]@wh.iov.cn>
Sent: Sunday, March 13, 2022 9:48 PM
To: Peter Daszak <[redacted]@ecohealthalliance.org>
Cc: 胡犇 <[redacted]@wh.iov.cn>; 周鹏 <[redacted]@wh.iov.cn>; 李泓萤 <[redacted]@ecohealthalliance.org>; Aleksei Chmura <[redacted]@ecohealthalliance.org>
Subject: Re: Re: RaTG13 sequence?

Thanks, Peter. No response to him any more. I just appreciate that he is a good scientist and I can persuade him. I realize that it an effort with nothing.

> -----原始邮件-----
> **发件人:**"Peter Daszak" <[redacted]@ecohealthalliance.org>
> **发送时间:**2022-03-13 20:49:51 (星期日)
> **收件人:** "石正丽" <[redacted]@wh.iov.cn>
> **抄送:** "胡犇" <[redacted]@wh.iov.cn>, "周鹏" <[redacted]@wh.iov.cn>, "李泓萤" <[redacted]@ecohealthalliance.org>, "Aleksei Chmura"

[redacted]

Released by Chairman Rand Paul

<chmura@ecohealthalliance.org>
主题: Re: RaTG13 sequence?

Dear zhengli,

I strongly recommend you don't answer more questions from Jesse bloom. The questions may seem harmless, like he is trying to find out more about basic information, but his goals are to continue attacking you, the WIV, and our collaboration. He has already asked me about the RaTG13 information separately, and I responded with a single sentence to tell him the sequence is incomplete at the end of the genome. In other words he already knew the answer but wrote to you separately anyway, I believe he is trying to see if one of us says a different response so h Evan accuse us of lying.

With someone like this, if you give home more than a short response, he will use the information against you. He has done this with us in the past by making public statements about things we've said in emails to him and criticizing us.

For example, if you tell him that you've done other recombinant virus work - he will now tell other people and journalists could now write a story that accuses us of continuing our NIH work even after being told to stop. This is not true and it is unfair, but that is how the press are working here.

Obviously what you've said to him is not a problem, but I strongly advise not to continue the conversation if he keeps coming back with more questions.

Also I really appreciate you copying me into the email chain - I am tracking his accusations online and it's important to see what he's up to.

Cheers,

Peter

Peter Daszak

President
EcoHealth Alliance

520 8th Avenue, New York, NY10018-6507, USA

www.EcoHealthAlliance.org

On Mar 12, 2022, at 11:07 PM, 石正丽 <[redacted]@wh.iov.cn> wrote:

We have tried many oral samples and never found coronavirus positive. I believe, like most of animal coronaviruses, bat coronaviruses are intestinal tropism and are transmitted through fecal to oral route. But I cann't exclude the possibility of transit replication in the respiratory tract.

> -----原始邮件-----
> **发件人:**"Bloom PhD, Jesse D" <[redacted]@fredhutch.org>
> **发送时间:**2022-03-13 11:44:18 (星期日)
> **收件人:** "石正丽" <[redacted]@wh.iov.cn>
> **抄送:** "胡犇" <[redacted]@wh.iov.cn>, "周鹏" <[redacted]@wh.iov.cn>, "李泓萤" <li@ecohealthalliance.org>, "Peter Daszak" <[redacted]@ecohealthalliance.org>
> **主题:** Re: Re: Re: RaTG13 sequence?
>
> Since we're on this interesting thread, can I ask one more question? Is it known how sarbecoviruses naturally transmit in bats? Is it fecal oral or respiratory or unknown?
>
> --
> Jesse Bloom
> Professor, Fred Hutchinson Cancer Research Center
> Investigator, Howard Hughes Medical Institute
>
> ---
>
> **From:** 石正丽 <[redacted]@wh.iov.cn>
> **Date:** Saturday, March 12, 2022 at 7:28 PM
> **To:** Bloom PhD, Jesse D <[redacted]@fredhutch.org>

[redacted]

Released by Chairman Rand Paul

Cc: 胡犇 <[redacted]@wh.iov.cn>, 周鹏 <[redacted]@wh.iov.cn>, 李泓萤 <[redacted]@ecohealthalliance.org>, Peter Daszak <[redacted]@ecohealthalliance.org>
Subject: Re: Re: Re: RaTG13 sequence?

I have the same thought as you regarding the low binding affinity between the bat ACE2 and SARS-related CoV. The ACE2 allele is one reason, the other reason may be related to the long evolution history between them. The virus needs a low binding affinity and low replication in the cells to quarantine the cohabit with their natural hosts. Some of them has high binding affinity to human ACE2 is just coincidental.

-----原始邮件-----
发件人:"Bloom PhD, Jesse D" <[redacted]@fredhutch.org>
发送时间:2022-03-13 11:15:03 (星期日)
收件人: "石正丽" <[redacted]@wh.iov.cn>
抄送: "胡犇" <[redacted]@wh.iov.cn>, "周鹏" <[redacted]@wh.iov.cn>, "李泓萤" <[redacted]@ecohealthalliance.org>, "Peter Daszak" <[redacted]@ecohealthalliance.org>
主题: Re: Re: RaTG13 sequence?

Hi Zhengli,

That makes sense. I think it's unfortunate that the interview wasn't clear that it probably just meant the missing termini: when the interview said "not correctly sequenced" that sounds very broad and got a lot of people including me confused.

I'm not surprised that RaTG13 doesn't bind human ACE2, but am more surprised about the lack of binding to *R. affinis* ACE2. But I suppose there could be other unknown alleles of *R. affinis* ACE2 similar to what you describe in your Guo et al "Evolutionary arms race" paper and maybe RaTG13 binds well to some other allele different than the one we tested. Do you know if that's the case?

Thanks for following up on this by the way, there is so much confusion about this that I appreciate you taking time to clarify.

--Jesse

--
Jesse Bloom
Professor, Fred Hutchinson Cancer Research Center
Investigator, Howard Hughes Medical Institute

From: 石正丽 <[redacted]@wh.iov.cn>
Date: Saturday, March 12, 2022 at 7:01 PM
To: Bloom PhD, Jesse D <[redacted]@fredhutch.org>
Cc: 胡犇 <[redacted]@wh.iov.cn>, 周鹏 <[redacted]@wh.iov.cn>, 李泓萤 <[redacted]@ecohealthalliance.org>, Peter Daszak <[redacted]@ecohealthalliance.org>
Subject: Re: Re: RaTG13 sequence?

Sorry, I missed the email address of Peter.

The TG13 sequence was not complete at its first publication, the missing parts are the 5' and 3' end. We are confident about our sequencing and you can find all the original data in the GenBank, including from NGS and PCR amplification sequencing. We submitted the original data later than the full-length genome, it's not because we wanted to hide something as someone speculated. I feel extremely sad to see those speculation regarding TG13. After COVIS-19, we have tried to work on the ACE2 utilization of TG13 with pseudovirus and binding assay and we have the same results with the published ones and yours. Recently, we have tried to work on recombinant virus based on WIV1 backbone, we couldn't rescue the WIV1-TG13-spike neither. That's mean the TG13 has a low binding affinity to human ACE2, that's the truth, the only truth!

Best regards,

Zhengli,

[redacted]

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-----原始邮件-----
发件人:"Bloom PhD, Jesse D" <[redacted]@fredhutch.org>
发送时间:2022-03-13 10:35:05 (星期日)
收件人: "石正丽" <[redacted]@wh.iov.cn>
抄送: "胡犇" <[redacted]@wh.iov.cn>, "周鹏" <[redacted]@wh.iov.cn>, "李泓萤" <[redacted]@ecohealthalliance.org>
主题: Re: RaTG13 sequence?

Hi Zhengli,

I think you accidentally sent your message to me rather than to Peter Daszak. Anyway, here is a PDF of the article with the recent interview where he says RaTG13 isn't sequenced correctly. Maybe he just means the termini of the RaTG13 genome that you updated with recent RACE sequencing?

If you have any insight, let me know as people are definitely asking a lot about this after reading his interview.

Thanks,
Jesse

--
Jesse Bloom
Professor, Fred Hutchinson Cancer Research Center
Investigator, Howard Hughes Medical Institute

From: 石正丽 <[redacted]@wh.iov.cn>
Date: Saturday, March 12, 2022 at 6:05 PM
To:
Cc: Bloom PhD, Jesse D <[redacted]@fredhutch.org>, 胡犇 <[redacted]@wh.iov.cn>, 周鹏 <[redacted]@wh.iov.cn>, 李泓萤 <[redacted]@ecohealthalliance.org>
Subject: Fw: RaTG13 sequence?

Hi, Peter,

I got the email below. I'm not able to read the article. What do you mean regarding the sequencing issue?

Best regards,

Zhengli,

-----原始邮件-----
发件人:"Bloom PhD, Jesse D" <[redacted]@fredhutch.org>
发送时间:2022-03-12 01:53:51 (星期六)
收件人: "[redacted]@wh.iov.cn" <[redacted]@wh.iov.cn>, "[redacted]@wh.iov.cn" <[redacted]@wh.iov.cn>
抄送:
主题: RaTG13 sequence?

Hi Zhengli and Peng,

I was just reading a new interview with Peter Daszak (https://theintercept.com/2022/03/11/covid-nih-ecohealth-peter-daszak-interview/). In it, he says there are parts of the RaTG13 genome that "aren't correctly sequenced."

I was curious if you knew what he meant, in particular which parts are incorrect if the RaTG13 genome indeed isn't correctly sequenced as Peter is saying.

I was especially wondering if the errors might be in the spike? We've been using the RBDs in experiments, and finding it doesn't bind any bat ACE2s we have tested particularly well (see Figure 1b of https://www.nature.com/articles/s41586-022-04464-z_reference.pdf).

I was wondering if this could be affected by whatever sequencing problems Peter is referring to?

Thanks,
Jesse

--

Released by Chairman Rand Paul

Jesse Bloom
Professor, Fred Hutchinson Cancer Research Center
Investigator, Howard Hughes Medical Institute

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Released by Chairman Rand Paul

From: [redacted]@wh.iov.cn <[redacted]@wh.iov.cn>
Sent: Sunday, March 13, 2022 7:36 PM EDT
To: jbloom <[redacted]@fredhutch.org>
CC: zlshi <[redacted]@wh.iov.cn>; huben <[redacted]@wh.iov.cn>; Hongying Li <[redacted]@ecohealthalliance.org>; Peter Daszak <[redacted]@ecohealthalliance.org>
Subject: Re: RaTG13 sequence?

No. I still believe it is naturally weak ACE2-usage, reflecting a trend of evolution.

---- 回复的原邮件 ----

发件人	Bloom PhD, Jesse D<[redacted]@fredhutch.org>
日期	2022年03月13日 21:44
收件人	[redacted]@wh.iov.cn<[redacted]@wh.iov.cn>
抄送至	zlshi<[redacted]@wh.iov.cn>、huben<[redacted]@wh.iov.cn>、Hongying Li<[redacted]@ecohealthalliance.org>、Peter Daszak<[redacted]@ecohealthalliance.org>
主题	Re: RaTG13 sequence?

Hi Peng,

In terms of the other receptor, do you mean the receptor for the RBD clade containing viruses like Rf1 and HKU3? (The ones shown in orange in Figure 1 here?) I obviously agree finding the receptor for that clade is important. But since RaTG13 phylogenetically clusters far more closely with other ACE2-binding viruses and does have modest ACE2 affinity for some ACE2s (like human and mouse), then I'd be very surprised if it isn't ACE2-utilizing.

Or do you mean maybe there is some unknown secondary receptor even among strong ACE2 binding viruses not in the Rf1 / HKU3 clade?

--Jesse

--
Jesse Bloom
Professor, Fred Hutchinson Cancer Research Center
Investigator, Howard Hughes Medical Institute

From: [redacted]@wh.iov.cn <[redacted]@wh.iov.cn>
Date: Saturday, March 12, 2022 at 9:04 PM
To: Bloom PhD, Jesse D <[redacted]@fredhutch.org>
Cc: zlshi <[redacted]@wh.iov.cn>, huben <[redacted]@wh.iov.cn>, Hongying Li <[redacted]@ecohealthalliance.org>, Peter Daszak <[redacted]@ecohealthalliance.org>
Subject: Re: RaTG13 sequence?

Regarding the receptor, I also want to emphasize that there should be at least one more unknown receptor (let's say X) responsible for Sarbecovirus transmission in bats, particularly for the majority that don't use ACE2. So, let's move our focus out of ACE2, but take an evolutionary point of view: is ACE2-usage the trend of evolution or not-usage the direction? Then you may understand that RaTG13 may just lie in the boundary of the two directions.

---- 回复的原邮件 ----

发件人	Bloom PhD, Jesse D<[redacted]@fredhutch.org>
日期	2022年03月13日 11:44
收件人	石正丽<[redacted]@wh.iov.cn>
抄送至	胡犇<[redacted]@wh.iov.cn>、周鹏<p[redacted]@wh.iov.cn>、李泓萤<[redacted]i@ecohealthalliance.org>、Peter Daszak<[redacted]@ecohealthalliance.org>
主题	Re: Re: Re: RaTG13 sequence?

?

--
Jesse Bloom
Professor, Fred Hutchinson Cancer Research Center
Investigator, Howard Hughes Medical Institute

[redacted]

Released by Chairman Rand Paul

From: 石正丽 <[redacted]@wh.iov.cn>
Date: Saturday, March 12, 2022 at 7:28 PM
To: Bloom PhD, Jesse D <[redacted]@fredhutch.org>
Cc: 胡犇 <[redacted]@wh.iov.cn>, 周鹏 <[redacted]@wh.iov.cn>, 李泓萤 <[redacted]@ecohealthalliance.org>, Peter Daszak <[redacted]@ecohealthalliance.org>
Subject: Re: Re: Re: RaTG13 sequence?

I have the same thought as you regarding the low binding affinity between the bat ACE2 and SARS-related CoV. The ACE2 allele is one reason, the other reason may be related to the long evolution history between them. The virus needs a low binding affinity and low replication in the cells to quarantine the cohabit with their natural hosts. Some of them has high binding affinity to human ACE2 is just coincidental.

-----原始邮件-----
发件人:"Bloom PhD, Jesse D" <[redacted]@fredhutch.org>
发送时间:2022-03-13 11:15:03 (星期日)
收件人: "石正丽" <[redacted]@wh.iov.cn>
抄送: "胡犇" <[redacted]@wh.iov.cn>, "周鹏" <[redacted]@wh.iov.cn>, "李泓萤" <[redacted]@ecohealthalliance.org>, "Peter Daszak" <[redacted]@ecohealthalliance.org>
主题: Re: Re: RaTG13 sequence?

Hi Zhengli,

That makes sense. I think it's unfortunate that the interview wasn't clear that it probably just meant the missing termini: when the interview said "not correctly sequenced" that sounds very broad and got a lot of people including me confused.

I'm not surprised that RaTG13 doesn't bind human ACE2, but am more surprised about the lack of binding to *R. affinis* ACE2. But I suppose there could be other unknown alleles of *R. affinis* ACE2 similar to what you describe in your Guo et al "Evolutionary arms race" paper and maybe RaTG13 binds well to some other allele different than the one we tested. Do you know if that's the case?

Thanks for following up on this by the way, there is so much confusion about this that I appreciate you taking time to clarify.

--Jesse

--
Jesse Bloom
Professor, Fred Hutchinson Cancer Research Center
Investigator, Howard Hughes Medical Institute

From: 石正丽 <[redacted]@wh.iov.cn>
Date: Saturday, March 12, 2022 at 7:01 PM
To: Bloom PhD, Jesse D <[redacted]@fredhutch.org>
Cc: 胡犇 <[redacted]@wh.iov.cn>, 周鹏 <[redacted]@wh.iov.cn>, 李泓萤 <[redacted]@ecohealthalliance.org>, Peter Daszak <[redacted]@ecohealthalliance.org>
Subject: Re: Re: RaTG13 sequence?

Sorry, I missed the email address of Peter.

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Best regards,

Zhengli,

[redacted]

Released by Chairman Rand Paul

-----原始邮件-----
发件人:"Bloom PhD, Jesse D" <[redacted]@fredhutch.org>
发送时间:2022-03-13 10:35:05 (星期日)
收件人: "石正丽" <[redacted]@wh.iov.cn>
抄送: "胡犇" <[redacted]@wh.iov.cn>, "周鹏" <[redacted]@wh.iov.cn>, "李泓萤" <[redacted]@ecohealthalliance.org>
主题: Re: RaTG13 sequence?

Hi Zhengli,

I think you accidentally sent your message to me rather than to Peter Daszak. Anyway, here is a PDF of the article with the recent interview where he says RaTG13 isn't sequenced correctly. Maybe he just means the termini of the RaTG13 genome that you updated with recent RACE sequencing?

If you have any insight, let me know as people are definitely asking a lot about this after reading his interview.

Thanks,
Jesse

--
Jesse Bloom
Professor, Fred Hutchinson Cancer Research Center
Investigator, Howard Hughes Medical Institute

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Subject: Fw: RaTG13 sequence?

Hi, Peter,

I got the email below. I'm not able to read the article. What do you mean regarding the sequencing issue?

Best regards,

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> 发件人:"Bloom PhD, Jesse D" <[redacted]@fredhutch.org>
> 发送时间:2022-03-12 01:53:51 (星期六)
> 收件人: "[redacted]@wh.iov.cn" <[redacted]@wh.iov.cn>, "[redacted]@wh.iov.cn" <[redacted]@wh.iov.cn>
> 抄送:
> 主题: RaTG13 sequence?
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>
> Thanks,
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Released by Chairman Rand Paul

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Jesse Bloom
Professor, Fred Hutchinson Cancer Research Center
Investigator, Howard Hughes Medical Institute

Released by Chairman Rand Paul

From: [redacted]@wh.iov.cn <[redacted]@wh.iov.cn>
Sent: Sunday, March 13, 2022 12:04 AM EST
To: jbloom <[redacted]@fredhutch.org>
CC: zlshi <[redacted]@wh.iov.cn>; huben <[redacted]@wh.iov.cn>; Hongying Li <[redacted]@ecohealthalliance.org>; Peter Daszak <[redacted]@ecohealthalliance.org>
Subject: Re: RaTG13 sequence?

Regarding the receptor, I also want to emphasize that there should be at least one more unknown receptor (let's say X) responsible for Sarbecovirus transmission in bats, particularly for the majority that don't use ACE2. So, let's move our focus out of ACE2, but take an evolutionary point of view: is ACE2-usage the trend of evolution or not-usage the direction? Then you may understand that RaTG13 may just lie in the boundary of the two directions.

---- 回复的原邮件 ----

发件人	Bloom PhD, Jesse D<[redacted]@fredhutch.org>
日期	2022年03月13日 11:44
收件人	石正丽<[redacted]@wh.iov.cn>
抄送至	胡犇<[redacted]@wh.iov.cn>、周鹏<p[redacted]@wh.iov.cn>、李泓萤<li@ecohealthalliance.org>、Peter Daszak<[redacted]@ecohealthalliance.org>
主题	Re: Re: Re: RaTG13 sequence?

Since we're on this interesting thread, can I ask one more question? Is it known how sarbecoviruses naturally transmit in bats? Is it fecal oral or respiratory or unknown?

--
Jesse Bloom
Professor, Fred Hutchinson Cancer Research Center
Investigator, Howard Hughes Medical Institute

From: 石正丽 <[redacted]@wh.iov.cn>
Date: Saturday, March 12, 2022 at 7:28 PM
To: Bloom PhD, Jesse D <[redacted]@fredhutch.org>
Cc: 胡犇 <[redacted]@wh.iov.cn>, 周鹏 <[redacted]@wh.iov.cn>, 李泓萤 <[redacted]@ecohealthalliance.org>, Peter Daszak <[redacted]@ecohealthalliance.org>
Subject: Re: Re: Re: RaTG13 sequence?

I have the same thought as you regarding the low binding affinity between the bat ACE2 and SARS-related CoV. The ACE2 allele is one reason, the other reason may be related to the long evolution history between them. The virus needs a low binding affinity and low replication in the cells to quarantine the cohabit with their natural hosts. Some of them has high binding affinity to human ACE2 is just coincidental.

> -----原始邮件-----
> **发件人:**"Bloom PhD, Jesse D" <[redacted]@fredhutch.org>
> **发送时间:**2022-03-13 11:15:03 (星期日)
> **收件人:** "石正丽" <[redacted]@wh.iov.cn>
> **抄送:** "胡犇" <[redacted]@wh.iov.cn>, "周鹏" <[redacted]@wh.iov.cn>, "李泓萤" <[redacted]@ecohealthalliance.org>, "Peter Daszak" <[redacted]@ecohealthalliance.org>
> **主题:** Re: Re: RaTG13 sequence?
>
> Hi Zhengli,
>
> That makes sense. I think it's unfortunate that the interview wasn't clear that it probably just meant the missing termini: when the interview said "not correctly sequenced" that sounds very broad and got a lot of people including me confused.
>
> I'm not surprised that RaTG13 doesn't bind human ACE2, but am more surprised about the lack of binding to *R. affinis* ACE2. But I suppose there could be other unknown alleles of *R. affinis* ACE2 similar to what you describe in your Guo et al "Evolutionary arms race" paper and maybe RaTG13 binds well to some other allele different than the one we tested. Do you know if that's the case?
>
> Thanks for following up on this by the way, there is so much confusion about this that I appreciate you taking time to clarify.
>
> --Jesse
>
> --
> Jesse Bloom

[redacted]

Released by Chairman Rand Paul

Professor, Fred Hutchinson Cancer Research Center
Investigator, Howard Hughes Medical Institute

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Investigator, Howard Hughes Medical Institute

[redacted]

Released by Chairman Rand Paul

From: "Ford, Andrew (NIH/NIAID) [E]" <[redacted]@nih.gov>
To: "Crawford, Chase (NIH/NIAID) [E]" <[redacted]@nih.gov>
Cc: NIAID BUGS <[redacted]@niaid.nih.gov>, NIAID OCGR Leg <[redacted]@mail.nih.gov>, "Erbelding, Emily (NIH/NIAID) [E]" <[redacted]@nih.gov>
Subject: Re: ACTION by COB today (10/31): Review updated feedback on Risky Research Review Act
Date: Thu, 31 Oct 2024 11:57:40 -0400
Importance: Normal

Hey Chase,

We will get back to you.

Andrew

Sent from my iPhone

On Oct 31, 2024, at 11:55 AM, Crawford, Chase (NIH/NIAID) [E] <[redacted]@nih.gov> wrote:

Good Morning,

HHS has shared the attached updated feedback on S.4667 (Risky Research Review Act). **Please review the updated Oct. 2024 feedback and provide any must-change edits only by COB today (10/31).**

In case helpful, we also have attached a document showing the changes since the last version of feedback that NIAID reviewed as well as a reference copy of NIAID's previous technical comments on the bill text.

Please let us know if you have any questions.

Thanks,
Chase

From: Crawford, Chase (NIH/NIAID) [E]
Sent: Friday, October 11, 2024 12:20 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; NIAID DCR-OCGR [redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Read, Sarah (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: ACTION by 10a Thurs (10/17): Review compiled HHS comments on revised bill text for Risky Research Review Act

Released by Chairman Rand Paul

Good Afternoon,

NIAID has been asked to review the attached compiled HHS comments on S.4667 (Risky Research Review Act), as amended. OSP, OER, and ORS also are reviewing. As you may recall, NIAID previously provided NIH OD with comments on the revised bill text, which are attached for your reference, as well as high-level bullets (see email chain below).

ACTION: By 10a Thursday (10/17), please provide any new edits/comments in the attached "HHS points" document.

Please let us know if you have any questions.

Thanks,
Chase

From: Crawford, Chase (NIH/NIAID) [E]
Sent: Monday, September 30, 2024 2:31 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; NIAID DCR-OCGR [redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: FYI - Update on TA for revised bill text for Risky Research Review Act

FYI – Bldg. 1 has asked NIAID to provide a few top line bullets outlining the types of comments that were submitted on the redline version of the bill. NIAID plans to share the below bullets and indicate that NIAID shares many of the concerns raised by OER, ORS, and OSP (their top line bullets are copied further below). We will request a copy of the consolidated NIH TA and share it with you if/when we receive. Please let us know if you have any questions at this time. Thanks, Chase

NIAID

- NIAID notes that, to avoid confusion, the definitions in the bill pertaining to scientific and/or current policies should be consistent with definitions in science and those policies, including the USG Policy for Oversight of DURC and PEPP (https://www.whitehouse.gov/wp-content/uploads/2024/05/USG-Policy-for-Oversight-of-DURC-and-PEPP.pdf). Further, as written, some definitions are overly broad and could slow research in critical areas, including research on antimicrobial resistance and the H5 influenza outbreak in dairy cattle.
- NIAID also notes that, as written, the proposed Board may lack essential expertise in infectious diseases and biosecurity.
- NIAID notes that it is unclear if it is the drafters' intent to prohibit funding for an entire award prior to Board approval or only work related to potential "high-risk" research. Similarly, there is a later provision that would require a pause in research due to a change in circumstance, but it is unclear if such a pause would apply to an entire award or only work related to potential "high-risk research.

OER

- It is unclear what added value the Board may have over current processes. The Board seems redundant with existing/current efforts and/or those being implemented following OSTP's mandate on DURC/PEPP.
- **The Board's scope is very broad and may apply to a variety of research areas. We defer to OSP on the included research definitions.**
- The Board will have significant control over funding decisions, which may interfere with existing statute on NIH funding activities.

- We have concerns about the Board reaching out directly to applicants/recipients, which is outside traditional NIH reporting procedures.
- The required timeline of some Board activities is unclear.
- Flagged in previous TA, we have concerns about the confidentiality of application information and recommend more details be provided on how such information will be used or protected.
- Flagged in previous TA, some terms such as "proposal" and "entity" should be updated to better agree with NIH terminology.
- Flagged in previous TA, requirements for the validation of all applicant attestations related to research risk would be extremely challenging to implement.

ORS

- Concern over the confusion and differences between agent listing, some definition and intent of this as compared to the new DURC PEPP policy and also the current/ transparent process by which select agents are added or removed. We would recommend alignment 100% in line with the current SA policies and DURC PEPP policies. Curious if this Board would be subject to posting in the Federal Register with public comment, or would function in a more draconian approach.
- Acknowledging that risk assessment is best when diverse voices are heard, the lack and actually clear refusal to ensure persons with experience in high and maximum containment principles are included would not provide a comprehensive and scientifically robust review of this work.
- The Board would be all political appointees, and finding someone with no experience in this space would likely select for persons who only do not favor this work. The goals feel less neutral and scientifically based and much more politically centric.
- The agent listings are highly concerning and would have an immediate negative impact to science and public health. The mention of Influenza A viruses, for example, would include all work with H5N1 viruses which are having a significant impact on our poultry and dairy farms. Research into vaccines, treatment, spread and evolution of these viruses is critical to ensure to curb this outbreak and to prevent those in the future. The same could be said for the inclusion of all mpox. The current outbreak and identification of Clade I is highly concerning and without scientists able to pivot nimbly, the outcome is concerning.
- Page 18 of the document, line 26-30 appear to replace the work of IBCs and IREs and biosafety professionals across the country. The composition of this board would not have the appropriate expertise, training or experience to appropriately determine these requirements. It also seems quite granular for a board of this nature.
- Concerns about sensitivity of grant and project submissions from the confidentiality side- defer to OER and OSP.
- Page 17 regarding employee disciplines. This section would make people charged with compliance consistently and constantly afraid for their jobs. A punitive reporting process would have the opposite impact that I think is intended. Transparency on situations is important but its unclear what would happen because of these reports.

We have significant concerns about this bill and approach this would take for the oversight of biological research. Based on timelines and reviews, plus the lack of appropriate experience, many researchers would likely leave critical research fields and the work would be paused having negative and catastrophic impact to the biomedical enterprise and by extension human and animal health and safety.

OSP

Topline points:

- **While some aspects of this bill related to scope are improved, there continue to be significant concerns about the impact on biomedical research.**
- Strengthening biosafety and biosecurity oversight of life sciences research is a key priority of this Administration, as outlined in the National Biodefense Strategy. We believe the bill as drafted would significantly undermine life sciences research, and its oversight provisions fail to target the subset of research posing greatest risk. As such, we do not support this legislation.
- The Administration has recently strengthened, streamlined, and expanded oversight of potentially high risk life science research in the May 2024 United States Government Policy for Oversight of Dual Use Research of Concern Pathogens with Enhanced Pandemic Potential ("DURC/PEPP policy"). This policy expands and strengthens a tiered system of oversight for all federally funded research that includes a requirement for

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research on pathogens with enhanced pandemic potential to undergo extra departmental review. The policy also:

- Defines an expanded scope of pathogen and toxin research subject to additional oversight by the U.S. Government;
- Provides a unified framework to support the consistent identification and oversight of research proposals that require enhanced oversight that accounts for safety, security, and ethical considerations; and
- Delineates the roles and responsibilities of principal investigators, research institutions, and Federal departments and agencies that conduct, fund, or oversee research within the scope of the policy.

- The bill seems to create redundancies with some reforms recently introduced by the DURC/PEPP policy, which was developed following significant interagency discussions directed by Congress and informed by the National Science Advisory Board for Biosecurity, public comment, and other expert input.
- As currently drafted, this legislation has the potential to negatively impact innovation and the U.S. competitive edge in life sciences research, including our ability to attract and retain the best scientists.
- However, the Administration welcomes efforts from Congress to further strengthen biosafety and biosecurity in the life sciences.
  - For example, we would welcome discussions on how the risk-based oversight processes established in the DURC policy for federally funded research could be extended to non-federally funded research.
- We recognize that biosafety and biosecurity oversight responsibilities are currently shared across many different departments and agencies and welcome discussions on appropriate entities for oversight of the highest risk research.

Some of our concerns with the bill are:

- **Scope:** While steps have been made toward harmonization of the scope of the Board's oversight with the new *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* (2024 OSTP DURC/PEPP Policy), some of the listed experiments in the "dual use research of concern" definition do not match those in the policy, and other articulated in-scope research in the bill including the "gain of function research" term continues to be in conflict with USG policy. These definition differences will be challenging to deconflict for the research community. Many of the USG definitions were determined following significant interagency discussions directed by Congress and informed by the National Science Advisory Board for Biosecurity, public comment, and other expert input.
  - This could result in delays to critical biosurveillance efforts such as COVID-19 testing, H5N1 monitoring, and detection of emerging outbreaks of Ebola and other diseases. It could also result in delays for development of vaccines, therapeutics, and biomedical, agricultural, and other life sciences research writ large (including research that is not associated with pathogens or toxins and raises no identified national security threats, such as cancer research).
  - If the statute only provided the board the responsibility to review federally-funded research involving DURC and PEPP, as defined in the DURC/PEPP policy, it would ensure oversight resources are used most efficiently to assess and mitigate risks to the public while avoiding unintended negative consequences for the nation's biomedical enterprise. We believe this is the intent of the bill but as written the definitions are not harmonized. (We recommend other definitions in the text be aligned to current U.S. Government policy, including "life sciences research.")
  - We recommend that the definitions and scope of review be fully harmonized with the DURC/PEPP policy and not include a separate list of pathogens.
  - A large amount of scientific research involves gain or loss of function; it's a fundamental process in science. For example, some types of immune therapy cause the immune system to gain function to fight against a disease. Unfortunately, the term "gain of function" has often being misconstrued to suggest all research that causes a gain of function is highly risky, which is inaccurate. In fact, most research involving a GOF does not confer significant additional risk or require additional oversight. NIH does not define the term GOF and current federal policy does not define or operationalize the term. The research that requires strict oversight involves enhancing the transmissibility and/or virulence of a pathogen such that it would pose an increased pandemic potential in humans. The USG policy on oversight of DURC and PEPP (effective May 2025) also does not use the term GOF when describing research that requires additional oversight because of its higher risk. As it appears

Released by Chairman Rand Paul

the intent of the term "GOF" in this bill is to refer specially to research that has the potential to enhance the transmissibility or virulence of a potential pandemic pathogen, for clarity we would recommend the use of the term "pathogen with enhanced pandemic potential" in the 2024 OSTP policy that addresses this type of research, as well as it's associated definition. This would help to avoid the ongoing confusion surrounding the term GOF.

- **Board processes and makeup:** While biosafety expertise is now included, the makeup and processes of the board could introduce a number of issues. For example, the limitations on prior federal service and designation of participation in high-risk research as a "conflict of interest" could limit the board from accessing relevant national security and life sciences expertise. The exclusion of those involved in high-risk research, based on the definition in the draft legislation, could exclude anyone with a current BSL3 or BSL4 program, excluding individuals with key expertise on how to conduct work safely. These limitations may also exclude individuals who work in government with relevant knowledge of intelligence and threat assessments. We also recommend relaxing the limitations on membership of the board and note that a number of the timelines are untenable (e.g., Congressional notification requirements within 3 days of identifying a potential conflict of interest; publishing procedures in the Federal Register within 90 days of the appointment of initial members; etc.). We note that several provisions relating to the membership of the Board or its support staff are vague, including the requirement that Board members be "impartial" and that support staff be prohibited from "directly or indirectly influenc[ing]" the Board. The proposed legislation would also politicize independent peer review by making the constituent members presidential appointees.

- **Review process:** While a path for expedited review has been added, there could still be major issues with continuity of science due to delays of reviews or membership being confirmed. Among other concerns, in particular, this will significantly impede the USG's ability to prepare for and detect emerging infectious diseases/epidemics/pandemics and will also significantly impede the USG's research response to an epidemic/pandemic. We recommend establishing a default rule that research may proceed if a decision is not made within a fixed timeframe to ensure that any lapse in function by the Board (e.g., delays in confirmation) do not result in life sciences research grinding to a halt. We also recommend a formal appeals process and an exemption to public reporting requirements if the information could pose national security risks.

- **Review criteria:** The bill does not articulate a principle or threshold that guides whether the board should or should not approve a study for funding – for example, should the Board approve research where it determines that the potential public health benefits of the research outweigh the potential risks to U.S. national security? Or should some other standard govern the Board's review? Any statute mandating this style of review should clarify the applicable standard.

- **Classified review and intelligence concerns:** We recommend striking provisions that mandate the provision of security clearances to Board members, Board staff, and members of Congress, or that require these individuals to access and review all classified research funded by any agency. Those provisions extend beyond the scope of oversight that is reasonable for this board to take on and they may impinge on the constitutional authority of the Executive to control classified national security information. We also recommend that clauses be included to enable the intelligence community to respond to requests from the Board in a manner consistent with the protection of intelligence sources and methods.

- **Enforcement:** The enforcement provisions are extreme and may raise significant legal and privacy concerns. Those provisions mandate a suite of harsh penalties for any violations of certain provisions of the statute, including technical or unintentional violations; they allow for no flexibility in determining the severity of punishment; they provide the aggrieved party with no process; and they mandate public identification of aggrieved individuals. These provisions could broadly disincentivize individuals from working in life sciences research and funding agencies, which could send research outside of this country and compromise progress

Released by Chairman Rand Paul

on public health, safety, and national security. We recommend that enforcement provisions be focused on willful violations and significantly reduced or adjusted.

Given the above concerns, as drafted, this legislation has the potential to negatively impact innovation and delay the development of lifesaving technologies. While the Administration does not support this legislation, we remain committed to working with the Committee on biosafety and biosecurity.

From: Crawford, Chase (NIH/NIAID) [E]
Sent: Wednesday, September 25, 2024 1:45 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; NIAID DCR-OCGR [redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: ACTION by COB Friday (9/27): Review revised bill text for Risky Research Review Act

Good Afternoon,

NIAID has been asked to review the revised bill text for the Risky Research Review Act (PDF of bill text and Word doc of the redline are attached). This morning, the attached version of the bill was reported out of the Senate Committee on Homeland Security & Governmental Affairs (HSGAC) and now awaits further Senate consideration.

As you may recall, NIH and other OPDIVs provided comments on a previous version of the bill (previous NIAID comments attached for reference). HHS is now requesting any new comments that OPDIVS may have.

ACTION: By COB Friday (9/27), please review the attached redline and provide any new comments directly in the document.

Thanks,
Chase

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Tuesday, July 16, 2024 6:07 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: URGENT review by 8am Wed. 7/17: HHS Comments to OMB on Risky Research Review Act
Importance: High

Hello all,

Released by Chairman Rand Paul

Thank you for your review of the consolidated HHS comments on the Risky Research Review Act. DMID has suggested adding some of the comments NIAID put forward earlier this week. We have incorporated these comments in highlighted text in the attached document. The comments are listed below by page number for ease of review.

Please let us know by no later than 8am tomorrow, Wednesday, July 17th, if you have any concerns with putting forward these previously NIAID-cleared edits.

Thank you again for all your help with this quick turnaround request. Please let me know if you have any questions.

Thanks,
Sara

Re-submitted NIAID comments in the attached document (highlighted in yellow):
p. 1: New NIH comment
p. 2: NIH addition to OASH/OHRP comment
p. 3: New NIH comment
p. 4: NIH addition to OASH/OHRP comment
p. 9: NIH edit to OGC comment to broaden scope to all agencies (previously flagged by OCGR-Leg)
p. 10: NIH addition (from NIAID) to existing NIH comment
p. 12: NIH addition to OIG comment
p. 14: NIH addition to OGC comment
p. 16: NIH addition (from NIAID) to existing NIH comment

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Tuesday, July 16, 2024 12:24 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: Please review by COB today Tues 7/16: HHS Comments to OMB on Risky Research Review Act
Importance: High

Hello all,

Background
Thank you again for your assistance in reviewing the Risky Research Review Act. HHS has compiled comments on the bill from throughout HHS to provide them to the Office of Management and Budget (OMB) for consideration. HHS is asking NIH to review the attached document on quick turnaround.

The comments included in the document provide high-level concerns across HHS. In particular, we have flagged a comment on the bottom of page 9 with a proposed clarifying edit for your review.

Action Item

Released by Chairman Rand Paul

Please review the attached draft HHS comments on the Risky Research Review Act and provide your concurrence, or any edits, by COB today, Tuesday July 16th. If you have any concerns with OCGR-Leg's proposed edit to the comment on page 9, please let us know.

Please note that NIH OLPA is also working on a separate request from the Senate Health, Education, Labor, and Pensions (HELP) Committee (Chair: Sen. Bernie Sanders, I-VT) for technical assistance on this bill. OLPA plans to include the specific NIAID comments shared yesterday in this separate request. We anticipate we may be asked to review consolidated NIH comments for the HELP Committee this week.

Thank you for your ongoing assistance with reviewing this bill. Please let me know if you have any questions.

Thanks,
Sara

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Monday, July 15, 2024 12:26 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: Additional OSP comments: TA on Risky Research Review Act

Hello all,

For your awareness, we are providing the attached comments on the Risky Research Review Act from the NIH Office of Science Policy (OSP). We anticipate receiving consolidated NIH comments on the bill, and we will share these as soon as we have them.

Please let me know if you have any questions.

Thanks,
Sara

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Monday, July 15, 2024 10:35 AM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: For review by noon Monday 7/15: Review draft NIAID TA on Risky Research Review Act
Importance: High

Hello all,

Released by Chairman Rand Paul

Thank you for your quick review of the draft NIAID TA on the Risky Research Review Act. In the attached revised draft, I have incorporated additional edits from DMID/Dr. Erbelding and DEA. If there are no objections, I will submit these to NIH OLPA by their noon deadline today.

I am also attaching for your reference additional comments on the bill provided by NIH OER and NIH ORS/DOHS.

Please let me know if you have any questions or concerns.

Thanks,
Sara

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Friday, July 12, 2024 4:06 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: URGENT ACTION by 10am Monday 7/15: Review draft NIAID TA on Risky Research Review Act
Importance: High

Hello all,

Background
Thank you very much for your quick work to comment on the Risky Research Review Act. NIH OLPA has asked us to prioritize comments to flag the most urgent or concerning items and/or those needing clarification.

Action Item
We have compiled the comments that meet NIH OLPA's request into the attached draft technical assistance document. Please note that NIH OLPA has requested examples, where possible. We have tried to add some examples to emphasize key points, but we welcome any suggestions and/or corrections as needed.

We would appreciate your review and any edits by 10am Monday, July 15th. Given the quick turnaround, we are asking the Divisions to review concurrently with the NIAID OD.

Please note that NIH OSP, NIH ORS/DOHS, and NIH OER will also be reviewing and providing comments. We will be sure to share with you any consolidated NIH comments that we receive.

Thank you for your help with this quick turnaround request. Please let me know if you have any questions.

Thanks,
Sara

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Thursday, July 11, 2024 10:51 AM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>

Released by Chairman Rand Paul

Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Subject: URGENT ACTION by 12pm Friday 7/12: TA on Risky Research Review Act
Importance: High

Good morning,

Background
HHS has been asked by the Senate Homeland Security and Governmental Affairs Committee (Chair: Sen. Gary Peters, D-MI; Ranking Member: Sen. Rand Paul, R-KY) to provide technical assistance (TA) on the attached draft legislation entitled the Risky Research Review Act.

The draft bill would require the establishment of an independent life sciences research security board to review federal funding for certain proposed life sciences research as defined by the bill. NIAID is mentioned briefly on page 4 in a section describing limitations on membership of the board.

HHS reports that the Committee intends to consider the bill on July 24. A number of HHS OpDivs and offices, including ASPR, CDC, and FDA, have been asked to review the bill along with NIH.

Action Item
By noon tomorrow, Friday July 12, please review the attached draft legislation and provide any technical comments in the attached HHS TA template. Please note that NIH ORS/DOHS and NIH OSP are also reviewing the bill on behalf of NIH.

As you complete your review, please keep in mind the HHS guidance on technical assistance below. Please let me know if you have any questions.

Thanks,
Sara

To ensure that the Department's comments are given full consideration, please observe the following guidelines in providing your office's comments:

1. *Are there provisions of this bill that would conflict with Department or Administration policy, and how?*
2. *Are there provisions that would pose difficulties for the operation or management of HHS programs, and how?*
3. *Are there any other significant issues that you can identify?*
4. *If you recommend specific changes, supply reasons and explanations, if the reasons are not obvious.*

For review - Risky Research Review Act Feedback Oct 2024.docx
Track changes of feedback.docx
For reference -redline2 NIAID comments.docx

Released by Chairman Rand Paul

From: "Ford, Andrew (NIH/NIAID) [E]" <[redacted]@nih.gov>
To: "Crawford, Chase (NIH/NIAID) [E]" <[redacted]@nih.gov>
Cc: NIAID OCGR Leg <[redacted]@mail.nih.gov>, "Erbelding, Emily (NIH/NIAID) [E]" <[redacted]@nih.gov>, NIAID BUGS <[redacted]@niaid.nih.gov>, "DDSM Correspondences" <[redacted]@mail.nih.gov>
Subject: Re: ACTION by 10a Thurs (10/17): Review compiled HHS comments on revised bill text for Risky Research Review Act
Date: Thu, 17 Oct 2024 09:58:14 -0400
Importance: Normal

Hey Chase,

DMID does not have any comments.

Thank you for the opportunity to review.

Andrew

From: Crawford, Chase (NIH/NIAID) [E] <[redacted]@nih.gov>
Date: Friday, October 11, 2024 at 12:21 PM
To: NIAID BUGS <[redacted]@niaid.nih.gov>, NIAID DEA DART <[redacted]@mail.nih.gov>, NIAID DIR-OCGR <[redacted]@mail.nih.gov>, NIAID DCR-OCGR <[redacted]@mail.nih.gov>, Nealy, Michael (NIH/NIAID) [E] <[redacted]@nih.gov>, Harper, Jill (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>, Parker, Marie (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>, Read, Sarah (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>, Billet, Courtney (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg <[redacted]@mail.nih.gov>, Erbelding, Emily (NIH/NIAID) [E] <[redacted]@nih.gov>, Holland, Steven (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>, Hanson, Christopher (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>, Poe, Kelly (NIH/NIAID) [E] <[redacted]@nih.gov>, Gilles, Sharon (NIH/NIAID) [E] <[redacted]@nih.gov>, DDSM Correspondences <[redacted]@mail.nih.gov>
Subject: ACTION by 10a Thurs (10/17): Review compiled HHS comments on revised bill text for Risky Research Review Act

Good Afternoon,

NIAID has been asked to review the attached compiled HHS comments on S.4667 (Risky Research Review Act), as amended. OSP, OER, and ORS also are reviewing. As you may recall, NIAID previously provided NIH OD with comments on the revised bill text, which are attached for your reference, as well as high-level bullets (see email chain below).

ACTION: By 10a Thursday (10/17), please provide any new edits/comments in the attached "HHS points" document.

Please let us know if you have any questions.

Thanks,
Chase

From: Crawford, Chase (NIH/NIAID) [E]
Sent: Monday, September 30, 2024 2:31 PM
To: NIAID BUGS <[redacted]@niaid.nih.gov>; NIAID DEA DART <[redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; NIAID DCR-OCGR <[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] <[redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E]

Released by Chairman Rand Paul

[redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>

Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>

Subject: FYI - Update on TA for revised bill text for Risky Research Review Act

FYI – Bldg. 1 has asked NIAID to provide a few top line bullets outlining the types of comments that were submitted on the redline version of the bill. NIAID plans to share the below bullets and indicate that NIAID shares many of the concerns raised by OER, ORS, and OSP (their top line bullets are copied further below). We will request a copy of the consolidated NIH TA and share it with you if/when we receive. Please let us know if you have any questions at this time. Thanks, Chase

NIAID

- NIAID notes that, to avoid confusion, the definitions in the bill pertaining to scientific and/or current policies should be consistent with definitions in science and those policies, including the USG Policy for Oversight of DURC and PEPP (https://www.whitehouse.gov/wp-content/uploads/2024/05/USG-Policy-for-Oversight-of-DURC-and-PEPP.pdf). Further, as written, some definitions are overly broad and could slow research in critical areas, including research on antimicrobial resistance and the H5 influenza outbreak in dairy cattle.
- NIAID also notes that, as written, the proposed Board may lack essential expertise in infectious diseases and biosecurity.
- NIAID notes that it is unclear if it is the drafters' intent to prohibit funding for an entire award prior to Board approval or only work related to potential "high-risk" research. Similarly, there is a later provision that would require a pause in research due to a change in circumstance, but it is unclear if such a pause would apply to an entire award or only work related to potential "high-risk research.

OER

- It is unclear what added value the Board may have over current processes. The Board seems redundant with existing/current efforts and/or those being implemented following OSTP's mandate on DURC/PEPP.
- **The Board's scope is very broad and may apply to a variety of research areas. We defer to OSP on the included research definitions.**
- The Board will have significant control over funding decisions, which may interfere with existing statute on NIH funding activities.
- We have concerns about the Board reaching out directly to applicants/recipients, which is outside traditional NIH reporting procedures.
- The required timeline of some Board activities is unclear.
- Flagged in previous TA, we have concerns about the confidentiality of application information and recommend more details be provided on how such information will be used or protected.
- Flagged in previous TA, some terms such as "proposal" and "entity" should be updated to better agree with NIH terminology.
- Flagged in previous TA, requirements for the validation of all applicant attestations related to research risk would be extremely challenging to implement.

ORS

- Concern over the confusion and differences between agent listing, some definition and intent of this as compared to the new DURC PEPP policy and also the current/ transparent process by which select agents are added or removed. We would recommend alignment 100% in line with the current SA policies and DURC PEPP policies. Curious if this Board would be subject to posting in the Federal Register with public comment, or would function in a more draconian approach.
- Acknowledging that risk assessment is best when diverse voices are heard, the lack and actually clear refusal to ensure persons with experience in high and maximum containment principles are included would not provide a comprehensive and scientifically robust review of this work.

- The Board would be all political appointees, and finding someone with no experience in this space would likely select for persons who only do not favor this work. The goals feel less neutral and scientifically based and much more politically centric.
- The agent listings are highly concerning and would have an immediate negative impact to science and public health. The mention of Influenza A viruses, for example, would include all work with H5N1 viruses which are having a significant impact on our poultry and dairy farms. Research into vaccines, treatment, spread and evolution of these viruses is critical to ensure to curb this outbreak and to prevent those in the future. The same could be said for the inclusion of all mpox. The current outbreak and identification of Clade I is highly concerning and without scientists able to pivot nimbly, the outcome is concerning.
- Page 18 of the document, line 26-30 appear to replace the work of IBCs and IREs and biosafety professionals across the country. The composition of this board would not have the appropriate expertise, training or experience to appropriately determine these requirements. It also seems quite granular for a board of this nature.
- Concerns about sensitivity of grant and project submissions from the confidentiality side- defer to OER and OSP.
- Page 17 regarding employee disciplines. This section would make people charged with compliance consistently and constantly afraid for their jobs. A punitive reporting process would have the opposite impact that I think is intended. Transparency on situations is important but its unclear what would happen because of these reports.

We have significant concerns about this bill and approach this would take for the oversight of biological research. Based on timelines and reviews, plus the lack of appropriate experience, many researchers would likely leave critical research fields and the work would be paused having negative and catastrophic impact to the biomedical enterprise and by extension human and animal health and safety.

OSP

Topline points:

While some aspects of this bill related to scope are improved, there continue to be significant concerns about the impact on biomedical research.

Strengthening biosafety and biosecurity oversight of life sciences research is a key priority of this Administration, as outlined in the National Biodefense Strategy. We believe the bill as drafted would significantly undermine life sciences research, and its oversight provisions fail to target the subset of research posing greatest risk. As such, we do not support this legislation.

The Administration has recently strengthened, streamlined, and expanded oversight of potentially high risk life science research in the May 2024 United States Government Policy for Oversight of Dual Use Research of Concern Pathogens with Enhanced Pandemic Potential ("DURC/PEPP policy"). This policy expands and strengthens a tiered system of oversight for all federally funded research that includes a requirement for research on pathogens with enhanced pandemic potential to undergo extra departmental review. The policy also:

Defines an expanded scope of pathogen and toxin research subject to additional oversight by the U.S. Government;

Provides a unified framework to support the consistent identification and oversight of research proposals that require enhanced oversight that accounts for safety, security, and ethical considerations; and

Delineates the roles and responsibilities of principal investigators, research institutions, and Federal departments and agencies that conduct, fund, or oversee research within the scope of the policy.

The bill seems to create redundancies with some reforms recently introduced by the DURC/PEPP policy, which was developed following significant interagency discussions directed by Congress and informed by the National Science Advisory Board for Biosecurity, public comment, and other expert input.

As currently drafted, this legislation has the potential to negatively impact innovation and the U.S. competitive edge in life sciences research, including our ability to attract and retain the best scientists.

However, the Administration welcomes efforts from Congress to further strengthen biosafety and biosecurity in the life sciences.

For example, we would welcome discussions on how the risk-based oversight processes established in the DURC policy for federally funded research could be extended to non-federally funded research.

We recognize that biosafety and biosecurity oversight responsibilities are currently shared across many different departments and agencies and welcome discussions on appropriate entities for oversight of the highest risk research.

Some of our concerns with the bill are:

Scope: While steps have been made toward harmonization of the scope of the Board's oversight with the new *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* (2024 OSTP DURC/PEPP Policy), some of the listed experiments in the "dual use research of concern" definition do not match those in the policy, and other articulated in-scope research in the bill including the "gain of function research" term continues to be in conflict with USG policy. These definition differences will be challenging to deconflict for the research community. Many of the USG definitions were determined following significant interagency discussions directed by Congress and informed by the National Science Advisory Board for Biosecurity, public comment, and other expert input.

- This could result in delays to critical biosurveillance efforts such as COVID-19 testing, H5N1 monitoring, and detection of emerging outbreaks of Ebola and other diseases. It could also result in delays for development of vaccines, therapeutics, and biomedical, agricultural, and other life sciences research writ large (including research that is not associated with pathogens or toxins and raises no identified national security threats, such as cancer research).
- If the statute only provided the board the responsibility to review federally-funded research involving DURC and PEPP, as defined in the DURC/PEPP policy, it would ensure oversight resources are used most efficiently to assess and mitigate risks to the public while avoiding unintended negative consequences for the nation's biomedical enterprise. We believe this is the intent of the bill but as written the definitions are not harmonized. (We recommend other definitions in the text be aligned to current U.S. Government policy, including "life sciences research.")
- We recommend that the definitions and scope of review be fully harmonized with the DURC/PEPP policy and not include a separate list of pathogens.
- A large amount of scientific research involves gain or loss of function; it's a fundamental process in science. For example, some types of immune therapy cause the immune system to gain function to fight against a disease. Unfortunately, the term "gain of function" has often being misconstrued to suggest all research that causes a gain of function is highly risky, which is inaccurate. In fact, most research involving a GOF does not confer significant additional risk or require additional oversight. NIH does not define the term GOF and current federal policy does not define or operationalize the term. The research that requires strict oversight involves enhancing the transmissibility and/or virulence of a pathogen such that it would pose an increased pandemic potential in humans. The USG policy on oversight of DURC and PEPP (effective May 2025) also does not use the term GOF when describing research that requires additional oversight because of its higher risk. As it appears the intent of the term "GOF" in this bill is to refer specially to research that has the potential to enhance the transmissibility or virulence of a potential pandemic pathogen, for clarity we would recommend the use of the term "pathogen with enhanced pandemic potential" in the 2024 OSTP policy that addresses this type of research, as well as it's associated definition. This would help to avoid the ongoing confusion surrounding the term GOF.

Board processes and makeup: While biosafety expertise is now included, the makeup and processes of the board could introduce a number of issues. For example, the limitations on prior federal service and designation of participation in high-risk research as a "conflict of interest" could limit the board from accessing relevant national security and life sciences expertise. The exclusion of those involved in high-risk research, based on the definition in the draft legislation, could exclude anyone with a current BSL3 or BSL4 program, excluding individuals with key expertise on how to conduct work safely. These limitations may also exclude individuals who work in government with relevant knowledge of intelligence and threat assessments. We also recommend relaxing the limitations on membership of the board and note that a number of the timelines are untenable (e.g., Congressional notification requirements within 3 days of identifying a potential conflict of interest; publishing procedures in the Federal Register within 90 days of the appointment of initial members; etc.). We note that several provisions relating to the membership of the Board or its support staff are vague, including the requirement that Board members be "impartial" and that support staff be prohibited from "directly or indirectly influenc[ing]" the Board. The proposed legislation would also politicize independent peer review by making the constituent members presidential appointees.

Review process: While a path for expedited review has been added, there could still be major issues with continuity of science due to delays of reviews or membership being confirmed. Among other concerns, in

Released by Chairman Rand Paul

particular, this will significantly impede the USG's ability to prepare for and detect emerging infectious diseases/epidemics/pandemics and will also significantly impede the USG's research response to an epidemic/pandemic. We recommend establishing a default rule that research may proceed if a decision is not made within a fixed timeframe to ensure that any lapse in function by the Board (e.g., delays in confirmation) do not result in life sciences research grinding to a halt. We also recommend a formal appeals process and an exemption to public reporting requirements if the information could pose national security risks.

Review criteria: The bill does not articulate a principle or threshold that guides whether the board should or should not approve a study for funding – for example, should the Board approve research where it determines that the potential public health benefits of the research outweigh the potential risks to U.S. national security? Or should some other standard govern the Board's review? Any statute mandating this style of review should clarify the applicable standard.

Classified review and intelligence concerns: We recommend striking provisions that mandate the provision of security clearances to Board members, Board staff, and members of Congress, or that require these individuals to access and review all classified research funded by any agency. Those provisions extend beyond the scope of oversight that is reasonable for this board to take on and they may impinge on the constitutional authority of the Executive to control classified national security information. We also recommend that clauses be included to enable the intelligence community to respond to requests from the Board in a manner consistent with the protection of intelligence sources and methods.

Enforcement: The enforcement provisions are extreme and may raise significant legal and privacy concerns. Those provisions mandate a suite of harsh penalties for any violations of certain provisions of the statute, including technical or unintentional violations; they allow for no flexibility in determining the severity of punishment; they provide the aggrieved party with no process; and they mandate public identification of aggrieved individuals. These provisions could broadly disincentivize individuals from working in life sciences research and funding agencies, which could send research outside of this country and compromise progress on public health, safety, and national security. We recommend that enforcement provisions be focused on willful violations and significantly reduced or adjusted.

Given the above concerns, as drafted, this legislation has the potential to negatively impact innovation and delay the development of lifesaving technologies. While the Administration does not support this legislation, we remain committed to working with the Committee on biosafety and biosecurity.

From: Crawford, Chase (NIH/NIAID) [E]
Sent: Wednesday, September 25, 2024 1:45 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; NIAID DCR-OCGR [redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: ACTION by COB Friday (9/27): Review revised bill text for Risky Research Review Act

Good Afternoon,

Released by Chairman Rand Paul

NIAID has been asked to review the revised bill text for the Risky Research Review Act (PDF of bill text and Word doc of the redline are attached). This morning, the attached version of the bill was reported out of the Senate Committee on Homeland Security & Governmental Affairs (HSGAC) and now awaits further Senate consideration.

As you may recall, NIH and other OPDIVs provided comments on a previous version of the bill (previous NIAID comments attached for reference). HHS is now requesting any new comments that OPDIVS may have.

ACTION: By COB Friday (9/27), please review the attached redline and provide any new comments directly in the document.

Thanks,
Chase

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Tuesday, July 16, 2024 6:07 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: URGENT review by 8am Wed. 7/17: HHS Comments to OMB on Risky Research Review Act
Importance: High

Hello all,

Thank you for your review of the consolidated HHS comments on the Risky Research Review Act. DMID has suggested adding some of the comments NIAID put forward earlier this week. We have incorporated these comments in highlighted text in the attached document. The comments are listed below by page number for ease of review.

Please let us know by no later than 8am tomorrow, Wednesday, July 17th, if you have any concerns with putting forward these previously NIAID-cleared edits.

Thank you again for all your help with this quick turnaround request. Please let me know if you have any questions.

Thanks,
Sara

Re-submitted NIAID comments in the attached document (highlighted in yellow):
p. 1: New NIH comment
p. 2: NIH addition to OASH/OHRP comment
p. 3: New NIH comment
p. 4: NIH addition to OASH/OHRP comment
p. 9: NIH edit to OGC comment to broaden scope to all agencies (previously flagged by OCGR-Leg)
p. 10: NIH addition (from NIAID) to existing NIH comment
p. 12: NIH addition to OIG comment
p. 14: NIH addition to OGC comment
p. 16: NIH addition (from NIAID) to existing NIH comment

Released by Chairman Rand Paul

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Tuesday, July 16, 2024 12:24 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: Please review by COB today Tues 7/16: HHS Comments to OMB on Risky Research Review Act
Importance: High

Hello all,

Background
Thank you again for your assistance in reviewing the Risky Research Review Act. HHS has compiled comments on the bill from throughout HHS to provide them to the Office of Management and Budget (OMB) for consideration. HHS is asking NIH to review the attached document on quick turnaround.

The comments included in the document provide high-level concerns across HHS. In particular, we have flagged a comment on the bottom of page 9 with a proposed clarifying edit for your review.

Action Item
Please review the attached draft HHS comments on the Risky Research Review Act and provide your concurrence, or any edits, by COB today, Tuesday July 16th. If you have any concerns with OCGR-Leg's proposed edit to the comment on page 9, please let us know.

Please note that NIH OLPA is also working on a separate request from the Senate Health, Education, Labor, and Pensions (HELP) Committee (Chair: Sen. Bernie Sanders, I-VT) for technical assistance on this bill. OLPA plans to include the specific NIAID comments shared yesterday in this separate request. We anticipate we may be asked to review consolidated NIH comments for the HELP Committee this week.

Thank you for your ongoing assistance with reviewing this bill. Please let me know if you have any questions.

Thanks,
Sara

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Monday, July 15, 2024 12:26 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: Additional OSP comments: TA on Risky Research Review Act

Released by Chairman Rand Paul

Hello all,

For your awareness, we are providing the attached comments on the Risky Research Review Act from the NIH Office of Science Policy (OSP). We anticipate receiving consolidated NIH comments on the bill, and we will share these as soon as we have them.

Please let me know if you have any questions.

Thanks,
Sara

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Monday, July 15, 2024 10:35 AM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: For review by noon Monday 7/15: Review draft NIAID TA on Risky Research Review Act
Importance: High

Hello all,

Thank you for your quick review of the draft NIAID TA on the Risky Research Review Act. In the attached revised draft, I have incorporated additional edits from DMID/Dr. Erbelding and DEA. If there are no objections, I will submit these to NIH OLPA by their noon deadline today.

I am also attaching for your reference additional comments on the bill provided by NIH OER and NIH ORS/DOHS.

Please let me know if you have any questions or concerns.

Thanks,
Sara

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Friday, July 12, 2024 4:06 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: URGENT ACTION by 10am Monday 7/15: Review draft NIAID TA on Risky Research Review Act
Importance: High

Hello all,

Released by Chairman Rand Paul

Background
Thank you very much for your quick work to comment on the Risky Research Review Act. NIH OLPA has asked us to prioritize comments to flag the most urgent or concerning items and/or those needing clarification.

Action Item
We have compiled the comments that meet NIH OLPA's request into the attached draft technical assistance document. Please note that NIH OLPA has requested examples, where possible. We have tried to add some examples to emphasize key points, but we welcome any suggestions and/or corrections as needed.

We would appreciate your review and any edits by 10am Monday, July 15th. Given the quick turnaround, we are asking the Divisions to review concurrently with the NIAID OD.

Please note that NIH OSP, NIH ORS/DOHS, and NIH OER will also be reviewing and providing comments. We will be sure to share with you any consolidated NIH comments that we receive.

Thank you for your help with this quick turnaround request. Please let me know if you have any questions.

Thanks,
Sara

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Thursday, July 11, 2024 10:51 AM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Subject: URGENT ACTION by 12pm Friday 7/12: TA on Risky Research Review Act
Importance: High

Good morning,

Background
HHS has been asked by the Senate Homeland Security and Governmental Affairs Committee (Chair: Sen. Gary Peters, D-MI; Ranking Member: Sen. Rand Paul, R-KY) to provide technical assistance (TA) on the attached draft legislation entitled the Risky Research Review Act.

The draft bill would require the establishment of an independent life sciences research security board to review federal funding for certain proposed life sciences research as defined by the bill. NIAID is mentioned briefly on page 4 in a section describing limitations on membership of the board.

HHS reports that the Committee intends to consider the bill on July 24. A number of HHS OpDivs and offices, including ASPR, CDC, and FDA, have been asked to review the bill along with NIH.

Action Item
By noon tomorrow, Friday July 12, please review the attached draft legislation and provide any technical comments in the attached HHS TA template. Please note that NIH ORS/DOHS and NIH OSP are also reviewing the bill on behalf of NIH.

As you complete your review, please keep in mind the HHS guidance on technical assistance below. Please let me know if you have any questions.

Thanks,

Released by Chairman Rand Paul

Sara

To ensure that the Department's comments are given full consideration, please observe the following guidelines in providing your office's comments:

Are there provisions of this bill that would conflict with Department or Administration policy, and how?

Are there provisions that would pose difficulties for the operation or management of HHS programs, and how?

Are there any other significant issues that you can identify?

If you recommend specific changes, supply reasons and explanations, if the reasons are not obvious.

Released by Chairman Rand Paul

From: "Ford, Andrew (NIH/NIAID) [E]" <[redacted]@nih.gov>
To: "Crawford, Chase (NIH/NIAID) [E]" <[redacted]@nih.gov>
Cc: NIAID OCGR Leg <[redacted]@mail.nih.gov>, "Erbelding, Emily (NIH/NIAID) [E]" <[redacted]@nih.gov>, NIAID BUGS <[redacted]@niaid.nih.gov>
Subject: Re: ACTION by 10a Thurs (10/17): Review compiled HHS comments on revised bill text for Risky Research Review Act
Date: Fri, 11 Oct 2024 12:24:59 -0400
Importance: Normal

Thanks Chase – will do

From: Crawford, Chase (NIH/NIAID) [E] <[redacted]@nih.gov>
Date: Friday, October 11, 2024 at 12:21 PM
To: NIAID BUGS <[redacted]@niaid.nih.gov>, NIAID DEA DART <[redacted]@mail.nih.gov>, NIAID DIR-OCGR <[redacted]@mail.nih.gov>, NIAID DCR-OCGR <[redacted]@mail.nih.gov>, Nealy, Michael (NIH/NIAID) [E] <[redacted]@nih.gov>, Harper, Jill (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>, Parker, Marie (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>, Read, Sarah (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>, Billet, Courtney (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg <[redacted]@mail.nih.gov>, Erbelding, Emily (NIH/NIAID) [E] <[redacted]@nih.gov>, Holland, Steven (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>, Hanson, Christopher (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>, Poe, Kelly (NIH/NIAID) [E] <[redacted]@nih.gov>, Gilles, Sharon (NIH/NIAID) [E] <[redacted]@nih.gov>, DDSM Correspondences <[redacted]@mail.nih.gov>
Subject: ACTION by 10a Thurs (10/17): Review compiled HHS comments on revised bill text for Risky Research Review Act

Good Afternoon,

NIAID has been asked to review the attached compiled HHS comments on S.4667 (Risky Research Review Act), as amended. OSP, OER, and ORS also are reviewing. As you may recall, NIAID previously provided NIH OD with comments on the revised bill text, which are attached for your reference, as well as high-level bullets (see email chain below).

ACTION: By 10a Thursday (10/17), please provide any new edits/comments in the attached "HHS points" document.

Please let us know if you have any questions.

Thanks,
Chase

From: Crawford, Chase (NIH/NIAID) [E]
Sent: Monday, September 30, 2024 2:31 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; NIAID DCR-OCGR [redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E]

Released by Chairman Rand Paul

[redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: FYI - Update on TA for revised bill text for Risky Research Review Act

FYI – Bldg. 1 has asked NIAID to provide a few top line bullets outlining the types of comments that were submitted on the redline version of the bill. NIAID plans to share the below bullets and indicate that NIAID shares many of the concerns raised by OER, ORS, and OSP (their top line bullets are copied further below). We will request a copy of the consolidated NIH TA and share it with you if/when we receive. Please let us know if you have any questions at this time. Thanks, Chase

NIAID

- NIAID notes that, to avoid confusion, the definitions in the bill pertaining to scientific and/or current policies should be consistent with definitions in science and those policies, including the USG Policy for Oversight of DURC and PEPP (https://www.whitehouse.gov/wp-content/uploads/2024/05/USG-Policy-for-Oversight-of-DURC-and-PEPP.pdf). Further, as written, some definitions are overly broad and could slow research in critical areas, including research on antimicrobial resistance and the H5 influenza outbreak in dairy cattle.
- NIAID also notes that, as written, the proposed Board may lack essential expertise in infectious diseases and biosecurity.
- NIAID notes that it is unclear if it is the drafters' intent to prohibit funding for an entire award prior to Board approval or only work related to potential "high-risk" research. Similarly, there is a later provision that would require a pause in research due to a change in circumstance, but it is unclear if such a pause would apply to an entire award or only work related to potential "high-risk research.

OER

- It is unclear what added value the Board may have over current processes. The Board seems redundant with existing/current efforts and/or those being implemented following OSTP's mandate on DURC/PEPP.
- **The Board's scope is very broad and may apply to a variety of research areas. We defer to OSP on the included research definitions.**
- The Board will have significant control over funding decisions, which may interfere with existing statute on NIH funding activities.
- We have concerns about the Board reaching out directly to applicants/recipients, which is outside traditional NIH reporting procedures.
- The required timeline of some Board activities is unclear.
- Flagged in previous TA, we have concerns about the confidentiality of application information and recommend more details be provided on how such information will be used or protected.
- Flagged in previous TA, some terms such as "proposal" and "entity" should be updated to better agree with NIH terminology.
- Flagged in previous TA, requirements for the validation of all applicant attestations related to research risk would be extremely challenging to implement.

ORS

- Concern over the confusion and differences between agent listing, some definition and intent of this as compared to the new DURC PEPP policy and also the current/ transparent process by which select agents are added or removed. We would recommend alignment 100% in line with the current SA policies and DURC PEPP policies. Curious if this Board would be subject to posting in the Federal Register with public comment, or would function in a more draconian approach.
- Acknowledging that risk assessment is best when diverse voices are heard, the lack and actually clear refusal to ensure persons with experience in high and maximum containment principles are included would not provide a comprehensive and scientifically robust review of this work.
- The Board would be all political appointees, and finding someone with no experience in this space would likely select for persons who only do not favor this work. The goals feel less neutral and scientifically based and much more politically centric.
- The agent listings are highly concerning and would have an immediate negative impact to science and public health. The mention of Influenza A viruses, for example, would include all work with H5N1 viruses which are having a significant impact on our poultry and dairy farms. Research into vaccines, treatment, spread and evolution of

Released by Chairman Rand Paul

these viruses is critical to ensure to curb this outbreak and to prevent those in the future. The same could be said for the inclusion of all mpox. The current outbreak and identification of Clade I is highly concerning and without scientists able to pivot nimbly, the outcome is concerning.

- Page 18 of the document, line 26-30 appear to replace the work of IBCs and IREs and biosafety professionals across the country. The composition of this board would not have the appropriate expertise, training or experience to appropriately determine these requirements. It also seems quite granular for a board of this nature.
- Concerns about sensitivity of grant and project submissions from the confidentiality side- defer to OER and OSP.
- Page 17 regarding employee disciplines. This section would make people charged with compliance consistently and constantly afraid for their jobs. A punitive reporting process would have the opposite impact that I think is intended. Transparency on situations is important but its unclear what would happen because of these reports.

We have significant concerns about this bill and approach this would take for the oversight of biological research. Based on timelines and reviews, plus the lack of appropriate experience, many researchers would likely leave critical research fields and the work would be paused having negative and catastrophic impact to the biomedical enterprise and by extension human and animal health and safety.

OSP

Topline points:

While some aspects of this bill related to scope are improved, there continue to be significant concerns about the impact on biomedical research.

Strengthening biosafety and biosecurity oversight of life sciences research is a key priority of this Administration, as outlined in the National Biodefense Strategy. We believe the bill as drafted would significantly undermine life sciences research, and its oversight provisions fail to target the subset of research posing greatest risk. As such, we do not support this legislation.

The Administration has recently strengthened, streamlined, and expanded oversight of potentially high risk life science research in the May 2024 United States Government Policy for Oversight of Dual Use Research of Concern Pathogens with Enhanced Pandemic Potential ("DURC/PEPP policy"). This policy expands and strengthens a tiered system of oversight for all federally funded research that includes a requirement for research on pathogens with enhanced pandemic potential to undergo extra departmental review. The policy also:

Defines an expanded scope of pathogen and toxin research subject to additional oversight by the U.S. Government;

Provides a unified framework to support the consistent identification and oversight of research proposals that require enhanced oversight that accounts for safety, security, and ethical considerations; and

Delineates the roles and responsibilities of principal investigators, research institutions, and Federal departments and agencies that conduct, fund, or oversee research within the scope of the policy.

The bill seems to create redundancies with some reforms recently introduced by the DURC/PEPP policy, which was developed following significant interagency discussions directed by Congress and informed by the National Science Advisory Board for Biosecurity, public comment, and other expert input.

As currently drafted, this legislation has the potential to negatively impact innovation and the U.S. competitive edge in life sciences research, including our ability to attract and retain the best scientists.

However, the Administration welcomes efforts from Congress to further strengthen biosafety and biosecurity in the life sciences.

For example, we would welcome discussions on how the risk-based oversight processes established in the DURC policy for federally funded research could be extended to non-federally funded research.

We recognize that biosafety and biosecurity oversight responsibilities are currently shared across many different departments and agencies and welcome discussions on appropriate entities for oversight of the highest risk research.

Some of our concerns with the bill are:

Scope: While steps have been made toward harmonization of the scope of the Board's oversight with the new *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* (2024 OSTP DURC/PEPP Policy), some of the listed experiments in the "dual use research of concern" definition do not match those in the policy, and other articulated in-scope research in the bill including the "gain of function research" term continues to be in conflict with USG policy. These definition differences will be challenging to deconflict for the research community. Many of the USG definitions were

Released by Chairman Rand Paul

determined following significant interagency discussions directed by Congress and informed by the National Science Advisory Board for Biosecurity, public comment, and other expert input.

- This could result in delays to critical biosurveillance efforts such as COVID-19 testing, H5N1 monitoring, and detection of emerging outbreaks of Ebola and other diseases. It could also result in delays for development of vaccines, therapeutics, and biomedical, agricultural, and other life sciences research writ large (including research that is not associated with pathogens or toxins and raises no identified national security threats, such as cancer research).
- If the statute only provided the board the responsibility to review federally-funded research involving DURC and PEPP, as defined in the DURC/PEPP policy, it would ensure oversight resources are used most efficiently to assess and mitigate risks to the public while avoiding unintended negative consequences for the nation's biomedical enterprise. We believe this is the intent of the bill but as written the definitions are not harmonized. (We recommend other definitions in the text be aligned to current U.S. Government policy, including "life sciences research.")
- We recommend that the definitions and scope of review be fully harmonized with the DURC/PEPP policy and not include a separate list of pathogens.
- A large amount of scientific research involves gain or loss of function; it's a fundamental process in science. For example, some types of immune therapy cause the immune system to gain function to fight against a disease. Unfortunately, the term "gain of function" has often being misconstrued to suggest all research that causes a gain of function is highly risky, which is inaccurate. In fact, most research involving a GOF does not confer significant additional risk or require additional oversight. NIH does not define the term GOF and current federal policy does not define or operationalize the term. The research that requires strict oversight involves enhancing the transmissibility and/or virulence of a pathogen such that it would pose an increased pandemic potential in humans. The USG policy on oversight of DURC and PEPP (effective May 2025) also does not use the term GOF when describing research that requires additional oversight because of its higher risk. As it appears the intent of the term "GOF" in this bill is to refer specially to research that has the potential to enhance the transmissibility or virulence of a potential pandemic pathogen, for clarity we would recommend the use of the term "pathogen with enhanced pandemic potential" in the 2024 OSTP policy that addresses this type of research, as well as it's associated definition. This would help to avoid the ongoing confusion surrounding the term GOF.

Board processes and makeup: While biosafety expertise is now included, the makeup and processes of the board could introduce a number of issues. For example, the limitations on prior federal service and designation of participation in high-risk research as a "conflict of interest" could limit the board from accessing relevant national security and life sciences expertise. The exclusion of those involved in high-risk research, based on the definition in the draft legislation, could exclude anyone with a current BSL3 or BSL4 program, excluding individuals with key expertise on how to conduct work safely. These limitations may also exclude individuals who work in government with relevant knowledge of intelligence and threat assessments. We also recommend relaxing the limitations on membership of the board and note that a number of the timelines are untenable (e.g., Congressional notification requirements within 3 days of identifying a potential conflict of interest; publishing procedures in the Federal Register within 90 days of the appointment of initial members; etc.). We note that several provisions relating to the membership of the Board or its support staff are vague, including the requirement that Board members be "impartial" and that support staff be prohibited from "directly or indirectly influenc[ing]" the Board. The proposed legislation would also politicize independent peer review by making the constituent members presidential appointees.

Review process: While a path for expedited review has been added, there could still be major issues with continuity of science due to delays of reviews or membership being confirmed. Among other concerns, in particular, this will significantly impede the USG's ability to prepare for and detect emerging infectious diseases/epidemics/pandemics and will also significantly impede the USG's research response to an epidemic/pandemic. We recommend establishing a default rule that research may proceed if a decision is not made within a fixed timeframe to ensure that any lapse in function by the Board (e.g., delays in confirmation) do not result in life sciences research grinding to a halt. We also recommend a formal appeals process and an exemption to public reporting requirements if the information could pose national security risks.

Released by Chairman Rand Paul

Review criteria: The bill does not articulate a principle or threshold that guides whether the board should or should not approve a study for funding – for example, should the Board approve research where it determines that the potential public health benefits of the research outweigh the potential risks to U.S. national security? Or should some other standard govern the Board's review? Any statute mandating this style of review should clarify the applicable standard.

Classified review and intelligence concerns: We recommend striking provisions that mandate the provision of security clearances to Board members, Board staff, and members of Congress, or that require these individuals to access and review all classified research funded by any agency. Those provisions extend beyond the scope of oversight that is reasonable for this board to take on and they may impinge on the constitutional authority of the Executive to control classified national security information. We also recommend that clauses be included to enable the intelligence community to respond to requests from the Board in a manner consistent with the protection of intelligence sources and methods.

Enforcement: The enforcement provisions are extreme and may raise significant legal and privacy concerns. Those provisions mandate a suite of harsh penalties for any violations of certain provisions of the statute, including technical or unintentional violations; they allow for no flexibility in determining the severity of punishment; they provide the aggrieved party with no process; and they mandate public identification of aggrieved individuals. These provisions could broadly disincentivize individuals from working in life sciences research and funding agencies, which could send research outside of this country and compromise progress on public health, safety, and national security. We recommend that enforcement provisions be focused on willful violations and significantly reduced or adjusted.

Given the above concerns, as drafted, this legislation has the potential to negatively impact innovation and delay the development of lifesaving technologies. While the Administration does not support this legislation, we remain committed to working with the Committee on biosafety and biosecurity.

From: Crawford, Chase (NIH/NIAID) [E]
Sent: Wednesday, September 25, 2024 1:45 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; NIAID DCR-OCGR [redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: ACTION by COB Friday (9/27): Review revised bill text for Risky Research Review Act

Good Afternoon,

NIAID has been asked to review the revised bill text for the Risky Research Review Act (PDF of bill text and Word doc of the redline are attached). This morning, the attached version of the bill was reported out of the Senate Committee on Homeland Security & Governmental Affairs (HSGAC) and now awaits further Senate consideration.

As you may recall, NIH and other OPDIVs provided comments on a previous version of the bill (previous NIAID comments attached for reference). HHS is now requesting any new comments that OPDIVS may have.

Released by Chairman Rand Paul

ACTION: By COB Friday (9/27), please review the attached redline and provide any new comments directly in the document.

Thanks,
Chase

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Tuesday, July 16, 2024 6:07 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: URGENT review by 8am Wed. 7/17: HHS Comments to OMB on Risky Research Review Act
Importance: High

Hello all,

Thank you for your review of the consolidated HHS comments on the Risky Research Review Act. DMID has suggested adding some of the comments NIAID put forward earlier this week. We have incorporated these comments in highlighted text in the attached document. The comments are listed below by page number for ease of review.

Please let us know by no later than 8am tomorrow, Wednesday, July 17th, if you have any concerns with putting forward these previously NIAID-cleared edits.

Thank you again for all your help with this quick turnaround request. Please let me know if you have any questions.

Thanks,
Sara

Re-submitted NIAID comments in the attached document (highlighted in yellow):
p. 1: New NIH comment
p. 2: NIH addition to OASH/OHRP comment
p. 3: New NIH comment
p. 4: NIH addition to OASH/OHRP comment
p. 9: NIH edit to OGC comment to broaden scope to all agencies (previously flagged by OCGR-Leg)
p. 10: NIH addition (from NIAID) to existing NIH comment
p. 12: NIH addition to OIG comment
p. 14: NIH addition to OGC comment
p. 16: NIH addition (from NIAID) to existing NIH comment

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Tuesday, July 16, 2024 12:24 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-

Released by Chairman Rand Paul

[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: Please review by COB today Tues 7/16: HHS Comments to OMB on Risky Research Review Act
Importance: High

Hello all,

Background
Thank you again for your assistance in reviewing the Risky Research Review Act. HHS has compiled comments on the bill from throughout HHS to provide them to the Office of Management and Budget (OMB) for consideration. HHS is asking NIH to review the attached document on quick turnaround.

The comments included in the document provide high-level concerns across HHS. In particular, we have flagged a comment on the bottom of page 9 with a proposed clarifying edit for your review.

Action Item
Please review the attached draft HHS comments on the Risky Research Review Act and provide your concurrence, or any edits, by COB today, Tuesday July 16th. If you have any concerns with OCGR-Leg's proposed edit to the comment on page 9, please let us know.

Please note that NIH OLPA is also working on a separate request from the Senate Health, Education, Labor, and Pensions (HELP) Committee (Chair: Sen. Bernie Sanders, I-VT) for technical assistance on this bill. OLPA plans to include the specific NIAID comments shared yesterday in this separate request. We anticipate we may be asked to review consolidated NIH comments for the HELP Committee this week.

Thank you for your ongoing assistance with reviewing this bill. Please let me know if you have any questions.

Thanks,
Sara

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Monday, July 15, 2024 12:26 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: Additional OSP comments: TA on Risky Research Review Act

Hello all,

For your awareness, we are providing the attached comments on the Risky Research Review Act from the NIH Office of Science Policy (OSP). We anticipate receiving consolidated NIH comments on the bill, and we will share these as soon as we have them.

Released by Chairman Rand Paul

Please let me know if you have any questions.

Thanks,
Sara

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Monday, July 15, 2024 10:35 AM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: For review by noon Monday 7/15: Review draft NIAID TA on Risky Research Review Act
Importance: High

Hello all,

Thank you for your quick review of the draft NIAID TA on the Risky Research Review Act. In the attached revised draft, I have incorporated additional edits from DMID/Dr. Erbelding and DEA. If there are no objections, I will submit these to NIH OLPA by their noon deadline today.

I am also attaching for your reference additional comments on the bill provided by NIH OER and NIH ORS/DOHS.

Please let me know if you have any questions or concerns.

Thanks,
Sara

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Friday, July 12, 2024 4:06 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: URGENT ACTION by 10am Monday 7/15: Review draft NIAID TA on Risky Research Review Act
Importance: High

Hello all,

Background
Thank you very much for your quick work to comment on the Risky Research Review Act. NIH OLPA has asked us to prioritize comments to flag the most urgent or concerning items and/or those needing clarification.

Action Item

Released by Chairman Rand Paul

We have compiled the comments that meet NIH OLPA's request into the attached draft technical assistance document. Please note that NIH OLPA has requested examples, where possible. We have tried to add some examples to emphasize key points, but we welcome any suggestions and/or corrections as needed.

We would appreciate your review and any edits by 10am Monday, July 15th. Given the quick turnaround, we are asking the Divisions to review concurrently with the NIAID OD.

Please note that NIH OSP, NIH ORS/DOHS, and NIH OER will also be reviewing and providing comments. We will be sure to share with you any consolidated NIH comments that we receive.

Thank you for your help with this quick turnaround request. Please let me know if you have any questions.

Thanks,
Sara

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Thursday, July 11, 2024 10:51 AM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Subject: URGENT ACTION by 12pm Friday 7/12: TA on Risky Research Review Act
Importance: High

Good morning,

Background
HHS has been asked by the Senate Homeland Security and Governmental Affairs Committee (Chair: Sen. Gary Peters, D-MI; Ranking Member: Sen. Rand Paul, R-KY) to provide technical assistance (TA) on the attached draft legislation entitled the Risky Research Review Act.

The draft bill would require the establishment of an independent life sciences research security board to review federal funding for certain proposed life sciences research as defined by the bill. NIAID is mentioned briefly on page 4 in a section describing limitations on membership of the board.

HHS reports that the Committee intends to consider the bill on July 24. A number of HHS OpDivs and offices, including ASPR, CDC, and FDA, have been asked to review the bill along with NIH.

Action Item
By noon tomorrow, Friday July 12, please review the attached draft legislation and provide any technical comments in the attached HHS TA template. Please note that NIH ORS/DOHS and NIH OSP are also reviewing the bill on behalf of NIH.

As you complete your review, please keep in mind the HHS guidance on technical assistance below. Please let me know if you have any questions.

Thanks,
Sara

To ensure that the Department's comments are given full consideration, please observe the following guidelines in providing your office's comments:

Released by Chairman Rand Paul

Are there provisions of this bill that would conflict with Department or Administration policy, and how?

Are there provisions that would pose difficulties for the operation or management of HHS programs, and how?

Are there any other significant issues that you can identify?

If you recommend specific changes, supply reasons and explanations, if the reasons are not obvious.

Released by Chairman Rand Paul

From: "Crawford, Chase (NIH/NIAID) [E]" <[redacted]@nih.gov>

To: NIAID BUGS <[redacted]@niaid.nih.gov>, NIAID DEA DART <[redacted]@mail.nih.gov>, "NIAID DIR-OCGR" <[redacted]@mail.nih.gov>, NIAID DCR-OCGR <NIAIDDCR-[redacted]@mail.nih.gov>, "Nealy, Michael (NIH/NIAID) [E]" <[redacted]@nih.gov>, "Harper, Jill (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Parker, Marie (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Read, Sarah (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Billet, Courtney (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>

Cc: NIAID OCGR Leg <[redacted]@mail.nih.gov>, "Erbelding, Emily (NIH/NIAID) [E]" <[redacted]@nih.gov>, "Holland, Steven (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Hanson, Christopher (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Poe, Kelly (NIH/NIAID) [E]" <[redacted]@nih.gov>, "Gilles, Sharon (NIH/NIAID) [E]" <[redacted]@nih.gov>, "DDSM Correspondences" <[redacted]@mail.nih.gov>

Subject: ACTION by 10a Thurs (10/17): Review compiled HHS comments on revised bill text for Risky Research Review Act

Date: Fri, 11 Oct 2024 12:20:27 -0400

Importance: Normal

Attachments: HHS_points_on_updated_S4667.docx; For_reference_-redline2_NIAID_comments.docx

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Good Afternoon,

NIAID has been asked to review the attached compiled HHS comments on S.4667 (Risky Research Review Act), as amended. OSP, OER, and ORS also are reviewing. As you may recall, NIAID previously provided NIH OD with comments on the revised bill text, which are attached for your reference, as well as high-level bullets (see email chain below).

ACTION: By 10a Thursday (10/17), please provide any new edits/comments in the attached "HHS points" document.

Please let us know if you have any questions.

Thanks,
Chase

From: Crawford, Chase (NIH/NIAID) [E]
Sent: Monday, September 30, 2024 2:31 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; NIAID DCR-OCGR [redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: FYI - Update on TA for revised bill text for Risky Research Review Act

FYI – Bldg. 1 has asked NIAID to provide a few top line bullets outlining the types of comments that were submitted on the redline version of the bill. NIAID plans to share the below bullets and indicate that NIAID shares many of the concerns raised by OER, ORS, and OSP (their top line bullets are copied further below). We will request a copy of the consolidated NIH TA and share it with you if/when we receive. Please let us know if you have any questions at this time. Thanks, Chase

NIAID

- NIAID notes that, to avoid confusion, the definitions in the bill pertaining to scientific and/or current policies should be consistent with definitions in science and those policies, including the USG Policy for Oversight of DURC and PEPP (https://www.whitehouse.gov/wp-content/uploads/2024/05/USG-Policy-for-Oversight-of-DURC-and-PEPP.pdf). Further, as written, some definitions are overly broad and could slow research in critical areas, including research on antimicrobial resistance and the H5 influenza outbreak in dairy cattle.
- NIAID also notes that, as written, the proposed Board may lack essential expertise in infectious diseases and biosecurity.
- NIAID notes that it is unclear if it is the drafters' intent to prohibit funding for an entire award prior to Board approval or only work related to potential "high-risk" research. Similarly, there is a later provision that would require a pause in research due to a change in circumstance, but it is unclear if such a pause would apply to an entire award or only work related to potential "high-risk research.

OER

- It is unclear what added value the Board may have over current processes. The Board seems redundant with existing/current efforts and/or those being implemented following OSTP's mandate on DURC/PEPP.
- **The Board's scope is very broad and may apply to a variety of research areas. We defer to OSP on the included research definitions.**
- The Board will have significant control over funding decisions, which may interfere with existing statute on NIH funding activities.
- We have concerns about the Board reaching out directly to applicants/recipients, which is outside traditional NIH reporting procedures.
- The required timeline of some Board activities is unclear.
- Flagged in previous TA, we have concerns about the confidentiality of application information and recommend more details be provided on how such information will be used or protected.
- Flagged in previous TA, some terms such as "proposal" and "entity" should be updated to better agree with NIH terminology.
- Flagged in previous TA, requirements for the validation of all applicant attestations related to research risk would be extremely challenging to implement.

ORS

- Concern over the confusion and differences between agent listing, some definition and intent of this as compared to the new DURC PEPP policy and also the current/ transparent process by which select agents are added or removed. We would recommend alignment 100% in line with the current SA policies and DURC PEPP policies. Curious if this Board would be subject to posting in the Federal Register with public comment, or would function in a more draconian approach.
- Acknowledging that risk assessment is best when diverse voices are heard, the lack and actually clear refusal to ensure persons with experience in high and maximum containment principles are included would not provide a comprehensive and scientifically robust review of this work.
- The Board would be all political appointees, and finding someone with no experience in this space would likely select for persons who only do not favor this work. The goals feel less neutral and scientifically based and much more politically centric.
- The agent listings are highly concerning and would have an immediate negative impact to science and public health. The mention of Influenza A viruses, for example, would include all work with H5N1 viruses which are having a significant impact on our poultry and dairy farms. Research into vaccines, treatment, spread and evolution of these viruses is critical to ensure to curb this outbreak and to prevent those in the future. The same could be said for the inclusion of all mpox. The current outbreak and identification of Clade I is highly concerning and without scientists able to pivot nimbly, the outcome is concerning.
- Page 18 of the document, line 26-30 appear to replace the work of IBCs and IREs and biosafety professionals across the country. The composition of this board would not have the appropriate expertise, training or experience to appropriately determine these requirements. It also seems quite granular for a board of this nature.
- Concerns about sensitivity of grant and project submissions from the confidentiality side- defer to OER and OSP.

- Page 17 regarding employee disciplines. This section would make people charged with compliance consistently and constantly afraid for their jobs. A punitive reporting process would have the opposite impact that I think is intended. Transparency on situations is important but its unclear what would happen because of these reports.

We have significant concerns about this bill and approach this would take for the oversight of biological research. Based on timelines and reviews, plus the lack of appropriate experience, many researchers would likely leave critical research fields and the work would be paused having negative and catastrophic impact to the biomedical enterprise and by extension human and animal health and safety.

OSP

Topline points:

- **While some aspects of this bill related to scope are improved, there continue to be significant concerns about the impact on biomedical research.**
- Strengthening biosafety and biosecurity oversight of life sciences research is a key priority of this Administration, as outlined in the National Biodefense Strategy. We believe the bill as drafted would significantly undermine life sciences research, and its oversight provisions fail to target the subset of research posing greatest risk. As such, we do not support this legislation.
- The Administration has recently strengthened, streamlined, and expanded oversight of potentially high risk life science research in the May 2024 United States Government Policy for Oversight of Dual Use Research of Concern Pathogens with Enhanced Pandemic Potential ("DURC/PEPP policy"). This policy expands and strengthens a tiered system of oversight for all federally funded research that includes a requirement for research on pathogens with enhanced pandemic potential to undergo extra departmental review. The policy also:
    - Defines an expanded scope of pathogen and toxin research subject to additional oversight by the U.S. Government;
    - Provides a unified framework to support the consistent identification and oversight of research proposals that require enhanced oversight that accounts for safety, security, and ethical considerations; and
    - Delineates the roles and responsibilities of principal investigators, research institutions, and Federal departments and agencies that conduct, fund, or oversee research within the scope of the policy.
- The bill seems to create redundancies with some reforms recently introduced by the DURC/PEPP policy, which was developed following significant interagency discussions directed by Congress and informed by the National Science Advisory Board for Biosecurity, public comment, and other expert input.
- As currently drafted, this legislation has the potential to negatively impact innovation and the U.S. competitive edge in life sciences research, including our ability to attract and retain the best scientists.
- However, the Administration welcomes efforts from Congress to further strengthen biosafety and biosecurity in the life sciences.
    - For example, we would welcome discussions on how the risk-based oversight processes established in the DURC policy for federally funded research could be extended to non-federally funded research.
- We recognize that biosafety and biosecurity oversight responsibilities are currently shared across many different departments and agencies and welcome discussions on appropriate entities for oversight of the highest risk research.

Some of our concerns with the bill are:

- **Scope:** While steps have been made toward harmonization of the scope of the Board's oversight with the new *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* (2024 OSTP DURC/PEPP Policy), some of the listed experiments in the "dual use research of concern" definition do not match those in the policy, and other articulated in-scope research in the bill including the "gain of function research" term continues to be in conflict with USG policy. These definition differences will be challenging to deconflict for the research community. Many of the USG definitions were determined following significant interagency discussions directed by Congress and informed by the National Science Advisory Board for Biosecurity, public comment, and other expert input.
    - This could result in delays to critical biosurveillance efforts such as COVID-19 testing, H5N1 monitoring, and detection of emerging outbreaks of Ebola and other diseases. It could also result in delays for development of vaccines, therapeutics, and biomedical, agricultural, and other life sciences research

Released by Chairman Rand Paul

writ large (including research that is not associated with pathogens or toxins and raises no identified national security threats, such as cancer research).
    - If the statute only provided the board the responsibility to review federally-funded research involving DURC and PEPP, as defined in the DURC/PEPP policy, it would ensure oversight resources are used most efficiently to assess and mitigate risks to the public while avoiding unintended negative consequences for the nation's biomedical enterprise. We believe this is the intent of the bill but as written the definitions are not harmonized. (We recommend other definitions in the text be aligned to current U.S. Government policy, including "life sciences research.")
    - We recommend that the definitions and scope of review be fully harmonized with the DURC/PEPP policy and not include a separate list of pathogens.
    - A large amount of scientific research involves gain or loss of function; it's a fundamental process in science. For example, some types of immune therapy cause the immune system to gain function to fight against a disease. Unfortunately, the term "gain of function" has often being misconstrued to suggest all research that causes a gain of function is highly risky, which is inaccurate. In fact, most research involving a GOF does not confer significant additional risk or require additional oversight. NIH does not define the term GOF and current federal policy does not define or operationalize the term. The research that requires strict oversight involves enhancing the transmissibility and/or virulence of a pathogen such that it would pose an increased pandemic potential in humans. The USG policy on oversight of DURC and PEPP (effective May 2025) also does not use the term GOF when describing research that requires additional oversight because of its higher risk. As it appears the intent of the term "GOF" in this bill is to refer specially to research that has the potential to enhance the transmissibility or virulence of a potential pandemic pathogen, for clarity we would recommend the use of the term "pathogen with enhanced pandemic potential" in the 2024 OSTP policy that addresses this type of research, as well as it's associated definition. This would help to avoid the ongoing confusion surrounding the term GOF.

- **Board processes and makeup:** While biosafety expertise is now included, the makeup and processes of the board could introduce a number of issues. For example, the limitations on prior federal service and designation of participation in high-risk research as a "conflict of interest" could limit the board from accessing relevant national security and life sciences expertise. The exclusion of those involved in high-risk research, based on the definition in the draft legislation, could exclude anyone with a current BSL3 or BSL4 program, excluding individuals with key expertise on how to conduct work safely. These limitations may also exclude individuals who work in government with relevant knowledge of intelligence and threat assessments. We also recommend relaxing the limitations on membership of the board and note that a number of the timelines are untenable (e.g., Congressional notification requirements within 3 days of identifying a potential conflict of interest; publishing procedures in the Federal Register within 90 days of the appointment of initial members; etc.). We note that several provisions relating to the membership of the Board or its support staff are vague, including the requirement that Board members be "impartial" and that support staff be prohibited from "directly or indirectly influenc[ing]" the Board. The proposed legislation would also politicize independent peer review by making the constituent members presidential appointees.

- **Review process:** While a path for expedited review has been added, there could still be major issues with continuity of science due to delays of reviews or membership being confirmed. Among other concerns, in particular, this will significantly impede the USG's ability to prepare for and detect emerging infectious diseases/epidemics/pandemics and will also significantly impede the USG's research response to an epidemic/pandemic. We recommend establishing a default rule that research may proceed if a decision is not made within a fixed timeframe to ensure that any lapse in function by the Board (e.g., delays in confirmation) do not result in life sciences research grinding to a halt. We also recommend a formal appeals process and an exemption to public reporting requirements if the information could pose national security risks.

- **Review criteria:** The bill does not articulate a principle or threshold that guides whether the board should or should not approve a study for funding – for example, should the Board approve research where it determines that the potential public health benefits of the research outweigh the potential risks to U.S.

Released by Chairman Rand Paul

national security? Or should some other standard govern the Board's review? Any statute mandating this style of review should clarify the applicable standard.

- **Classified review and intelligence concerns:** We recommend striking provisions that mandate the provision of security clearances to Board members, Board staff, and members of Congress, or that require these individuals to access and review all classified research funded by any agency. Those provisions extend beyond the scope of oversight that is reasonable for this board to take on and they may impinge on the constitutional authority of the Executive to control classified national security information. We also recommend that clauses be included to enable the intelligence community to respond to requests from the Board in a manner consistent with the protection of intelligence sources and methods.

- **Enforcement:** The enforcement provisions are extreme and may raise significant legal and privacy concerns. Those provisions mandate a suite of harsh penalties for any violations of certain provisions of the statute, including technical or unintentional violations; they allow for no flexibility in determining the severity of punishment; they provide the aggrieved party with no process; and they mandate public identification of aggrieved individuals. These provisions could broadly disincentivize individuals from working in life sciences research and funding agencies, which could send research outside of this country and compromise progress on public health, safety, and national security. We recommend that enforcement provisions be focused on willful violations and significantly reduced or adjusted.

Given the above concerns, as drafted, this legislation has the potential to negatively impact innovation and delay the development of lifesaving technologies. While the Administration does not support this legislation, we remain committed to working with the Committee on biosafety and biosecurity.

From: Crawford, Chase (NIH/NIAID) [E]
Sent: Wednesday, September 25, 2024 1:45 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; NIAID DCR-OCGR [redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: ACTION by COB Friday (9/27): Review revised bill text for Risky Research Review Act

Good Afternoon,

NIAID has been asked to review the revised bill text for the Risky Research Review Act (PDF of bill text and Word doc of the redline are attached). This morning, the attached version of the bill was reported out of the Senate Committee on Homeland Security & Governmental Affairs (HSGAC) and now awaits further Senate consideration.

As you may recall, NIH and other OPDIVs provided comments on a previous version of the bill (previous NIAID comments attached for reference). HHS is now requesting any new comments that OPDIVS may have.

ACTION: By COB Friday (9/27), please review the attached redline and provide any new comments directly in the document.

Released by Chairman Rand Paul

Thanks,
Chase

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Tuesday, July 16, 2024 6:07 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: URGENT review by 8am Wed. 7/17: HHS Comments to OMB on Risky Research Review Act
Importance: High

Hello all,

Thank you for your review of the consolidated HHS comments on the Risky Research Review Act. DMID has suggested adding some of the comments NIAID put forward earlier this week. We have incorporated these comments in highlighted text in the attached document. The comments are listed below by page number for ease of review.

Please let us know by no later than 8am tomorrow, Wednesday, July 17th, if you have any concerns with putting forward these previously NIAID-cleared edits.

Thank you again for all your help with this quick turnaround request. Please let me know if you have any questions.

Thanks,
Sara

Re-submitted NIAID comments in the attached document (highlighted in yellow):
p. 1: New NIH comment
p. 2: NIH addition to OASH/OHRP comment
p. 3: New NIH comment
p. 4: NIH addition to OASH/OHRP comment
p. 9: NIH edit to OGC comment to broaden scope to all agencies (previously flagged by OCGR-Leg)
p. 10: NIH addition (from NIAID) to existing NIH comment
p. 12: NIH addition to OIG comment
p. 14: NIH addition to OGC comment
p. 16: NIH addition (from NIAID) to existing NIH comment

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Tuesday, July 16, 2024 12:24 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>

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Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: Please review by COB today Tues 7/16: HHS Comments to OMB on Risky Research Review Act
Importance: High

Hello all,

Background
Thank you again for your assistance in reviewing the Risky Research Review Act. HHS has compiled comments on the bill from throughout HHS to provide them to the Office of Management and Budget (OMB) for consideration. HHS is asking NIH to review the attached document on quick turnaround.

The comments included in the document provide high-level concerns across HHS. In particular, we have flagged a comment on the bottom of page 9 with a proposed clarifying edit for your review.

Action Item
Please review the attached draft HHS comments on the Risky Research Review Act and provide your concurrence, or any edits, by COB today, Tuesday July 16th. If you have any concerns with OCGR-Leg's proposed edit to the comment on page 9, please let us know.

Please note that NIH OLPA is also working on a separate request from the Senate Health, Education, Labor, and Pensions (HELP) Committee (Chair: Sen. Bernie Sanders, I-VT) for technical assistance on this bill. OLPA plans to include the specific NIAID comments shared yesterday in this separate request. We anticipate we may be asked to review consolidated NIH comments for the HELP Committee this week.

Thank you for your ongoing assistance with reviewing this bill. Please let me know if you have any questions.

Thanks,
Sara

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Monday, July 15, 2024 12:26 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: Additional OSP comments: TA on Risky Research Review Act

Hello all,

For your awareness, we are providing the attached comments on the Risky Research Review Act from the NIH Office of Science Policy (OSP). We anticipate receiving consolidated NIH comments on the bill, and we will share these as soon as we have them.

Please let me know if you have any questions.

Thanks,

Released by Chairman Rand Paul

Sara

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Monday, July 15, 2024 10:35 AM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: For review by noon Monday 7/15: Review draft NIAID TA on Risky Research Review Act
Importance: High

Hello all,

Thank you for your quick review of the draft NIAID TA on the Risky Research Review Act. In the attached revised draft, I have incorporated additional edits from DMID/Dr. Erbelding and DEA. If there are no objections, I will submit these to NIH OLPA by their noon deadline today.

I am also attaching for your reference additional comments on the bill provided by NIH OER and NIH ORS/DOHS.

Please let me know if you have any questions or concerns.

Thanks,
Sara

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Friday, July 12, 2024 4:06 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: URGENT ACTION by 10am Monday 7/15: Review draft NIAID TA on Risky Research Review Act
Importance: High

Hello all,

Background
Thank you very much for your quick work to comment on the Risky Research Review Act. NIH OLPA has asked us to prioritize comments to flag the most urgent or concerning items and/or those needing clarification.

Action Item
We have compiled the comments that meet NIH OLPA's request into the attached draft technical assistance document. Please note that NIH OLPA has requested examples, where possible. We have tried to add some examples to emphasize key points, but we welcome any suggestions and/or corrections as needed.

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We would appreciate your review and any edits by 10am Monday, July 15th. Given the quick turnaround, we are asking the Divisions to review concurrently with the NIAID OD.

Please note that NIH OSP, NIH ORS/DOHS, and NIH OER will also be reviewing and providing comments. We will be sure to share with you any consolidated NIH comments that we receive.

Thank you for your help with this quick turnaround request. Please let me know if you have any questions.

Thanks,
Sara

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Thursday, July 11, 2024 10:51 AM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Subject: URGENT ACTION by 12pm Friday 7/12: TA on Risky Research Review Act
Importance: High

Good morning,

Background
HHS has been asked by the Senate Homeland Security and Governmental Affairs Committee (Chair: Sen. Gary Peters, D-MI; Ranking Member: Sen. Rand Paul, R-KY) to provide technical assistance (TA) on the attached draft legislation entitled the Risky Research Review Act.

The draft bill would require the establishment of an independent life sciences research security board to review federal funding for certain proposed life sciences research as defined by the bill. NIAID is mentioned briefly on page 4 in a section describing limitations on membership of the board.

HHS reports that the Committee intends to consider the bill on July 24. A number of HHS OpDivs and offices, including ASPR, CDC, and FDA, have been asked to review the bill along with NIH.

Action Item
By noon tomorrow, Friday July 12, please review the attached draft legislation and provide any technical comments in the attached HHS TA template. Please note that NIH ORS/DOHS and NIH OSP are also reviewing the bill on behalf of NIH.

As you complete your review, please keep in mind the HHS guidance on technical assistance below. Please let me know if you have any questions.

Thanks,
Sara

To ensure that the Department's comments are given full consideration, please observe the following guidelines in providing your office's comments:

1. *Are there provisions of this bill that would conflict with Department or Administration policy, and how?*

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2. *Are there provisions that would pose difficulties for the operation or management of HHS programs, and how?*

3. *Are there any other significant issues that you can identify?*

4. *If you recommend specific changes, supply reasons and explanations, if the reasons are not obvious.*

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From: "Crawford, Chase (NIH/NIAID) [E]" <[redacted]@nih.gov>
To: NIAID BUGS <[redacted]@niaid.nih.gov>, NIAID DEA DART <[redacted]@mail.nih.gov>, "NIAID DIR-OCGR" <[redacted]@mail.nih.gov>, NIAID DCR-OCGR <NIAIDDCR-[redacted]@mail.nih.gov>, "Nealy, Michael (NIH/NIAID) [E]" <[redacted]@nih.gov>, "Harper, Jill (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Parker, Marie (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Read, Sarah (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Billet, Courtney (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg <[redacted]@mail.nih.gov>, "Erbelding, Emily (NIH/NIAID) [E]" <[redacted]@nih.gov>, "Holland, Steven (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Hanson, Christopher (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Poe, Kelly (NIH/NIAID) [E]" <[redacted]@nih.gov>, "Gilles, Sharon (NIH/NIAID) [E]" <[redacted]@nih.gov>, "DDSM Correspondences" <[redacted]@mail.nih.gov>
Subject: ACTION by COB today (10/31): Review updated feedback on Risky Research Review Act
Date: Thu, 31 Oct 2024 11:55:03 -0400
Importance: Normal
Attachments: For_review_-_Risky_Research_Review_Act_Feedback_Oct_2024.docx; Track_changes_of_feedback.docx; For_reference_-redline2_NIAID_comments.docx

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Good Morning,

HHS has shared the attached updated feedback on S.4667 (Risky Research Review Act). **Please review the updated Oct. 2024 feedback and provide any must-change edits only by COB today (10/31).**

In case helpful, we also have attached a document showing the changes since the last version of feedback that NIAID reviewed as well as a reference copy of NIAID's previous technical comments on the bill text.

Please let us know if you have any questions.

Thanks,
Chase

From: Crawford, Chase (NIH/NIAID) [E]
Sent: Friday, October 11, 2024 12:20 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; NIAID DCR-OCGR [redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Read, Sarah (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: ACTION by 10a Thurs (10/17): Review compiled HHS comments on revised bill text for Risky Research Review Act

Good Afternoon,

NIAID has been asked to review the attached compiled HHS comments on S.4667 (Risky Research Review Act), as amended. OSP, OER, and ORS also are reviewing. As you may recall, NIAID previously provided NIH OD with comments on

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the revised bill text, which are attached for your reference, as well as high-level bullets (see email chain below).

ACTION: By 10a Thursday (10/17), please provide any new edits/comments in the attached "HHS points" document.

Please let us know if you have any questions.

Thanks,
Chase

From: Crawford, Chase (NIH/NIAID) [E]
Sent: Monday, September 30, 2024 2:31 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; NIAID DCR-OCGR [redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: FYI - Update on TA for revised bill text for Risky Research Review Act

FYI – Bldg. 1 has asked NIAID to provide a few top line bullets outlining the types of comments that were submitted on the redline version of the bill. NIAID plans to share the below bullets and indicate that NIAID shares many of the concerns raised by OER, ORS, and OSP (their top line bullets are copied further below). We will request a copy of the consolidated NIH TA and share it with you if/when we receive. Please let us know if you have any questions at this time. Thanks, Chase

NIAID

- NIAID notes that, to avoid confusion, the definitions in the bill pertaining to scientific and/or current policies should be consistent with definitions in science and those policies, including the USG Policy for Oversight of DURC and PEPP (https://www.whitehouse.gov/wp-content/uploads/2024/05/USG-Policy-for-Oversight-of-DURC-and-PEPP.pdf). Further, as written, some definitions are overly broad and could slow research in critical areas, including research on antimicrobial resistance and the H5 influenza outbreak in dairy cattle.
- NIAID also notes that, as written, the proposed Board may lack essential expertise in infectious diseases and biosecurity.
- NIAID notes that it is unclear if it is the drafters' intent to prohibit funding for an entire award prior to Board approval or only work related to potential "high-risk" research. Similarly, there is a later provision that would require a pause in research due to a change in circumstance, but it is unclear if such a pause would apply to an entire award or only work related to potential "high-risk research.

OER

- It is unclear what added value the Board may have over current processes. The Board seems redundant with existing/current efforts and/or those being implemented following OSTP's mandate on DURC/PEPP.
- **The Board's scope is very broad and may apply to a variety of research areas. We defer to OSP on the included research definitions.**
- The Board will have significant control over funding decisions, which may interfere with existing statute on NIH funding activities.
- We have concerns about the Board reaching out directly to applicants/recipients, which is outside traditional NIH reporting procedures.
- The required timeline of some Board activities is unclear.
- Flagged in previous TA, we have concerns about the confidentiality of application information and recommend more details be provided on how such information will be used or protected.

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- Flagged in previous TA, some terms such as “proposal” and “entity” should be updated to better agree with NIH terminology.
- Flagged in previous TA, requirements for the validation of all applicant attestations related to research risk would be extremely challenging to implement.

ORS

- Concern over the confusion and differences between agent listing, some definition and intent of this as compared to the new DURC PEPP policy and also the current/ transparent process by which select agents are added or removed. We would recommend alignment 100% in line with the current SA policies and DURC PEPP policies. Curious if this Board would be subject to posting in the Federal Register with public comment, or would function in a more draconian approach.
- Acknowledging that risk assessment is best when diverse voices are heard, the lack and actually clear refusal to ensure persons with experience in high and maximum containment principles are included would not provide a comprehensive and scientifically robust review of this work.
- The Board would be all political appointees, and finding someone with no experience in this space would likely select for persons who only do not favor this work. The goals feel less neutral and scientifically based and much more politically centric.
- The agent listings are highly concerning and would have an immediate negative impact to science and public health. The mention of Influenza A viruses, for example, would include all work with H5N1 viruses which are having a significant impact on our poultry and dairy farms. Research into vaccines, treatment, spread and evolution of these viruses is critical to ensure to curb this outbreak and to prevent those in the future. The same could be said for the inclusion of all mpox. The current outbreak and identification of Clade I is highly concerning and without scientists able to pivot nimbly, the outcome is concerning.
- Page 18 of the document, line 26-30 appear to replace the work of IBCs and IREs and biosafety professionals across the country. The composition of this board would not have the appropriate expertise, training or experience to appropriately determine these requirements. It also seems quite granular for a board of this nature.
- Concerns about sensitivity of grant and project submissions from the confidentiality side- defer to OER and OSP.
- Page 17 regarding employee disciplines. This section would make people charged with compliance consistently and constantly afraid for their jobs. A punitive reporting process would have the opposite impact that I think is intended. Transparency on situations is important but its unclear what would happen because of these reports.

We have significant concerns about this bill and approach this would take for the oversight of biological research. Based on timelines and reviews, plus the lack of appropriate experience, many researchers would likely leave critical research fields and the work would be paused having negative and catastrophic impact to the biomedical enterprise and by extension human and animal health and safety.

OSP

Topline points:

- **While some aspects of this bill related to scope are improved, there continue to be significant concerns about the impact on biomedical research.**
- Strengthening biosafety and biosecurity oversight of life sciences research is a key priority of this Administration, as outlined in the National Biodefense Strategy. We believe the bill as drafted would significantly undermine life sciences research, and its oversight provisions fail to target the subset of research posing greatest risk. As such, we do not support this legislation.
- The Administration has recently strengthened, streamlined, and expanded oversight of potentially high risk life science research in the May 2024 United States Government Policy for Oversight of Dual Use Research of Concern Pathogens with Enhanced Pandemic Potential (“DURC/PEPP policy”). This policy expands and strengthens a tiered system of oversight for all federally funded research that includes a requirement for research on pathogens with enhanced pandemic potential to undergo extra departmental review. The policy also:
    - Defines an expanded scope of pathogen and toxin research subject to additional oversight by the U.S. Government;
    - Provides a unified framework to support the consistent identification and oversight of research proposals that require enhanced oversight that accounts for safety, security, and ethical considerations; and

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  - Delineates the roles and responsibilities of principal investigators, research institutions, and Federal departments and agencies that conduct, fund, or oversee research within the scope of the policy.
- The bill seems to create redundancies with some reforms recently introduced by the DURC/PEPP policy, which was developed following significant interagency discussions directed by Congress and informed by the National Science Advisory Board for Biosecurity, public comment, and other expert input.
- As currently drafted, this legislation has the potential to negatively impact innovation and the U.S. competitive edge in life sciences research, including our ability to attract and retain the best scientists.
- However, the Administration welcomes efforts from Congress to further strengthen biosafety and biosecurity in the life sciences.
  - For example, we would welcome discussions on how the risk-based oversight processes established in the DURC policy for federally funded research could be extended to non-federally funded research.
- We recognize that biosafety and biosecurity oversight responsibilities are currently shared across many different departments and agencies and welcome discussions on appropriate entities for oversight of the highest risk research.

Some of our concerns with the bill are:

- **Scope:** While steps have been made toward harmonization of the scope of the Board's oversight with the new *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* (2024 OSTP DURC/PEPP Policy), some of the listed experiments in the "dual use research of concern" definition do not match those in the policy, and other articulated in-scope research in the bill including the "gain of function research" term continues to be in conflict with USG policy. These definition differences will be challenging to deconflict for the research community. Many of the USG definitions were determined following significant interagency discussions directed by Congress and informed by the National Science Advisory Board for Biosecurity, public comment, and other expert input.
  - This could result in delays to critical biosurveillance efforts such as COVID-19 testing, H5N1 monitoring, and detection of emerging outbreaks of Ebola and other diseases. It could also result in delays for development of vaccines, therapeutics, and biomedical, agricultural, and other life sciences research writ large (including research that is not associated with pathogens or toxins and raises no identified national security threats, such as cancer research).
  - If the statute only provided the board the responsibility to review federally-funded research involving DURC and PEPP, as defined in the DURC/PEPP policy, it would ensure oversight resources are used most efficiently to assess and mitigate risks to the public while avoiding unintended negative consequences for the nation's biomedical enterprise. We believe this is the intent of the bill but as written the definitions are not harmonized. (We recommend other definitions in the text be aligned to current U.S. Government policy, including "life sciences research.")
  - We recommend that the definitions and scope of review be fully harmonized with the DURC/PEPP policy and not include a separate list of pathogens.
  - A large amount of scientific research involves gain or loss of function; it's a fundamental process in science. For example, some types of immune therapy cause the immune system to gain function to fight against a disease. Unfortunately, the term "gain of function" has often being misconstrued to suggest all research that causes a gain of function is highly risky, which is inaccurate. In fact, most research involving a GOF does not confer significant additional risk or require additional oversight. NIH does not define the term GOF and current federal policy does not define or operationalize the term. The research that requires strict oversight involves enhancing the transmissibility and/or virulence of a pathogen such that it would pose an increased pandemic potential in humans. The USG policy on oversight of DURC and PEPP (effective May 2025) also does not use the term GOF when describing research that requires additional oversight because of its higher risk. As it appears the intent of the term "GOF" in this bill is to refer specially to research that has the potential to enhance the transmissibility or virulence of a potential pandemic pathogen, for clarity we would recommend the use of the term "pathogen with enhanced pandemic potential" in the 2024 OSTP policy that addresses this type of research, as well as it's associated definition. This would help to avoid the ongoing confusion surrounding the term GOF.

- **Board processes and makeup:** While biosafety expertise is now included, the makeup and processes of the board could introduce a number of issues. For example, the limitations on prior federal service and

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designation of participation in high-risk research as a "conflict of interest" could limit the board from accessing relevant national security and life sciences expertise. The exclusion of those involved in high-risk research, based on the definition in the draft legislation, could exclude anyone with a current BSL3 or BSL4 program, excluding individuals with key expertise on how to conduct work safely. These limitations may also exclude individuals who work in government with relevant knowledge of intelligence and threat assessments. We also recommend relaxing the limitations on membership of the board and note that a number of the timelines are untenable (e.g., Congressional notification requirements within 3 days of identifying a potential conflict of interest; publishing procedures in the Federal Register within 90 days of the appointment of initial members; etc.). We note that several provisions relating to the membership of the Board or its support staff are vague, including the requirement that Board members be "impartial" and that support staff be prohibited from "directly or indirectly influenc[ing]" the Board. The proposed legislation would also politicize independent peer review by making the constituent members presidential appointees.

- **Review process:** While a path for expedited review has been added, there could still be major issues with continuity of science due to delays of reviews or membership being confirmed. Among other concerns, in particular, this will significantly impede the USG's ability to prepare for and detect emerging infectious diseases/epidemics/pandemics and will also significantly impede the USG's research response to an epidemic/pandemic. We recommend establishing a default rule that research may proceed if a decision is not made within a fixed timeframe to ensure that any lapse in function by the Board (e.g., delays in confirmation) do not result in life sciences research grinding to a halt. We also recommend a formal appeals process and an exemption to public reporting requirements if the information could pose national security risks.

- **Review criteria:** The bill does not articulate a principle or threshold that guides whether the board should or should not approve a study for funding – for example, should the Board approve research where it determines that the potential public health benefits of the research outweigh the potential risks to U.S. national security? Or should some other standard govern the Board's review? Any statute mandating this style of review should clarify the applicable standard.

- **Classified review and intelligence concerns:** We recommend striking provisions that mandate the provision of security clearances to Board members, Board staff, and members of Congress, or that require these individuals to access and review all classified research funded by any agency. Those provisions extend beyond the scope of oversight that is reasonable for this board to take on and they may impinge on the constitutional authority of the Executive to control classified national security information. We also recommend that clauses be included to enable the intelligence community to respond to requests from the Board in a manner consistent with the protection of intelligence sources and methods.

- **Enforcement:** The enforcement provisions are extreme and may raise significant legal and privacy concerns. Those provisions mandate a suite of harsh penalties for any violations of certain provisions of the statute, including technical or unintentional violations; they allow for no flexibility in determining the severity of punishment; they provide the aggrieved party with no process; and they mandate public identification of aggrieved individuals. These provisions could broadly disincentivize individuals from working in life sciences research and funding agencies, which could send research outside of this country and compromise progress on public health, safety, and national security. We recommend that enforcement provisions be focused on willful violations and significantly reduced or adjusted.

Given the above concerns, as drafted, this legislation has the potential to negatively impact innovation and delay the development of lifesaving technologies. While the Administration does not support this legislation, we remain committed to working with the Committee on biosafety and biosecurity.

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From: Crawford, Chase (NIH/NIAID) [E]
Sent: Wednesday, September 25, 2024 1:45 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; NIAID DCR-OCGR [redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: ACTION by COB Friday (9/27): Review revised bill text for Risky Research Review Act

Good Afternoon,

NIAID has been asked to review the revised bill text for the Risky Research Review Act (PDF of bill text and Word doc of the redline are attached). This morning, the attached version of the bill was reported out of the Senate Committee on Homeland Security & Governmental Affairs (HSGAC) and now awaits further Senate consideration.

As you may recall, NIH and other OPDIVs provided comments on a previous version of the bill (previous NIAID comments attached for reference). HHS is now requesting any new comments that OPDIVS may have.

ACTION: By COB Friday (9/27), please review the attached redline and provide any new comments directly in the document.

Thanks,
Chase

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Tuesday, July 16, 2024 6:07 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: URGENT review by 8am Wed. 7/17: HHS Comments to OMB on Risky Research Review Act
Importance: High

Hello all,

Thank you for your review of the consolidated HHS comments on the Risky Research Review Act. DMID has suggested adding some of the comments NIAID put forward earlier this week. We have incorporated these comments in highlighted text in the attached document. The comments are listed below by page number for ease of review.

Please let us know by no later than 8am tomorrow, Wednesday, July 17th, if you have any concerns with putting forward these previously NIAID-cleared edits.

Thank you again for all your help with this quick turnaround request. Please let me know if you have any questions.

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Thanks,
Sara

Re-submitted NIAID comments in the attached document (highlighted in yellow):
p. 1: New NIH comment
p. 2: NIH addition to OASH/OHRP comment
p. 3: New NIH comment
p. 4: NIH addition to OASH/OHRP comment
p. 9: NIH edit to OGC comment to broaden scope to all agencies (previously flagged by OCGR-Leg)
p. 10: NIH addition (from NIAID) to existing NIH comment
p. 12: NIH addition to OIG comment
p. 14: NIH addition to OGC comment
p. 16: NIH addition (from NIAID) to existing NIH comment

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Tuesday, July 16, 2024 12:24 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: Please review by COB today Tues 7/16: HHS Comments to OMB on Risky Research Review Act
Importance: High

Hello all,

Background
Thank you again for your assistance in reviewing the Risky Research Review Act. HHS has compiled comments on the bill from throughout HHS to provide them to the Office of Management and Budget (OMB) for consideration. HHS is asking NIH to review the attached document on quick turnaround.

The comments included in the document provide high-level concerns across HHS. In particular, we have flagged a comment on the bottom of page 9 with a proposed clarifying edit for your review.

Action Item
Please review the attached draft HHS comments on the Risky Research Review Act and provide your concurrence, or any edits, by COB today, Tuesday July 16th. If you have any concerns with OCGR-Leg's proposed edit to the comment on page 9, please let us know.

Please note that NIH OLPA is also working on a separate request from the Senate Health, Education, Labor, and Pensions (HELP) Committee (Chair: Sen. Bernie Sanders, I-VT) for technical assistance on this bill. OLPA plans to include the specific NIAID comments shared yesterday in this separate request. We anticipate we may be asked to review consolidated NIH comments for the HELP Committee this week.

Thank you for your ongoing assistance with reviewing this bill. Please let me know if you have any questions.

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Thanks,
Sara

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Monday, July 15, 2024 12:26 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: Additional OSP comments: TA on Risky Research Review Act

Hello all,

For your awareness, we are providing the attached comments on the Risky Research Review Act from the NIH Office of Science Policy (OSP). We anticipate receiving consolidated NIH comments on the bill, and we will share these as soon as we have them.

Please let me know if you have any questions.

Thanks,
Sara

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Monday, July 15, 2024 10:35 AM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: For review by noon Monday 7/15: Review draft NIAID TA on Risky Research Review Act
Importance: High

Hello all,

Thank you for your quick review of the draft NIAID TA on the Risky Research Review Act. In the attached revised draft, I have incorporated additional edits from DMID/Dr. Erbelding and DEA. If there are no objections, I will submit these to NIH OLPA by their noon deadline today.

I am also attaching for your reference additional comments on the bill provided by NIH OER and NIH ORS/DOHS.

Please let me know if you have any questions or concerns.

Thanks,
Sara

Released by Chairman Rand Paul

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Friday, July 12, 2024 4:06 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: URGENT ACTION by 10am Monday 7/15: Review draft NIAID TA on Risky Research Review Act
Importance: High

Hello all,

Background
Thank you very much for your quick work to comment on the Risky Research Review Act. NIH OLPA has asked us to prioritize comments to flag the most urgent or concerning items and/or those needing clarification.

Action Item
We have compiled the comments that meet NIH OLPA's request into the attached draft technical assistance document. Please note that NIH OLPA has requested examples, where possible. We have tried to add some examples to emphasize key points, but we welcome any suggestions and/or corrections as needed.

We would appreciate your review and any edits by 10am Monday, July 15th. Given the quick turnaround, we are asking the Divisions to review concurrently with the NIAID OD.

Please note that NIH OSP, NIH ORS/DOHS, and NIH OER will also be reviewing and providing comments. We will be sure to share with you any consolidated NIH comments that we receive.

Thank you for your help with this quick turnaround request. Please let me know if you have any questions.

Thanks,
Sara

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Thursday, July 11, 2024 10:51 AM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Subject: URGENT ACTION by 12pm Friday 7/12: TA on Risky Research Review Act
Importance: High

Good morning,

Background
HHS has been asked by the Senate Homeland Security and Governmental Affairs Committee (Chair: Sen. Gary Peters, D-MI; Ranking Member: Sen. Rand Paul, R-KY) to provide technical assistance (TA) on the attached draft legislation entitled the Risky Research Review Act.

Released by Chairman Rand Paul

The draft bill would require the establishment of an independent life sciences research security board to review federal funding for certain proposed life sciences research as defined by the bill. NIAID is mentioned briefly on page 4 in a section describing limitations on membership of the board.

HHS reports that the Committee intends to consider the bill on July 24. A number of HHS OpDivs and offices, including ASPR, CDC, and FDA, have been asked to review the bill along with NIH.

Action Item
By noon tomorrow, Friday July 12, please review the attached draft legislation and provide any technical comments in the attached HHS TA template. Please note that NIH ORS/DOHS and NIH OSP are also reviewing the bill on behalf of NIH.

As you complete your review, please keep in mind the HHS guidance on technical assistance below. Please let me know if you have any questions.

Thanks,
Sara

To ensure that the Department's comments are given full consideration, please observe the following guidelines in providing your office's comments:

1. *Are there provisions of this bill that would conflict with Department or Administration policy, and how?*
2. *Are there provisions that would pose difficulties for the operation or management of HHS programs, and how?*
3. *Are there any other significant issues that you can identify?*
4. *If you recommend specific changes, supply reasons and explanations, if the reasons are not obvious.*

Released by Chairman Rand Paul

HHS Review of S.4667 Risky Research Review Act
As amended by HSGAC on September 25, 2024

HHS appreciates the opportunity to review S. 4667, as amended by the Peters-Paul substitute amendment. Please note this is not formal Department TA or Administrations views. However, as there remain many similarities between the introduced bill and substitute amendment, we are also attaching the formal TA we shared with the committee in July. to the introduced bill, for reference.

While some aspects of this bill related to scope are improved, there continue to be significant concerns about the impact on biomedical research.

Strengthening biosafety and biosecurity oversight of life sciences research is a key priority of this Administration, as outlined in the National Biodefense Strategy. We believe the bill as drafted would significantly undermine life sciences research, and its oversight provisions fail to target the subset of research posing greatest risk.

As currently drafted, this legislation has the potential to negatively impact innovation and the U.S. competitive edge in life sciences research, including our ability to attract and retain the best scientists.

While HHS continues to have serious concerns with this legislation as drafted, we remain committed to working with the Committee and Congress on biosafety and biosecurity.

More detailed concerns are described below by category.

Redundant with DURC/PEPP policy

- The Administration has recently strengthened, streamlined, and expanded oversight of potentially high risk life science research in the May 2024 United States Government Policy for Oversight of Dual Use Research of Concern Pathogens with Enhanced Pandemic Potential ("DURC/PEPP policy"). This policy expands and strengthens a tiered system of oversight for all federally funded research that includes a requirement for research on pathogens with enhanced pandemic potential to undergo extra departmental review. The policy also:
    - Defines an expanded scope of pathogen and toxin research subject to additional oversight by the U.S. Government;
    - Provides a unified framework to support the consistent identification and oversight of research proposals that require enhanced oversight that accounts for safety, security, and ethical considerations; and
    - Delineates the roles and responsibilities of principal investigators, research institutions, and Federal departments and agencies that conduct, fund, or oversee research within the scope of the policy.

Released by Chairman Rand Paul

- The bill seems to create redundancies with some reforms recently introduced by the DURC/PEPP policy, which was developed following significant interagency discussions directed by Congress and informed by the National Science Advisory Board for Biosecurity, public comment, and other expert input.
- However, HHS welcomes efforts from Congress to further strengthen biosafety and biosecurity in the life sciences. For example, we would welcome discussions on how the risk-based oversight processes established in the DURC policy for federally funded research could be extended to non-federally funded research.

Scope/Definitions

- While steps have been made toward harmonization of the scope of the Board's oversight with the new *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* (2024 OSTP DURC/PEPP Policy), some of the listed experiments in the "dual use research of concern" definition do not match those in the policy, and other articulated in-scope research in the bill including the "gain of function research" term continues to be in conflict with USG policy. These definition differences will be challenging to deconflict for the research community. Many of the USG definitions were determined following significant interagency discussions directed by Congress and informed by the National Science Advisory Board for Biosecurity, public comment, and other expert input. We recommend that the definitions and scope of review be fully harmonized with the DURC/PEPP policy and not include a separate list of pathogens. Many of the definitions of research that is subject to requirements of this proposed legislation are very broad and not all are in line with existing policies, which is likely to cause confusion in the research community.
    - This could result in delays to critical biosurveillance efforts such as COVID-19 testing, H5N1 monitoring, and detection of emerging outbreaks of Ebola and other diseases. It could also result in delays for development of vaccines, therapeutics, and biomedical, agricultural, and other life sciences research writ large (including research that is not associated with pathogens or toxins and raises no identified national security threats, such as cancer research).
    - If the statute only provided the board the responsibility to review federally-funded research involving DURC and PEPP, as defined in the DURC/PEPP policy, it would ensure oversight resources are used most efficiently to assess and mitigate risks to the public while avoiding unintended negative consequences for the nation's biomedical enterprise. We believe this is the intent of the bill but as written the definitions are not harmonized.
    - A large amount of scientific research involves gain or loss of function; it's a fundamental process in science. For example, some types of immune therapy cause the immune system to gain function to fight against a disease. Unfortunately, the term "gain of function" has often being misconstrued to suggest all research that causes a gain of function is highly risky, which is inaccurate. In fact, most research involving a GOF does not confer significant additional risk or require additional oversight. NIH does not define the term GOF and current federal policy does not define or operationalize the term. The research that requires strict oversight involves enhancing the transmissibility and/or

Released by Chairman Rand Paul

virulence of a pathogen such that it would pose an increased pandemic potential in humans. The USG policy on oversight of DURC and PEPP (effective May 2025) also does not use the term GOF when describing research that requires additional oversight because of its higher risk. As it appears the intent of the term "GOF" in this bill is to refer specially to research that has the potential to enhance the transmissibility or virulence of a potential pandemic pathogen, for clarity we would recommend the use of the term "pathogen with enhanced pandemic potential" in the 2024 OSTP policy that addresses this type of research, as well as it's associated definition. This would help to avoid the ongoing confusion surrounding the term GOF.

- The list of "high-consequence pathogens" is concerning and would have an immediate negative impact to science and public health. The mention of Influenza A viruses, for example, would include all work with H5N1 viruses which are having a significant impact on our poultry and dairy farms. Research into vaccines, treatment, spread and evolution of these viruses is critical to ensure to curb this outbreak and to prevent those in the future. The same could be said for the inclusion of all mpox. The current outbreak and identification of Clade I is highly concerning and without scientists able to pivot nimbly, the outcome is concerning. We are also concerned with the catchall language that could expand the scope of pathogens and categories the board reviews simply by a majority vote from the board.
    - Given that certain types of research with any "wild-type or synthetic" pathogen among the listed species would apparently require review by the new Board, this appears to suggest that research with viruses engineered or adapted for decreased pathogenicity (e.g. certain mouse-adapted or tissue-culture-adapted strains) would be considered "high-consequence" even if they have been deliberately altered to decrease the research risk, e.g. for exploration of drug-resistance mechanisms at lower BSL levels.
    - Category XVIII "any synthetic construct of a pathogen or category of pathogen described in this clause" may be confusing regarding what it adds to the "wild-type or synthetic" pathogens already listed – what is meant by "synthetic construct" in addition to previous use of "synthetic" and does this mean that using only a piece of a "high-consequence pathogen" (e.g. synthesizing the receptor-binding site and studying receptor affinity in vitro, or synthesizing a viral or bacterial enzyme and studying inhibitors in vitro) would potentially still be considered "high-consequence"?
    - Subparagraph B is auto-referential creating an exclusion for seasonal influenza unless genetic sequences have been introduced from the list of pathogens that includes influenza A – does this mean that any introduction of genetic material from one seasonal influenza virus into another seasonal influenza virus would be considered "high-consequence"?
    - Some other included pathogens besides influenza may be commonly circulating in the population, and classifying them as automatically "high-consequence" could potentially delay or interfere with clinical diagnosis and care depending on how the other criteria for centralized Board review are interpreted (e.g. all sarbecoviruses, all mpox viruses).

Released by Chairman Rand Paul

    - According to the next section at the bottom of the page, it looks like maybe only experiments that meet DURC/GOF criteria with these agents would need centralized board review, and if it were possible to obtain clarification that non-DURC/GOF experiments are not subject to the Act provisions that might mitigate some of the potential concerns, but there is the possibility that uncertainty about interpretation could still have major impact on willingness to conduct or review research in some of the relevant areas of importance for public health.
- The text of the proposed legislation reads as if the Life Sciences Research Security Board could review all life sciences research. Throughout the text of the proposed legislation, the terms used seem to vary between "high-risk life sciences research," which is defined very specifically, and broader terms like "life sciences research." The scope of review seems far beyond what a single Board could reasonably be able to review especially given the broad definition of life sciences research, even if limited to high-risk life sciences research and even with the Board trying to develop expert committees. Creating such a broad scope of review for the Board risk delays of important research, which does not rise to the level of high-risk life sciences research, that could be adequately addressed at a more local or Agency review level and is already subject to laws, regulations, guidances, and policies.

Expertise/Board Processes and Makeup

- While biosafety expertise is now included, the makeup and processes of the board could introduce a number of issues. For example, the limitations on prior federal service and designation of participation in high-risk research as a “conflict of interest” could limit the board from accessing relevant national security and life sciences expertise. The exclusion of those involved in high-risk research, based on the definition in the draft legislation, could exclude anyone with a current BSL3 or BSL4 program, excluding individuals with key expertise on how to conduct work safely. These limitations may also exclude individuals who work in government with relevant knowledge of intelligence, threat assessments, and biosecurity. Risk assessment is best when diverse voices are heard, the lack and actually clear refusal to ensure persons with experience in high and maximum containment principles are included would not provide a comprehensive and scientifically robust review of this work.
- We also recommend relaxing the limitations on membership of the board and note that a number of the timelines are untenable (e.g., Congressional notification requirements within 3 days of identifying a potential conflict of interest; publishing procedures in the Federal Register within 90 days of the appointment of initial members; etc.). We note that several provisions relating to the membership of the Board or its support staff are vague, including the requirement that Board members be “impartial” and that support staff be prohibited from “directly or indirectly influenc[ing]” the Board. The proposed legislation would also politicize independent peer review by making the constituent members presidential appointees.
- As drafted, the Board will have significant control over funding decisions, which may interfere with existing statute on NIH funding activities.
- We have concerns about the Board reaching out directly to applicants/recipients, which is outside traditional NIH reporting procedures.

Released by Chairman Rand Paul

- Regarding support from agencies to board personnel, it is unclear how an agency representative can be expected to both provide technical assistance but not indirectly influence the board. Technical assistance should factor into the decision.
- Regarding 7904 (b)(3), if such disclosure is required drafters should be specific as to what laws on protection of commercial confidential information and trade secrets are being waived.

Review Process and Criteria

- While a path for expedited review has been added, there could still be major issues with continuity of science due to delays of reviews or membership being confirmed. Among other concerns, in particular, this will significantly impede the USG's ability to prepare for and detect emerging infectious diseases/epidemics/pandemics and will also significantly impede the USG's research response to an epidemic/pandemic. We recommend establishing a default rule that research may proceed if a decision is not made within a fixed timeframe to ensure that any lapse in function by the Board (e.g., delays in confirmation) do not result in life sciences research grinding to a halt. We also recommend a formal appeals process and an exemption to public reporting requirements if the information could pose national security risks.
- The bill does not articulate a principle or threshold that guides whether the board should or should not approve a study for funding – for example, should the Board approve research where it determines that the potential public health benefits of the research outweigh the potential risks to U.S. national security? Or should some other standard govern the Board's review? Any statute mandating this style of review should clarify the applicable standard.
- It is unclear if it is the drafters' intent to prohibit funding for an entire award prior to Board approval or only work related to potential "high-risk" research. Similarly, there is a later provision that would require a pause in research due to a change in circumstance, but it is unclear if such a pause would apply to an entire award or only work related to potential "high-risk research.

Classified review and intelligence concerns

- We recommend striking provisions that mandate the provision of security clearances to Board members, Board staff, and members of Congress, or that require these individuals to access and review all classified research funded by any agency. Those provisions extend beyond the scope of oversight that is reasonable for this board to take on and they may impinge on the constitutional authority of the Executive to control classified national security information. We also recommend that clauses be included to enable the intelligence community to respond to requests from the Board in a manner consistent with the protection of intelligence sources and methods.

Enforcement

Released by Chairman Rand Paul

- The enforcement provisions are extreme and may raise significant legal and privacy concerns. Those provisions mandate a suite of harsh penalties for any violations of certain provisions of the statute, including technical or unintentional violations; they allow for no flexibility in determining the severity of punishment; they provide the aggrieved party with no process; and they mandate public identification of aggrieved individuals. These provisions could broadly disincentivize individuals from working in life sciences research and funding agencies, which could send research outside of this country and compromise progress on public health, safety, and national security. We recommend that enforcement provisions be focused on willful violations and significantly reduced or adjusted.

Released by Chairman Rand Paul

From: "Crawford, Chase (NIH/NIAID) [E]" <[redacted]@nih.gov>
To: "Ford, Andrew (NIH/NIAID) [E]" <[redacted]@nih.gov>
Cc: NIAID OCGR Leg <[redacted]@mail.nih.gov>, "Erbelding, Emily (NIH/NIAID) [E]" <[redacted]@nih.gov>, NIAID BUGS <[redacted]@niaid.nih.gov>, "DDSM Correspondences" <[redacted]@mail.nih.gov>
Subject: RE: ACTION by 10a Thurs (10/17): Review compiled HHS comments on revised bill text for Risky Research Review Act
Date: Thu, 17 Oct 2024 09:59:10 -0400
Importance: Normal

Thanks, Andrew. -- Chase

From: Ford, Andrew (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Thursday, October 17, 2024 9:58 AM
To: Crawford, Chase (NIH/NIAID) [E] [redacted]@nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; NIAID BUGS [redacted]@niaid.nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: Re: ACTION by 10a Thurs (10/17): Review compiled HHS comments on revised bill text for Risky Research Review Act

Hey Chase,

DMID does not have any comments.

Thank you for the opportunity to review.

Andrew

From: Crawford, Chase (NIH/NIAID) [E] <[redacted]@nih.gov>
Date: Friday, October 11, 2024 at 12:21 PM
To: NIAID BUGS <[redacted]@niaid.nih.gov>, NIAID DEA DART <[redacted]@mail.nih.gov>, NIAID DIR-OCGR <[redacted]@mail.nih.gov>, NIAID DCR-OCGR <[redacted]@mail.nih.gov>, Nealy, Michael (NIH/NIAID) [E] <[redacted]@nih.gov>, Harper, Jill (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>, Parker, Marie (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>, Read, Sarah (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>, Billet, Courtney (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg <[redacted]@mail.nih.gov>, Erbelding, Emily (NIH/NIAID) [E] <[redacted]@nih.gov>, Holland, Steven (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>, Hanson, Christopher (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>, Poe, Kelly (NIH/NIAID) [E] <[redacted]@nih.gov>, Gilles, Sharon (NIH/NIAID) [E] <[redacted]@nih.gov>, DDSM Correspondences <[redacted]@mail.nih.gov>
Subject: ACTION by 10a Thurs (10/17): Review compiled HHS comments on revised bill text for Risky Research Review Act

Good Afternoon,

NIAID has been asked to review the attached compiled HHS comments on S.4667 (Risky Research Review Act), as amended. OSP, OER, and ORS also are reviewing. As you may recall, NIAID previously provided NIH OD with comments on the revised bill text, which are attached for your reference, as well as high-level bullets (see email chain below).

ACTION: By 10a Thursday (10/17), please provide any new edits/comments in the attached "HHS points" document.

Released by Chairman Rand Paul

Please let us know if you have any questions.

Thanks,
Chase

From: Crawford, Chase (NIH/NIAID) [E]
Sent: Monday, September 30, 2024 2:31 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; NIAID DCR-OCGR [redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: FYI - Update on TA for revised bill text for Risky Research Review Act

FYI – Bldg. 1 has asked NIAID to provide a few top line bullets outlining the types of comments that were submitted on the redline version of the bill. NIAID plans to share the below bullets and indicate that NIAID shares many of the concerns raised by OER, ORS, and OSP (their top line bullets are copied further below). We will request a copy of the consolidated NIH TA and share it with you if/when we receive. Please let us know if you have any questions at this time. Thanks, Chase

NIAID

- NIAID notes that, to avoid confusion, the definitions in the bill pertaining to scientific and/or current policies should be consistent with definitions in science and those policies, including the USG Policy for Oversight of DURC and PEPP (https://www.whitehouse.gov/wp-content/uploads/2024/05/USG-Policy-for-Oversight-of-DURC-and-PEPP.pdf). Further, as written, some definitions are overly broad and could slow research in critical areas, including research on antimicrobial resistance and the H5 influenza outbreak in dairy cattle.
- NIAID also notes that, as written, the proposed Board may lack essential expertise in infectious diseases and biosecurity.
- NIAID notes that it is unclear if it is the drafters' intent to prohibit funding for an entire award prior to Board approval or only work related to potential "high-risk" research. Similarly, there is a later provision that would require a pause in research due to a change in circumstance, but it is unclear if such a pause would apply to an entire award or only work related to potential "high-risk research.

OER

- It is unclear what added value the Board may have over current processes. The Board seems redundant with existing/current efforts and/or those being implemented following OSTP's mandate on DURC/PEPP.
- **The Board's scope is very broad and may apply to a variety of research areas. We defer to OSP on the included research definitions.**
- The Board will have significant control over funding decisions, which may interfere with existing statute on NIH funding activities.
- We have concerns about the Board reaching out directly to applicants/recipients, which is outside traditional NIH reporting procedures.
- The required timeline of some Board activities is unclear.
- Flagged in previous TA, we have concerns about the confidentiality of application information and recommend more details be provided on how such information will be used or protected.
- Flagged in previous TA, some terms such as "proposal" and "entity" should be updated to better agree with NIH terminology.
- Flagged in previous TA, requirements for the validation of all applicant attestations related to research risk would be extremely challenging to implement.

ORS

- Concern over the confusion and differences between agent listing, some definition and intent of this as compared to the new DURC PEPP policy and also the current/ transparent process by which select agents are added or removed. We would recommend alignment 100% in line with the current SA policies and DURC PEPP policies. Curious if this Board would be subject to posting in the Federal Register with public comment, or would function in a more draconian approach.
- Acknowledging that risk assessment is best when diverse voices are heard, the lack and actually clear refusal to ensure persons with experience in high and maximum containment principles are included would not provide a comprehensive and scientifically robust review of this work.
- The Board would be all political appointees, and finding someone with no experience in this space would likely select for persons who only do not favor this work. The goals feel less neutral and scientifically based and much more politically centric.
- The agent listings are highly concerning and would have an immediate negative impact to science and public health. The mention of Influenza A viruses, for example, would include all work with H5N1 viruses which are having a significant impact on our poultry and dairy farms. Research into vaccines, treatment, spread and evolution of these viruses is critical to ensure to curb this outbreak and to prevent those in the future. The same could be said for the inclusion of all mpox. The current outbreak and identification of Clade I is highly concerning and without scientists able to pivot nimbly, the outcome is concerning.
- Page 18 of the document, line 26-30 appear to replace the work of IBCs and IREs and biosafety professionals across the country. The composition of this board would not have the appropriate expertise, training or experience to appropriately determine these requirements. It also seems quite granular for a board of this nature.
- Concerns about sensitivity of grant and project submissions from the confidentiality side- defer to OER and OSP.
- Page 17 regarding employee disciplines. This section would make people charged with compliance consistently and constantly afraid for their jobs. A punitive reporting process would have the opposite impact that I think is intended. Transparency on situations is important but its unclear what would happen because of these reports.

We have significant concerns about this bill and approach this would take for the oversight of biological research. Based on timelines and reviews, plus the lack of appropriate experience, many researchers would likely leave critical research fields and the work would be paused having negative and catastrophic impact to the biomedical enterprise and by extension human and animal health and safety.

OSP

Topline points:

While some aspects of this bill related to scope are improved, there continue to be significant concerns about the impact on biomedical research.

Strengthening biosafety and biosecurity oversight of life sciences research is a key priority of this Administration, as outlined in the National Biodefense Strategy. We believe the bill as drafted would significantly undermine life sciences research, and its oversight provisions fail to target the subset of research posing greatest risk. As such, we do not support this legislation.

The Administration has recently strengthened, streamlined, and expanded oversight of potentially high risk life science research in the May 2024 United States Government Policy for Oversight of Dual Use Research of Concern Pathogens with Enhanced Pandemic Potential ("DURC/PEPP policy"). This policy expands and strengthens a tiered system of oversight for all federally funded research that includes a requirement for research on pathogens with enhanced pandemic potential to undergo extra departmental review. The policy also:

- Defines an expanded scope of pathogen and toxin research subject to additional oversight by the U.S. Government;
- Provides a unified framework to support the consistent identification and oversight of research proposals that require enhanced oversight that accounts for safety, security, and ethical considerations; and
- Delineates the roles and responsibilities of principal investigators, research institutions, and Federal departments and agencies that conduct, fund, or oversee research within the scope of the policy.

The bill seems to create redundancies with some reforms recently introduced by the DURC/PEPP policy, which was developed following significant interagency discussions directed by Congress and informed by the National Science Advisory Board for Biosecurity, public comment, and other expert input.

As currently drafted, this legislation has the potential to negatively impact innovation and the U.S. competitive edge in life sciences research, including our ability to attract and retain the best scientists.

Released by Chairman Rand Paul

However, the Administration welcomes efforts from Congress to further strengthen biosafety and biosecurity in the life sciences.

For example, we would welcome discussions on how the risk-based oversight processes established in the DURC policy for federally funded research could be extended to non-federally funded research.

We recognize that biosafety and biosecurity oversight responsibilities are currently shared across many different departments and agencies and welcome discussions on appropriate entities for oversight of the highest risk research.

Some of our concerns with the bill are:

Scope: While steps have been made toward harmonization of the scope of the Board's oversight with the new *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* (2024 OSTP DURC/PEPP Policy), some of the listed experiments in the "dual use research of concern" definition do not match those in the policy, and other articulated in-scope research in the bill including the "gain of function research" term continues to be in conflict with USG policy. These definition differences will be challenging to deconflict for the research community. Many of the USG definitions were determined following significant interagency discussions directed by Congress and informed by the National Science Advisory Board for Biosecurity, public comment, and other expert input.

This could result in delays to critical biosurveillance efforts such as COVID-19 testing, H5N1 monitoring, and detection of emerging outbreaks of Ebola and other diseases. It could also result in delays for development of vaccines, therapeutics, and biomedical, agricultural, and other life sciences research writ large (including research that is not associated with pathogens or toxins and raises no identified national security threats, such as cancer research).

If the statute only provided the board the responsibility to review federally-funded research involving DURC and PEPP, as defined in the DURC/PEPP policy, it would ensure oversight resources are used most efficiently to assess and mitigate risks to the public while avoiding unintended negative consequences for the nation's biomedical enterprise. We believe this is the intent of the bill but as written the definitions are not harmonized. (We recommend other definitions in the text be aligned to current U.S. Government policy, including "life sciences research.")

We recommend that the definitions and scope of review be fully harmonized with the DURC/PEPP policy and not include a separate list of pathogens.

A large amount of scientific research involves gain or loss of function; it's a fundamental process in science. For example, some types of immune therapy cause the immune system to gain function to fight against a disease. Unfortunately, the term "gain of function" has often being misconstrued to suggest all research that causes a gain of function is highly risky, which is inaccurate. In fact, most research involving a GOF does not confer significant additional risk or require additional oversight. NIH does not define the term GOF and current federal policy does not define or operationalize the term. The research that requires strict oversight involves enhancing the transmissibility and/or virulence of a pathogen such that it would pose an increased pandemic potential in humans. The USG policy on oversight of DURC and PEPP (effective May 2025) also does not use the term GOF when describing research that requires additional oversight because of its higher risk. As it appears the intent of the term "GOF" in this bill is to refer specially to research that has the potential to enhance the transmissibility or virulence of a potential pandemic pathogen, for clarity we would recommend the use of the term "pathogen with enhanced pandemic potential" in the 2024 OSTP policy that addresses this type of research, as well as it's associated definition. This would help to avoid the ongoing confusion surrounding the term GOF.

Board processes and makeup: While biosafety expertise is now included, the makeup and processes of the board could introduce a number of issues. For example, the limitations on prior federal service and designation of participation in high-risk research as a "conflict of interest" could limit the board from accessing relevant national security and life sciences expertise. The exclusion of those involved in high-risk research, based on the definition in the draft legislation, could exclude anyone with a current BSL3 or BSL4 program, excluding individuals with key expertise on how to conduct work safely. These limitations may also exclude individuals who work in government with relevant knowledge of intelligence and threat assessments. We also recommend relaxing the limitations on membership of the board and note that a number of the timelines are untenable (e.g., Congressional notification requirements within 3 days of identifying a potential conflict of

Released by Chairman Rand Paul

interest; publishing procedures in the Federal Register within 90 days of the appointment of initial members; etc.). We note that several provisions relating to the membership of the Board or its support staff are vague, including the requirement that Board members be "impartial" and that support staff be prohibited from "directly or indirectly influenc[ing]" the Board. The proposed legislation would also politicize independent peer review by making the constituent members presidential appointees.

Review process: While a path for expedited review has been added, there could still be major issues with continuity of science due to delays of reviews or membership being confirmed. Among other concerns, in particular, this will significantly impede the USG's ability to prepare for and detect emerging infectious diseases/epidemics/pandemics and will also significantly impede the USG's research response to an epidemic/pandemic. We recommend establishing a default rule that research may proceed if a decision is not made within a fixed timeframe to ensure that any lapse in function by the Board (e.g., delays in confirmation) do not result in life sciences research grinding to a halt. We also recommend a formal appeals process and an exemption to public reporting requirements if the information could pose national security risks.

Review criteria: The bill does not articulate a principle or threshold that guides whether the board should or should not approve a study for funding – for example, should the Board approve research where it determines that the potential public health benefits of the research outweigh the potential risks to U.S. national security? Or should some other standard govern the Board's review? Any statute mandating this style of review should clarify the applicable standard.

Classified review and intelligence concerns: We recommend striking provisions that mandate the provision of security clearances to Board members, Board staff, and members of Congress, or that require these individuals to access and review all classified research funded by any agency. Those provisions extend beyond the scope of oversight that is reasonable for this board to take on and they may impinge on the constitutional authority of the Executive to control classified national security information. We also recommend that clauses be included to enable the intelligence community to respond to requests from the Board in a manner consistent with the protection of intelligence sources and methods.

Enforcement: The enforcement provisions are extreme and may raise significant legal and privacy concerns. Those provisions mandate a suite of harsh penalties for any violations of certain provisions of the statute, including technical or unintentional violations; they allow for no flexibility in determining the severity of punishment; they provide the aggrieved party with no process; and they mandate public identification of aggrieved individuals. These provisions could broadly disincentivize individuals from working in life sciences research and funding agencies, which could send research outside of this country and compromise progress on public health, safety, and national security. We recommend that enforcement provisions be focused on willful violations and significantly reduced or adjusted.

Given the above concerns, as drafted, this legislation has the potential to negatively impact innovation and delay the development of lifesaving technologies. While the Administration does not support this legislation, we remain committed to working with the Committee on biosafety and biosecurity.

From: Crawford, Chase (NIH/NIAID) [E]
Sent: Wednesday, September 25, 2024 1:45 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; NIAID DCR-OCGR [redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>;

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Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: ACTION by COB Friday (9/27): Review revised bill text for Risky Research Review Act

Good Afternoon,

NIAID has been asked to review the revised bill text for the Risky Research Review Act (PDF of bill text and Word doc of the redline are attached). This morning, the attached version of the bill was reported out of the Senate Committee on Homeland Security & Governmental Affairs (HSGAC) and now awaits further Senate consideration.

As you may recall, NIH and other OPDIVs provided comments on a previous version of the bill (previous NIAID comments attached for reference). HHS is now requesting any new comments that OPDIVS may have.

ACTION: By COB Friday (9/27), please review the attached redline and provide any new comments directly in the document.

Thanks,
Chase

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Tuesday, July 16, 2024 6:07 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: URGENT review by 8am Wed. 7/17: HHS Comments to OMB on Risky Research Review Act
Importance: High

Hello all,

Thank you for your review of the consolidated HHS comments on the Risky Research Review Act. DMID has suggested adding some of the comments NIAID put forward earlier this week. We have incorporated these comments in highlighted text in the attached document. The comments are listed below by page number for ease of review.

Please let us know by no later than 8am tomorrow, Wednesday, July 17th, if you have any concerns with putting forward these previously NIAID-cleared edits.

Thank you again for all your help with this quick turnaround request. Please let me know if you have any questions.

Thanks,
Sara

Re-submitted NIAID comments in the attached document (highlighted in yellow):
p. 1: New NIH comment
p. 2: NIH addition to OASH/OHRP comment
p. 3: New NIH comment
p. 4: NIH addition to OASH/OHRP comment

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p. 9: NIH edit to OGC comment to broaden scope to all agencies (previously flagged by OCGR-Leg)
p. 10: NIH addition (from NIAID) to existing NIH comment
p. 12: NIH addition to OIG comment
p. 14: NIH addition to OGC comment
p. 16: NIH addition (from NIAID) to existing NIH comment

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Tuesday, July 16, 2024 12:24 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: Please review by COB today Tues 7/16: HHS Comments to OMB on Risky Research Review Act
Importance: High

Hello all,

Background
Thank you again for your assistance in reviewing the Risky Research Review Act. HHS has compiled comments on the bill from throughout HHS to provide them to the Office of Management and Budget (OMB) for consideration. HHS is asking NIH to review the attached document on quick turnaround.

The comments included in the document provide high-level concerns across HHS. In particular, we have flagged a comment on the bottom of page 9 with a proposed clarifying edit for your review.

Action Item
Please review the attached draft HHS comments on the Risky Research Review Act and provide your concurrence, or any edits, by COB today, Tuesday July 16th. If you have any concerns with OCGR-Leg's proposed edit to the comment on page 9, please let us know.

Please note that NIH OLPA is also working on a separate request from the Senate Health, Education, Labor, and Pensions (HELP) Committee (Chair: Sen. Bernie Sanders, I-VT) for technical assistance on this bill. OLPA plans to include the specific NIAID comments shared yesterday in this separate request. We anticipate we may be asked to review consolidated NIH comments for the HELP Committee this week.

Thank you for your ongoing assistance with reviewing this bill. Please let me know if you have any questions.

Thanks,
Sara

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Monday, July 15, 2024 12:26 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E]

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[redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: Additional OSP comments: TA on Risky Research Review Act

Hello all,

For your awareness, we are providing the attached comments on the Risky Research Review Act from the NIH Office of Science Policy (OSP). We anticipate receiving consolidated NIH comments on the bill, and we will share these as soon as we have them.

Please let me know if you have any questions.

Thanks,
Sara

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Monday, July 15, 2024 10:35 AM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: For review by noon Monday 7/15: Review draft NIAID TA on Risky Research Review Act
Importance: High

Hello all,

Thank you for your quick review of the draft NIAID TA on the Risky Research Review Act. In the attached revised draft, I have incorporated additional edits from DMID/Dr. Erbelding and DEA. If there are no objections, I will submit these to NIH OLPA by their noon deadline today.

I am also attaching for your reference additional comments on the bill provided by NIH OER and NIH ORS/DOHS.

Please let me know if you have any questions or concerns.

Thanks,
Sara

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Friday, July 12, 2024 4:06 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR <NIAIDDIR-[redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>;

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Holland, Steven (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Hanson, Christopher (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>; DDSM Correspondences [redacted]@mail.nih.gov>
Subject: URGENT ACTION by 10am Monday 7/15: Review draft NIAID TA on Risky Research Review Act
Importance: High

Hello all,

Background
Thank you very much for your quick work to comment on the Risky Research Review Act. NIH OLPA has asked us to prioritize comments to flag the most urgent or concerning items and/or those needing clarification.

Action Item
We have compiled the comments that meet NIH OLPA's request into the attached draft technical assistance document. Please note that NIH OLPA has requested examples, where possible. We have tried to add some examples to emphasize key points, but we welcome any suggestions and/or corrections as needed.

We would appreciate your review and any edits by 10am Monday, July 15th. Given the quick turnaround, we are asking the Divisions to review concurrently with the NIAID OD.

Please note that NIH OSP, NIH ORS/DOHS, and NIH OER will also be reviewing and providing comments. We will be sure to share with you any consolidated NIH comments that we receive.

Thank you for your help with this quick turnaround request. Please let me know if you have any questions.

Thanks,
Sara

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Thursday, July 11, 2024 10:51 AM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; NIAID DIR-OCGR [redacted]@mail.nih.gov>; Nealy, Michael (NIH/NIAID) [E] [redacted]@nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Parker, Marie (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>
Subject: URGENT ACTION by 12pm Friday 7/12: TA on Risky Research Review Act
Importance: High

Good morning,

Background
HHS has been asked by the Senate Homeland Security and Governmental Affairs Committee (Chair: Sen. Gary Peters, D-MI; Ranking Member: Sen. Rand Paul, R-KY) to provide technical assistance (TA) on the attached draft legislation entitled the Risky Research Review Act.

The draft bill would require the establishment of an independent life sciences research security board to review federal funding for certain proposed life sciences research as defined by the bill. NIAID is mentioned briefly on page 4 in a section describing limitations on membership of the board.

HHS reports that the Committee intends to consider the bill on July 24. A number of HHS OpDivs and offices, including ASPR, CDC, and FDA, have been asked to review the bill along with NIH.

Action Item

Released by Chairman Rand Paul

By noon tomorrow, Friday July 12, please review the attached draft legislation and provide any technical comments in the attached HHS TA template. Please note that NIH ORS/DOHS and NIH OSP are also reviewing the bill on behalf of NIH.

As you complete your review, please keep in mind the HHS guidance on technical assistance below. Please let me know if you have any questions.

Thanks,
Sara

To ensure that the Department's comments are given full consideration, please observe the following guidelines in providing your office's comments:

Are there provisions of this bill that would conflict with Department or Administration policy, and how?

Are there provisions that would pose difficulties for the operation or management of HHS programs, and how?

Are there any other significant issues that you can identify?

If you recommend specific changes, supply reasons and explanations, if the reasons are not obvious.

Released by Chairman Rand Paul

Topline points:

- Strengthening biosafety and biosecurity oversight of life sciences research is a key priority of this Administration, as outlined in the National Biodefense Strategy. We believe the bill as drafted would significantly undermine life sciences research without commensurate security benefit. As such, we do not support this legislation.
- The Administration has recently strengthened, streamlined, and expanded oversight of potentially high risk life science research in the May 2024 United States Government Policy for Oversight of Dual Use Research of Concern Pathogens with Enhanced Pandemic Potential ("DURC/PEPP policy"). This policy expands and strengthens a tiered system of oversight for all federally funded research that includes a requirement for research on pathogens with enhanced pandemic potential to undergo extra departmental review. The policy also:
    - Defines an expanded scope of pathogen and toxin research subject to additional oversight by the U.S. Government;
    - Provides a unified framework to support the consistent identification and oversight of research proposals that require enhanced oversight that accounts for safety, security, and ethical considerations; and
    - Delineates the roles and responsibilities of principal investigators, research institutions, and Federal departments and agencies that conduct, fund, or oversee research within the scope of the policy.
- The Administration also strongly believes in the importance of ensuring the highest level of integrity in scientific and technological processes, and has supported the establishment and enforcement of policies that maintain integrity in the conduct of scientific research and in the collection of scientific or technological data. In support of this, the Administration published a report on Protecting the Integrity of Government Science in January 2022.
- The bill seems to create redundancies with some reforms recently introduced by the DURC/PEPP policy, which was developed following significant interagency discussions directed by Congress and informed by the National Science Advisory Board for Biosecurity, public comment, and other expert input.
- The bill retains a number of problematic details that could negatively impact innovation and the U.S. competitive edge in life sciences research, including our ability to attract and retain the best scientists.
- However, the Administration welcomes efforts from Congress to further strengthen biosafety and biosecurity in the life sciences.
    - For example, we would welcome discussions on how the risk-based oversight processes established in the DURC policy for federally funded research could be extended to non-federally funded research.
- We recognize that biosafety and biosecurity oversight responsibilities are currently shared across many different departments and agencies and welcome discussions on appropriate entities for oversight of the highest risk research.

Some of our concerns with the bill are:

- **Scope:** The legislation continues to codify a list of pathogens, which would reduce the flexibility of funding agencies to adapt to changes from natural and anthropogenic evolution. It also continues to enable the board to review routine life science research outside of the "high risk" definition on a case-by-case basis, and it is unclear how this would be implemented in practice without significantly impacting research review timelines.

- **Board processes and makeup:** The makeup and processes of the board could introduce a number of issues. For example, the limitations on prior federal service and designation of participation in high-risk research as a "conflict of interest" could limit the board from accessing relevant national security and life sciences expertise. The exclusion of those involved in high-risk research, based on the definition in the draft legislation, could exclude anyone with a current BSL3 or BSL4 program, excluding individuals with key expertise on how to conduct work safely. These limitations may also exclude individuals who work in government with relevant knowledge of intelligence and threat assessments.

- **Review criteria:** The bill does not articulate a principle or threshold that guides whether the board should or should not approve a study for funding – for example, should the Board approve research where it determines that the potential public health benefits of the research outweigh the potential risks to U.S. national security? Or should some other standard govern the Board's review? Any statute mandating this style of review should clarify the applicable standard.

- **Classified review and intelligence concerns:** The legislation continues to authorize the board to access and review all classified research funded by any agency, including non-life sciences research. Those provisions extend beyond the scope of oversight that is reasonable for this board to take on and they may impinge on the constitutional authority of the Executive to control classified national security information.

- **Enforcement:** The enforcement provisions are extreme and may raise significant legal and privacy concerns. Those provisions mandate a suite of harsh penalties for violations of certain provisions of the statute, including technical violations; they allow for no flexibility in determining the severity of punishment; they provide the aggrieved party with no process; and they mandate public identification of aggrieved individuals. These provisions may dissuade scientists from pursuing any research that might be potentially considered high-risk.

- **Authorities:** Agencies have raised concerns about how the legislation would conflict with and impede their existing authorities, including those related to grantmaking. For example, DOD has noted the legislation would curtail DOD's flexibility and weaken DOD's Title 10 authorities to fund research that is in the best interest of national security. In several places the legislation raises privacy concerns by requiring sharing of information that is normally protected under the Privacy Act. In addition, USAID has noted that ambiguity in the definition of federal funding could imply that contributions to other bodies such as CEPI are required to go through this process, which could limit U.S. Government's ability to effectively work with such organizations.

Released by Chairman Rand Paul

Given the above concerns, as drafted, this legislation has the potential to negatively impact innovation and delay the development of lifesaving technologies. While the Administration does not support this legislation, we remain committed to working with the Committee on biosafety and biosecurity.

Released by Chairman Rand Paul

~~HHS Review of S.4667 Risky Research Review Act~~
~~As amended by HSGAC on September 25, 2024~~

~~HHS appreciates the opportunity to review S. 4667, as amended by the Peters-Paul substitute amendment. Please note this is not formal Department TA or Administrations views. However, as there remain many similarities between the introduced bill and substitute amendment, we are also attaching the formal TA we shared with the committee in July. to the introduced bill, for reference.~~

~~While some aspects of this bill related to scope are improved, there continue to be significant concerns about the impact on biomedical research.~~

Topline points:

- Strengthening biosafety and biosecurity oversight of life sciences research is a key priority of this Administration, as outlined in the National Biodefense Strategy. We believe the bill as drafted would significantly undermine life sciences research~~, and its oversight provisions fail to target the subset of research posing greatest risk.~~ without commensurate security benefit. As such, we do not support this legislation.

- ~~As currently drafted, this legislation has the potential to negatively impact innovation and the U.S. competitive edge in life sciences research, including our ability to attract and retain the best scientists.~~

~~While HHS continues to have serious concerns with this legislation as drafted, we remain committed to working with the Committee and Congress on biosafety and biosecurity.~~

~~More detailed concerns are described below by category.~~

~~Redundant with DURC/PEPP policy~~

- The Administration has recently strengthened, streamlined, and expanded oversight of potentially high risk life science research in the May 2024 United States Government Policy for Oversight of Dual Use Research of Concern Pathogens with Enhanced Pandemic Potential ("DURC/PEPP policy"). This policy expands and strengthens a tiered system of oversight for all federally funded research that includes a requirement for research on pathogens with enhanced pandemic potential to undergo extra departmental review. The policy also:
    - Defines an expanded scope of pathogen and toxin research subject to additional oversight by the U.S. Government;
    - Provides a unified framework to support the consistent identification and oversight of research proposals that require enhanced oversight that accounts for safety, security, and ethical considerations; and

Released by Chairman Rand Paul

  - Delineates the roles and responsibilities of principal investigators, research institutions, and Federal departments and agencies that conduct, fund, or oversee research within the scope of the policy.

- The Administration also strongly believes in the importance of ensuring the highest level of integrity in scientific and technological processes, and has supported the establishment and enforcement of policies that maintain integrity in the conduct of scientific research and in the collection of scientific or technological data. In support of this, the Administration published a report on Protecting the Integrity of Government Science in January 2022.
- The bill seems to create redundancies with some reforms recently introduced by the DURC/PEPP policy, which was developed following significant interagency discussions directed by Congress and informed by the National Science Advisory Board for Biosecurity, public comment, and other expert input.
- The bill retains a number of problematic details that could negatively impact innovation and the U.S. competitive edge in life sciences research, including our ability to attract and retain the best scientists.
- However, ~~HHS~~the Administration welcomes efforts from Congress to further strengthen biosafety and biosecurity in the life sciences.
  - For example, we would welcome discussions on how the risk-based oversight processes established in the DURC policy for federally funded research could be extended to non-federally funded research.
- We recognize that biosafety and biosecurity oversight responsibilities are currently shared across many different departments and agencies and welcome discussions on appropriate entities for oversight of the highest risk research.
  - ~~o~~

Some

~~Scope/Definitions~~

- ~~While steps have been made toward harmonization of the scope of the Board's oversight with the new *United States Government Policy for Oversight of Dual Use Research of Concern and Pathogens with Enhanced Pandemic Potential* (2024 OSTP DURC/PEPP Policy), some of the listed experiments in the "dual use research of concern" definition do not match those in the policy, and other articulated in-scope research in the bill including the "gain of function research" term continues to be in conflict with USG policy. These definition differences will be challenging to deconflict for the research community. Many of the USG definitions were determined following significant interagency discussions directed by Congress and informed by the National Science Advisory Board for Biosecurity, public comment, and other expert input. We recommend that the definitions and scope of review be fully harmonized with the DURC/PEPP policy and not include a separate list of pathogens. Many of the definitions of research that is subject to requirements of this proposed legislation are very broad and not all are in line with existing policies, which is likely to cause confusion in the research community.~~
  - ~~This could result in delays to critical biosurveillance efforts such as COVID-19 testing, H5N1 monitoring, and detection of emerging outbreaks of Ebola and other diseases. It could also result in delays for development of vaccines, therapeutics, and biomedical, agricultural, and other life sciences research writ large (including research that is not associated with pathogens or toxins and raises no identified national security threats, such as cancer research).~~

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- If the statute only provided the board the responsibility to review federally-funded research involving DURC and PEPP, as defined in the DURC/PEPP policy, it would ensure oversight resources are used most efficiently to assess and mitigate risks to the public while avoiding unintended negative consequences for the nation's biomedical enterprise. We believe this is the intent of the bill but as written the definitions are not harmonized.
- A large amount of scientific research involves gain or loss of function; it's a fundamental process in science. For example, some types of immune therapy cause the immune system to gain function to fight against a disease. Unfortunately, the term "gain of function" has often being misconstrued to suggest all research that causes a gain of function is highly risky, which is inaccurate. In fact, most research involving a GOF does not confer significant additional risk or require additional oversight. NIH does not define the term GOF and current federal policy does not define or operationalize the term. The research that requires strict oversight involves enhancing the transmissibility and/or virulence of a pathogen such that it would pose an increased pandemic potential in humans. The USG policy on oversight of DURC and PEPP (effective May 2025) also does not use the term GOF when describing research that requires additional oversight because of its higher risk. As it appears the intent of the term "GOF" in this bill is to refer specially to research that has the potential to enhance the transmissibility or virulence of a potential pandemic pathogen, for clarity we would recommend the use of the term "pathogen with enhanced pandemic potential" in the 2024 OSTP policy that addresses this type of research, as well as it's associated definition. This would help to avoid the ongoing confusion surrounding the term GOF.

The list of "high-consequence pathogens" is concerning and would have an immediate negative impact to science and public health. The mention of Influenza A viruses, for example, would include all work with H5N1 viruses which are having a significant impact on our poultry and dairy farms. Research into vaccines, treatment, spread and evolution of these viruses is critical to ensure to curb this outbreak and to prevent those in the future. The same could be said for the inclusion of all mpox. The current outbreak and identification of Clade I is highly concerning and without scientists able to pivot nimbly, the outcome is concerning. We are also concerned with the catchall language that could expand the scope of pathogens and categories the board reviews simply by a majority vote from the board.**of our concerns with the bill are:**

- **Scope:** The legislation continues to codify a list of pathogens, which would reduce the flexibility of funding agencies to adapt to changes from natural and anthropogenic evolution. It also continues to enable the board to review routine life science research outside of the "high risk" definition on a case-by-case basis, and it is unclear how this would be implemented in practice without significantly impacting research review timelines.

- **Board processes and makeup:** The

  - Given that certain types of research with any "wild-type or synthetic" pathogen among the listed species would apparently require review by the new Board, this appears to suggest that research with viruses engineered or adapted for decreased pathogenicity (e.g. certain mouse-adapted or tissue-culture-adapted strains) would be considered "high-consequence" even if they have been deliberately altered to decrease the research risk, e.g. for exploration of drug-resistance mechanisms at lower BSL levels.
  - Category XVIII "any synthetic construct of a pathogen or category of pathogen described in this clause" may be confusing regarding what it adds to the "wild-type or synthetic"

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pathogens already listed – what is meant by "synthetic construct" in addition to previous use of "synthetic" and does this mean that using only a piece of a "high-consequence pathogen" (e.g. synthesizing the receptor-binding site and studying receptor affinity in vitro, or synthesizing a viral or bacterial enzyme and studying inhibitors in vitro) would potentially still be considered "high-consequence"?

- Subparagraph B is auto-referential creating an exclusion for seasonal influenza unless genetic sequences have been introduced from the list of pathogens that includes influenza A – does this mean that any introduction of genetic material from one seasonal influenza virus into another seasonal influenza virus would be considered "high-consequence"?
- **Some** other included pathogens besides influenza may be commonly circulating in the population, and classifying them as automatically "high-consequence" could potentially delay or interfere with clinical diagnosis and care depending on how the other criteria for centralized Board review are interpreted (e.g. all sarbecoviruses, all mpox viruses).
- According to the next section at the bottom of the page, it looks like maybe only experiments that meet DURC/GOF criteria with these agents would need centralized board review, and if it were possible to obtain clarification that non-DURC/GOF experiments are not subject to the Act provisions that might mitigate some of the potential concerns, but there is the possibility that uncertainty about interpretation could still have major impact on willingness to conduct or review research in some of the relevant areas of importance for public health.

- The text of the proposed legislation reads as if the Life Sciences Research Security Board could review all life sciences research. Throughout the text of the proposed legislation, the terms used seem to vary between "high-risk life sciences research," which is defined very specifically, and broader terms like "life sciences research." The scope of review seems far beyond what a single Board could reasonably be able to review especially given the broad definition of life sciences research, even if limited to high-risk life sciences research and even with the Board trying to develop expert committees. Creating such a broad scope of review for the Board risk delays of important research, which does not rise to the level of high-risk life sciences research, that could be adequately addressed at a more local or Agency review level and is already subject to laws, regulations, guidances, and policies.

Expertise/Board Processes and Makeup

- While biosafety expertise is now included, the makeup and processes of the board could introduce a number of issues. For example, the limitations on prior federal service and designation of participation in high-risk research as a "conflict of interest" could limit the board from accessing relevant national security and life sciences expertise. The exclusion of those involved in high-risk research, based on the definition in the draft legislation, could exclude anyone with a current BSL3 or BSL4 program, excluding individuals with key expertise on how to conduct work safely. These limitations may also exclude individuals who work in government with relevant knowledge of intelligence, threat assessments, and biosecurity. Risk assessment is best when diverse voices are heard, the lack and actually clear refusal to ensure persons with experience in high and maximum containment principles are included would not provide a comprehensive and scientifically robust review of this work. and threat assessments.
- We also recommend relaxing the limitations on membership of the board and note that a number of the timelines are untenable (e.g., Congressional notification requirements within 3 days of identifying a potential conflict of interest; publishing procedures in the Federal Register within 90 days of the appointment of initial members; etc.). We note that several provisions relating to the

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membership of the Board or its support staff are vague, including the requirement that Board members be "impartial" and that support staff be prohibited from "directly or indirectly influenc[ing]" the Board. The proposed legislation would also politicize independent peer review by making the constituent members presidential appointees.

- As drafted, the Board will have significant control over funding decisions, which may interfere with existing statute on NIH funding activities.
- We have concerns about the Board reaching out directly to applicants/recipients, which is outside traditional NIH reporting procedures.
- Regarding support from agencies to board personnel, it is unclear how an agency representative can be expected to both provide technical assistance but not indirectly influence the board. Technical assistance should factor into the decision.
- Regarding 7904 (b)(3), if such disclosure is required drafters should be specific as to what laws on protection of commercial confidential information and trade secrets are being waived.

Review Process and Criteria

- While a path for expedited review has been added, there could still be major issues with continuity of science due to delays of reviews or membership being confirmed. Among other concerns, in particular, this will significantly impede the USG's ability to prepare for and detect emerging infectious diseases/epidemics/pandemics and will also significantly impede the USG's research response to an epidemic/pandemic. We recommend establishing a default rule that research may proceed if a decision is not made within a fixed timeframe to ensure that any lapse in function by the Board (e.g., delays in confirmation) do not result in life sciences research grinding to a halt. We also recommend a formal appeals process and an exemption to public reporting requirements if the information could pose national security risks.
- **criteria:** The bill does not articulate a principle or threshold that guides whether the board should or should not approve a study for funding – for example, should the Board approve research where it determines that the potential public health benefits of the research outweigh the potential risks to U.S. national security? Or should some other standard govern the Board's review? Any statute mandating this style of review should clarify the applicable standard.
- It is unclear if it is the drafters' intent to prohibit funding for an entire award prior to Board approval or only work related to potential "high-risk" research. Similarly, there is a later provision that would require a pause in research due to a change in circumstance, but it is unclear if such a pause would apply to an entire award or only work related to potential "high-risk research.

Classified review and intelligence concerns

- We recommend striking provisions that mandate the provision of security clearances to Board members, Board staff, and members of Congress, or that require these individuals**:** The legislation continues to authorize the board to access and review all classified research funded by any agency, including non-life sciences research. Those provisions extend beyond the scope of oversight that is reasonable for this board to take on and they may impinge on the constitutional authority of the Executive to control classified national security information. We also recommend that clauses be included to enable the intelligence

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~~community to respond to requests from the Board in a manner consistent with the protection of intelligence sources and methods.~~

Enforcement

- **:** The enforcement provisions are extreme and may raise significant legal and privacy concerns. Those provisions mandate a suite of harsh penalties for ~~any~~ violations of certain provisions of the statute, including technical ~~or unintentional~~ violations; they allow for no flexibility in determining the severity of punishment; they provide the aggrieved party with no process; and they mandate public identification of aggrieved individuals. These provisions ~~could broadly disincentivize individuals~~may dissuade scientists from ~~working in life sciences~~pursuing any research ~~and funding agencies, which could send~~that might be potentially considered high-risk.

- **Authorities:** Agencies have raised concerns about how the legislation would conflict with and impede their existing authorities, including those related to grantmaking. For example, DOD has noted the legislation would curtail DOD's flexibility and weaken DOD's Title 10 authorities to fund research ~~outside~~that is in the best interest of ~~this country and compromise progress on public health, safety, and~~ national security. In several places the legislation raises privacy concerns by requiring sharing of information that is normally protected under the Privacy Act. In addition, USAID has noted that ambiguity in the definition of federal funding could imply that contributions to other bodies such as CEPI are required to go through this process, which could limit U.S. Government's ability to effectively work with such organizations.

-

Given ~~We recommend that enforcement provisions be focused on willful violations~~the above concerns, as drafted, this legislation has the potential to negatively impact innovation and delay the development of lifesaving technologies. While the Administration does not support this legislation, we remain committed to working with the Committee on biosafety and ~~significantly reduced or adjusted.~~biosecurity.

-

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From: "Spiro, David (NIH/FIC) [E]" <[redacted]@nih.gov>
To: "Doc Spiro [redacted]@gmail.com)" <[redacted]@gmail.com>
Subject: Narrative
Date: Tue, 18 Feb 2025 09:36:54 -0500
Importance: Normal
Attachments: Narrative.docx

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Narrative:

The narrative of this story is the following:

We have come to a point in biomedical history where it is possible to create billions of distinct viral species with minimal effort for people trained in the technologies.

How did we come to this point? Was it a PSY OP or was it the natural development of technology occurring due to natural scientific sociological processes with emergent properties? What I mean by this is, did we develop the technology for ultra sophisticated bioweapons development due to behind-the-scenes machinations and funding to develop bio weapons for military purposes, or did the technology for bio weapons development occur due to standard grant peer review processes and scientific trends. i.e., an unexpected emergent property

And the participants in the development of the technology to make buy a weapons, were they aware that they were making bio weapons? Were they paid directly by members of the Defense-Intelligence enterprise? Or was NIH given increased funding for biodefense and steered in the direction of bioweapons development by members of the defense intelligence enterprise? Who at NIH new? Fauci, Collins, previous NIH heads? Division heads?

Things to look up:

> When did biodefense funding increase dramatically for NIAID? Try to find old budget presentations from DMD.
>
> Find the blue ribbon panel on influenza research circa 2000 and six

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CREID pro QUO

From:	Peter Daszak on behalf of Peter Daszak [redacted]@ecohealthalliance.org>
To:	Laing, Eric; Thomas Hughes
Cc:	Wang Linfa; Danielle E. ANDERSON PhD; Ralph S. Baric; Baric, Toni C; Sims, Amy C; Chris Broder; Supaporn Wacharapluesadee; Aleksei Chmura; Alison Andre; Luke Hamel; Hongying Li; Emily Hagan; Noam Ross; Kevin Olival
Subject:	EIDRC impact scores from NIH
Date:	Monday, November 18, 2019 9:26:16 PM
Attachments:	Study section roster 1573258030732.pdf EIDRC Southeast Asia v7 FINAL_FINAL.pdf
Importance:	High

Dear All,

Just to let you know that we've got the results back from NIH. EHA submitted two EIDRC proposals, and we were linked to a third one as a subcontract. Out of these, the only one to get a score was the Southeast Asia EIDRC (EID-SEARCH) which you are all collaborators on. I also know of another good group that wasn't scored, so just to get a score is actually a good result…

Our 'impact score' was 32, which normally would put us right on the edge of being funded. I've already contacted the NIAID program officer (Jean Patterson) to ask about the likelihood of being funded. She told me that NIH staff are currently working out the structure of the network and a funding plan. She felt our proposal was well-received and scored well enough to be considered, and she asked me to hold off for a week or two and then they'd know more.

My take on this is that they're now deciding what the geography and scope of the network should be, how many EIDRC centers they can afford to fund, and then they'll decide priorities for funding. With this being strongly driven by NIAID's internal concerns about their reach into different geographies, it's really going to be a decision driven by their own considerations of who else is in the mix and what strengths/weaknesses different proposals have. That means we're in with a chance, but we don't really know the factors driving a decision.

I'll contact NIAID again in a few days, but in the meantime, please do the following: 1) try not to share this information with colleagues because we don't want to have a situation where they scored better than us and we got funded, leading to a bad feeling (or worse, the other way round!); 2) if you meet people from NIAID, tell them how keen and enthusiastic you are about the proposal and the work we're conducting (I've attached the final text again as a reminder) – you never know how this might help. Key people at NIAID who will be making this decision are: Tony Fauci (head of NIAID), Cristina Cassetti (Deputy Head, and in charge of this line of work), Jean Patterson (Program Officer directly in charge of the EIDRCs), Eun-Chung Park (also directly in charge of this work), Pat Repik (I think she's involved).

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From: "Marrazzo, Jeanne (NIH/NIAID) [E]" <[redacted]@nih.gov>
To: "Selgrade, Sara (NIH/NIAID) [E]" <[redacted]@nih.gov>
Cc: "Auchincloss, Hugh (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Harper, Jill (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Billet, Courtney (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, NIAID OCGR Leg <[redacted]@mail.nih.gov>
Subject: RE: For your awareness: materials requested for Dr. Tabak
Date: Thu, 30 Nov 2023 07:42:04 -0500
Importance: Normal

Thanks Sara, this is a very comprehensive and helpful document. JM

****

Jeanne Marrazzo, MD, MPH
Director, National Institute of Allergy and Infectious Diseases
Building 31, Room 7A-03
31 Center Drive, MSC 2520
National Institutes of Health
Bethesda, MD 20892-2520

NIAID Front Office Phone [redacted]
Fax: [redacted]

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Wednesday, November 29, 2023 7:30 PM
To: Marrazzo, Jeanne (NIH/NIAID) [E] [redacted]@nih.gov>
Cc: Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; NIAID OCGR Leg [redacted]@mail.nih.gov>
Subject: For your awareness: materials requested for Dr. Tabak

Hello Dr. Marrazzo,

NIH OLPA has asked for NIAID assistance with preparing background materials for Dr. Tabak for a potential congressional staff briefing.

As you are aware, there has been recent congressional interest in certain coronavirus studies conducted at RML. It is possible that Dr. Tabak may provide a briefing on this research to staff to the House Labor-HHS Appropriations Subcommittee (Chair: Rep. Robert Aderholt, R-AL) in the coming weeks. NIH OLPA has asked us to review a draft background document for Dr. Tabak. The NIH Office of Research Services (Division of Occupational Health and Safety) has reviewed as well.

The legislative team worked with DIR/RML to add information requested by OLPA and make additional NIAID edits for accuracy. The attached document with NIAID edits was reviewed by Hugh, Jill, and Courtney, and will be provided to NIH OLPA for review and potential use by Dr. Tabak.

Please let me know if you have any questions.

Thanks,
Sara

Released by Chairman Rand Paul

From: "Selgrade, Sara (NIH/NIAID) [E]" <[redacted]@nih.gov>
To: "Marrazzo, Jeanne (NIH/NIAID) [E]" <[redacted]@nih.gov>
Cc: "Auchincloss, Hugh (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Harper, Jill (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Billet, Courtney (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, NIAID OCGR Leg <[redacted]@mail.nih.gov>
Subject: For your awareness: materials requested for Dr. Tabak
Date: Wed, 29 Nov 2023 19:29:32 -0500
Importance: Normal
Attachments: TBD_Approps_Briefing_on_RML_NIAID_edits.docx

Hello Dr. Marrazzo,

NIH OLPA has asked for NIAID assistance with preparing background materials for Dr. Tabak for a potential congressional staff briefing.

As you are aware, there has been recent congressional interest in certain coronavirus studies conducted at RML. It is possible that Dr. Tabak may provide a briefing on this research to staff to the House Labor-HHS Appropriations Subcommittee (Chair: Rep. Robert Aderholt, R-AL) in the coming weeks. NIH OLPA has asked us to review a draft background document for Dr. Tabak. The NIH Office of Research Services (Division of Occupational Health and Safety) has reviewed as well.

The legislative team worked with DIR/RML to add information requested by OLPA and make additional NIAID edits for accuracy. The attached document with NIAID edits was reviewed by Hugh, Jill, and Courtney, and will be provided to NIH OLPA for review and potential use by Dr. Tabak.

Please let me know if you have any questions.

Thanks,
Sara

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DRAFT, PRE-DECISIONAL

Background on Bat CoV Research at RML and recent media inquiries

Background:

Prompted by a recent article in the Daily Mail and a FOX News program video featuring a blog post on the White Coast Waste (WCW) Project website, Kathryn has reached out for additional information about an incident and documents related to Dr. Munster's research at RML. There are many confusing media statements on the issue, as well as the vague request from Kathryn. To help clarify the facts, please see information below.

Proposal:

Dr. Tabak to have a call with Kathryn to talk through some of the misinformation. Please see high level points here and additional background below.

TPs:

- WIV-1 the virus studied at RML in 2016 and published in 2018 is not a progenitor to SARS-CoV-2.
- WIV-1 is a naturally occurring bat coronavirus and is named WIV-1 because scientists at WIV were the first to discover and characterize the virus.
- RML researchers did not receive the virus or bats from WIV.
- RML followed standard procedures to procure the bats for research and used a USDA approved licensed dealer.

~~TPs~~**Background:**

- RML has an over 100-year history studying emerging infectious diseases, pandemics including Rocky Mountain spotted fever, Lyme disease, bubonic plague, chronic wasting disease, Ebola, Zika, and yellow fever.
- A BSL-4 facility was ~~constructed~~ completed at RML in 2008 (under President Bush) and put into service in 2009.8 ~~(under President Bush).~~
    - These are the safest and most strictly regulated infectious disease facilities for high consequence pathogens.
    - BSL-4s undergo the highest levels of scrutiny on research, safety, security, and personnel reliability.
- Why Research Coronaviruses (CoV) at RML?
    - CoV are responsible for many common colds, but in the 21st century, they have caused 3 ~~very~~ serious and deadly ~~world-wide pandemics~~ outbreaks – the 2003 SARS-1 pandemic (SARS-CoV-1), the 2013 MERS outbreak (MERS-CoV), and the 2019 COVID-19 pandemic (SARS-CoV-2).
    - Many CoV ~~use~~ live in bats as a ~~reservoir~~ natural host – often the bats have limited to no signs of disease caused by~~are unaffected by~~ the infection.

Commented [B[1]: I believe 2009 is more appropriate here, since construction was completed in 2008, but initial facility approval received in 2009 and the first studies began in late 2009/early 2010.
Brose, Megan (NIH/OD/ORS) [E]
2023-11-27 12:32:00

Commented [SS([2R1]: Edits to address for accuracy
Selgrade, Sara (NIH/NIAID) [E]
2023-11-28 20:11:00

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DRAFT, PRE-DECISIONAL

- There has been a long-standing interest among RML scientists ~~i~~on CoV infections and potential for spillover from animals to humans~~among RML scientists~~.
- CoV are considered to be among the likely causes of future pandemics.

- WIV-1
  - WIV-1 is a coronavirus that was isolated from bats and characterized by WIV scientists.
  - It is not closely related to nor a progenitor of SARS-CoV-1/2 nor~~or~~ MERS-CoV.
  - WIV scientists posted the WIV-1 sequence on a public database.
  - U.S. scientists used that sequence to construct a virus using standard virology methods that they outlined in a 2016 ~~PNAS~~*Viruses* article.
    - They did not get actual virus from WIV.
    - The RML scientists collaborated with the U.S. scientists (University of North Carolina) ~~that~~ who had constructed the WIV-1 and got the virus from them for their studies.
    - RML scientists do not and have never collaborated directly with WIV scientists.
- Research at RML on WIV-1
  - Because of the interest in CoV, RML scientists decided to study WIV-1 to determine if WIV-1 had potential to spread to people ~~and be a potential pandemic pathogen~~.
    - Identifying ~~potential pandemic~~ critical pathogens is an essential~~a~~ research goal in preventing future pandemics.
  - **WIV-1 did not grow well in the bats and the bats did not shed the virus.**
  - The work was ~~done~~performed in 2016 and published in 2018 – well before COVID-19 was ever identified.

Tough Q/As:

1. Did Daily Mail reach out to NIH prior to the article for comment?

   No, the Daily Mail did not ask NIH to comment. Additional background, Daily Mail rarely asks NIH to comment on upcoming articles regarding NIH.

2. Does RML fund GOF research?

   The 2016 study was a natural history study of WIV-1 and there were no GOF aspects of the study. The viruses used in the experiment were as they wea~~s~~re found in nature and were not changed by the investigators. All work is reviewed by the Institutional Biosafety Committee and, as applicable, the Dual Use Research of Concern Institutional Review Entity prior to being conducted.

Commented [NIH3]: NIAID - please confirm this point. Are there papers that someone from RML and WIV are co-authors?
NIH
2023-11-27 12:35:00

Commented [SS([4R3]: To OLPA: NIAID can confirm this statement. We cannot speak to affiliations of individual scientists prior to, or subsequent to, their collaborations with RML. As you are aware, other components of NIH have provided grants directly to WIV in the past.
Selgrade, Sara (NIH/NIAID) [E]
2023-11-28 16:42:00

Commented [M[5]: Not sure if you want a broader statement here. Feel free to delete if preferred. Could always pull language from other letters to add if needed.
McCormick-Ell, Jessica (NIH/OD/ORS) [E]
2023-11-27 17:10:00

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DRAFT, PRE-DECISIONAL

3. Does RML have collaborations with Wuhan Institute of Virology?

No, RML scientists do not and have never collaborated directly with WIV scientists.

Commented [NIH6]: NIAID - please see comment above.
NIH
2023-11-27 12:38:00

Commented [SS([7R6]: To OLPA: NIAID can confirm this statement. We cannot speak to affiliations of individual scientists prior to, or subsequent to, their collaborations with RML. As you are aware, other components of NIH have provided grants directly to WIV in the past.
Selgrade, Sara (NIH/NIAID) [E]
2023-11-29 08:12:00

4. Why does RML use bats for research on risky pathogens?

RML has a long history of studying emerging infectious diseases. RML has been using bats in research for at least 50 years. Some of the work using bats at RML has~~ve~~have included studies on rabies and MERS-CoV. Coronaviruses (CoV) are a large family of viruses. They are primarily respiratory viruses and are responsible for many common colds. They have also been the cause of three ~~very serious~~recent serious and deadly ~~and recent~~ outbreaks or pandemics: the 2003 SARS-1 pandemic (SARS-CoV-1), the 2013 MERS outbreak (MERS-CoV), and the 2019 COVID-19 pandemic (SARS-CoV-2). CoV often use bats as a reservoir. The emergence of SARS-CoV-1 and MERS-CoV, spurred great interest in improving the NIH's understanding of the diversity CoVs. Since CoV are considered to be among the likely pathogens to cause future pandemics, it is imperative to study bat CoV for their potential to cause current and future pandemics.

Because of the interest in CoV, RML scientists decided to study WIV-1 to see if it grew well in the bats and if the bats shed the virus. In other words, the research was to determine if WIV-1 had potential to spread to people ~~and be a potential pandemic pathogen~~. RML scientists collaborated with UNC scientists to obtain the WIV-1 virus, constructed in the UNC lab, from them. The experiments were done at RML's BSL-4 facility. It is important to note that, WIV-1 is not a human pathogen and is not a progenitor of SARS-CoV-2. ~~The~~ Further, the RML study demonstrated that WIV-1 did not grow well in bats and that the bats did not shed the virus, quite different from what turned out to be the case for SARS-CoV-2. The work was done in 2016 and published in 2018 in ~~*PNAS*~~*Viruses*.

5. What safety measures are in place to protect this research?

RML constructed a BSL-4 facility ~~and began using it~~ in 2008 and began using it in 2009~~8~~. BSL-4 facilities are the safest and most strictly regulated infectious disease facilities for high consequence pathogens. They have the highest levels of scrutiny on research, safety, security, and personnel reliability. These facilities meet the requirements outlined in national guidelines and regulations, such as the Biosafety in Microbiological and Biomedical Laboratories (BMBL) 6th edition, the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules, and the Select Agent regulations. These facilities are inspected annually by external agencies, such as the Federal Select Agent Program (FSAP) and the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC), to ensure compliance with federal regulations and industry standards. Additionally, all research involving recombinant DNA and those studies conducted at high and maximum containment (BSL-3 and BSL-4)

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are reviewed by the RML Institutional Biosafety Committee (IBC) prior to study initiation to ensure all procedures are conducted safely and in accordance with guidelines and regulations. Additionally, NIH intramural policies stipulate that ~~A~~any research ~~that has the potential to be considered Dual Use Research of Concern or involves Pathogens of Pandemic Potential~~ with Risk Group 3 and 4 pathogens must be reviewed by the NIH Dual Use Research of Concern Institutional Review Entity (DURC-IRE) to ensure appropriate risk mitigation procedures are in place.

FOX News Program Allegations

1. There is new evidence that Dr. Fauci helped deliver a coronavirus strain to the U.S. a year before the pandemic.

   Facts: ~~*NIAID please add a few sentences about the Director's lack of involvement in intramural research decisions*~~ NIH, including NIAID, intramural scientists propose promising scientific approaches to address biomedical research challenges in their fields of expertise. Following any appropriate biosafety and regulatory approvals as relevant for the research, the scientists conduct the research and report their discoveries in the scientific literature. In the normal course of business, NIH and NIAID leadership do not have a role in the proposal or conduct of specific intramural research projects.- Dr. Fauci had no role in virus procurement, delivery, or research planning.

   The study in question did not use any virus shipped from Wuhan. The virus was created at UNC using the WIV-1 sequence publicly available on GenBank since 2013.

2. The U.S. government funded research and trained a researcher at Wuhan Institute of Virology.

   Facts: The study in question did not have any collaborations with WIV. Unrelated to the study in question, t~~T~~he NIH has awarded funding to WIV for research as a subawardee on the EcoHealth Alliance R-01 from 2014 to 2020.

   After a thorough compliance review, NIH referred WIV to HHS for debarment. HHS debarred WIV from receiving U.S. funding for at least 10 years beginning in July 2023.

3. Documents uncovered by the WCW Project show that in 2018, NIH scientists went to the lab at Wuhan and brought the virus to a lab in the U.S.

   Facts: WIV-1 was isolated from bats and characterized by WIV scientists. The sequence to this virus has been publicly available since 2013. As outlined in a 2016 *PNAS* article, UNC researchers used the sequence to construct a virus using standard methods. The virus constructed in the U.S. was shared with RML researchers and used to study if WIV-

Commented [SS([8]: To OLPA: as above, noting that the subaward under the EHA grant is not the only funding NIH has provided to WIV. Other components of NIH have had prior grants directly to WIV.
Selgrade, Sara (NIH/NIAID) [E]
2023-11-29 08:09:00

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1 CoV could replicate in Egyptian fruit bats. No RML researchers traveled to Wuhan, nor were any viruses brought back or shipped to RML.

4. NIH obtained Egyptian fruit bats from a zoo in Maryland, transported them across state lines to Montana, and experimented on them with a coronavirus.

Facts: The work done at RML in 2016 used Egyptian fruit bats obtained by standard procurement and procedures and delivered to RML via a USDA approved animal provider with the appropriate permits in place. These bats were infected with WIV-1 to determine its ability to replicate in bats; it was found to be poorly able to do so in this experiment.

5. RML in Montana has a history of infected animals escaping, unauthorized people getting into the lab, and bioweapons development.

Facts: This work was done in an RML facility first used in 20098. The facility contains high containment laboratories, employs the highest possible safety standards to protect scientists and the surrounding community. RML has a longstanding history of excellent biosafety and biocontainment practices with minimal incidents that have posed negligible to no risk to personnel or the community. There have been zero incidents of unauthorized individuals accessing any high or maximum containment labs. RML does not conduct research on bioweapons development. The referenced report of an infected animal escape was taken out of context from a mandatory regulatory report to the Federal Select Agent Program ~~where~~in which a rodent escaped from its home cage but remained contained in the BSL-4 lab and was subsequently recaptured. The animal remained within the BSL-4 primary containment barrier and never escaped the laboratory.

6. NIH is spending $125 million of COVID relief funds to expand its bat laboratories.

Facts: The CARES Act provided funding specifically for the construction of NIAID vaccine and infectious disease research facilities, including the BSL-2 animal facility that will allow RML scientists to better respond to new and emerging pandemic threats. The facility is designed to enable research with a number of different types of animal models, not just bats. The animals housed at the BSL-2 facility could be subsequently used in experiments requiring BSL-3 or BSL-4 containment, as appropriate. These BSL-3 and -4 facilities are already existing at RML.

UK Daily Mail Article Allegations

1. NIH infected 12 Egyptian fruit bats with a SARS-like virus called WIV-1 at RML in Montana in 2018.

Facts: At RML, experimental studies to help understand if WIV-1 CoV could replicate in

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Egyptian fruit bats were conducted in the highest ~~level~~ biosafety level lab, ~~a~~ BSL-4, in December 2016. The results of this study were published in *Viruses* in 2018.

2. The WIV-1 coronavirus was shipped from WIV.

   Facts: The WIV-1 virus is named for the institute in China that first identified it. The WIV-1 virus studied at RML was not shipped to the U.S. from China. The WIV-1 genetic sequence was shared in a public database by WIV scientists. UNC investigators employed commonly used virological techniques to generate the virus from the publicly shared sequence.

3. The research determined the novel virus could not cause a 'robust infection'.
   Facts: The results of the study, which were published in the journal *Viruses* in 2018, demonstrated that WIV-1 did not replicate well in Egyptian fruit bats.

4. The group WCW Project is now using the Freedom of Information Act to request more details about the experiment.

   Facts: Since 2019, NIH has received 178 FOIA requests from WCW. Of those, 128 are closed. NIH will continue to respond to WCW FOIA requests.

5. Catoctin Wildlife Preserve (CWP) has a history of animal welfare violations and was fined $12,000 in 2012 for poor and dangerous animal housing and inadequate animal care.

   Facts: NIH relies on USDA approved animal providers and complies with all import and transport permits, where applicable. The bats were procured by an ~~a~~ USDA licensed dealer (Prim Gen) who sourced research naïve Egyptian fruit bats from the Catoctin Wildlife Preserve that were used in the 2016 study.

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From: "Sizemore, Christine (NIH/FIC) [E]" <[redacted]@nih.gov>
To: "Spiro, David (NIH/FIC) [E]" <[redacted]@nih.gov>
Subject: RE: Did you see this petition?
Date: Thu, 20 Jul 2023 10:29:32 -0400
Importance: Normal
Inline-Images: image001.png

Wow – I did not know all of this!
For me its all about scientific elitism and the few at the top pulling strings. I agree, there is no evidence that Fauci orchestrated this but then again, I am not sure about this either.
I am not sure about anything any more … all I can say is that the upper crust at NIH and in the global research arena does pull strings and control messages.

From: Spiro, David (NIH/FIC) [E] [redacted]@nih.gov>
Sent: Thursday, July 20, 2023 10:23 AM
To: Sizemore, Christine (NIH/FIC) [E] [redacted]@nih.gov>
Subject: RE: Did you see this petition?

Yes, I did and I also watched portions of the hearing with Andersen and Garry. The House report is a skewed and doesn't take into account some of the details revealed in the hearing. After watching the hearing, I think Fauci and Collins were involved, I am not convinced that this was orchestrated by Fauci. Jeremy Farrar was the initiator of the article and Fauci sat in on a call. Andersen said that Fauci played a minimal role in the talks and that they changed their point of view based on analysis of the data. Given my review of the genomic data, this seems reasonable. I think the paper is most likely an honest assessment of data. Quickly done, no doubt but there was an emergency situation.
What confuses me is why Fauci publicly pretended that he didn't know the investigators and I wonder if this is because he placed his thumb on the post-peer review process leading to an award of CREID centers for Garry and Andersen. The peer review took place in November, but the grants weren't awarded until April I believe. After the call for proximal origin. Andersen said that the peer review couldn't possibly have been tampered with, but you and I both know that awarding large cooperative agreements goes beyond peer review and the NIAID OD could have weighed in. The other strange thing was awarding a CREID center to Dascak after Trump specifically blocked an earlier grant to EcoHealth alliance.

From: Sizemore, Christine (NIH/FIC) [E] [redacted]@nih.gov>
Sent: Thursday, July 20, 2023 9:20 AM
To: Spiro, David (NIH/FIC) [E] [redacted]@nih.gov>
Subject: RE: Did you see this petition?

Have you read that report from the committee that I sent recently? I would have agreed with you until I saw the actual emails and Slack channel conversations… I am still siding with you that it should not be retracted, also because that sets precedence. But what went on behind the scenes is pretty bad.

From: Spiro, David (NIH/FIC) [E] [redacted]@nih.gov>
Sent: Thursday, July 20, 2023 9:01 AM
To: Sizemore, Christine (NIH/FIC) [E] [redacted]@nih.gov>
Subject: RE: Did you see this petition?

Hi,
I don't agree with the petition.
I think it is an important first analysis of the data available at the time and is part of a series of investigations by the authors and collaborators attempting to find the origin through genomic and epi analysis.

Released by Chairman Rand Paul

The problem came with how the Dems and NIH leadership used it as a weapon to silence scientific debate. It is also an important historical record at this point.

From: Sizemore, Christine (NIH/FIC) [E] [redacted]@nih.gov>
Sent: Thursday, July 20, 2023 8:29 AM
To: Spiro, David (NIH/FIC) [E] [redacted]@nih.gov>
Subject: Did you see this petition?

Petition to withdraw the Proximal Origins paper…
What do you think? I am a bit torn here…. On one hand, if this were a paper that summarizes the state of knowledge about SARS-CoV2 as of Feb 2020 and speculates what the origins may be, and then it turns out, as is part of science, that there is more to it, I would not have a problem with the paper. But now that is has been shown that it was not a full accounting of how the authors felt about potential origins, but clearly drove a specific narrative, I am not sure what to think any more. I know that scientific publications will never be able to present all possible scenarios and of course show the conclusions of the authors (and not also list other conclusions by other scientists)… so in that sense, the paper is not any different there.

https://mailchi.mp/biosafetynow/retract-proximal-origins?e=4bbd46214d

Christine

Christine F. Sizemore, Ph.D.
Director, Division of International Relations

[redacted]

Fogarty International Center
National Institutes of Health, USA

31 Center Drive, B2C11
Bethesda, Maryland 20892

People take different roads seeking fulfillment and happiness. Just because they're not on your road doesn't mean they've gotten lost. --- *H. Jackson Brown, Jr.*

Released by Chairman Rand Paul

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To: "Sizemore, Christine (NIH/FIC) [E]" <[redacted]@nih.gov>
Subject: RE: Did you see this petition?
Date: Thu, 20 Jul 2023 10:23:03 -0400
Importance: Normal
Inline-Images: image001.png

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Released by Chairman Rand Paul

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https://mailchi.mp/biosafetynow/retract-proximal-origins?e=4bbd46214d

Christine

Christine F. Sizemore, Ph.D.
Director, Division of International Relations

[redacted]

Fogarty International Center
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31 Center Drive, B2C11
Bethesda, Maryland 20892

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To: "Ford, Andrew (NIH/NIAID) [E]" <[redacted]@nih.gov>
Cc: "Erbelding, Emily (NIH/NIAID) [E]" <[redacted]@nih.gov>, "Lyon, Rickie (NIH/NIAID) [C]" <[redacted]@niaid.nih.gov>, "Post, Diane (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Ison, Michael (NIH/NIAID) [E]" <[redacted]@nih.gov>
Subject: RE: Please advise by COB today 3/21: Additional questions related to SRG review of EHA grant
Date: Tue, 21 Mar 2023 14:44:34 -0400
Importance: Normal
Attachments: Summary_Statements_Media_Statement_es.docx

Hi Andrew,
See attached. Let me know if there are any other questions.
Thanks!
Erik

From: Ford, Andrew (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Tuesday, March 21, 2023 10:52 AM
To: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Cc: Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Ford, Andrew (NIH/NIAID) [E] [redacted]@nih.gov>; Lyon, Rickie (NIH/NIAID) [C] [redacted]@niaid.nih.gov>; Post, Diane (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Ison, Michael (NIH/NIAID) [E] [redacted]@nih.gov>
Subject: FW: Please advise by COB today 3/21: Additional questions related to SRG review of EHA grant
Importance: High

Hey Erik,

Per Sara's email below, documents related to the SRG review of the EHA award are likely to be provided to the congressional requestors later this week. Attached is a media statement (third attachment) drafted by OLPA that notes a few potential vulnerabilities from comments in the summary statements. Could you please review attached media statement **and** the questions bolded below and send to me any edits/comments/responses by **COB today, Tuesday, March 21, 2023.**

Thanks,
Andrew

From: Sara Selgrade <[redacted]@nih.gov>
Date: Tuesday, March 21, 2023 at 10:37 AM
To: NIAID BUGS [redacted]@niaid.nih.gov>, NIAID DEA DART <[redacted]@mail.nih.gov>, "Linde, Emily (NIH/NIAID) [E]" [redacted]@mail.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>, "Auchincloss, Hugh (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Harper, Jill (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Billet, Courtney (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, Emily Erbelding <[redacted]@nih.gov>, "Poe, Kelly (NIH/NIAID) [E]" [redacted]@nih.gov>, "Gilles, Sharon (NIH/NIAID) [E]" [redacted]@nih.gov>
Subject: Please advise by COB today 3/21: Additional questions related to SRG review of EHA grant

Good morning,

Background

Released by Chairman Rand Paul

As you recall, NIH OLPA reached out recently to make us aware of congressional requests for documents related to Scientific Review Group (SRG) review of the original and renewal EHA award. NIH OLPA has indicated that HHS is likely to provide these to the congressional requestors later this week.

NIH OLPA has drafted the attached "media statement" that notes a few potential vulnerabilities from comments in the summary statements. They have asked us if we have additional information on these points (bolded questions below):

Vulnerabilities:

1. In the 2013 review, critique number 3 mentions that a potential overlap with PREDICT was noted. **Does NIAID have additional information that we could share about how it was determined this was not double billing?**
2. In the same critique, there is a note that the potential risk to human subjects is not fully addressed. **Did NIAID work with the grantee to address these concerns before funding?**
3. In the 2019 review, critique number 2 mentions that the letters from the two Chinese institutions were identical. **Do you know if there was follow-up regarding this?**

Action Item
By COB today, Tuesday March 21, please review the "media statement" document and provide any edits or comments. Please also provide any information responsive to the bolded questions above. If these questions are better referred to OER or other NIH components, please let us know.

Thanks,
Sara

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Wednesday, March 8, 2023 2:17 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>
Subject: Please advise by 10am tomorrow: Documents for congressional requests related to EHA grant
Importance: High

Hello all,

Background
As you may be aware, the House Select Subcommittee on the Coronavirus Pandemic, as well as the House Energy and Commerce Committee, have requested documents related to EcoHealth Alliance's NIH grants.

NIH OLPA has been working with NIH OER and others to provide documents responsive to the two requests outlined below. Please note the highlighted requests from NIH OLPA outlined below regarding these document productions.

Action Item
Please let us know by 10am tomorrow, Thursday March 9, if you know of any additional documentation or have any concerns to flag as requested by NIH OLPA.

1. Congressional Request: All documents related to the Scientific Review Group (SRG) review of the initial R01 grant.

Note from OCGR-Leg: NIH OLPA/NIH OER has identified the two attached documents below responsive to this request. Please note that we suggested that OLPA should also consult with the Center for Scientific Review.

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<< File: December 18 2013 Summary Statement (1).pdf >> << File: February 14 2019 Type 2 Summary Statement.pdf >>

NIH OLPA questions related to these documents:

1. If you know of any additional documentation from the SRG review we could share with Congress, please flag for OLPA. We have asked OER/OPERA to confirm as well. [note from OCGR-Leg: please advise if NIAID would have responsive documents. If so, we can assist with keywords and individuals for a CIT search for documents]
2. Are there any sensitivities you would like to flag? OLPA will work with OGC to redact personally identifiable information before transmission to Congress.

2. Energy & Commerce Committee Request (Follow up to prior document production consisting of Type 5 Checklists from the initial R01):

Questions from the congressional staff, with proposed responses from NIH OER in red:
Following up on the production of the Type 5 checklist documents, we noticed there was not an Award Worksheet Report for Year 6 of the EcoHealth award or Year 1 of the EcoHealth R02 award (depending on how you look at it).

Based on this HHS OIG report (see excerpt below), the NIH may have closeout documentation for the EcoHealth R01 award.
https://oig.hhs.gov/oei/reports/oei-07-11-00190.pdf. However, we would like clarification on the following: When a grant award is renewed, do NIH staff complete closeout documentation for the R01 grant in lieu of the Award Worksheet Report? NIH Response: No.

If not, do NIH staff complete an Award Worksheet Report for Year 6 (the Year 1 for the R02 award)? NIH Response: Yes.
If there is closeout documentation for the EcoHealth R01, please provide these materials as responsive to the request for the grant file. NIH Response: There is no closeout documentation at this time, because the award continued with the renewal (Type 2).
If instead there is no closeout documentation and there is an Award Worksheet Report, please provide the Year 6 Award Worksheet Report and any other subsequent Award Worksheet Reports. NIH Response: The Year 6 Award Worksheet Reports are attached.

<< File: AWS4298904 9.28.22.pdf >> << File: AWS3993758 9.15.21.pdf >> << File: AWS3672471 7.15.20.pdf >>
<< File: AWS3602757 4.27.20.pdf >> << File: AWS3438397 8.5.19.pdf >> << File: AWS3424934 7.24.19.pdf >>

For background - OER/OPERA Response:
Thanks to our OPERA colleagues, we can offer the following explanation. There are actually 6 award worksheets for the Type 2 due to the actions outlined below:

- 7-24-19: initial award
- 8-5-19: budget adjustment
- 4-27-20: termination—award zero'd out
- 7-15-20: award reinstated
- 9-15-21: award extended (mid-budget period)
- 9-28-22: WIV termination; budget renegotiated to remove aims involving WIV

NIH OLPA questions related to these responses/documents:
Please let us know if you have any concerns or flags

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Sara Selgrade, Ph.D.
Section Chief for Legislative Activities
Legislative Affairs and Correspondence Management Branch
Office of Communications and Government Relations
NIAID/NIH/DHHS
Bldg. 31, Room 7A17, MSC 2520
Bethesda, MD 20892-2520
Phone: [redacted]
[redacted]@mail.nih.gov

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The information in this e mail and any of its attachments is confidential and may contain sensitive information. It should not be used by anyone who is not the original intended recipient. If you have received this e-mail in error please inform the sender and delete it from your mailbox or any other storage devices. National Institute of Allergy and Infectious Diseases shall not accept liability for any statements made that are sender's own and not expressly made on behalf of the NIAID by one of its representatives.

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Information to share with OCPL

Background:

The attached summary statements are from the Scientific Review Group, also known as peer review, of the initial application (review conducted in 2013) and the review of the renewal application (review conducted in 2019). The summary statement is the official record of these reviews. NIH peer reviewers use a 9-point scale for scoring NIH grant applications. A score of 1 means exceptional and 9 means poor, with 5 considered an average score. Impact scores run from 10 to 90 and are based on the normalized average of all reviewer impact/priority scores. Generally speaking, impact scores of 10 to 30 are most likely to be funded; scores between 31 and 45 might be funded; and scores greater than 46 are rarely funded.

The review panel roster is posted publicly on the NIH website. These two rosters can be found:
https://public.era.nih.gov/pubroster/preRosIndex.era?AGENDA=265100&CID=102597

https://public.era.nih.gov/pubroster/preRosIndex.era?AGENDA=356932&CID=102597

Tough Q/As:

Did the NIH grant to EcoHealth Alliance with a subaward to WIV support ePPP research?

- As these reviews show the research proposed in the grant application sought to understand how bat coronaviruses evolve naturally in the environment to become transmissible to the human population. This included studying viral diversity in bat reservoirs, surveying people who work in live animal markets or other jobs with high exposure to wildlife for evidence of bat-coronavirus infection and analyzing data to predict which newly discovered viruses pose the greatest threat to human health.
- NIH did not approve funding for research proposing to enhance SARS-CoV transmissibility or virulence in humans in China or elsewhere.
- The body of science produced under the grant, including the bat coronavirus sequences identified by the researchers and published in the scientific literature, showed that the viruses studied were evolutionarily quite distant from SARS-CoV-2 and could not have been the source of SARS-CoV-2.

Vulnerabilities:

- In the 2013 review, critique number 3 mentions that a potential overlap with PREDICT was noted.
- In the same critique, there is a note that the potential risk to human subjects is not fully addressed and therefore, raises concerns.
- In the 2019 review, critique number 2 mentions that the letters from the two Chinese institutions were identical.

Commented [SE([1]: Suggest adding a bullet that reviewer comments including risk to human subjects and potential overlap were address prior to award being made. This was documented in the 2014 Checklist for R01AI110964-01.
Erik Stemmy
2023-03-21 14:30:00

Commented [SE([2]: Overlap was addressed via JIT: fieldwork for the PREDICT program ended in June 2014 and PREDICT fully ended in September 2014. This award was funded 5/27/2014.
Erik Stemmy [2]
2023-03-21 14:27:00

Commented [SE([3]: It needs to be noted that the "risk" evaluated in the human subjects section is in no way related to the chimeric virus work. This section evaluates whether the risk of the research activities to be performed directly on the human subjects is adequately addressed. In this case it was the blood draws/sample collection and interview questions and did not involve any of the chimeric viruses. The risk noted was the potential financial risk to subjects that may have been involved in illegal wildlife trade potentially losing their source of income. See link below for reviewer guidelines for HS protections:
https://grants.nih.gov/grants/peer/guidelines_general/Guidelines_for_the_Review_of_the_Human_Subjects.pdf

This risk was addressed in the JIT submission.
Erik Stemmy [3]
2023-03-21 14:19:00

Commented [SE([4]: The same general language was used for the two letters of support, but the scientific details of the roles of each institution were appropriately included in the other sections of the application.
Erik Stemmy [4]
2023-03-21 14:42:00

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From: "Ranganathan, Rajesh (NIH/OD) [C]" [redacted]@nih.gov>
To: "Hudson, Kathy (NIH/OD) [E]" [redacted]@nih.gov>, "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Subject: FW: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)
Date: Thu, 18 Nov 2010 21:30:16 -0500
Importance: Normal

This is what I wrote back...I hope it strikes the right tone...

R
------ Forwarded Message
From: "Ranganathan, Rajesh (NIH/OD) [C]" [redacted]@nih.gov
Date: Thu, 18 Nov 2010 21:29:23 -0500
To: "Hatchett, Richard J." [redacted]@nss.eop.gov
Cc: "Burrus-Shaw, Cyndi (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: Re: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)

Richard:

We have discussed this internally amongst a subset of the exec. Team and the consensus is that it is too early for us to have a conversation about CAN, not yet having implemented anything related to CAN. Furthermore, I have only been here 2+ weeks and hence would be out of my depth with respect to MCMI. The main concern is that we would be wasting Ms. Avery's time. It would be unfortunate to risk any dampening of enthusiasm around what CAN could achieve by having a briefing at this high level prematurely.

Would it be possible at this point to diplomatically request that the meeting with Ms. Avery be postponed to a later date, when we are in fact ready to brief her in a substantive way?

And given that you are about to move to BARDA, would it make sense for you and I to chat once you get settled in that new role? However, if you feel that there would still be value in us talking now, I would be happy to come over on Monday to meet 1 on 1 with you.

Please let me know what you think.

Rajesh

On 11/18/10 8:51 AM, "Hatchett, Richard J." [redacted]@nss.eop.gov wrote:

> Rajesh,

> Sorry, I should have clarified that in our initial exchanges, as I assumed that was the context in which JJ spoke with you. We have an overlapping (and
> in fact prior) interest in CAN because of the President's biodefense initiative, and I was taking advantage of JJ's intro to contact you on MCMI (I

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> hadn't heard that you'd been selected for the position before JJ contacted me).
>
I'm actually in the late stages of negotiating a move to BARDA (the Biomedical
> Advanced Research & Development Authority) as deputy director and I don't think JJ knew this when he spoke with you. It will be good to be coordinated
> with you in that regard as well.

> With respect to Heidi, she comes from the intelligence community so doesn't have a scientific or pharmaceutical background, but as you'll see she is a
> very quick study. She oversaw White House coordination of the response to the pandemic and has been acutely sensitized to the deficiencies of our
> countermeasures development efforts. I think she'll be most interested to hear about your and Dr. Collins's vision for CAN and how it will facilitate
> translational efforts at NIH.

> It's probably worth your reviewing the HHS Medical Countermeasures Enterprise Review document just to get your head in the game. For the better part of a
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> competitiveness of the US biopharmaceutical industry in the process).

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Do you have a brief bio you could send over by any chance?
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Best regards, and I look forward to meeting you on Monday -
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> Best,
Richard
>

> ----- Original Message -----
From: Ranganathan, Rajesh (NIH/OD) [C] [redacted]@nih.gov
> To: Hatchett, Richard J.
Sent: Wed Nov 17 21:02:12 2010
> Subject: Re: Discussion about Cures Acceleration Network and the President's

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> Medical Countermeasures Initiative (MCMI)

>

> Rajesh

> On 11/17/10 5:55 PM, "Hatchett, Richard J."
[redacted]@nss.eop.gov wrote:
>
Cyndi, Rajesh --
>>
Thanks for being flexible. Ms. Avery was very interested in joining the
>> discussion. We'll meet in her office (EEOB 426) but why don't you come a few
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Best,
>> Richard

>> -----Original Message-----
From: Burrus-Shaw, Cyndi (NIH/OD) [E] [mailto [redacted]@nih.gov]
>> Sent: Wednesday, November 17, 2010 5:50 PM
To: Hatchett, Richard J.
>> Cc: Ranganathan, Rajesh (NIH/OD) [C]
Subject: RE: Discussion about Cures Acceleration Network and the President's
>> Medical Countermeasures Initiative (MCMI)

>> Yes - that is fine. Dr. Ranganathan will be there on 11/22 at 12:00 pm.
Please confirm that the location is still the same (EEOB, 421). Many thanks.
>>
Best,
>> Cyndi

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From: Hatchett, Richard J. [mailto [redacted]@nss.eop.gov]
>> Sent: Wednesday, November 17, 2010 5:46 PM
To: Burrus-Shaw, Cyndi (NIH/OD) [E]
>> Subject: RE: Discussion about Cures Acceleration Network and the President's
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From: "Ranganathan, Rajesh (NIH/OD) [C]" [redacted]@nih.gov>
To: "Hudson, Kathy (NIH/OD) [E]" [redacted]@nih.gov>
Cc: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Subject: Re: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)
Date: Thu, 18 Nov 2010 21:17:50 -0500
Importance: Normal

Ok, thanks. Will deflect. I was not asking to be involved in this stuff - it was just meant to be a casual conversation with one of our detailees...

Rajesh

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> From: Ranganathan, Rajesh (NIH/OD) [C]
> Sent: Thursday, November 18, 2010 6:51 PM
> To: Hudson, Kathy (NIH/OD) [E]
> Cc: Tabak, Lawrence (NIH/OD) [E]
> Subject: FW: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)
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> Subject: Re: Discussion about Cures Acceleration Network and the President's
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From: "Ranganathan, Rajesh (NIH/OD) [C]" [redacted]@nih.gov
> Date: Wed, 17 Nov 2010 20:50:57 -0500
To: "Hatchett, Richard J." [redacted]@nss.eop.gov
> Subject: Re: Discussion about Cures Acceleration Network and the President's
Medical Countermeasures Initiative (MCMI)
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Cc: Ranganathan, Rajesh (NIH/OD) [C]
>> Subject: RE: Discussion about Cures Acceleration Network and the President's
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From: "Ranganathan, Rajesh (NIH/OD) [C]" [redacted]@nih.gov>
To: "Hudson, Kathy (NIH/OD) [E]" [redacted]@nih.gov>
Cc: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Subject: FW: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)
Date: Thu, 18 Nov 2010 18:51:28 -0500
Importance: Normal

Kathy:

Some background for you (I was able to tell Larry in person)..Tony sent me to JJ McGowan, who thought that Richard Hatchett, currently on detail to the White House is someone I should talk to because he might have the skill set to help with NCTS. I checked in with Larry and we agreed that I should certainly meet such people and hear them out. So, when Richard reached out, I agreed to go down to the EEOB to meet him. He appears to have mentioned that he is meeting me to Ms. Heidi Avery (Deputy Homeland Security Adviser to the President), who now wants to join in and the meeting got moved to Monday to accommodate her schedule. Please see below for what Richard thinks Ms. Avery wants to know.

Two issues: a) there is not much I can say about CAN or anything else re: NCTS on Monday, and b) as a contractor, I should not be reprenseting the NIH externally. Larry has arranged from Robin from DPCPSI to go with me to ensure that the NIH is represented by an employee.

But I am wondering if this meeting with Ms. Avery should even happen - feels too early in the process Please advise on the ramifications of cancelling/postponing on her vs. taking the meeting and not saying anything substantive... Thanks.

Rajesh

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From: "Hatchett, Richard J." [redacted]@nss.eop.gov
Date: Thu, 18 Nov 2010 08:51:35 -0500
To: "Ranganathan, Rajesh (NIH/OD) [C]" [redacted]@nih.gov
Subject: Re: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)

Rajesh,

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Do you have a brief bio you could send over by any chance?

Best regards, and I look forward to meeting you on Monday -
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Date: Wed, 17 Nov 2010 20:50:57 -0500
To: "Hatchett, Richard J." [redacted]@nss.eop.gov
Subject: Re: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)

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Released by Chairman Rand Paul

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> Sent: Wednesday, November 17, 2010 5:50 PM
To: Hatchett, Richard J.
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Subject: RE: Discussion about Cures Acceleration Network and the President's
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> Yes - that is fine. Dr. Ranganathan will be there on 11/22 at 12:00 pm.
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From: "Kawazoe, Robin (NIH/OD) [E]" [redacted]@mail.nih.gov>
To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Subject: Re: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)
Date: Thu, 18 Nov 2010 22:30:37 -0500
Importance: Normal

Larry,

Do you know what Raj means when he said he would "deflect?" Does that mean postpone the meeting?

Robin

----- Original Message -----
From: Tabak, Lawrence (NIH/OD) [E]
To: Ranganathan, Rajesh (NIH/OD) [C]; Hudson, Kathy (NIH/OD) [E]
Cc: Burrus-Shaw, Cyndi (NIH/OD) [E]
Sent: Thu Nov 18 21:27:59 2010
Subject: RE: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)

Agree
Thanks
larry

-----Original Message-----
From: Ranganathan, Rajesh (NIH/OD) [C]
Sent: Thursday, November 18, 2010 9:18 PM
To: Hudson, Kathy (NIH/OD) [E]
Cc: Tabak, Lawrence (NIH/OD) [E]
Subject: Re: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)

Ok, thanks. Will deflect. I was not asking to be involved in this stuff - it
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Rajesh

On 11/18/10 9:14 PM, "Hudson, Kathy (NIH/OD) [E]" [redacted]@nih.gov
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To: Hudson, Kathy (NIH/OD) [E]
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To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Subject: Re: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)
Date: Thu, 18 Nov 2010 22:46:32 -0500
Importance: Normal

Yes! Thank you.

Robin

----- Original Message -----
From: Tabak, Lawrence (NIH/OD) [E]
To: Kawazoe, Robin (NIH/OD) [E]
Sent: Thu Nov 18 22:33:02 2010
Subject: Re: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)

Yes

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To: Tabak, Lawrence (NIH/OD) [E]
Sent: Thu Nov 18 22:30:37 2010
Subject: Re: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)

Larry,

Do you know what Raj means when he said he would "deflect?" Does that mean postpone the meeting?

Robin

----- Original Message -----
From: Tabak, Lawrence (NIH/OD) [E]
To: Ranganathan, Rajesh (NIH/OD) [C]; Hudson, Kathy (NIH/OD) [E]
Cc: Burrus-Shaw, Cyndi (NIH/OD) [E]
Sent: Thu Nov 18 21:27:59 2010
Subject: RE: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)

Agree
Thanks
larry

-----Original Message-----
From: Ranganathan, Rajesh (NIH/OD) [C]
Sent: Thursday, November 18, 2010 9:18 PM
To: Hudson, Kathy (NIH/OD) [E]
Cc: Tabak, Lawrence (NIH/OD) [E]
Subject: Re: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)

Released by Chairman Rand Paul

Ok, thanks. Will deflect. I was not asking to be involved in this stuff - it was just meant to be a casual conversation with one of our detailees...

Rajesh

On 11/18/10 9:14 PM, "Hudson, Kathy (NIH/OD) [E]" [redacted]@nih.gov wrote:

Thanks for asking. My knee jerk reaction is to support your misgivings. I
> think it is a bad idea for a whole bunch of reasons. JJ erred in pointing you to the white house. Protocol dictates that we don't talk to the white house
> without going through hhs. It would be okay to yak with one of our detailees but this has taken a turn. Plus, I suspect you know next to nothing about
> biosecurity and BARDA. This is not really your domain and frankly, not a central issue to NCTS at the outset. It IS the domain of other NIH staff who
> would probably be a little miffed about why you are suddenly in the middle of their "space." NIAID has programs in this arena and you should learn about
> them but they ain't coming into to ncts at the get go and the politics around biosecurity is complex.
>
I would suggest to Richard that the meeting be "delayed" until you have a
> better understanding of what Francis has in mind, yadda yadda.

>

>

> -----Original Message-----
From: Ranganathan, Rajesh (NIH/OD) [C]
> Sent: Thursday, November 18, 2010 6:51 PM
To: Hudson, Kathy (NIH/OD) [E]
> Cc: Tabak, Lawrence (NIH/OD) [E]
Subject: FW: Discussion about Cures Acceleration Network and the President's
> Medical Countermeasures Initiative (MCMI)

> Kathy:

> Some background for you (I was able to tell Larry in person)..Tony sent me to JJ McGowan, who thought that Richard Hatchett, currently on detail to the
> White House is someone I should talk to because he might have the skill set to help with NCTS. I checked in with Larry and we agreed that I should
> certainly meet such people and hear them out. So, when Richard reached out, I agreed to go down to the EEOB to meet him. He appears to have mentioned
> that he is meeting me to Ms. Heidi Avery (Deputy Homeland Security Adviser to the President), who now wants to join in and the meeting got moved to
> Monday to accommodate her schedule. Please see below for what Richard thinks Ms. Avery wants to know.
>
Two issues: a) there is not much I can say about CAN or anything else re:
> NCTS on Monday, and b) as a contractor, I should not be reprenseting the NIH externally. Larry has arranged from Robin from DPCPSI to go with me to
> ensure that the NIH is represented by an employee.

> But I am wondering if this meeting with Ms. Avery should even happen - feels too early in the process Please advise on the ramifications of
> cancelling/postponing on her vs. taking the meeting and not saying anything

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> substantive... Thanks.

> Rajesh

> ------ Forwarded Message
From: "Hatchett, Richard J." [redacted]@nss.eop.gov
> Date: Thu, 18 Nov 2010 08:51:35 -0500
To: "Ranganathan, Rajesh (NIH/OD) [C]" [redacted]@nih.gov
> Subject: Re: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)
>
Rajesh,
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Sorry, I should have clarified that in our initial exchanges, as I assumed
> that was the context in which JJ spoke with you. We have an overlapping (and in fact prior) interest in CAN because of the President's biodefense
> initiative, and I was taking advantage of JJ's intro to contact you on MCMI (I hadn't heard that you'd been selected for the position before JJ
> contacted me).

> I'm actually in the late stages of negotiating a move to BARDA (the Biomedical Advanced Research & Development Authority) as deputy director and
> I don't think JJ knew this when he spoke with you. It will be good to be coordinated with you in that regard as well.
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With respect to Heidi, she comes from the intelligence community so doesn't
> have a scientific or pharmaceutical background, but as you'll see she is a very quick study. She oversaw White House coordination of the response to
> the pandemic and has been acutely sensitized to the deficiencies of our countermeasures development efforts. I think she'll be most interested to
> hear about your and Dr. Collins's vision for CAN and how it will facilitate translational efforts at NIH.
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It's probably worth your reviewing the HHS Medical Countermeasures
> Enterprise Review document just to get your head in the game. For the better part of a decade, our efforts on MCMs have focused on traditional
> government approaches to financing technology development (R&D funds for academia, advanced development contracts for industry, and procurement
> contracts serving as the main "reward") with some twiddling of other pull incentives, with only marginal success against threats we can define and not
> much progress in developing true rapid response capabilities.

> The main conceptual novelty of MCMI is the focus on adjusting the cost side of the equation by making strategic investments at what we've been calling
> the "chokepoints" of product development - the places where projects are failing or dying on the vine for reasons other than lack of safety or
> efficacy. The overarching goal of MCMI is to change the nature of the public-private partnership governing product development efforts in this
> area, changing the role of government from one of "funder" to active strategic collaboration. This is where I think what we are doing will be of
> interest to you: we are using the national security imperative to maintain focus and drive budgets but adopting an approach which ought to be fungible
> to other areas where our translational efforts are faltering. Heidi's goal won't be to co-opt CAN but to think strategically with you about how what we
> are doing might serve to enhance our drug development efforts more broadly (and hopefully preserve the competitiveness of the US biopharmaceutical
> industry in the process).

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Happy to chat further but I think that's the kernel of what she'll be
> interested in discussing with you.

> Do you have a brief bio you could send over by any chance?

> Best regards, and I look forward to meeting you on Monday -
Richard
>
Best,
> Richard

> ------ Forwarded Message
From: "Ranganathan, Rajesh (NIH/OD) [C]" [redacted]@nih.gov
> Date: Wed, 17 Nov 2010 20:50:57 -0500
To: "Hatchett, Richard J." [redacted]@nss.eop.gov
> Subject: Re: Discussion about Cures Acceleration Network and the President's
Medical Countermeasures Initiative (MCMI)
>
Richard:
>
Can you give me some background on what Ms. Avery is likely to be interested
> in hearing about. Is there anything I should know about MCMI to be
appropriately prepared?
>
On 11/17/10 5:55 PM, "Hatchett, Richard J."
> <[redacted]@nss.eop.gov> wrote:

>> Cyndi, Rajesh --

>> Thanks for being flexible. Ms. Avery was very interested in joining the
discussion. We'll meet in her office (EEOB 426) but why don't you come a few
>> minutes early and meet me in 421?

>> Best,
Richard
>>
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Sent: Wednesday, November 17, 2010 5:50 PM
>> To: Hatchett, Richard J.
Cc: Ranganathan, Rajesh (NIH/OD) [C]
>> Subject: RE: Discussion about Cures Acceleration Network and the President's
Medical Countermeasures Initiative (MCMI)
>>
Yes - that is fine. Dr. Ranganathan will be there on 11/22 at 12:00 pm.
>> Please confirm that the location is still the same (EEOB, 421). Many thanks.

>> Best,
Cyndi
>>
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>> From: Hatchett, Richard J. [mailto [redacted]@nss.eop.gov]
Sent: Wednesday, November 17, 2010 5:46 PM
>> To: Burrus-Shaw, Cyndi (NIH/OD) [E]
Subject: RE: Discussion about Cures Acceleration Network and the President's
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Released by Chairman Rand Paul

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Thanks,
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To: "Ranganathan, Rajesh (NIH/OD) [C]" [redacted]@nih.gov>
Cc: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Subject: RE: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)
Date: Thu, 18 Nov 2010 21:14:33 -0500
Importance: Normal

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Subject: FW: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)

Kathy:

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Best regards, and I look forward to meeting you on Monday -
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From: "Sanders, Ashley (NIH/OD) [E]" <[redacted]@nih.gov>
To: "Miller, David A. (NK) (FBI)" <[redacted]@fbi.gov>
Cc: "Stemmy, Erik (NIH/NIAID) [E]" <[redacted]@nih.gov>, "Shannon, Mike (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: FW: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Date: Fri, 22 May 2020 15:17:48 -0400
Importance: Normal
Attachments: SF_424_AI110964.docx

Hi David,

In preparation for our call on Tuesday, Erik (cc'd) has provided responses to your initial questions below (also attached).

Hope you have a great holiday weekend!
Ashley

Ashley M. Sanders, MPS
Senior Program Investigations Officer
NIH, OMA, Division Program Integrity
6011 Executive Blvd.
Rockville, Maryland 20852
Office: [redacted]
Cell: [redacted]
[redacted]@nih.gov

SF 424 AI110964-06 (received date 11/05/2018)
Both SF 424s seem to be describing "gain of function" experiments. On page 192 of SF 424 AI110964-06 (received date 11/05/2018) under P3CO Research, it indicates they are conducting gain of function of SARSr-CoV.

The funding pause on gain-of-function (GoF) experiments was in place from 2014-2017, and explicitly involved work reasonably anticipated to enhance the transmissibility or pathogenicity of influenza, MERS-CoV, or SARS-CoV. As such, that policy would not have applied to SARS-related coronaviruses (SARSr-CoV). The replacement policy, Potential Pandemic Pathogen Care and Oversight (P3CO), requires additional review and oversight of experiments that are anticipated to increase a potential pandemic pathogen's transmissibility or pathogenicity *in humans*. The viruses created under this award are chimeric bat viruses, which generally would not be anticipated to cause enhanced disease or transmission in people. When evaluating experiments for potential GoF or P3CO we determine the likelihood of altering one of these attributes compared to the wild-type or circulating viral strain.

Were they also conducting Seemless Cloining and Assembly? From a review of their experimental details, it looks as if they were generating recombinant DNA of the viruses using WIV1 as the backbone but I could not determine if they were using Seemless Cloning techniques.

I'm not aware of them using seamless cloning. Standard techniques for investigators in this field are to create cDNA molecular clones, which are then expressed in cull culture.

I could not determine exactly where they were conducting these gain of function experiments. I know UNC-Chapel Hill has done these but within the document, I could not determine where this was occurring. Do you know where this was occurring?

GoF experiments were not conducted as part of this award. While chimeric viruses were created via this award, they would not be considered GoF since the results did not confer attributes that were not already exhibited by the wild type versions of the viruses. For example, expressing the spike protein of SARS-CoV in the WIV-1 backbone did not increase the pathogenicity of WIV-1 beyond that of SARS-CoV. This award did not support work to manipulate CoV genomes or create chimeric viruses at Wuhan Institute of Virology; such work was performed at UNC-CH.

It then appears that the recombinant DNA of the virus was then injected into humanized mice. However, again I couldn't determine where this occurred or was to occur. On page 187 of the same SF 424 under **"Vertebrate Animals"** it indicates that work with vertebrate animals will be conducted at Wuhan University at the School of Medicine and UNC – CH. Then under **"Laboratory Mice"** it states that lab mice will be sourced commercially by Wuhan Center for Animal Experiment at Wuhan University and that humanized mice will be bread at University of Wuhan and UNC – CH. Furthermore, the mice will be inoculated with the virus.

Recombinant viral cDNA is not directly injected into humanized mice. Rather, these molecular clones are used to grow virus in culture to create an inoculum used in infectivity studies. Both WIV and UNC-CH performed studies with molecular clones, which included infecting mice with the resulting recombinant viruses.

Under **"UNC Facilities where selected agents to be used"** it continues with all mouse studies at UNC-CH will be performed…." However, on page 200 of the same SF 424 there is a letter from UNC – CH stating "The work to be performed by UNC-CH does not include animal and/or human research subjects." I know that was a lot of information but where exactly was the experimentation of injecting the humanized mice with the recombinant DNA occurring?

I believe this to be a typographical error on the part of UNC's business office. The application describes animal work at UNC. Budget justifications and the consortium agreement also include references to this work. I believe UNC mean to say that the work "… does not include human research subjects."

SF 424 AI110964-01 (received date 06/05/2013)
In this SF 424 Aim 3 seems indicative of gain of function experimentation (**C3a** and **C3b**) although it does not use that exact term.

The receipt date of this application was June of 2013, and the term "gain-of-function" was not widely used before the USG funding pause was announced in 2014. C3a and C3b describe work using pseudovirus assays, which would not have been considered GoF as they do not involve creating full replicating viruses.

On page 119 of AI110964-01 under "**C3d) Humanized mouse *in vivo* infection experiments"** it states that humanized mouse in vivo experiments in humanized mice was occurring at the Wuhan Institute of Virology. I did not see the location where these gain of function experiments were being done but if the injections were occurring at WIV then was the recombinant DNA also generated at WIV? Was Seemless Cloning also being done?

This is not GoF work. The humanized mouse experiments described in C3d refer to work with *wild type* viruses isolated from wild bats. Refer to the section stating: "We will passage isolated bat-CoVs in permissive cells twice…" This is a standard virological technique to create an inoculum to infect animals. In no portion of C3d do they describe any manipulation of isolated virus, therefore this does not describe any kind of gain-of-function studies, nor does it involve the creation of any recombinant DNA or viruses. Characterization of naturally occurring viruses was *explicitly excluded* from the GoF policy. Further, the USG P3CO Policy Guidance states that "Wild-type pathogens that are circulating in or have been recovered from nature are not enhanced PPPs, regardless of their pandemic potential."

RPPR (AI110964-05)
Finally, in the RPPR (6/1/2017-5/31/2018) on page 28 under "**In Vivo Infection of Human ACE2 Expressing Mice with SARSr-Cov S Protein variants",** it appears to be showing the results from their gain of function experiments as described in the SF 424. This is more of less the same as the question above, but do you know where this occurred?

These are not the results of GoF experiments. The figure you reference (Fig 35) shows weight loss and lung viral titers of chimeric viruses with bat CoV (wild type WIV-1, SHC014, WIV16, and 4231) spike proteins expressed on the WIV-1

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backbone. Weight loss and viral titers were comparable across all chimeras when compared to the wild type (Fig 35a, red series; Fig 35b small box pattern). There are no statistical differences reported, so the chimeric viruses have not gained any function/attribute they did not already exhibit.

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To: "Miller, David A. (NK) (FBI)" <[redacted]@fbi.gov>
Cc: "Stemmy, Erik (NIH/NIAID) [E]" <[redacted]@nih.gov>, "Shannon, Mike (NIH/OD) [E]" <[redacted]@nih.gov>
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Released by Chairman Rand Paul

From: "Stemmy, Erik (NIH/NIAID) [E]" </O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=585133D3FA194F06AA618678B2817C22-STEMMYEJ>
To: "Sanders, Ashley (NIH/OD) [E]" <[redacted]@nih.gov>, "Linde, Emily (NIH/NIAID) [E]" <[redacted]@mail.nih.gov>
Cc: "Shannon, Mike (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Date: Thu, 21 May 2020 17:49:51 -0400
Importance: Normal
Attachments: SF_424_AI110964.docx

Hi Ashley,
Since we'll only have a short time on Tuesday I thought it might be helpful to provide the agent my responses to the original questions. There may be some misunderstanding of gain-of-function experiments, so hopefully this will clarify some things or at least provide a framework for our discussion next week.

Thanks!
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From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Thursday, May 21, 2020 3:04 PM
To: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>; Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Erik,

Thank you for providing this information. We would like to set up a call with the agent as they may need additional context or have other questions. Would you be available next Tuesday around 11:30AM? I'll set up a conference line for us and send an invite.

If that time doesn't work for you, please let me know alternative times you have available.

Thank you,
Ashley

From: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Thursday, May 21, 2020 11:22 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>; Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,
I would be happy to answer questions related to this award. Would it be best if I just addressed the comments at the end of this email thread? I'll say generally that NIAID has an extensive review process for P3CO (and formerly for GoF) and that all of this work was formally evaluated by the respective committees and determined not to be gain-of-function, nor subject to P3CO oversight. We also continually monitored the progress (until the award was terminated) for evidence of unexpected increases in viral replication.

Erik

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
5601 Fishers Lane, Room 8E18
Bethesda, MD 20892-9825
Phone: [redacted]
Email: [redacted]@nih.gov

From: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Sent: Thursday, May 21, 2020 6:17 AM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

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The Program Official for this grant, Dr. Stemmy, who is copied on this email, would be the most appropriate POC for these questions.

Regards,

Emily

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Wednesday, May 20, 2020 1:00 PM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Good afternoon,

We are following up on a time-sensitive request for information from the FBI. Please let us know if you are able to accommodate their request or if you can recommend a POC to address the concerns.

Thank you,
Ashley

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Sent: Wednesday, May 13, 2020 11:59 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Good afternoon Emily,

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Would you be able to provide a response to the below-captured questions and/or be available for a joint call with our office and the agent? If not, who would be the best SME on this matter? I'm sure you understand, since this is a sensitive matter, we need to maintain confidentiality and limit the touch-points within NIH. I'm happy to discuss further if you have any questions.

Thank you,
Ashley

Ashley M. Sanders, MPS
Senior Program Investigations Officer
NIH, OMA, Division Program Integrity
6011 Executive Blvd.
Rockville, Maryland 20852
Office: [redacted]
[redacted]@nih.gov

FBI Questions:

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Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Date: Thu, 21 May 2020 11:22:11 -0400
Importance: Normal

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Cc: "Shannon, Mike (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Date: Fri, 22 May 2020 11:05:47 -0400
Importance: Normal
Attachments: message_v2.rpmsg

Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov) has sent you a prot

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From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Thursday, May 21, 2020 3:04 PM
To: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>; Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Erik,

Thank you for providing this information. We would like to set up a call with the agent as they may need additional context or have other questions. Would you be available next Tuesday around 11:30AM? I'll set up a conference line for us and send an invite.

If that time doesn't work for you, please let me know alternative times you have available.

Thank you,
Ashley

From: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Thursday, May 21, 2020 11:22 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>; Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,
I would be happy to answer questions related to this award. Would it be best if I just addressed the comments at the end of this email thread? I'll say generally that NIAID has an extensive review process for P3CO (and formerly for GoF) and that all of this work was formally evaluated by the respective committees and determined not to be gain-of-function, nor subject to P3CO oversight. We also continually monitored the progress (until the award was terminated) for evidence of unexpected increases in viral replication.

Erik

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
5601 Fishers Lane, Room 8E18
Bethesda, MD 20892-9825
Phone: [redacted]
Email: [redacted]@nih.gov

From: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Sent: Thursday, May 21, 2020 6:17 AM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
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Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

Released by Chairman Rand Paul

The Program Official for this grant, Dr. Stemmy, who is copied on this email, would be the most appropriate POC for these questions.

Regards,

Emily

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Wednesday, May 20, 2020 1:00 PM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Good afternoon,

We are following up on a time-sensitive request for information from the FBI. Please let us know if you are able to accommodate their request or if you can recommend a POC to address the concerns.

Thank you,
Ashley

From: Sanders, Ashley (NIH/OD) [E]
Sent: Wednesday, May 13, 2020 11:59 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Good afternoon Emily,

OMA/DPI received questions related to an FBI inquiry for the following NIAID grants: 1R01AI110964-01 through 2R01AI110964-06. The agent is requesting clarification on the details of the study, where certain aspects were performed, and whether seamless cloning techniques were used. I note you were the last official to sign off on 4/27/20.

Would you be able to provide a response to the below-captured questions and/or be available for a joint call with our office and the agent? If not, who would be the best SME on this matter? I'm sure you understand, since this is a sensitive matter, we need to maintain confidentiality and limit the touch-points within NIH. I'm happy to discuss further if you have any questions.

Thank you,
Ashley

Ashley M. Sanders, MPS
Senior Program Investigations Officer
NIH, OMA, Division Program Integrity
6011 Executive Blvd.
Rockville, Maryland 20852
Office: [redacted]
[redacted]@nih.gov

FBI Questions:

SF 424 AI110964-06 (received date 11/05/2018)

Both SF 424s seem to be describing "gain of function" experiments. On page 192 of SF 424 AI110964-06 (received date 11/05/2018) under P3CO Research, it indicates they are conducting gain of function of SARSr-CoV. Were they also conducting Seemless Cloining and Assembly? From a review of their experimental details, it looks as if they were generating recombinant DNA of the viruses using WIV1 as the backbone but I could not determine if they were using Seemless Cloning techniques. I could not determine exactly where they were conducting these gain of function experiments. I know UNC-Chapel Hill has done these but within the document, I could not determine where this was occurring. Do you know where this was occurring?

It then appears that the recombinant DNA of the virus was then injected into humanized mice. However, again I couldn't determine where this occurred or was to occur. On page 187 of the same SF 424 under **"Vertebrate Animals"** it indicates that work with vertebrate animals will be conducted at Wuhan University at the School of Medicine and UNC – CH. Then under **"Laboratory Mice"** it states that lab mice will be sourced commercially by Wuhan Center for Animal Experiment at Wuhan University and that humanized mice will be bread at University of Wuhan and UNC – CH. Furthermore, the mice will be inoculated with the virus. Under **"UNC Facilities where selected agents to be used"** it continues with all mouse studies at UNC-CH will be performed…." However, on page 200 of the same SF 424 there is a letter from UNC – CH stating "The work to be performed by UNC-CH does not include animal and/or human research subjects." I know that was a lot of information but where exactly was the experimentation of injecting the humanized mice with the recombinant DNA occurring?

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In this SF 424 Aim 3 seems indicative of gain of function experimentation (**C3a** and **C3b**) although it does not use that exact term. On page 119 of AI110964-01 under "**C3d) Humanized mouse *in vivo* infection experiments"** it states that humanized mouse in vivo experiments in humanized mice was occurring at the Wuhan Institute of Virology. I did not see the location where these gain of function experiments were being done but if the injections were occurring at WIV then was the recombinant DNA also generated at WIV? Was Seemless Cloning also being done?

RPPR (AI110964-05)

Finally, in the RPPR (6/1/2017-5/31/2018) on page 28 under "**In Vivo Infection of Human ACE2 Expressing Mice with SARSr-Cov S Protein variants",** it appears to be showing the results from their gain of function experiments as described in the SF 424. This is more of less the same as the question above, but do you know where this occurred?

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The funding pause on gain-of-function (GoF) experiments was in place from 2014-2017, and explicitly involved work reasonably anticipated to enhance the transmissibility or pathogenicity of influenza, MERS-CoV, or SARS-CoV. As such, that policy would not have applied to SARS-related coronaviruses (SARSr-CoV). The replacement policy, Potential Pandemic Pathogen Care and Oversight (P3CO), requires additional review and oversight of experiments that are anticipated to increase a potential pandemic pathogen's transmissibility or pathogenicity *in humans*. The viruses created under this award are chimeric bat viruses, which generally would not be anticipated to cause enhanced disease or transmission in people. When evaluating experiments for potential GoF or P3CO we determine the likelihood of altering one of these attributes compared to the wild-type or circulating viral strain.

Were they also conducting Seemless Cloining and Assembly? From a review of their experimental details, it looks as if they were generating recombinant DNA of the viruses using WIV1 as the backbone but I could not determine if they were using Seemless Cloning techniques.

I'm not aware of them using seamless cloning. Standard techniques for investigators in this field are to create cDNA molecular clones, which are then expressed in cull culture.

I could not determine exactly where they were conducting these gain of function experiments. I know UNC-Chapel Hill has done these but within the document, I could not determine where this was occurring. Do you know where this was occurring?

GoF experiments were not conducted as part of this award. While chimeric viruses were created via this award, they would not be considered GoF since the results did not confer attributes that were not already exhibited by the wild type versions of the viruses. For example, expressing the spike protein of SARS-CoV in the WIV-1 backbone did not increase the pathogenicity of WIV-1 beyond that of SARS-CoV. This award did not support work to manipulate CoV genomes or create chimeric viruses at Wuhan Institute of Virology; such work was performed at UNC-CH.

It then appears that the recombinant DNA of the virus was then injected into humanized mice. However, again I couldn't determine where this occurred or was to occur. On page 187 of the same SF 424 under **"Vertebrate Animals"** it indicates that work with vertebrate animals will be conducted at Wuhan University at the School of Medicine and UNC – CH. Then under **"Laboratory Mice"** it states that lab mice will be sourced commercially by Wuhan Center for Animal Experiment at Wuhan University and that humanized mice will be bread at University of Wuhan and UNC – CH. Furthermore, the mice will be inoculated with the virus.

Recombinant viral cDNA is not directly injected into humanized mice. Rather, these molecular clones are used to grow virus in culture to create an inoculum used in infectivity studies. Both WIV and UNC-CH performed studies with molecular clones, which included infecting mice with the resulting recombinant viruses.

Under **"UNC Facilities where selected agents to be used"** it continues with all mouse studies at UNC-CH will be performed…." However, on page 200 of the same SF 424 there is a letter from UNC – CH stating

"The work to be performed by UNC-CH does not include animal and/or human research subjects." I know that was a lot of information but where exactly was the experimentation of injecting the humanized mice with the recombinant DNA occurring?

I believe this to be a typographical error on the part of UNC's business office. The application describes animal work at UNC. Budget justifications and the consortium agreement also include references to this work. I believe UNC mean to say that the work "… does not include human research subjects."

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The receipt date of this application was June of 2013, and the term "gain-of-function" was not widely used before the USG funding pause was announced in 2014. C3a and C3b describe work using pseudovirus assays, which would not have been considered GoF as they do not involve creating full replicating viruses.

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This is not GoF work. The humanized mouse experiments described in C3d refer to work with *wild type* viruses isolated from wild bats. Refer to the section stating: "We will passage isolated bat-CoVs in permissive cells twice…" This is a standard virological technique to create an inoculum to infect animals. In no portion of C3d do they describe any manipulation of isolated virus, therefore this does not describe any kind of gain-of-function studies, nor does it involve the creation of any recombinant DNA or viruses. Characterization of naturally occurring viruses was *explicitly excluded* from the GoF policy. Further, the USG P3CO Policy Guidance states that "Wild-type pathogens that are circulating in or have been recovered from nature are not enhanced PPPs, regardless of their pandemic potential."

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These are not the results of GoF experiments. The figure you reference (Fig 35) shows weight loss and lung viral titers of chimeric viruses with bat CoV (wild type WIV-1, SHC014, WIV16, and 4231) spike proteins expressed on the WIV-1 backbone. Weight loss and viral titers were comparable across all chimeras when compared to the wild type (Fig 35a, red series; Fig 35b small box pattern). There are no statistical differences reported, so the chimeric viruses have not gained any function/attribute they did not already exhibit.

Released by Chairman Rand Paul

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#26590074.1

Released by Chairman Rand Paul

From: "Bulls, Michelle G. (NIH/OD) [E]" <[redacted]@nih.gov>
To: "Lauer, Michael (NIH/OD) [E]" <[redacted]@nih.gov>
Cc: "Bulls, Michelle G. (NIH/OD) [E]" <[redacted]@nih.gov>, "Black, Jodi (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: FW: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Date: Thu, 10 Sep 2020 12:43:04 -0400
Importance: Normal

Hi Mike,

See way down below where OMA asks for information for the OIG and FBI regarding Eco Health Alliance. Emily referred them back to you, based on the nature of their questions. This is a sticky one—and from the beginning, NIAID were told to refer these detailed questions to you given the situation. Is it okay for us to provide her with a response to send that is accurate so that OMA does not have to translate? Or would you like for her to just respond and without context, that will be tricky for OMA and will cause more questions. Let me know…

Michelle

From: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Sent: Thursday, September 10, 2020 11:44 AM
To: Bulls, Michelle G. (NIH/OD) [E] [redacted]@nih.gov>; Dean, Diane (NIH/OD) [E] [redacted]@od31em1.od.nih.gov>
Subject: FW: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Good morning,

I wanted to alert you to this request. I referred them to Mike as we have discussed and just sent the following response to their latest inquiry and will let you know if I hear more.

Thanks,

Emily

From: Linde, Emily (NIH/NIAID) [E]
Sent: Thursday, September 10, 2020 11:40 AM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

For this award the most relevant and accurate source of information is Dr. Mike Lauer, Deputy Director for Extramural Research.

Thanks,

Emily

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Thursday, September 10, 2020 10:40 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>

Released by Chairman Rand Paul

Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Hi Emily,

These questions are specific to whether or not this particular NIAID grant was terminated early or ended as per a usual course of action. I'm not clear as to why I would need to go to the Deputy Director of NIH for OER for a response to a question on decisions and grant determinations made by NIAID.

OMA properly and routinely seeks and receives information from IC's on grants and grant activity in support of audits and investigations, in accordance with Manual Chapter 1754 and 1752, as we are responsible to fully coordinate responses to OIG/FBI/DOJ etc. to support ongoing investigations. I must ensure our response is from the most relevant and accurate source of information, and answered in a timely manner.

Is there a reason these inquiries are being directed outside of the IC?

Thanks for your help,
Ashley

From: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Sent: Wednesday, September 9, 2020 3:26 PM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

Questions for that nature on this award should be referred to Dr. Mike Lauer, Deputy Director for Extramural Research.

Thanks,

Emily

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Wednesday, September 9, 2020 3:15 PM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Good afternoon Emily,

I'm following-up on this inquiry – originally the questions circled around the scientific terms of the grant and Erik Stemmy provided the context to the FBI. In a recent discussion with HHS OIG and the FBI, they noted they received information that the below-grant with Ecohealth Alliance was "suspended" or "terminated". I've reviewed QVR and do not see an indication of that action other than the attached "Closeout of Award" email stating the end of the grant was 4/24/20 with a request for the FFR and FRPPR. Was this just a typical end of term closeout, or was it terminated early? If terminated/suspended, the OIG has the following questions:

1. What information did NIH/NIAID receive, and from whom, that noted a concern for continuing to fund this research?
2. What was the reasoning for NIAID ending the grant and/or collaboration with Ecohealth Alliance?

Released by Chairman Rand Paul

3. What was communicated to the PI (Dr. Daszak) and/or Ecohealth?

Please let me know if you're able to provide this information.

Thank you,
Ashley

Ashley M. Sanders, MPS
Supervisor, DPI Program Investigations
NIH, OMA, Division Program Integrity
6011 Executive Blvd.
Rockville, Maryland 20852
Office: [redacted]
Cell: [redacted]
[redacted]@nih.gov

From: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Thursday, May 21, 2020 5:50 PM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>; Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,
Since we'll only have a short time on Tuesday I thought it might be helpful to provide the agent my responses to the original questions. There may be some misunderstanding of gain-of-function experiments, so hopefully this will clarify some things or at least provide a framework for our discussion next week.

Thanks!
Erik

p.s. I've also pasted the response directly below in case there is an issue adding an attachment to an encrypted message.

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Sent: Thursday, May 21, 2020 3:04 PM
To: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>; Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Erik,

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If that time doesn't work for you, please let me know alternative times you have available.

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Hi Ashley,
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Erik

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
5601 Fishers Lane, Room 8E18
Bethesda, MD 20892-9825
Phone: [redacted]
Email: [redacted]@nih.gov

Released by Chairman Rand Paul

From: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Sent: Thursday, May 21, 2020 6:17 AM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

The Program Official for this grant, Dr. Stemmy, who is copied on this email, would be the most appropriate POC for these questions.

Regards,

Emily

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Wednesday, May 20, 2020 1:00 PM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
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Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Good afternoon,

We are following up on a time-sensitive request for information from the FBI. Please let us know if you are able to accommodate their request or if you can recommend a POC to address the concerns.

Thank you,
Ashley

From: Sanders, Ashley (NIH/OD) [E]
Sent: Wednesday, May 13, 2020 11:59 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Good afternoon Emily,

OMA/DPI received questions related to an FBI inquiry for the following NIAID grants: 1R01AI110964-01 through 2R01AI110964-06. The agent is requesting clarification on the details of the study, where certain aspects were performed, and whether seamless cloning techniques were used. I note you were the last official to sign off on 4/27/20.

Would you be able to provide a response to the below-captured questions and/or be available for a joint call with our office and the agent? If not, who would be the best SME on this matter? I'm sure you understand, since this is a sensitive matter, we need to maintain confidentiality and limit the touch-points within NIH. I'm happy to discuss further if you have any questions.

Thank you,
Ashley

Released by Chairman Rand Paul

Ashley M. Sanders, MPS
Senior Program Investigations Officer
NIH, OMA, Division Program Integrity
6011 Executive Blvd.
Rockville, Maryland 20852
Office: [redacted]
[redacted]@nih.gov

FBI Questions:

SF 424 AI110964-06 (received date 11/05/2018)
Both SF 424s seem to be describing "gain of function" experiments. On page 192 of SF 424 AI110964-06 (received date 11/05/2018) under P3CO Research, it indicates they are conducting gain of function of SARSr-CoV. Were they also conducting Seemless Cloining and Assembly? From a review of their experimental details, it looks as if they were generating recombinant DNA of the viruses using WIV1 as the backbone but I could not determine if they were using Seemless Cloning techniques. I could not determine exactly where they were conducting these gain of function experiments. I know UNC-Chapel Hill has done these but within the document, I could not determine where this was occurring. Do you know where this was occurring?
It then appears that the recombinant DNA of the virus was then injected into humanized mice. However, again I couldn't determine where this occurred or was to occur. On page 187 of the same SF 424 under **"Vertebrate Animals"** it indicates that work with vertebrate animals will be conducted at Wuhan University at the School of Medicine and UNC – CH. Then under **"Laboratory Mice"** it states that lab mice will be sourced commercially by Wuhan Center for Animal Experiment at Wuhan University and that humanized mice will be bread at University of Wuhan and UNC – CH. Furthermore, the mice will be inoculated with the virus. Under **"UNC Facilities where selected agents to be used"** it continues with all mouse studies at UNC-CH will be performed…." However, on page 200 of the same SF 424 there is a letter from UNC – CH stating "The work to be performed by UNC-CH does not include animal and/or human research subjects." I know that was a lot of information but where exactly was the experimentation of injecting the humanized mice with the recombinant DNA occurring?

SF 424 AI110964-01 (received date 06/05/2013)
In this SF 424 Aim 3 seems indicative of gain of function experimentation (**C3a** and **C3b**) although it does not use that exact term. On page 119 of AI110964-01 under "**C3d) Humanized mouse *in vivo* infection experiments"** it states that humanized mouse in vivo experiments in humanized mice was occurring at the Wuhan Institute of Virology. I did not see the location where these gain of function experiments were being done but if the injections were occurring at WIV then was the recombinant DNA also generated at WIV? Was Seemless Cloning also being done?

RPPR (AI110964-05)
Finally, in the RPPR (6/1/2017-5/31/2018) on page 28 under "**In Vivo Infection of Human ACE2 Expressing Mice with SARSr-Cov S Protein variants",** it appears to be showing the results from their gain of function experiments as described in the SF 424. This is more of less the same as the question above, but do you know where this occurred?

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From: "Lauer, Michael (NIH/OD) [E]" <[redacted]@nih.gov>
To: "Bulls, Michelle G. (NIH/OD) [E]" <[redacted]@nih.gov>
Cc: "Black, Jodi (NIH/OD) [E]" <[redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: Re: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Date: Fri, 11 Sep 2020 04:36:36 -0400
Importance: Normal

Thanks Michelle – I agree with your plan we should handle this. We might also want to include OGC / Anna Jacobs in our conversations with OMA.

Best, Mike

Note: This conversation is restricted, so you might not be able to cut or copy from it. See the information above the To line for more details. Also, while the conversation is restricted, the conversation owner can send the message to other people.

From: "Bulls, Michelle G. (NIH/OD) [E]" [redacted]@nih.gov>
Date: Thursday, September 10, 2020 at 12:43 PM
To: "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>
Cc: "Bulls, Michelle G. (NIH/OD) [E]" [redacted]@nih.gov>, "Black, Jodi (NIH/OD) [E]" [redacted]@nih.gov>
Subject: FW: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Mike,

See way down below where OMA asks for information for the OIG and FBI regarding Eco Health Alliance. Emily referred them back to you, based on the nature of their questions. This is a sticky one—and from the beginning, NIAID were told to refer these detailed questions to you given the situation. Is it okay for us to provide her with a response to send that is accurate so that OMA does not have to translate? Or would you like for her to just respond and without context, that will be tricky for OMA and will cause more questions. Let me know…

Michelle

From: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Sent: Thursday, September 10, 2020 11:44 AM
To: Bulls, Michelle G. (NIH/OD) [E] [redacted]@nih.gov>; Dean, Diane (NIH/OD) [E] [redacted]@od31em1.od.nih.gov>
Subject: FW: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Good morning,

I wanted to alert you to this request. I referred them to Mike as we have discussed and just sent the following response to their latest inquiry and will let you know if I hear more.

Thanks,

Emily

From: Linde, Emily (NIH/NIAID) [E]
Sent: Thursday, September 10, 2020 11:40 AM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>

Released by Chairman Rand Paul

Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

For this award the most relevant and accurate source of information is Dr. Mike Lauer, Deputy Director for Extramural Research.

Thanks,

Emily

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Thursday, September 10, 2020 10:40 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Hi Emily,

These questions are specific to whether or not this particular NIAID grant was terminated early or ended as per a usual course of action. I'm not clear as to why I would need to go to the Deputy Director of NIH for OER for a response to a question on decisions and grant determinations made by NIAID.

OMA properly and routinely seeks and receives information from IC's on grants and grant activity in support of audits and investigations, in accordance with Manual Chapter 1754 and 1752, as we are responsible to fully coordinate responses to OIG/FBI/DOJ etc. to support ongoing investigations. I must ensure our response is from the most relevant and accurate source of information, and answered in a timely manner.

Is there a reason these inquiries are being directed outside of the IC?

Thanks for your help,
Ashley

From: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Sent: Wednesday, September 9, 2020 3:26 PM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

Questions for that nature on this award should be referred to Dr. Mike Lauer, Deputy Director for Extramural Research.

Thanks,

Emily

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Wednesday, September 9, 2020 3:15 PM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>

Released by Chairman Rand Paul

Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Good afternoon Emily,

I'm following-up on this inquiry – originally the questions circled around the scientific terms of the grant and Erik Stemmy provided the context to the FBI. In a recent discussion with HHS OIG and the FBI, they noted they received information that the below-grant with Ecohealth Alliance was "suspended" or "terminated". I've reviewed QVR and do not see an indication of that action other than the attached "Closeout of Award" email stating the end of the grant was 4/24/20 with a request for the FFR and FRPPR. Was this just a typical end of term closeout, or was it terminated early? If terminated/suspended, the OIG has the following questions:

1. What information did NIH/NIAID receive, and from whom, that noted a concern for continuing to fund this research?
2. What was the reasoning for NIAID ending the grant and/or collaboration with Ecohealth Alliance?
3. What was communicated to the PI (Dr. Daszak) and/or Ecohealth?

Please let me know if you're able to provide this information.

Thank you,
Ashley

Ashley M. Sanders, MPS
Supervisor, DPI Program Investigations
NIH, OMA, Division Program Integrity
6011 Executive Blvd.
Rockville, Maryland 20852
Office: [redacted]
Cell: [redacted]
[redacted]@nih.gov

From: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Thursday, May 21, 2020 5:50 PM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>; Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,
Since we'll only have a short time on Tuesday I thought it might be helpful to provide the agent my responses to the original questions. There may be some misunderstanding of gain-of-function experiments, so hopefully this will clarify some things or at least provide a framework for our discussion next week.

Thanks!
Erik

p.s. I've also pasted the response directly below in case there is an issue adding an attachment to an encrypted message.

SF 424 AI110964-06 (received date 11/05/2018)
Both SF 424s seem to be describing "gain of function" experiments. On page 192 of SF 424 AI110964-06 (received date 11/05/2018) under P3CO Research, it indicates they are conducting gain of function of SARSr-CoV.

The funding pause on gain-of-function (GoF) experiments was in place from 2014-2017, and explicitly involved work reasonably anticipated to enhance the transmissibility or pathogenicity of influenza, MERS-CoV, or SARS-CoV. As such, that policy would not have applied to SARS-related coronaviruses (SARSr-CoV). The replacement policy, Potential Pandemic Pathogen Care and Oversight (P3CO), requires additional review and oversight of experiments that are anticipated to increase a potential pandemic pathogen's transmissibility or pathogenicity *in humans*. The viruses created under this award are chimeric bat viruses, which generally would not be anticipated to cause enhanced disease or transmission in people. When evaluating experiments for potential GoF or P3CO we determine the likelihood of altering one of these attributes compared to the wild-type or circulating viral strain.

Were they also conducting Seemless Cloining and Assembly? From a review of their experimental details, it looks as if they were generating recombinant DNA of the viruses using WIV1 as the backbone but I could not determine if they were using Seemless Cloning techniques.

I'm not aware of them using seamless cloning. Standard techniques for investigators in this field are to create cDNA molecular clones, which are then expressed in cull culture.

I could not determine exactly where they were conducting these gain of function experiments. I know UNC-Chapel Hill has done these but within the document, I could not determine where this was occurring. Do you know where this was occurring?

GoF experiments were not conducted as part of this award. While chimeric viruses were created via this award, they would not be considered GoF since the results did not confer attributes that were not already exhibited by the wild type versions of the viruses. For example, expressing the spike protein of SARS-CoV in the WIV-1 backbone did not increase the pathogenicity of WIV-1 beyond that of SARS-CoV. This award did not support work to manipulate CoV genomes or create chimeric viruses at Wuhan Institute of Virology; such work was performed at UNC-CH.

It then appears that the recombinant DNA of the virus was then injected into humanized mice. However, again I couldn't determine where this occurred or was to occur. On page 187 of the same SF 424 under **"Vertebrate Animals"** it indicates that work with vertebrate animals will be conducted at Wuhan University at the School of Medicine and UNC – CH. Then under **"Laboratory Mice"** it states that lab mice will be sourced commercially by Wuhan Center for Animal Experiment at Wuhan University and that humanized mice will be bread at University of Wuhan and UNC – CH. Furthermore, the mice will be inoculated with the virus.

Recombinant viral cDNA is not directly injected into humanized mice. Rather, these molecular clones are used to grow virus in culture to create an inoculum used in infectivity studies. Both WIV and UNC-CH performed studies with molecular clones, which included infecting mice with the resulting recombinant viruses.

Under **"UNC Facilities where selected agents to be used"** it continues with all mouse studies at UNC-CH will be performed…." However, on page 200 of the same SF 424 there is a letter from UNC – CH stating "The work to be performed by UNC-CH does not include animal and/or human research subjects." I know that was a lot of information but where exactly was the experimentation of injecting the humanized mice with the recombinant DNA occurring?

I believe this to be a typographical error on the part of UNC's business office. The application describes animal work at UNC. Budget justifications and the consortium agreement also include references to this work. I believe UNC mean to say that the work "… does not include human research subjects."

SF 424 AI110964-01 (received date 06/05/2013)
In this SF 424 Aim 3 seems indicative of gain of function experimentation (**C3a** and **C3b**) although it does not use that exact term.

The receipt date of this application was June of 2013, and the term "gain-of-function" was not widely used before the USG funding pause was announced in 2014. C3a and C3b describe work using pseudovirus assays, which would not have been considered GoF as they do not involve creating full replicating viruses.

Released by Chairman Rand Paul

On page 119 of AI110964-01 under "**C3d) Humanized mouse *in vivo* infection experiments"** it states that humanized mouse in vivo experiments in humanized mice was occurring at the Wuhan Institute of Virology. I did not see the location where these gain of function experiments were being done but if the injections were occurring at WIV then was the recombinant DNA also generated at WIV? Was Seemless Cloning also being done?

This is not GoF work. The humanized mouse experiments described in C3d refer to work with *wild type* viruses isolated from wild bats. Refer to the section stating: "We will passage isolated bat-CoVs in permissive cells twice…" This is a standard virological technique to create an inoculum to infect animals. In no portion of C3d do they describe any manipulation of isolated virus, therefore this does not describe any kind of gain-of-function studies, nor does it involve the creation of any recombinant DNA or viruses. Characterization of naturally occurring viruses was *explicitly excluded* from the GoF policy. Further, the USG P3CO Policy Guidance states that "Wild-type pathogens that are circulating in or have been recovered from nature are not enhanced PPPs, regardless of their pandemic potential."

RPPR (AI110964-05)
Finally, in the RPPR (6/1/2017-5/31/2018) on page 28 under "**In Vivo Infection of Human ACE2 Expressing Mice with SARSr-Cov S Protein variants",** it appears to be showing the results from their gain of function experiments as described in the SF 424. This is more of less the same as the question above, but do you know where this occurred?

These are not the results of GoF experiments. The figure you reference (Fig 35) shows weight loss and lung viral titers of chimeric viruses with bat CoV (wild type WIV-1, SHC014, WIV16, and 4231) spike proteins expressed on the WIV-1 backbone. Weight loss and viral titers were comparable across all chimeras when compared to the wild type (Fig 35a, red series; Fig 35b small box pattern). There are no statistical differences reported, so the chimeric viruses have not gained any function/attribute they did not already exhibit.

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Thursday, May 21, 2020 3:04 PM
To: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>; Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Erik,

Thank you for providing this information. We would like to set up a call with the agent as they may need additional context or have other questions. Would you be available next Tuesday around 11:30AM? I'll set up a conference line for us and send an invite.

If that time doesn't work for you, please let me know alternative times you have available.

Thank you,
Ashley

From: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Thursday, May 21, 2020 11:22 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>; Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,
I would be happy to answer questions related to this award. Would it be best if I just addressed the comments at the end of this email thread? I'll say generally that NIAID has an extensive review process for P3CO (and formerly for GoF) and that all of this work was formally evaluated by the respective committees and determined not to be gain-of-function, nor

Released by Chairman Rand Paul

subject to P3CO oversight. We also continually monitored the progress (until the award was terminated) for evidence of unexpected increases in viral replication.

Erik

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
5601 Fishers Lane, Room 8E18
Bethesda, MD 20892-9825
Phone: [redacted]
Email: [redacted]@nih.gov

From: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Sent: Thursday, May 21, 2020 6:17 AM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

The Program Official for this grant, Dr. Stemmy, who is copied on this email, would be the most appropriate POC for these questions.

Regards,

Emily

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Wednesday, May 20, 2020 1:00 PM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Good afternoon,

We are following up on a time-sensitive request for information from the FBI. Please let us know if you are able to accommodate their request or if you can recommend a POC to address the concerns.

Thank you,
Ashley

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Sent: Wednesday, May 13, 2020 11:59 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Released by Chairman Rand Paul

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Would you be able to provide a response to the below-captured questions and/or be available for a joint call with our office and the agent? If not, who would be the best SME on this matter? I'm sure you understand, since this is a sensitive matter, we need to maintain confidentiality and limit the touch-points within NIH. I'm happy to discuss further if you have any questions.

Thank you,
Ashley

Ashley M. Sanders, MPS
Senior Program Investigations Officer
NIH, OMA, Division Program Integrity
6011 Executive Blvd.
Rockville, Maryland 20852
Office: [redacted]
[redacted]@nih.gov

FBI Questions:

SF 424 AI110964-06 (received date 11/05/2018)
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RPPR (AI110964-05)
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in the SF 424. This is more of less the same as the question above, but do you know where this occurred?

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From: "Lauer, Michael (NIH/OD) [E]" <[redacted]@nih.gov>
To: "Sanders, Ashley (NIH/OD) [E]" <[redacted]@nih.gov>
Cc: "Shannon, Mike (NIH/OD) [E]" <[redacted]@nih.gov>, "Kearse, Deborah (NIH/OD) [E]" <[redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: Re: OIG/FBI Inquiry - NIAID 1-R01AI110964-01 - 2-R01AI110964-06
Date: Fri, 11 Sep 2020 16:21:38 -0400
Importance: Normal

Hi Ashley – I'd be happy to speak with you over the phone to tell you the story – an atypical one. I could ask Melanie to find a time for us to talk next week. Another option – and feel free to ignore – would be to speak this Sunday; I'd be happy to do that.

After we review the story, I can then send you relevant materials.

OGC (mainly Anna Jacobs) has been engaged and it might be appropriate to include her as well at some point.

Many thanks, Mike

Michael S Lauer, MD
NIH Deputy Director for Extramural Research
1 Center Drive, Building 1, Room 144
Bethesda, MD 20892
Phone: [redacted]
Email: [redacted]@nih.gov

Note: This conversation is restricted, so you might not be able to cut or copy from it. See the information above the To line for more details. Also, while the conversation is restricted, the conversation owner can send the message to other people.

From: "Sanders, Ashley (NIH/OD) [E]" [redacted]@nih.gov>
Date: Friday, September 11, 2020 at 4:00 PM
To: "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>
Cc: "Shannon, Mike (NIH/OD) [E]" [redacted]@nih.gov>, "Kearse, Deborah (NIH/OD) [E]" [redacted]@nih.gov>
Subject: OIG/FBI Inquiry - NIAID 1-R01AI110964-01 - 2-R01AI110964-06

Good afternoon Dr. Lauer,

We are following-up on an ongoing case related to the above-captioned grant with NIAID awarded to Ecohealth Alliance. OIG has now joined FBI on a broader-scope investigation and have asked for clarity on the closure/termination of this grant. Since this is a sensitive matter, they are concerned that any action or communication from NIH could affect their investigation and they requested internal-coordination to ensure confidentiality and to maintain the integrity of the case.

The questions are highlighted below in the original email to NIAID. I looked through RMARS and did not see anything related to this company or PI that would suggest OER has been active with this case; however, Ms. Linde noted any inquiry was to be directed to you. I hate to send such trivial questions to your attention, but since this is a time-sensitive request, I want to make sure we get the most accurate information from the best source.

Please let me know the best method for getting these questions answered.

Thank you,

Released by Chairman Rand Paul

Ashley

Ashley M. Sanders, MPS
Supervisor, DPI Program Investigations
NIH, OMA, Division Program Integrity
6011 Executive Blvd.
Rockville, Maryland 20852
Office: [redacted]
Cell: [redacted]
[redacted]@nih.gov

From: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Sent: Wednesday, September 9, 2020 3:26 PM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

Questions for that nature on this award should be referred to Dr. Mike Lauer, Deputy Director for Extramural Research.

Thanks,

Emily

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Wednesday, September 9, 2020 3:15 PM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Good afternoon Emily,

I'm following-up on this inquiry – originally the questions circled around the scientific terms of the grant and Erik Stemmy provided the context to the FBI. In a recent discussion with HHS OIG and the FBI, they noted they received information that the below-grant with Ecohealth Alliance was "suspended" or "terminated". I've reviewed QVR and do not see an indication of that action other than the attached "Closeout of Award" email stating the end of the grant was 4/24/20 with a request for the FFR and FRPPR. Was this just a typical end of term closeout, or was it terminated early? If terminated/suspended, the OIG has the following questions:

1. What information did NIH/NIAID receive, and from whom, that noted a concern for continuing to fund this research?
2. What was the reasoning for NIAID ending the grant and/or collaboration with Ecohealth Alliance?
3. What was communicated to the PI (Dr. Daszak) and/or Ecohealth?

Please let me know if you're able to provide this information.

Thank you,
Ashley

Ashley M. Sanders, MPS

Released by Chairman Rand Paul

Supervisor, DPI Program Investigations
NIH, OMA, Division Program Integrity
6011 Executive Blvd.
Rockville, Maryland 20852
Office: [redacted]
Cell: [redacted]
[redacted]@nih.gov

Released by Chairman Rand Paul

From: "Lauer, Michael (NIH/OD) [E]" <[redacted]@nih.gov>
To: "Bulls, Michelle G. (NIH/OD) [E]" <[redacted]@nih.gov>
Cc: "Black, Jodi (NIH/OD) [E]" <[redacted]@nih.gov>, "Lauer, Michael (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: Re: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Date: Sun, 13 Sep 2020 13:23:53 -0400
Importance: Normal

Thanks Michelle for the update and good to hear that NIAID backed up Emily.

I'll be talking with Ashley Sanders (OMA) from 8:30 AM to 9:00 to tell her the story behind the case.

Best, Mike

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From: "Bulls, Michelle G. (NIH/OD) [E]" [redacted]@nih.gov>
Date: Friday, September 11, 2020 at 9:23 AM
To: "Lauer, Michael (NIH/OD) [E]" [redacted]@nih.gov>
Cc: "Black, Jodi (NIH/OD) [E]" [redacted]@nih.gov>, "Bulls, Michelle G. (NIH/OD) [E]" [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Mike,
Just to provide you with an update on this one. Mike Shannon went to NIAIDs Deputy Director last evening to note that Emily was being "non-responsive" so the issue would be escalated. Emily said that as soon as the Deputy Director figured out which grant was involved, they knew that Emily had acted appropriately, and that OMA should be trusting her professional judgement. The Deputy Director is meeting with Mike Shannon today to discuss. You were not included in the emails from Mike Shannon at any point, not even as a FYI.

Really happy that NIAID leadership supported Emily—huge in this case. Just want you know what's going on in this space and the fact that Mike is meeting w/the Deputy Director today.

Thanks,
Michelle

From: Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
Sent: Friday, September 11, 2020 4:37 AM
To: Bulls, Michelle G. (NIH/OD) [E] [redacted]@nih.gov>
Cc: Black, Jodi (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
Subject: Re: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Thanks Michelle – I agree with your plan we should handle this. We might also want to include OGC / Anna Jacobs in our conversations with OMA.

Best, Mike

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Date: Thursday, September 10, 2020 at 12:43 PM
To: "Lauer, Michael (NIH/OD) [E]" <[redacted]@nih.gov>
Cc: "Bulls, Michelle G. (NIH/OD) [E]" <[redacted]@nih.gov>, "Black, Jodi (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: FW: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Mike,

See way down below where OMA asks for information for the OIG and FBI regarding Eco Health Alliance. Emily referred them back to you, based on the nature of their questions. This is a sticky one—and from the beginning, NIAID were told to refer these detailed questions to you given the situation. Is it okay for us to provide her with a response to send that is accurate so that OMA does not have to translate? Or would you like for her to just respond and without context, that will be tricky for OMA and will cause more questions. Let me know…

Michelle

From: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Sent: Thursday, September 10, 2020 11:44 AM
To: Bulls, Michelle G. (NIH/OD) [E] [redacted]@nih.gov>; Dean, Diane (NIH/OD) [E] [redacted]@od31em1.od.nih.gov>
Subject: FW: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Good morning,

I wanted to alert you to this request. I referred them to Mike as we have discussed and just sent the following response to their latest inquiry and will let you know if I hear more.

Thanks,

Emily

From: Linde, Emily (NIH/NIAID) [E]
Sent: Thursday, September 10, 2020 11:40 AM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

For this award the most relevant and accurate source of information is Dr. Mike Lauer, Deputy Director for Extramural Research.

Thanks,

Emily

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Thursday, September 10, 2020 10:40 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Released by Chairman Rand Paul

Hi Emily,

These questions are specific to whether or not this particular NIAID grant was terminated early or ended as per a usual course of action. I'm not clear as to why I would need to go to the Deputy Director of NIH for OER for a response to a question on decisions and grant determinations made by NIAID.

OMA properly and routinely seeks and receives information from IC's on grants and grant activity in support of audits and investigations, in accordance with Manual Chapter 1754 and 1752, as we are responsible to fully coordinate responses to OIG/FBI/DOJ etc. to support ongoing investigations. I must ensure our response is from the most relevant and accurate source of information, and answered in a timely manner.

Is there a reason these inquiries are being directed outside of the IC?

Thanks for your help,
Ashley

From: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Sent: Wednesday, September 9, 2020 3:26 PM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

Questions for that nature on this award should be referred to Dr. Mike Lauer, Deputy Director for Extramural Research.

Thanks,

Emily

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Wednesday, September 9, 2020 3:15 PM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

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Thank you,
Ashley

Ashley M. Sanders, MPS
Supervisor, DPI Program Investigations
NIH, OMA, Division Program Integrity
6011 Executive Blvd.
Rockville, Maryland 20852
Office: [redacted]
Cell: [redacted]
[redacted]@nih.gov

From: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Thursday, May 21, 2020 5:50 PM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>; Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,
Since we'll only have a short time on Tuesday I thought it might be helpful to provide the agent my responses to the original questions. There may be some misunderstanding of gain-of-function experiments, so hopefully this will clarify some things or at least provide a framework for our discussion next week.

Thanks!
Erik

p.s. I've also pasted the response directly below in case there is an issue adding an attachment to an encrypted message.

SF 424 AI110964-06 (received date 11/05/2018)
Both SF 424s seem to be describing "gain of function" experiments. On page 192 of SF 424 AI110964-06 (received date 11/05/2018) under P3CO Research, it indicates they are conducting gain of function of SARSr-CoV.

The funding pause on gain-of-function (GoF) experiments was in place from 2014-2017, and explicitly involved work reasonably anticipated to enhance the transmissibility or pathogenicity of influenza, MERS-CoV, or SARS-CoV. As such, that policy would not have applied to SARS-related coronaviruses (SARSr-CoV). The replacement policy, Potential Pandemic Pathogen Care and Oversight (P3CO), requires additional review and oversight of experiments that are anticipated to increase a potential pandemic pathogen's transmissibility or pathogenicity *in humans*. The viruses created under this award are chimeric bat viruses, which generally would not be anticipated to cause enhanced disease or transmission in people. When evaluating experiments for potential GoF or P3CO we determine the likelihood of altering one of these attributes compared to the wild-type or circulating viral strain.

Were they also conducting Seemless Cloining and Assembly? From a review of their experimental details, it looks as if they were generating recombinant DNA of the viruses using WIV1 as the backbone but I could not determine if they were using Seemless Cloning techniques.

I'm not aware of them using seamless cloning. Standard techniques for investigators in this field are to create cDNA molecular clones, which are then expressed in cull culture.

I could not determine exactly where they were conducting these gain of function experiments. I know UNC-Chapel Hill has done these but within the document, I could not determine where this was occurring. Do you know where this was occurring?

GoF experiments were not conducted as part of this award. While chimeric viruses were created via this award, they would not be considered GoF since the results did not confer attributes that were not already exhibited by the wild type versions of the viruses. For example, expressing the spike protein of SARS-CoV in the WIV-1 backbone did not increase the pathogenicity of WIV-1 beyond that of SARS-CoV. This award did not support work to manipulate CoV genomes or create chimeric viruses at Wuhan Institute of Virology; such work was performed at UNC-CH.

It then appears that the recombinant DNA of the virus was then injected into humanized mice. However, again I couldn't determine where this occurred or was to occur. On page 187 of the same SF 424 under **"Vertebrate Animals"** it indicates that work with vertebrate animals will be conducted at Wuhan University at the School of Medicine and UNC – CH. Then under **"Laboratory Mice"** it states that lab mice will be sourced commercially by Wuhan Center for Animal Experiment at Wuhan University and that humanized mice will be bread at University of Wuhan and UNC – CH. Furthermore, the mice will be inoculated with the virus.

Recombinant viral cDNA is not directly injected into humanized mice. Rather, these molecular clones are used to grow virus in culture to create an inoculum used in infectivity studies. Both WIV and UNC-CH performed studies with molecular clones, which included infecting mice with the resulting recombinant viruses.

Under **"UNC Facilities where selected agents to be used"** it continues with all mouse studies at UNC-CH will be performed…." However, on page 200 of the same SF 424 there is a letter from UNC – CH stating "The work to be performed by UNC-CH does not include animal and/or human research subjects." I know that was a lot of information but where exactly was the experimentation of injecting the humanized mice with the recombinant DNA occurring?

I believe this to be a typographical error on the part of UNC's business office. The application describes animal work at UNC. Budget justifications and the consortium agreement also include references to this work. I believe UNC mean to say that the work "… does not include human research subjects."

SF 424 AI110964-01 (received date 06/05/2013)
In this SF 424 Aim 3 seems indicative of gain of function experimentation (**C3a** and **C3b**) although it does not use that exact term.

The receipt date of this application was June of 2013, and the term "gain-of-function" was not widely used before the USG funding pause was announced in 2014. C3a and C3b describe work using pseudovirus assays, which would not have been considered GoF as they do not involve creating full replicating viruses.

On page 119 of AI110964-01 under "**C3d) Humanized mouse *in vivo* infection experiments"** it states that humanized mouse in vivo experiments in humanized mice was occurring at the Wuhan Institute of Virology. I did not see the location where these gain of function experiments were being done but if the injections were occurring at WIV then was the recombinant DNA also generated at WIV? Was Seemless Cloning also being done?

This is not GoF work. The humanized mouse experiments described in C3d refer to work with *wild type* viruses isolated from wild bats. Refer to the section stating: "We will passage isolated bat-CoVs in permissive cells twice…" This is a standard virological technique to create an inoculum to infect animals. In no portion of C3d do they describe any manipulation of isolated virus, therefore this does not describe any kind of gain-of-function studies, nor does it involve the creation of any recombinant DNA or viruses. Characterization of naturally occurring viruses was *explicitly excluded* from the GoF policy. Further, the USG P3CO Policy Guidance states that "Wild-type pathogens that are circulating in or have been recovered from nature are not enhanced PPPs, regardless of their pandemic potential."

RPPR (AI110964-05)
Finally, in the RPPR (6/1/2017-5/31/2018) on page 28 under "**In Vivo Infection of Human ACE2 Expressing Mice with SARSr-Cov S Protein variants",** it appears to be showing the results from their gain of function experiments as described in the SF 424. This is more of less the same as the question above, but do you know where this occurred?

Released by Chairman Rand Paul

These are not the results of GoF experiments. The figure you reference (Fig 35) shows weight loss and lung viral titers of chimeric viruses with bat CoV (wild type WIV-1, SHC014, WIV16, and 4231) spike proteins expressed on the WIV-1 backbone. Weight loss and viral titers were comparable across all chimeras when compared to the wild type (Fig 35a, red series; Fig 35b small box pattern). There are no statistical differences reported, so the chimeric viruses have not gained any function/attribute they did not already exhibit.

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Thursday, May 21, 2020 3:04 PM
To: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>; Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Erik,

Thank you for providing this information. We would like to set up a call with the agent as they may need additional context or have other questions. Would you be available next Tuesday around 11:30AM? I'll set up a conference line for us and send an invite.

If that time doesn't work for you, please let me know alternative times you have available.

Thank you,
Ashley

From: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Thursday, May 21, 2020 11:22 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>; Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,
I would be happy to answer questions related to this award. Would it be best if I just addressed the comments at the end of this email thread? I'll say generally that NIAID has an extensive review process for P3CO (and formerly for GoF) and that all of this work was formally evaluated by the respective committees and determined not to be gain-of-function, nor subject to P3CO oversight. We also continually monitored the progress (until the award was terminated) for evidence of unexpected increases in viral replication.

Erik

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
5601 Fishers Lane, Room 8E18
Bethesda, MD 20892-9825
Phone: [redacted]
Email: [redacted]@nih.gov

From: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Sent: Thursday, May 21, 2020 6:17 AM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>

Released by Chairman Rand Paul

Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

The Program Official for this grant, Dr. Stemmy, who is copied on this email, would be the most appropriate POC for these questions.

Regards,

Emily

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Wednesday, May 20, 2020 1:00 PM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Good afternoon,

We are following up on a time-sensitive request for information from the FBI. Please let us know if you are able to accommodate their request or if you can recommend a POC to address the concerns.

Thank you,
Ashley

From: Sanders, Ashley (NIH/OD) [E]
Sent: Wednesday, May 13, 2020 11:59 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Good afternoon Emily,

OMA/DPI received questions related to an FBI inquiry for the following NIAID grants: 1R01AI110964-01 through 2R01AI110964-06. The agent is requesting clarification on the details of the study, where certain aspects were performed, and whether seamless cloning techniques were used. I note you were the last official to sign off on 4/27/20.

Would you be able to provide a response to the below-captured questions and/or be available for a joint call with our office and the agent? If not, who would be the best SME on this matter? I'm sure you understand, since this is a sensitive matter, we need to maintain confidentiality and limit the touch-points within NIH. I'm happy to discuss further if you have any questions.

Thank you,
Ashley

Ashley M. Sanders, MPS
Senior Program Investigations Officer
NIH, OMA, Division Program Integrity
6011 Executive Blvd.

Released by Chairman Rand Paul

Rockville, Maryland 20852
Office: [redacted]
[redacted]@nih.gov

FBI Questions:

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To: "Lauer, Michael (NIH/OD) [E]" <[redacted]@nih.gov>
Cc: "Black, Jodi (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Date: Mon, 14 Sep 2020 16:42:00 -0400
Importance: Normal

Perfect! Thanks so much, Mike.

From: Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
Sent: Sunday, September 13, 2020 1:24 PM
To: Bulls, Michelle G. (NIH/OD) [E] [redacted]@nih.gov>
Cc: Black, Jodi (NIH/OD) [E] [redacted]@nih.gov>; Lauer, Michael (NIH/OD) [E] [redacted]@nih.gov>
Subject: Re: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

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I'll be talking with Ashley Sanders (OMA) from 8:30 AM to 9:00 to tell her the story behind the case.

Best, Mike

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Really happy that NIAID leadership supported Emily—huge in this case. Just want you know what's going on in this space and the fact that Mike is meeting w/the Deputy Director today.

Thanks,
Michelle

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Best, Mike

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To: "Lauer, Michael (NIH/OD) [E]" <[redacted]@nih.gov>
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Subject: FW: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

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Subject: FW: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Good morning,

I wanted to alert you to this request. I referred them to Mike as we have discussed and just sent the following response to their latest inquiry and will let you know if I hear more.

Thanks,

Emily

From: Linde, Emily (NIH/NIAID) [E]
Sent: Thursday, September 10, 2020 11:40 AM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

For this award the most relevant and accurate source of information is Dr. Mike Lauer, Deputy Director for Extramural Research.

Thanks,

Emily

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From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Thursday, September 10, 2020 10:40 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Hi Emily,

These questions are specific to whether or not this particular NIAID grant was terminated early or ended as per a usual course of action. I'm not clear as to why I would need to go to the Deputy Director of NIH for OER for a response to a question on decisions and grant determinations made by NIAID.

OMA properly and routinely seeks and receives information from IC's on grants and grant activity in support of audits and investigations, in accordance with Manual Chapter 1754 and 1752, as we are responsible to fully coordinate responses to OIG/FBI/DOJ etc. to support ongoing investigations. I must ensure our response is from the most relevant and accurate source of information, and answered in a timely manner.

Is there a reason these inquiries are being directed outside of the IC?

Thanks for your help,
Ashley

From: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Sent: Wednesday, September 9, 2020 3:26 PM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

Questions for that nature on this award should be referred to Dr. Mike Lauer, Deputy Director for Extramural Research.

Thanks,

Emily

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Wednesday, September 9, 2020 3:15 PM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Kearse, Deborah (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Good afternoon Emily,

I'm following-up on this inquiry – originally the questions circled around the scientific terms of the grant and Erik Stemmy provided the context to the FBI. In a recent discussion with HHS OIG and the FBI, they noted they received information that the below-grant with Ecohealth Alliance was "suspended" or "terminated". I've reviewed QVR and do not see an indication of that action other than the attached "Closeout of Award" email stating the end of the grant was 4/24/20 with a request for the FFR and FRPPR. Was this just a typical end of term closeout, or was it terminated early? If terminated/suspended, the OIG has the following questions:

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1. What information did NIH/NIAID receive, and from whom, that noted a concern for continuing to fund this research?
2. What was the reasoning for NIAID ending the grant and/or collaboration with Ecohealth Alliance?
3. What was communicated to the PI (Dr. Daszak) and/or Ecohealth?

Please let me know if you're able to provide this information.

Thank you,
Ashley

Ashley M. Sanders, MPS
Supervisor, DPI Program Investigations
NIH, OMA, Division Program Integrity
6011 Executive Blvd.
Rockville, Maryland 20852
Office: [redacted]
Cell: [redacted]
[redacted]@nih.gov

From: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Thursday, May 21, 2020 5:50 PM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>; Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,
Since we'll only have a short time on Tuesday I thought it might be helpful to provide the agent my responses to the original questions. There may be some misunderstanding of gain-of-function experiments, so hopefully this will clarify some things or at least provide a framework for our discussion next week.

Thanks!
Erik

p.s. I've also pasted the response directly below in case there is an issue adding an attachment to an encrypted message.

SF 424 AI110964-06 (received date 11/05/2018)
Both SF 424s seem to be describing "gain of function" experiments. On page 192 of SF 424 AI110964-06 (received date 11/05/2018) under P3CO Research, it indicates they are conducting gain of function of SARSr-CoV.

The funding pause on gain-of-function (GoF) experiments was in place from 2014-2017, and explicitly involved work reasonably anticipated to enhance the transmissibility or pathogenicity of influenza, MERS-CoV, or SARS-CoV. As such, that policy would not have applied to SARS-related coronaviruses (SARSr-CoV). The replacement policy, Potential Pandemic Pathogen Care and Oversight (P3CO), requires additional review and oversight of experiments that are anticipated to increase a potential pandemic pathogen's transmissibility or pathogenicity *in humans*. The viruses created under this award are chimeric bat viruses, which generally would not be anticipated to cause enhanced disease or transmission in people. When evaluating experiments for potential GoF or P3CO we determine the likelihood of altering one of these attributes compared to the wild-type or circulating viral strain.

Were they also conducting Seemless Cloining and Assembly? From a review of their experimental details, it looks as if they were generating recombinant DNA of the viruses using WIV1 as the backbone but I could not determine if they were

using Seemless Cloning techniques.

I'm not aware of them using seamless cloning. Standard techniques for investigators in this field are to create cDNA molecular clones, which are then expressed in cull culture.

I could not determine exactly where they were conducting these gain of function experiments. I know UNC-Chapel Hill has done these but within the document, I could not determine where this was occurring. Do you know where this was occurring?

GoF experiments were not conducted as part of this award. While chimeric viruses were created via this award, they would not be considered GoF since the results did not confer attributes that were not already exhibited by the wild type versions of the viruses. For example, expressing the spike protein of SARS-CoV in the WIV-1 backbone did not increase the pathogenicity of WIV-1 beyond that of SARS-CoV. This award did not support work to manipulate CoV genomes or create chimeric viruses at Wuhan Institute of Virology; such work was performed at UNC-CH.

It then appears that the recombinant DNA of the virus was then injected into humanized mice. However, again I couldn't determine where this occurred or was to occur. On page 187 of the same SF 424 under **"Vertebrate Animals"** it indicates that work with vertebrate animals will be conducted at Wuhan University at the School of Medicine and UNC – CH. Then under **"Laboratory Mice"** it states that lab mice will be sourced commercially by Wuhan Center for Animal Experiment at Wuhan University and that humanized mice will be bread at University of Wuhan and UNC – CH. Furthermore, the mice will be inoculated with the virus.

Recombinant viral cDNA is not directly injected into humanized mice. Rather, these molecular clones are used to grow virus in culture to create an inoculum used in infectivity studies. Both WIV and UNC-CH performed studies with molecular clones, which included infecting mice with the resulting recombinant viruses.

Under **"UNC Facilities where selected agents to be used"** it continues with all mouse studies at UNC-CH will be performed…." However, on page 200 of the same SF 424 there is a letter from UNC – CH stating "The work to be performed by UNC-CH does not include animal and/or human research subjects." I know that was a lot of information but where exactly was the experimentation of injecting the humanized mice with the recombinant DNA occurring?

I believe this to be a typographical error on the part of UNC's business office. The application describes animal work at UNC. Budget justifications and the consortium agreement also include references to this work. I believe UNC mean to say that the work "… does not include human research subjects."

SF 424 AI110964-01 (received date 06/05/2013)
In this SF 424 Aim 3 seems indicative of gain of function experimentation (**C3a** and **C3b**) although it does not use that exact term.

The receipt date of this application was June of 2013, and the term "gain-of-function" was not widely used before the USG funding pause was announced in 2014. C3a and C3b describe work using pseudovirus assays, which would not have been considered GoF as they do not involve creating full replicating viruses.

On page 119 of AI110964-01 under "**C3d) Humanized mouse *in vivo* infection experiments"** it states that humanized mouse in vivo experiments in humanized mice was occurring at the Wuhan Institute of Virology. I did not see the location where these gain of function experiments were being done but if the injections were occurring at WIV then was the recombinant DNA also generated at WIV? Was Seemless Cloning also being done?

This is not GoF work. The humanized mouse experiments described in C3d refer to work with *wild type* viruses isolated from wild bats. Refer to the section stating: "We will passage isolated bat-CoVs in permissive cells twice…" This is a standard virological technique to create an inoculum to infect animals. In no portion of C3d do they describe any manipulation of isolated virus, therefore this does not describe any kind of gain-of-function studies, nor does it involve the creation of any recombinant DNA or viruses. Characterization of naturally occurring viruses was *explicitly excluded*

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from the GoF policy. Further, the USG P3CO Policy Guidance states that "Wild-type pathogens that are circulating in or have been recovered from nature are not enhanced PPPs, regardless of their pandemic potential."

RPPR (AI110964-05)
Finally, in the RPPR (6/1/2017-5/31/2018) on page 28 under "**In Vivo Infection of Human ACE2 Expressing Mice with SARSr-Cov S Protein variants",** it appears to be showing the results from their gain of function experiments as described in the SF 424. This is more of less the same as the question above, but do you know where this occurred?

These are not the results of GoF experiments. The figure you reference (Fig 35) shows weight loss and lung viral titers of chimeric viruses with bat CoV (wild type WIV-1, SHC014, WIV16, and 4231) spike proteins expressed on the WIV-1 backbone. Weight loss and viral titers were comparable across all chimeras when compared to the wild type (Fig 35a, red series; Fig 35b small box pattern). There are no statistical differences reported, so the chimeric viruses have not gained any function/attribute they did not already exhibit.

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Thursday, May 21, 2020 3:04 PM
To: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>; Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Erik,

Thank you for providing this information. We would like to set up a call with the agent as they may need additional context or have other questions. Would you be available next Tuesday around 11:30AM? I'll set up a conference line for us and send an invite.

If that time doesn't work for you, please let me know alternative times you have available.

Thank you,
Ashley

From: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Thursday, May 21, 2020 11:22 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>; Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,
I would be happy to answer questions related to this award. Would it be best if I just addressed the comments at the end of this email thread? I'll say generally that NIAID has an extensive review process for P3CO (and formerly for GoF) and that all of this work was formally evaluated by the respective committees and determined not to be gain-of-function, nor subject to P3CO oversight. We also continually monitored the progress (until the award was terminated) for evidence of unexpected increases in viral replication.

Erik

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
5601 Fishers Lane, Room 8E18
Bethesda, MD 20892-9825

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Phone: [redacted]
Email: [redacted]@nih.gov

From: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Sent: Thursday, May 21, 2020 6:17 AM
To: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>; Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06

Hi Ashley,

The Program Official for this grant, Dr. Stemmy, who is copied on this email, would be the most appropriate POC for these questions.

Regards,

Emily

From: Sanders, Ashley (NIH/OD) [E] [redacted]@nih.gov>
Sent: Wednesday, May 20, 2020 1:00 PM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: RE: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Good afternoon,

We are following up on a time-sensitive request for information from the FBI. Please let us know if you are able to accommodate their request or if you can recommend a POC to address the concerns.

Thank you,
Ashley

From: Sanders, Ashley (NIH/OD) [E]
Sent: Wednesday, May 13, 2020 11:59 AM
To: Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: Shannon, Mike (NIH/OD) [E] [redacted]@nih.gov>
Subject: Grant Questions - FBI Inquiry - 1-R01AI110964-01 - 2-R01AI110964-06
Importance: High

Good afternoon Emily,

OMA/DPI received questions related to an FBI inquiry for the following NIAID grants: 1R01AI110964-01 through 2R01AI110964-06. The agent is requesting clarification on the details of the study, where certain aspects were performed, and whether seamless cloning techniques were used. I note you were the last official to sign off on 4/27/20.

Would you be able to provide a response to the below-captured questions and/or be available for a joint call with our office and the agent? If not, who would be the best SME on this matter? I'm sure you understand, since this is a sensitive matter, we need to maintain confidentiality and limit the touch-points within NIH. I'm happy to discuss further if you have any questions.

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Thank you,
Ashley

Ashley M. Sanders, MPS
Senior Program Investigations Officer
NIH, OMA, Division Program Integrity
6011 Executive Blvd.
Rockville, Maryland 20852
Office: [redacted]
[redacted]@nih.gov

FBI Questions:

SF 424 AI110964-06 (received date 11/05/2018)
Both SF 424s seem to be describing "gain of function" experiments. On page 192 of SF 424 AI110964-06 (received date 11/05/2018) under P3CO Research, it indicates they are conducting gain of function of SARSr-CoV. Were they also conducting Seemless Cloining and Assembly? From a review of their experimental details, it looks as if they were generating recombinant DNA of the viruses using WIV1 as the backbone but I could not determine if they were using Seemless Cloning techniques. I could not determine exactly where they were conducting these gain of function experiments. I know UNC-Chapel Hill has done these but within the document, I could not determine where this was occurring. Do you know where this was occurring?
It then appears that the recombinant DNA of the virus was then injected into humanized mice. However, again I couldn't determine where this occurred or was to occur. On page 187 of the same SF 424 under **"Vertebrate Animals"** it indicates that work with vertebrate animals will be conducted at Wuhan University at the School of Medicine and UNC – CH. Then under **"Laboratory Mice"** it states that lab mice will be sourced commercially by Wuhan Center for Animal Experiment at Wuhan University and that humanized mice will be bread at University of Wuhan and UNC – CH. Furthermore, the mice will be inoculated with the virus. Under **"UNC Facilities where selected agents to be used"** it continues with all mouse studies at UNC-CH will be performed…." However, on page 200 of the same SF 424 there is a letter from UNC – CH stating "The work to be performed by UNC-CH does not include animal and/or human research subjects." I know that was a lot of information but where exactly was the experimentation of injecting the humanized mice with the recombinant DNA occurring?

SF 424 AI110964-01 (received date 06/05/2013)
In this SF 424 Aim 3 seems indicative of gain of function experimentation (**C3a** and **C3b**) although it does not use that exact term. On page 119 of AI110964-01 under "**C3d) Humanized mouse *in vivo* infection experiments"** it states that humanized mouse in vivo experiments in humanized mice was occurring at the Wuhan Institute of Virology. I did not see the location where these gain of function experiments were being done but if the injections were occurring at WIV then was the recombinant DNA also generated at WIV? Was Seemless Cloning also being done?

RPPR (AI110964-05)
Finally, in the RPPR (6/1/2017-5/31/2018) on page 28 under "**In Vivo Infection of Human ACE2 Expressing Mice with SARSr-Cov S Protein variants",** it appears to be showing the results from their gain of function experiments as described in the SF 424. This is more of less the same as the question above, but do you know where this occurred?

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From: 胡犇 <[redacted]@wh.iov.cn>
Sent: Sunday, April 05, 2020 6:30 AM EDT
To: Alice Latinne <[redacted]@ecohealthalliance.org>
CC: Hongying Li <[redacted]@ecohealthalliance.org>; 石正丽 <[redacted]@wh.iov.cn>; Peter Daszak <[redacted]@ecohealthalliance.org>
Subject: Re: Re: Re: Re: China Maps used in the manuscript

Oh I see. It is named 4991 when submitted earlier as a partial sequence. We renamed it as RaTG13 when we publish as a full-length sequence.

So it would be OK. Only the deletion of "we" in the sentence will be enough.

Best

-----原始邮件-----
发件人:"Alice Latinne" <[redacted]@ecohealthalliance.org>
发送时间:2020-04-05 18:01:25 (星期日)
收件人: "胡犇" <[redacted]@wh.iov.cn>
抄送: "Hongying Li" <[redacted]@ecohealthalliance.org>, "石正丽" <[redacted]@wh.iov.cn>, "Peter Daszak" <[redacted]@ecohealthalliance.org>
主题: Re: Re: Re: China Maps used in the manuscript

Hi Ben,

1) RaTG13 is not included in the Figure 3. The closest sequence is a sequence from GenBank (KP876546) and published in 2016 in a paper from your lab:

Ge X-Y, Wang N, Zhang W, Hu B, Li B, Zhang Y-Z, Zhou J-H, Luo C-M, Yang X-L, Wu L-J, et al. (Ge2016 co-authors). 2016. Coexistence of multiple coronaviruses in several bat colonies in an abandoned mineshaft. Virologica Sinica 31:31-40.

This sequence is 100% identical to RaTG13, is it the same sample?

I'll delete the word "we" in the sentence.

2) I'll check and correct this as needed.

Cheers,
Alice

On Sun, Apr 5, 2020 at 4:24 PM 胡犇 <[redacted]@wh.iov.cn> wrote:

> Hi Alice,
>
> Thanks for the supplementary material.
>
> Now I have two more concerns regarding the manuscript:
>
> 1) In lines 48-49 in the PDF, you mentioned that "this emerging human virus is closely related to SARS-CoV, and also appears to have originated in horseshoe bats -- with its full genome 96% similar to a virus we discovered in Rhinolophus affinis".
> Here this virus refers to RaTG13. Could you please delete the word "we" in this sentence? Otherwise, some readers may think that RaTG13 was detected in our joint study (e.x.PREDICT) and we shared the sequence with EHA earlier. This may be used by some conspiracy theorists to make rumors.
>
> Actually, the sequence of RaTG13 was not included in the dataset I provided to you. It was not deposited into Genbank until this January. So I think it was not included in your dataset, and you used this sequence during the revision phase after COVID-19 outbreak.

[redacted]

Though not labeled clearly, RaTG13 is also shown in the phylogenetic tree in Figure 3 (the one most closely related to 2019-nCoV from Rhinolophus affinis in Yunnan). So could you please revise the figure legend of figure 3 as: Maximum clade credibility tree including 201 RdRp sequences from the *Sarbecovirus* lineage isolated in bats, including RaTG13 (Genbank accession numbers: MN996532) and two sequences of 2019-nCoV isolated in humans (GenBank accession numbers:MN908947 and MN975262).

This will mean that in your analysis you downloaded the sequence from public database, but it was not included in the original dataset of bat CoVs that I provided to you.

2) In lines 89-91 in the PDF. It says "Our geographic datasets included 694 α-CoV sequences from six zoogeographic regions (22 provinces) and 519 β-CoV sequences from five zoogeographic regions (21 provinces) .

The dataset contains some sequences detected from bats in Laos. Are the lao bat CoV sequences also counted in the 694 and 519 sequences? They are not from any Chinese province. If so,the numbers here needs to be corrected.

Besides, CAS now requires authors from CAS institutes to deposit coronavirus sequences not only in Genbank but also in the public database of China National Center for Bioinformation when we publish our researches. So I will submit the sequences which I submited to Genbank last year to the Chinese database next week.

If you have any questions please let me know.

Best

Ben

> -----原始邮件-----
> 发件人:"Alice Latinne" <[redacted]@ecohealthalliance.org>
> 发送时间:2020-04-04 22:26:44 (星期六)
> 收件人: "胡犇" <[redacted]@wh.iov.cn>
> 抄送: "Hongying Li" <[redacted]@ecohealthalliance.org>
> 主题: Re: Re: China Maps used in the manuscript
>
> Hi Ben,
>
> The supplementary material including Table S1 is attached. And yes it includes all the GenBank numbers you gave me (for the sequences you deposited in genbank by yourself) and all sequences already in GenBank from other studies. Please note that at this stage, I won't be able to modify the dataset, the analysis or the figures.
>
> Cheers,
> Alice
>
> On Wed, Apr 1, 2020 at 8:07 PM 胡犇 <[redacted]@wh.iov.cn> wrote:
>
> > Hi Alice,
> >
> > Can you please send me the Table S1 which shows the accession number of all sequences in the dataset used in the analysis? It includes both the sequences I share with you and the sequences you download from Genbank, right?
> >
> > Thank you!
> >
> > Ben
> >
> > > -----原始邮件-----
> > > 发件人:"Alice Latinne" <[redacted]@ecohealthalliance.org>
> > > 发送时间:2020-03-30 17:43:57 (星期一)
> > > 收件人: "胡犇" <[redacted]@wh.iov.cn>
> > > 抄送: "Hongying Li" <[redacted]@ecohealthalliance.org>
> > > 主题: Re: Re: Re: Re: Re: China Maps used in the manuscript

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Great! :)

On Mon, Mar 30, 2020 at 4:43 PM 胡犇 <[redacted]@wh.iov.cn> wrote:

> Absolutely OK. Thanks a lot, Alice!
>
> -----原始邮件-----
> **发件人:**"Alice Latinne" <[redacted]@ecohealthalliance.org>
> **发送时间:**2020-03-30 17:38:25 (星期一)
> **收件人:** "胡犇" <[redacted]@wh.iov.cn>
> **抄送:** "Hongying Li" [redacted]@ecohealthalliance.org>
> **主题:** Re: Re: Re: Re: China Maps used in the manuscript
>
> Hello,
>
> Here is the updated figure. I hope this is ok!
>
> Thanks,
> Alice
>
> On Sun, Mar 29, 2020 at 11:55 AM Alice Latinne <[redacted]@ecohealthalliance.org> wrote:
> > Hi all,
> >
> > I think using the new map from Hongying is too much work but I'll try. If not, I'll put two small China South Sea map on the figure
> >
> > On Sun, Mar 29, 2020 at 8:00 AM 胡犇 <[redacted]@wh.iov.cn> wrote:
> >
> > > Hi both!
> > >
> > > I think the map format that Hong Ying provided is even better. Thanks!
> > >
> > > -----原始邮件-----
> > > **发件人:**"Hongying Li" <[redacted]@ecohealthalliance.org>
> > > **发送时间:**2020-03-28 23:03:46 (星期六)
> > > **收件人:** "胡犇" <[redacted]@wh.iov.cn>
> > > **抄送:** "Alice Latinne" <[redacted]@ecohealthalliance.org>
> > > **主题:** Re: Re: Re: China Maps used in the manuscript
> > >
> > > Hi Both!
> > >
> > > I think either the South China Sea label can be smaller so it can fit into Figure 6 in two maps; Or the attached format of the South China Sea can be considered, which will fit better into Figure 6 I guess, but requires some more editing. But I defer to whatever you decide.
> > >
> > > Hongying
> > >
> > > On Sat, Mar 28, 2020 at 9:16 AM 胡犇 <[redacted]@wh.iov.cn> wrote:
> > >
> > > > Yes I would like to suggest that it appears twice in both figure A and B. But it seems that the space is limited and the layout need to be adjusted?
> > > >
> > > > What do you think, Hongying?
> > > >
> > > > -----原始邮件-----
> > > > **发件人:**"Alice Latinne" <[redacted]@ecohealthalliance.org>
> > > > **发送时间:**2020-03-28 17:30:57 (星期六)
> > > > **收件人:** "胡犇" <[redacted]@wh.iov.cn>
> > > > **抄送:** "Hongying Li" <[redacted]@ecohealthalliance.org>, "博士石正丽" <[redacted]@wh.iov.cn>, "Peter Daszak"

[redacted]

Released by Chairman Rand Paul

<[redacted]@ecohealthalliance.org>
主题: Re: Re: China Maps used in the manuscript

Hi Ben,

Is the new Figure 6 ok? Or do I have to put the South China Sea 2 times?

Thanks,
Alice

On Sat, Mar 28, 2020 at 3:32 PM 胡犇 <[redacted]@wh.iov.cn> wrote:

> Thanks a lot Alice. The maps now seems perfect.
>
> Please note that the two maps in Figure 6 also need to be modified (that could be easier I think, as only South China Sea need to be added)
>
> Best wishes
>
> Ben
>
> -----原始邮件-----
> 发件人:"Alice Latinne" <[redacted]@ecohealthalliance.org>
> 发送时间:2020-03-24 22:08:46 (星期二)
> 收件人: "Hongying Li" <[redacted]@ecohealthalliance.org>
> 抄送: "胡犇" <[redacted]@wh.iov.cn>, "博士石正丽" <[redacted]@wh.iov.cn>, "Peter Daszak" <[redacted]@ecohealthalliance.org>
> 主题: Re: China Maps used in the manuscript
>
> Hi Hongying and Ben,
>
> Yes I can edit this map as needed, thank you!! I'll work on this when I have time.
>
> The revised and submitted version of the paper is attached. Let me know if there is anything else that is problematic (hopefully not too much!).
>
> Thanks,
> Alice
>
> On Mon, Mar 23, 2020 at 9:59 PM Hongying Li <li@ecohealthalliance.org> wrote:
>> Hi Alice,
>>
>> Does the attached editable PPT work for you? I colored Shanghai and Xizang in red, and copied pasted south China sea from Ben's template.
>>
>> Hongying
>>
>> On Mon, Mar 23, 2020 at 10:35 AM Alice Latinne <[redacted]@ecohealthalliance.org> wrote:
>>> Hi Ben,
>>>
>>> I totally understand your concerns and will correct these issues. Could you send me a correct map in **pdf format**? This would be really helpful. I really need a pdf where I can change the colour of each province. I can't do it with the pptx you sent me.
>>>
>>> I hope life in Wuhan is getting easier these days!
>>>
>>> Best wishes,
>>> Alice
>>>
>>> On Sun, Mar 22, 2020 at 9:50 PM 胡犇 <[redacted]@wh.iov.cn> wrote:
>>>> Dear Alice,
>>>>
>>>> How is going? I don't know where you are now but since almost every country is facing the threat of COVID-19, I hope everything is fine with you.
>>>>
>>>> I am happy to know that our paper on Chinese bat coronavirus is almost accepted. Thank you so much for the contribution to this joint work.

[redacted]

Today, when I re-checked the figures, I suddenly had a new concern about the paper. The problem is about the maps of China appearing in the figures. It is not a scientific issue, but we must be very careful about it, because in China some people are extremely strict about the territorial integrity and sovereignty shown in the map.

The problems I found include:

1) In figure 1, Shanghai is missing in the map. In the province of Tibet, the region called South Tibet (which is actually controlled by India) is not included.

2) In all three maps, South China Sea is not shown. For Chinese people, a complete map of China should clearly include the South China Sea with a focus on nine-dashed line (I attached a model in the PPT for you to know how it should look like).

I know it will take you some more time to correct the maps. but please understand this concern. If we don't correct the problems, people may judge that Zhengli, me and our Chinese colleagues are making political mistakes. We don't wish that the maps will become a target of attack from those people. You may know that at this every special and sensitive time when COVID-19 occurs, there are some rumors about the research cooperation on coronaviruses between our lab and the US. So we may have to be more careful than before.

After the maps are modified, please send them to me to have a look before they are finally submitted.

If you have any question, please contact me.

Thanks, and take care!

Ben

> -----原始邮件-----
> 发件人:"Alice Latinne" <[redacted]@ecohealthalliance.org>
> 发送时间:2019-10-08 00:08:10 (星期二)
> 收件人: "胡犇老师" <[redacted]@wh.iov.cn>, "朱光剑" <[redacted]@126.com>, zhanglb <[redacted]@gaibr.gd.cn>, "Carlos Zambrana-Torrelio" <[redacted]@ecohealthalliance.org>, "Kevin Olival, PhD" <[redacted]@ecohealthalliance.org>, "博士石正丽" <[redacted]@wh.iov.cn>, "Peter Daszak" <[redacted]@ecohealthalliance.org>, "李贝" <[redacted]@126.com>, "张玮" <[redacted]@wh.iov.cn>, "Hongying Li" <li@ecohealthalliance.org>, "Aleksei MacDurian" <[redacted]@ecohealthalliance.org>, "Hume Field" <[redacted]@ecohealthalliance.org>, "Jon Epstein" <[redacted]@ecohealthalliance.org>, "Wang Linfa" <[redacted]@duke-nus.edu.sg>
> 抄送:
> 主题: China bat CoV paper submitted
>
> Dear Co-authors,
>
> I just wanted to let you know that I submitted our China bat CoV paper to Nature Communications yesterday. Thank you for all your comments and edits on previous versions of the paper, that was very helpful.
>
> Attached is the submitted version. I'll keep you updated. Finger's crossed...
>
> Best regards,
> Alice
>
> --
> **Alice Latinne, PhD**
>
> *Research Scientist*
> *PREDICT-2 Country Liaison, Thailand and Indonesia*
>
> EcoHealth Alliance
> 460 West 34th Street – 17th floor
> New York, NY 10001
>
> [redacted] (direct)

Released by Chairman Rand Paul

[redacted] (mobile)
www.ecohealthalliance.org

EcoHealth Alliance leads cutting-edge scientific research into the critical connections between human and wildlife health and delicate ecosystems. With this science, we develop solutions that prevent pandemics and promote conservation.

--
Alice Latinne, PhD

Research Scientist

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

[redacted] (mobile)
www.ecohealthalliance.org

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Alice Latinne, PhD

Research Scientist

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New York, NY 10001

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Research Scientist

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--
Alice Latinne, PhD

Research Scientist

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

[redacted] (mobile)

[redacted]

Released by Chairman Rand Paul

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Research Scientist

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--

Alice Latinne, PhD

Research Scientist

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460 West 34th Street – 17th floor
New York, NY 10001

[redacted] (mobile)
www.ecohealthalliance.org

[redacted]

Released by Chairman Rand Paul

> *EcoHealth Alliance leads cutting-edge scientific research into the critical connections between human and wildlife health and delicate ecosystems. With this science, we develop solutions that prevent pandemics and promote conservation.*

Released by Chairman Rand Paul

From: 胡犇 <[redacted]@wh.iov.cn>
Sent: Friday, April 10, 2020 11:24 AM EDT
To: Alice Latinne <[redacted]@ecohealthalliance.org>
CC: Hongying Li <[redacted]@ecohealthalliance.org>; 石正丽 <[redacted]@wh.iov.cn>; Peter Daszak <[redacted]@ecohealthalliance.org>; Kevin Olival <[redacted]@ecohealthalliance.org>
Subject: Re: Re: Re: Re: China Maps used in the manuscript

Hi Alice!

Just one more concern about the text. In the final version, please correct this expression in the Author contributions: "BH, GZ, LZ, HL, AAC and ZS provided samples or data".

Please write "BH, GZ, LZ, HL, AAC and ZS collected samples or provided data" instead. Otherwise, people may twisted the meaning and say that "WIV provided Chinese bat samples to a US lab".

Thank you!

Ben

> -----原始邮件-----
> **发件人:**"Alice Latinne" <[redacted]@ecohealthalliance.org>
> **发送时间:**2020-04-09 21:29:57 (星期四)
> **收件人:** "胡犇" <[redacted]@wh.iov.cn>
> **抄送:** "Hongying Li" <[redacted]@ecohealthalliance.org>, "石正丽" <[redacted]@wh.iov.cn>, "Peter Daszak" <[redacted]@ecohealthalliance.org>, "Kevin Olival" <[redacted]@ecohealthalliance.org>
> **主题:** Re: Re: Re: China Maps used in the manuscript
>
> Hi Ben,
>
> Hope all is well. Nat Comms requires that all sequences are publicly available in GenBank before they can formally accept our paper. So could you ask GenBank to release all sequences (MN312240 to MN312869) on April 15? I'll submit the revised final version to Nat Comms on the 13 or 14th.
>
> Thank you!
> Alice
>
> On Sun, Apr 5, 2020 at 5:01 PM Alice Latinne <[redacted]@ecohealthalliance.org> wrote:
>> Hi Ben,
>>
>> 1) RaTG13 is not included in the Figure 3. The closest sequence is a sequence from GenBank (KP876546) and published in 2016 in a paper from your lab:
>>
>> Ge X-Y, Wang N, Zhang W, Hu B, Li B, Zhang Y-Z, Zhou J-H, Luo C-M, Yang X-L, Wu L-J, et al. (Ge2016 co-authors). 2016. Coexistence of multiple coronaviruses in several bat colonies in an abandoned mineshaft. Virologica Sinica 31:31-40.
>>
>> This sequence is 100% identical to RaTG13, is it the same sample?
>>
>> I'll delete the word "we" in the sentence.
>>
>> 2) I'll check and correct this as needed.
>>
>> Cheers,
>> Alice
>>
>> On Sun, Apr 5, 2020 at 4:24 PM 胡犇 <[redacted]@wh.iov.cn> wrote:
>>> Hi Alice,
>>>
>>> Thanks for the supplementary material.

[redacted]

Released by Chairman Rand Paul

Now I have two more concerns regarding the manuscript:

1) In lines 48-49 in the PDF, you mentioned that "this emerging human virus is closely related to SARS-CoV, and also appears to have originated in horseshoe bats -- with its full genome 96% similar to a virus we discovered in Rhinolophus affinis".

Here this virus refers to RaTG13. Could you please delete the word "we" in this sentence? Otherwise, some readers may think that RaTG13 was detected in our joint study (e.x.PREDICT) and we shared the sequence with EHA earlier. This may be used by some conspiracy theorists to make rumors.

Actually, the sequence of RaTG13 was not included in the dataset I provided to you. It was not deposited into Genbank until this January. So I think it was not included in your dataset, and you used this sequence during the revision phase after COVID-19 outbreak.

Though not labeled clearly, RaTG13 is also shown in the phylogenetic tree in Figure 3 (the one most closely related to 2019-nCoV from Rhinolophus affinis in Yunnan). So could you please revise the figure legend of figure 3 as:
Maximum clade credibility tree including 201 RdRp sequences from the*Sarbecovirus* lineage isolated in bats, including RaTG13 (Genbank accession numbers: MN996532) and two sequences of 2019-nCoV isolated in humans (GenBank accession numbers:MN908947 and MN975262).

This will mean that in your analysis you downloaded the sequence from public database, but it was not included in the original dataset of bat CoVs that I provided to you.

2) In lines 89-91 in the PDF. It says 'Our geographic datasets included 694 α-CoV sequences from six zoogeographic regions (22 provinces) and 519 β-CoV sequences from five zoogeographic regions (21 provinces).

The dataset contains some sequences detected from bats in Laos. Are the lao bat CoV sequences also counted in the 694 and 519 sequences? They are not from any Chinese province. If so,the numbers here needs to be corrected.

Besides, CAS now requires authors from CAS institutes to deposit coronavirus sequences not only in Genbank but also in the public database of China National Center for Bioinformation when we publish our researches. So I will submit the sequences which I submited to Genbank last year to the Chinese database next week.

If you have any questions please let me know.

Best

Ben

-----原始邮件-----
发件人:"Alice Latinne" <[redacted]@ecohealthalliance.org>
发送时间:2020-04-04 22:26:44 (星期六)
收件人: "胡犇" <[redacted]@wh.iov.cn>
抄送: "Hongying Li" <[redacted]@ecohealthalliance.org>
主题: Re: Re: China Maps used in the manuscript

Hi Ben,

The supplementary material including Table S1 is attached. And yes it includes all the GenBank numbers you gave me (for the sequences you deposited in genbank by yourself) and all sequences already in GenBank from other studies. Please note that at this stage, I won't be able to modify the dataset, the analysis or the figures.

Cheers,
Alice

On Wed, Apr 1, 2020 at 8:07 PM 胡犇 <[redacted]@wh.iov.cn> wrote:

[redacted]

Released by Chairman Rand Paul

From: 胡犇 <[redacted]@wh.iov.cn>
Sent: Monday, April 13, 2020 10:45 PM EDT
To: Alice Latinne <[redacted]@ecohealthalliance.org>
CC: Hongying Li <[redacted]@ecohealthalliance.org>; 石正丽 <[redacted]@wh.iov.cn>; Peter Daszak <[redacted]@ecohealthalliance.org>; Kevin Olival <olival@ecohealthalliance.org>
Subject: Re: Re: Re: Re: Re: China Maps used in the manuscript

Hi all,

I wrote to Genbank requesting the sequences be released on 15th April, but I have written another mail just now asking them to keep those sequences confidential until further notification.

Best

Ben

-----原始邮件-----
发件人:"Alice Latinne" <[redacted]@ecohealthalliance.org>
发送时间:2020-04-14 10:34:00 (星期二)
收件人: "胡犇" <[redacted]@wh.iov.cn>
抄送: "Hongying Li" <[redacted]@ecohealthalliance.org>, "石正丽" <z[redacted]@wh.iov.cn>, "Peter Daszak" <[redacted]@ecohealthalliance.org>, "Kevin Olival" <olival@ecohealthalliance.org>
主题: Re: Re: Re: Re: China Maps used in the manuscript

Hi Ben,

I don't know if you wrote to GenBank already or not but as we have to delay the publication of the paper, we CAN'T release the sequences tomorrow (April 15). Could you please ask GenBank to release the sequences at a later date? I hope this is not too late.

Thanks,
Alice

On Thu, Apr 9, 2020 at 9:37 PM 胡犇 <[redacted]@wh.iov.cn> wrote:

> No problem, Alice. I will write to them tomorrow.
>
> Cheers
>
> Ben
>
> -----原始邮件-----
> **发件人:**"Alice Latinne" <[redacted]@ecohealthalliance.org>
> **发送时间:**2020-04-09 21:29:57 (星期四)
> **收件人:** "胡犇" <[redacted]@wh.iov.cn>
> **抄送:** "Hongying Li" <li@ecohealthalliance.org>, "石正丽" <[redacted]@wh.iov.cn>, "Peter Daszak" <[redacted]@ecohealthalliance.org>, "Kevin Olival" <olival@ecohealthalliance.org>
> **主题:** Re: Re: Re: China Maps used in the manuscript
>
> Hi Ben,
>
> Hope all is well. Nat Comms requires that all sequences are publicly available in GenBank before they can formally accept our paper. So could you ask GenBank to release all sequences (MN312240 to MN312869) on April 15? I'll submit the revised final version to Nat Comms on the 13 or 14th.

[redacted]

Released by Chairman Rand Paul

Thank you!
Alice

On Sun, Apr 5, 2020 at 5:01 PM Alice Latinne <[redacted]@ecohealthalliance.org> wrote:

> Hi Ben,
>
> 1) RaTG13 is not included in the Figure 3. The closest sequence is a sequence from GenBank (KP876546) and published in 2016 in a paper from your lab:
>
> Ge X-Y, Wang N, Zhang W, Hu B, Li B, Zhang Y-Z, Zhou J-H, Luo C-M, Yang X-L, Wu L-J, et al. (Ge2016 co-authors). 2016. Coexistence of multiple coronaviruses in several bat colonies in an abandoned mineshaft. Virologica Sinica 31:31-40.
>
> This sequence is 100% identical to RaTG13, is it the same sample?
>
> I'll delete the word "we" in the sentence.
>
> 2) I'll check and correct this as needed.
>
> Cheers,
> Alice
>
> On Sun, Apr 5, 2020 at 4:24 PM 胡犇 <[redacted]@wh.iov.cn> wrote:
>
> > Hi Alice,
> >
> > Thanks for the supplementary material.
> >
> > Now I have two more concerns regarding the manuscript:
> >
> > 1) In lines 48-49 in the PDF, you mentioned that "this emerging human virus is closely related to SARS-CoV, and also appears to have originated in horseshoe bats -- with its full genome 96% similar to a virus we discovered in Rhinolophus affinis".
> > Here this virus refers to RaTG13. Could you please delete the word "we" in this sentence? Otherwise, some readers may think that RaTG13 was detected in our joint study (e.x.PREDICT) and we shared the sequence with EHA earlier. This may be used by some conspiracy theorists to make rumors.
> >
> > Actually, the sequence of RaTG13 was not included in the dataset I provided to you. It was not deposited into Genbank until this January. So I think it was not included in your dataset, and you used this sequence during the revision phase after COVID-19 outbreak.
> >
> > Though not labeled clearly, RaTG13 is also shown in the phylogenetic tree in Figure 3 (the one most closely related to 2019-nCoV from Rhinolophus affinis in Yunnan). So could you please revise the figure legend of figure 3 as: Maximum clade credibility tree including 201 RdRp sequences from the*Sarbecovirus* lineage isolated in bats, including RaTG13 (Genbank accession numbers: MN996532) and two sequences of 2019-nCoV isolated in humans (GenBank accession numbers:MN908947 and MN975262).
> >
> > This will mean that in your analysis you downloaded the sequence from public database, but it was not included in the original dataset of bat CoVs that I provided to you.
> >
> > 2) In lines 89-91 in the PDF. It says 'Our geographic datasets included 694 α-CoV sequences from six zoogeographic regions (22 provinces) and 519 β-CoV sequences from five zoogeographic regions (21 provinces) .
> >
> > The dataset contains some sequences detected from bats in Laos. Are the lao bat CoV sequences also counted in the 694 and 519 sequences? They are not from any Chinese province. If so,the numbers here needs to be corrected.
> >
> > Besides, CAS now requires authors from CAS institutes to deposit coronavirus sequences not only in Genbank but also in the public database of China National Center for Bioinformation when we publish our researches. So I will submit the sequences which I submited to Genbank last year to the Chinese database next week.
> >
> > If you have any questions please let me know.

[redacted]

Released by Chairman Rand Paul

Best

Ben

-----原始邮件-----
发件人:"Alice Latinne" <[redacted]@ecohealthalliance.org>
发送时间:2020-04-04 22:26:44 (星期六)
收件人: "胡犇" <[redacted]@wh.iov.cn>
抄送: "Hongying Li" [redacted]@ecohealthalliance.org>
主题: Re: Re: China Maps used in the manuscript

Hi Ben,

The supplementary material including Table S1 is attached. And yes it includes all the GenBank numbers you gave me (for the sequences you deposited in genbank by yourself) and all sequences already in GenBank from other studies. Please note that at this stage, I won't be able to modify the dataset, the analysis or the figures.

Cheers,
Alice

On Wed, Apr 1, 2020 at 8:07 PM 胡犇 <[redacted]@wh.iov.cn> wrote:

Hi Alice,

Can you please send me the Table S1 which shows the accession number of all sequences in the dataset used in the analysis? It includes both the sequences I share with you and the sequences you download from Genbank, right?

Thank you!

Ben

-----原始邮件-----
发件人:"Alice Latinne" <[redacted]@ecohealthalliance.org>
发送时间:2020-03-30 17:43:57 (星期一)
收件人: "胡犇" <[redacted]@wh.iov.cn>
抄送: "Hongying Li" [redacted]@ecohealthalliance.org>
主题: Re: Re: Re: Re: Re: China Maps used in the manuscript

Great! :)

On Mon, Mar 30, 2020 at 4:43 PM 胡犇 <[redacted]@wh.iov.cn> wrote:

Absolutely OK. Thanks a lot, Alice!

-----原始邮件-----
发件人:"Alice Latinne" <[redacted]@ecohealthalliance.org>
发送时间:2020-03-30 17:38:25 (星期一)
收件人: "胡犇" <[redacted]@wh.iov.cn>
抄送: "Hongying Li" [redacted]@ecohealthalliance.org>
主题: Re: Re: Re: Re: China Maps used in the manuscript

Hello,

Here is the updated figure. I hope this is ok!

Thanks,
Alice

[redacted]

Released by Chairman Rand Paul

On Sun, Mar 29, 2020 at 11:55 AM Alice Latinne <[redacted]@ecohealthalliance.org> wrote:

Hi all,

I think using the new map from Hongying is too much work but I'll try. If not, I'll put two small China South Sea map on the figure

On Sun, Mar 29, 2020 at 8:00 AM 胡犇 <[redacted]@wh.iov.cn> wrote:

> Hi both!
>
> I think the map format that Hong Ying provided is even better. Thanks!
>
> -----原始邮件-----
> 发件人:"Hongying Li" <[redacted]@ecohealthalliance.org>
> 发送时间:2020-03-28 23:03:46 (星期六)
> 收件人: "胡犇" <[redacted]@wh.iov.cn>
> 抄送: "Alice Latinne" <[redacted]@ecohealthalliance.org>
> 主题: Re: Re: Re: China Maps used in the manuscript
>
> Hi Both!
>
> I think either the South China Sea label can be smaller so it can fit into Figure 6 in two maps; Or the attached format of the South China Sea can be considered, which will fit better into Figure 6 I guess, but requires some more editing. But I defer to whatever you decide.
>
> Hongying
>
> On Sat, Mar 28, 2020 at 9:16 AM 胡犇 <[redacted]@wh.iov.cn> wrote:
>
> > Yes I would like to suggest that it appears twice in both figure A and B. But it seems that the space is limited and the layout need to be adjusted?
> >
> > What do you think, Hongying?
> >
> > -----原始邮件-----
> > 发件人:"Alice Latinne" <[redacted]@ecohealthalliance.org>
> > 发送时间:2020-03-28 17:30:57 (星期六)
> > 收件人: "胡犇" <[redacted]@wh.iov.cn>
> > 抄送: "Hongying Li" <[redacted]@ecohealthalliance.org>, "博士石正丽" <[redacted]@wh.iov.cn>, "Peter Daszak" <[redacted]@ecohealthalliance.org>
> > 主题: Re: Re: China Maps used in the manuscript
> >
> > Hi Ben,
> >
> > Is the new Figure 6 ok? Or do I have to put the South China Sea 2 times?
> >
> > Thanks,
> > Alice
> >
> > On Sat, Mar 28, 2020 at 3:32 PM 胡犇 <[redacted]@wh.iov.cn> wrote:
> >
> > > Thanks a lot Alice. The maps now seems perfect.
> > >
> > > Please note that the two maps in Figure 6 also need to be modified (that could be easier I think, as only South China Sea need to be added)
> > >
> > > Best wishes
> > >
> > > Ben

Released by Chairman Rand Paul

-----原始邮件-----
发件人:"Alice Latinne" <[redacted]@ecohealthalliance.org>
发送时间:2020-03-24 22:08:46 (星期二)
收件人: "Hongying Li" <[redacted]@ecohealthalliance.org>
抄送: "胡犇" <[redacted]@wh.iov.cn>, "博士石正丽" <[redacted]@wh.iov.cn>, "Peter Daszak" <[redacted]@ecohealthalliance.org>
主题: Re: China Maps used in the manuscript

Hi Hongying and Ben,

Yes I can edit this map as needed, thank you!! I'll work on this when I have time.

The revised and submitted version of the paper is attached. Let me know if there is anything else that is problematic (hopefully not too much!).

Thanks,
Alice

On Mon, Mar 23, 2020 at 9:59 PM Hongying Li [redacted]@ecohealthalliance.org> wrote:

> Hi Alice,
>
> Does the attached editable PPT work for you? I colored Shanghai and Xizang in red, and copied pasted south China sea from Ben's template.
>
> Hongying
>
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>
> > Hi Ben,
> >
> > I totally understand your concerns and will correct these issues. Could you send me a correct map in **pdf format**? This would be really helpful. I really need a pdf where I can change the colour of each province. I can't do it with the pptx you sent me.
> >
> > I hope life in Wuhan is getting easier these days!
> >
> > Best wishes,
> > Alice
> >
> > On Sun, Mar 22, 2020 at 9:50 PM 胡犇 <[redacted]@wh.iov.cn> wrote:
> >
> > > Dear Alice,
> > >
> > > How is going? I don't know where you are now but since almost every country is facing the threat of COVID-19, I hope everything is fine with you.
> > >
> > > I am happy to know that our paper on Chinese bat coronavirus is almost accepted. Thank you so much for the contribution to this joint work.
> > >
> > > Today, when I re-checked the figures, I suddenly had a new concern about the paper. The problem is about the maps of China appearing in the figures. It is not a scientific issue, but we must be very careful about it, because in China some people are extremely strict about the territorial integrity and sovereignty shown in the map.
> > >
> > > The problems I found include:
> > >
> > > 1) In figure 1, Shanghai is missing in the map. In the province of Tibet, the region called South Tibet (which is actually controlled by India) is not included.
> > >
> > > 2) In all three maps, South China Sea is not shown. For Chinese people, a complete map of China should clearly include the South China Sea with a focus on nine-dashed line (I attached a model in the PPT for you to know how it should look like).
> > >
> > > I know it will take you some more time to correct the maps. but please understand this concern. If we don't correct the problems, people may judge that Zhengli, me and our Chinese colleagues are making political mistakes. We don't wish that the maps will become a target of attack from those people. You may know that at this every special and sensitive time when COVID-19 occurs, there

[redacted]

Released by Chairman Rand Paul

are some rumors about the research cooperation on coronaviruses between our lab and the US. So we may have to be more careful than before.

After the maps are modified, please send them to me to have a look before they are finally submitted.

If you have any question, please contact me.

Thanks, and take care!

Ben

> -----原始邮件-----
> **发件人:**"Alice Latinne" <[redacted]@ecohealthalliance.org>
> **发送时间:**2019-10-08 00:08:10 (星期二)
> **收件人:** "胡犇老师" <[redacted]@wh.iov.cn>, "朱光剑" <[redacted]@126.com>, zhanglb <[redacted]@gaibr.gd.cn>, "Carlos Zambrana-Torrelio" <[redacted]@ecohealthalliance.org>, "Kevin Olival, PhD" <[redacted]@ecohealthalliance.org>, "博士石正丽" <[redacted]@wh.iov.cn>, "Peter Daszak" <[redacted]@ecohealthalliance.org>, "李贝" <[redacted]@126.com>, "张玮" <[redacted]@wh.iov.cn>, "Hongying Li" <[redacted]@ecohealthalliance.org>, "Aleksei MacDurian" <[redacted]@ecohealthalliance.org>, "Hume Field" <[redacted]@ecohealthalliance.org>, "Jon Epstein" <[redacted]@ecohealthalliance.org>, "Wang Linfa" <[redacted]@duke-nus.edu.sg>
> **抄送:**
> **主题:** China bat CoV paper submitted
>
> Dear Co-authors,
>
> I just wanted to let you know that I submitted our China bat CoV paper to Nature Communications yesterday. Thank you for all your comments and edits on previous versions of the paper, that was very helpful.
>
> Attached is the submitted version. I'll keep you updated. Finger's crossed...
>
> Best regards,
> Alice
>
> --
> **Alice Latinne, PhD**
>
> *Research Scientist*
> *PREDICT-2 Country Liaison, Thailand and Indonesia*
>
> EcoHealth Alliance
> 460 West 34th Street – 17th floor
> New York, NY 10001
>
> [redacted] (direct)
> [redacted] (mobile)
> www.ecohealthalliance.org
>
> ***EcoHealth Alliance leads cutting-edge scientific research into the critical connections between human and wildlife health and delicate ecosystems. With this science, we develop solutions that prevent pandemics and promote conservation.***

--
Alice Latinne, PhD

Research Scientist

EcoHealth Alliance
460 West 34th Street – 17th floor
New York, NY 10001

[redacted] (mobile)

[redacted]

Released by Chairman Rand Paul

www.ecohealthalliance.org

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[redacted]

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[redacted]

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> *conservationNo*
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[redacted]

Released by Chairman Rand Paul

From: 石正丽 <[redacted]@wh.iov.cn>
Sent: Wednesday, August 11, 2021 11:22 PM EDT
To: Peter Daszak <[redacted]@ecohealthalliance.org>
CC: Alice Latinne <[redacted]@ecohealthalliance.org>; 胡犇 <[redacted]@wh.iov.cn>
Subject: Fw: Permission to adapt published figure

Dear Peter,

Have you received the request of the following email? I give my permission if you agree.

Best regards,

Zhengli,

-----原始邮件-----
发件人:"VANITHA MARIAPPAN" <[redacted]@ukm.edu.my>
发送时间:2021-08-12 11:07:45 (星期四)
收件人: [redacted]@wh.iov.cn
抄送:
主题: Permission to adapt published figure

Dear Zheng-Li Shi,

I'm Vanitha Mariappan, a researcher from Universiti Kebangsaan Malaysia, would like to seek your permission to adapt an image (Figure 4) published in your recent article 'Origin and cross-species transmission of bat coronaviruses in China' published in *Nat. Commun.* (2020) 11(1):4235.

My team and I are coming up with a book chapter on COVID-19 in our national language (Bahasa Melayu) and planning to incorporate the figure that you have published. The publisher will need to see written permission from the original author to allow us to adapt the figure in our book chapter.

Hence, I hope to hear from you favourably soon
Thank you and stay safe!
--
Best regards,
VM

Vanitha Mariappan, PhD
Center for Toxicology and Health Risk Studies (CORE),
Faculty of Health Sciences,
Universiti Kebangsaan Malaysia,
Jalan Raja Muda Abdul Aziz,
50300 Kuala Lumpur,
Malaysia
Tel: [redacted]

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Released by Chairman Rand Paul

From: 石正丽 <[redacted]@wh.iov.cn>
Sent: Saturday, April 30, 2022 8:44 AM EDT
To: Peter Daszak <[redacted]@ecohealthalliance.org>; 李泓萤 <[redacted]@ecohealthalliance.org>
CC: 周鹏 <[redacted]@wh.iov.cn>
Subject: Fw: RE: RE: Matters Arising regarding your Nature paper
Attachment(s): "Email to Nature.docx"

Dear Peter,

I hope you are doing well.

I forward a recent email from Clare Thomas. This is one of emails from Clare asked by some scientists regarding the RaTG13 sequence. I believe Jessie Bloom is the leading scientist among them. We prepared a draft to explain to Clare what Jessie Bloom has done for us. Can you please help us to edit and snapshot some of his comments on Chinese Scientist on his Twitter?

Best regards,

Zhengli,

> -----原始邮件-----
> **发件人:**"Clare Thomas" <[redacted]@nature.com>
> **发送时间:**2022-04-29 17:38:47 (星期五)
> **收件人:** "[redacted]@wh.iov.cn" <[redacted]@wh.iov.cn>
> **抄送:**
> **主题:** RE: RE: Matters Arising regarding your Nature paper
>
> Dear Zhengli,
>
> I hope you're well. We've been contacted again by several scientists regarding some of the methodological details that you clarified at the end of last year. Some of these scientists are asking the same questions as the correspondent who submitted the Matters Arising. I think this information needs to be provided publicly. We can either do a correction to the paper to add these details, or the person who originally wrote to us has provided some helpful suggestions below for how these methods details can be added to the relevant databases (please see the suggestions below). This would be our preference. Could you please add the information, as indicated, and let me know when you've done it so that I can let them know? Please let me know if you have any questions.
>
> Thanks in advance,
>
> Clare
>
> Second and most importantly, it seems that the information that was provided to me in your email and in the Word document prepared by the laboratory of Shi Zheng-Li has still not been shared publicly by the authors.
>
> For example, a few days ago I was asked by researcher Moreno Colaiacov about the RaTG13 sample that was "gone" and yet used later for 5'RACE. Unfortunately I could not answer him because you told me that this information was confidential.
>
> It would be really nice for this information that has been shared with me to be made public.
> For example, would it be possible for the authors to include the information as metadata in NCBI GenBank?
>
> For example:

[redacted]

1) Timeline information

"Year 2017: Amplification of full-length RdRp gene and ORF8 gene

Year 2018: NGS and gap filling of the genome sequence

September 2020: RACE for determination of the 5'end sequence"

and

"anal swab, not a fecal pellet, they used the High Pure Viral RNA kit for the RNA extraction"

"for the 5'race done in September 2020 they used the viral RNA previously extracted from that anal swab sample."

could go into the category called "description" for the Biosample accession of RaTG13 sample https://www.ncbi.nlm.nih.gov/biosample/?term=SAMN14082201, as in:

https://www.ncbi.nlm.nih.gov/biosample/SAMN02928182

2) The information about the "Method of genome sequence assembly" could go into the "Comment" section of the RaTG13 full sequence accession:

https://www.ncbi.nlm.nih.gov/nuccore/1916859392

3) the list of primers used for amplicons and the points related to the amplicon names could go into the "Strategy" section of the SRA Experiment accession:

https://www.ncbi.nlm.nih.gov/sra/SRX8357956 (see https://www.ncbi.nlm.nih.gov/sra/docs/submitmeta/ for details)

From: Clare Thomas
Sent: 29 November 2021 09:37
To: [redacted]@wh.iov.cn
Subject: RE: RE: Matters Arising regarding your Nature paper

Dear Zhengli,

Thank you very much.

All the best,

Clare

From: [redacted]@wh.iov.cn <[redacted]@wh.iov.cn>
Sent: 29 November 2021 09:07
To: Clare Thomas <[redacted]@nature.com>
Subject: Re: RE: Matters Arising regarding your Nature paper

[External - Use Caution]

Dear Clare,

[redacted]

Please see our answers as follows:

The reasons for the low bacterial reads in the raw sequencing data of RaTG13 could be:

1) The sample is anal swab, not a fecal pellet.

2) We used the High Pure Viral RNA Kit for the RNA extraction.

3) The sequencing depth was not high.

For the 5'race done in September 2020, we used the viral RNA previously extracted from that anal swab sample.

Best regards,

Zhengli,

[redacted]@wh.iov.cn

From: Clare Thomas

Date: 2021-11-24 19:51

To: [redacted]@wh.iov.cn

Subject: RE: Matters Arising regarding your Nature paper

Dear Zhengli,

Thanks again for providing very helpful responses to the Matters Arising. We do have an obligation to look into any comments about papers that we publish, particularly if they relate to concerns about insufficient methodological detail etc. I just wanted to ask you about a two more things, about the sample source, for the sake of completeness.

The Matters Arising author points to a preprint that claims the raw data contain lower levels of bacterial reads than would be expected from a fecal swab. I cannot see from the methods anywhere that the nature of the sample was described. Was it a fecal swab? If so, is there an explanation for the low bacterial reads, if indeed that claim is true?

And along the same lines, what was the sample used for the sequencing of the 5'end done in September 2020?

Thanks in advance for clarifying these details, which do seem pertinent to the methods described in our paper and therefore we do have to ask.

Once again I'm very sorry for having to trouble you on so many occasions with these queries.

With best wishes,

Clare

[redacted]

Released by Chairman Rand Paul

From: [redacted]@wh.iov.cn <[redacted]@wh.iov.cn>
Sent: 24 November 2021 09:10
To: Clare Thomas <[redacted]@nature.com>
Subject: Re: Matters Arising regarding your Nature paper

[External - Use Caution]

Dear Clare,

I'm sorry that you continue to recieve such emails. It's a pity that there are someone who is contining to doute and scruetine our work. This person has been interrupting me and my colleagues and want to find evidence to show that the SARS-CoV-2 is a lab leak. I don't think I should answer his unreasonable questions and crazy ideas. But for your refrence, I would like to send you more details although I think they are not whinth the duty of you and neither the scope of my publication in your journal.

Best regards,

Zhengli,

[redacted]@wh.iov.cn

From: Clare Thomas

Date: 2021-11-19 02:09

To: 石正丽

Subject: Matters Arising regarding your Nature paper

Dear Zhengli,

I hope you're well. I'm afraid we've been contacted by a scientist who has submitted a Matters Arising to the journal, regarding your 2020 Nature paper. I've attached the MA here.

One of the points raised is something we already discussed, which is why there is a difference in sequence identity between SARS-CoV and RaTG13 and SARS-CoV and the virus labelled Ra4991-Yunnan in the thesis which appeared online. You already responded to a journalist's query about this, and told us that the difference was due to different bioinformatics approaches.

The other concerns seem to be points that have not been raised with us before. The author notes that the original Nature paper did not contain any information about how the RaTG13 genome was assembled and has some concerns regarding the timeline of the sequencing and assembly as well as missing methods (e.g. primer sequences). The addendum touched on the timing of the sequencing, but not the methods, and the author has some concerns regarding the timeline and asks for further details to clarify how the full RaTG13 sequence was obtained.

Would you please be able to send us a response to these new concerns so that we can discuss how to proceed? If you could return a response within one week that would be greatly appreciated.

[redacted]

Released by Chairman Rand Paul

With best wishes,

Clare

Clare Thomas

Senior Editor

Nature

From: 石正丽 <[redacted]@wh.iov.cn>
Sent: 29 June 2021 00:13
To: Clare Thomas <[redacted]@nature.com>
Subject: Re: RE: RE: A question about the addendum to your Nature paper

[External - Use Caution]

Dear Clare,

Thank you for your information. I'm fine with the passing to the journalist on the information I told you.

Best regards,

Zhengli,

-----原始邮件-----
发件人:"Clare Thomas" <[redacted]@nature.com>
发送时间:2021-06-29 04:39:21 (星期二)
收件人: "[redacted]@wh.iov.cn" <[redacted]@wh.iov.cn>
抄送:
主题: RE: RE: A question about the addendum to your Nature paper

Dear Zhengli,

Thanks again for replying to my question about the discrepancy highlighted to us. We've received some queries about it from journalists. Conversations between editors and authors are confidential but I wanted to ask you if you would have any objection to our passing on the information that you have told us? Would you be willing for us to tell the journalists that you have told us that the bioinformatics approaches used to analyse the genome sequences in the Nature paper and the thesis were different? We are considering how to respond and wonder whether this might help dampen the speculation. Please could you let me know?

All the best,

Clare

[redacted]

Released by Chairman Rand Paul

From: [redacted]@wh.iov.cn <[redacted]@wh.iov.cn>
Sent: 27 June 2021 03:48
To: Clare Thomas <[redacted]@nature.com>
Subject: Re: RE: A question about the addendum to your Nature paper

[External - Use Caution]

Dear Clare,

I'm sorry for replying you late.

This kind of speculation by the anonymous person is damging the science. I thought it's not necessary to clarify the question when I received your email. But I did carefully check with my colleagues who did the sequence analyses. First, there is no doubt that the TG13 and 4991 are the same sample and also the only one we found in the past 17 years and show the closest relative to SARS-CoV-2. Second, the resason of the discrepancy come from different comparison strategy with different softwares. The data we published in Nature was produced by blastp in NCBI between TG13 and SARS-CoV Tor. The data in the thesis of our graduate student as indicated in the request email was produced by alignment of mutiple sequences using Mafft software followed by cauculation of identity by Bioedit.

In addition, the thesis of our graduate student is currently embargo becuase of knowledge property protection and we don't know why this thesis was uploded in the google drive and misused by the consparicy people.

I hope I clarify your concern.

Best regards,

Zhengli,

[redacted]@wh.iov.cn

From: Clare Thomas

Date: 2021-06-25 02:09

To: [redacted]@wh.iov.cn

Subject: RE: A question about the addendum to your Nature paper

Dear Zhengli,

I wonder whether you have had a chance to consider my email below? I am sorry to bug you about it, but

[redacted]

Released by Chairman Rand Paul

we do have an obligation to look into any queries that we receive about any Nature paper that we publish. I can imagine that you must be quite frustrated with these sorts of queries, but if there is an explanation for the apparent discrepancy highlighted to us then it would be great if you could please let us know.

Many thanks in advance and all the best,

Clare

From: Clare Thomas
Sent: 23 June 2021 17:07
To: [redacted]@wh.iov.cn' <[redacted]@wh.iov.cn>
Subject: A question about the addendum to your Nature paper

Dear Zhengli,

I hope you're well. We have been contacted by someone who claims that a thesis from the Wuhan Institute of Virology contains information that seemingly questions the relationship of RaTG13 to the sample originally named 4991. You can see the correspondence that we've received below. We have not clicked on these links, so have not looked at the thesis itself, but would you please be able to provide some clarification about these claims? I believe the concern is that if Ra4991 and RaTG13 are the same virus, as claimed in the addendum, then their identity to SARS-CoV should be the same and the table pasted below indicates that they differ to some extent in the spike gene.

Thanks in advance and best wishes,

Clare

Clare Thomas

Senior Editor

Nature

A Dissertation submitted to The University of Chinese Academy of Sciences in 2019 by Yu Ping at the Wuhan institute of Virology has recently surfaced online.

Original: https://drive.google.com/drive/folders/1cJBYAkjkZX9KbNfHCaeaaMhNDgff1elg

English
translation: https://docs.google.com/document/d/15U2uE7Eru0QxRbf8QVRPRMpssCoYhGvT/edit

The document has been uploaded by an anonymous user on Twitter, and contains potentially new information the RATG13 virus sequence and its relationship to bat sample 4991.

The RATG13 sequence was first mentioned in the article "A pneumonia outbreak associated with a new coronavirus of probable bat origin» published by Nature. In the addendum to this article, that was published November last year, the authors clarify that RATG13 sequence is the full virus sequence collected from bat sample 4991.

[redacted]

Released by Chairman Rand Paul

However, the newly uncovered thesis by Ping, raises new questions on the raw data in regards to the RATG13 sequence and its relationship to the 4991 sample. In the thesis the full sequence of bat sample 4991 is shown to be 75,4% identical in the spike gene compared to SARs-CoV Tor2.

Table 3.2 Comparison of ORF amino acid identities between bat SARSr-CoVs and human SARS-CoV Tor2.

CoV	ORF1a	S	ORF3	E	M	ORF6	ORF7	ORF8	N
LYRa11/Yunnan	95.8	89.2	90.8	98.6	97.7	95.2	94.2	15.4	97.8
WIV16/Yunnan	98.0	96.8	97.0	100.0	98.1	92.0	95.0	16.1	99.5
WIV1/Yunnan	97.9	92.1	96.7	100.0	98.1	93.6	95.0	16.9	99.7
Rs4084/Yunnan	97.9	89.8	97.0	98.6	98.1	96.8	95.9	85.9	99.5
Anlong-103/Guizhou	98.1	79.4	89.7	100.0	98.6	96.8	95.0	31.8	98.3
Rp3/Guangxi	96.5	78.5	83.5	100.0	97.2	92.0	95.0	15.4	97.8
HKU3-7/Guangdong	94.0	78.1	82.8	98.6	97.2	92.0	93.4	15.4	98.1
HKU3-1/Hong Kong	94.1	77.9	81.7	100.0	98.6	93.6	94.2	14.7	96.4
Rf1/Hubei	94.0	76.6	86.1	96.0	97.7	93.6	91.8	23.9	95.4
Jiyuan-84/Henan	94.0	76.8	86.8	96.0	97.7	92.0	94.2	25.3	96.2
Rp/Shaanxi	95.4	79.0	82.4	97.3	96.8	92.0	92.6	15.4	97.8
HeB2013/Hebei	94.1	76.8	87.2	96.0	97.7	93.6	93.4	25.3	96.2
JL2012/Jilin	93.2	74.6	86.1	97.3	97.2	87.3	90.1	NA	95.7
Ra4991_Yunnan	80.0	75.4	73.8	94.7	90.9	66.6	83.6	12.6	90.5
Rs5725_Yunnan	98.2	94.8	97.0	100.0	100.0	100.0	95.9	31.1	NC
Rs8561_Guangdong	80.4	75.2	70.5	94.7	89.6	68.2	83.6	12.6	92.8
Rs141456_Guangxi	96.1	78.6	83.5	98.6	98.6	88.8	94.2	16.3	98.1
BM48-31/Bulgaria	80.8	74.7	69.0	92.1	88.5	49.2	56.5	NP	87.2

NA, not available; NP, not present; NC, not complete.

This indicates that bat sample 4991 is not fully identical to RATG13 across the genome, as the RATG13 Spike is shown to be 76.59 percent identical to SARS-CoV Tor2 in the spike gene, thereby deviating by 1.1 percent.

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Registered Number: 00785998 England.

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From: 石正丽 <[redacted]@wh.iov.cn>
Sent: Tuesday, September 07, 2021 9:36 PM EDT
To: Peter Daszak <[redacted]@ecohealthalliance.org>
CC: 周鹏 <[redacted]@wh.iov.cn>; Hongying Li <[redacted]@ecohealthalliance.org>
Subject: Re: IMPORTANT - FW: bat coronavirus genetic data

Dear Peter,

Thank you for your reminding. I'll do what you suggest if I receive the email from Jesse Bloom. He is obsessive of the conspiracy that China is not transparent regarding the origin of COVID-19. I believe he is a brilliant scientist but don't understand why he stands with the conspiracy makers.

We are trying to update our database in cyber security and scientific data and hope to reopen it in several months.

Take cares.

Best regards,

Zhengli,

> -----原始邮件-----
> **发件人:**"Peter Daszak" <[redacted]@ecohealthalliance.org>
> **发送时间:**2021-09-08 05:24:47 (星期三)
> **收件人:** "Zhengli Shi" <[redacted]@wh.iov.cn>, "周鹏" <[redacted]@wh.iov.cn>
> **抄送:** "Hongying Li" <[redacted]@ecohealthalliance.org>
> **主题:** IMPORTANT - FW: bat coronavirus genetic data
>
> Hello Zhengli and Peng – I hope everything is going well. I have a couple of things to catch up on. The first and most important is this very annoying request from Jesse Bloom. He is the geneticist/phylogeny person who recently caused trouble over the partial genomes of SARS-CoV-2 that were deleted from a database by a Chinese researcher and he claimed this was done for suspicious reasons.
>
> Now he is asking me for sequence data from our joint work on bat-CoVs. The reason for this is that NIH has been asked by journalists to release the full proposal for our China R01 grant. I've been fighting this for many months, and NIH has also been refusing to release the details. Now journalists took the NIH to court and a judge forced them to release our grant proposals and annual reports for the last 7 years. Jesse Bloom has read the proposal and saw that I promised to share sequence data after 6 months publicly. He is now asking for all the data.
>
> I am writing because I know you have spoken and emailed with him and I believe he is the sort of person who will also email you directly. Please do NOT share agree to this request! If he asks for this data from the NIH grant work, tell him that I am the Principal Investigator and he needs to ask permission from me.
>
> I will respond to him sometime in the next few days and explain to him that all of the bat SARSr-CoV sequences are now uploaded onto Genbank. He will probably write back and ask for the raw data. I will then ignore his requests.
>
> The truth is that EcoHealth Alliance has a policy on how we work in foreign countries. We do this in a way that is respectful of local laws, and of scientists from the countries. We form partnerships (our alliance), like we have with you that are based on trust and respect for the country of origin of samples. We believe that samples and data belong to the country that they were collected in, and we never publish data or share it publicly unless it has been approved by the country of origin. In this case, some has been published, and he can download the Genbank references and work with those. Additionally, our grant was terminated and is now suspended, so I believe this sort of request is not appropriate.
>
> Cheers,
>
> Peter

[redacted]

Released by Chairman Rand Paul

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: [redacted]
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

---

From: Bloom PhD, Jesse D [redacted]@fredhutch.org>
Sent: Tuesday, September 7, 2021 3:23 PM
To: [redacted]@ecohealthalliance.org; [redacted]@ecohealthalliance.org
Subject: bat coronavirus genetic data

Hi Peter and Kevin,

Hope all is well.

I'm writing because I was just reading the text of R01 AI110964, and noticed that the resource sharing section said that all viral genetic data (presumably the raw sequencing data) would be publicly released no later than 6 months after it was acquired.

I'm very interested in analyzing as much data as possible about coronavirus sequences that were collected in China to better understand the evolution of SARS-CoV-2. I know Peter has publicly discussed at various times in late 2019 and early 2020 the discovery of additional ACE2-utilizing coronaviruses not yet published. Given the grants resource sharing terms, I wanted to ask if you could share those data? I'd of course be happy to collaborate in any analyses.

Thanks,
Jesse

Jesse Bloom
Professor, Fred Hutch Cancer Research Center
Affiliate Professor, Genome Sciences & Microbiology, University of Washington
Investigator, Howard Hughes Medical Institute

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From: [redacted]@wh.iov.cn <[redacted]@wh.iov.cn>
Sent: Saturday, April 30, 2022 9:22 PM EDT
To: Peter Daszak <[redacted]@ecohealthalliance.org>
CC: zlshi <[redacted]@wh.iov.cn>; Hongying Li <[redacted]@ecohealthalliance.org>
Subject: Re: Matters Arising regarding your Nature paper

Thanks Peter, sorry to hear that. Maybe these constant attacks are also damaging the international effort on pathogen discovery, which will eventually hurt the preparedness of future pandemic. I don't think Nature is happy to see that.

---- 回复的原邮件 ----

发件人	Peter Daszak<[redacted]@ecohealthalliance.org>
日期	2022年05月01日 05:40
收件人	石正丽<z[redacted]@wh.iov.cn>、Hongying Li<[redacted]@ecohealthalliance.org>
抄送至	周鹏<[redacted]@wh.iov.cn>
主题	RE: RE: RE: Matters Arising regarding your Nature paper

Hi Zhengli and Peng,

Sorry to read this – looks like Nature are falling into the trap of responding to these demands for more and more information as if they are genuine scientific concerns.

I think the best way to deal with this is to write a strong letter (and I will help by editing it and inserting the references), but I think you should probably also make the additions to the database. The problem is that, whatever the reason for these people writing into Nature, the editor is now asking for you to either: 1) have a correction to the paper, or 2) make edits and additions to the database that give further details on the methodology used and timing of sequencing etc..
If you don't do the changes to the database, the editor might then force you to make a correction to the paper. I think your response to Nature should say that this is unnecessary and inappropriate, and it is not normal scientific practice for such detailed information to be demanded. However in the interests of helping Nature deal with the letters they are receiving, you will reluctantly further information in the database. You could make the additions to the database very short and simple, because these requests are not really to help anyone understand the issue better, they're largely designed to claim that you didn't provide full information.

We've had the same thing with our Nature Communications paper, and with the 'competing interests' statement on our lancet paper ("Statement of support for scientists in China"). The original Lancet paper said 'no competing interests', but the editor made me draft 380 word statement that was longer than the actual letter, mainly because people had written to him to complain. I think this is going to happen for many others papers in the past and in the future. Every time we publish work, the lab leak people get ready to attack and demand corrections/changes. We've also had to respond to so many political attacks here in the same way. For example, NIH has made us change the language in our subcontracts, even though we already had language that covered their concerns. They're doing it because some politicians who believe in the lab leak theory write to them and make the letters public. They cover themselves by showing politicians that they are making us do more than others to continue our work. It's awful, but our response is always like this: "We first would like to point out that we have already addressed this issue. However, because you insist on us changing the wording, we will of course do that". It's the same thing with this request from Nature.

Give me a couple of days to go through the background documents and I'll edit the so it says that you find these constant attacks on the credibility of your work unnecessary and inappropriate, and that these are part of a series of online attacks on you and other scientists from China. I'll also put in links like you suggest.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: [redacted]
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

[redacted]

Released by Chairman Rand Paul

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

From: 石正丽 <[redacted]@wh.iov.cn>
Sent: Saturday, April 30, 2022 8:45 AM
To: Peter Daszak <[redacted]@ecohealthalliance.org>; 李泓萤 <[redacted]@ecohealthalliance.org>
Cc: 周鹏 <[redacted]@wh.iov.cn>
Subject: Fw: RE: RE: Matters Arising regarding your Nature paper

Dear Peter,

I hope you are doing well.

I forward a recent email from Clare Thomas. This is one of emails from Clare asked by some scientists regarding the RaTG13 sequence. I believe Jessie Bloom is the leading scientist among them. We prepared a draft to explain to Clare what Jessie Bloom has done for us. Can you please help us to edit and snapshot some of his comments on Chinese Scientist on his Twitter?

Best regards,

Zhengli,

> -----原始邮件-----
> **发件人:**"Clare Thomas" <[redacted]@nature.com>
> **发送时间:**2022-04-29 17:38:47 (星期五)
> **收件人:** "[redacted]@wh.iov.cn" <[redacted]@wh.iov.cn>
> **抄送:**
> **主题:** RE: RE: Matters Arising regarding your Nature paper
>
> Dear Zhengli,
>
> Dear Zhengli,
>
> I hope you're well. We've been contacted again by several scientists regarding some of the methodological details that you clarified at the end of last year. Some of these scientists are asking the same questions as the correspondent who submitted the Matters Arising. I think this information needs to be provided publicly. We can either do a correction to the paper to add these details, or the person who originally wrote to us has provided some helpful suggestions below for how these methods details can be added to the relevant databases (please see the suggestions below). This would be our preference. Could you please add the information, as indicated, and let me know when you've done it so that I can let them know? Please let me know if you have any questions.
>
> Thanks in advance,
>
> Clare
>
> Second and most importantly, it seems that the information that was provided to me in your email and in the Word document prepared by the laboratory of Shi Zheng-Li has still not been shared publicly by the authors.
>
> For example, a few days ago I was asked by researcher Moreno Colaiacov about the RaTG13 sample that was "gone" and yet used later for 5'RACE. Unfortunately I could not answer him because you told me that this information was confidential.
>
> It would be really nice for this information that has been shared with me to be made public.
> For example, would it be possible for the authors to include the information as metadata in NCBI GenBank?
>
> For example:
>
> 1) Timeline information
>
> "Year 2017: Amplification of full-length RdRp gene and ORF8 gene
>
> Year 2018: NGS and gap filling of the genome sequence

[redacted]

September 2020: RACE for determination of the 5'end sequence"

and

"anal swab, not a fecal pellet, they used the High Pure Viral RNA kit for the RNA extraction"

"for the 5'race done in September 2020 they used the viral RNA previously extracted from that anal swab sample."

could go into the category called "description" for the Biosample accession of RaTG13 sample https://www.ncbi.nlm.nih.gov/biosample/?term=SAMN14082201, as in:

https://www.ncbi.nlm.nih.gov/biosample/SAMN02928182

2) The information about the "Method of genome sequence assembly" could go into the "Comment" section of the RaTG13 full sequence accession:

https://www.ncbi.nlm.nih.gov/nuccore/1916859392

3) the list of primers used for amplicons and the points related to the amplicon names could go into the "Strategy" section of the SRA Experiment accession:

https://www.ncbi.nlm.nih.gov/sra/SRX8357956 (see https://www.ncbi.nlm.nih.gov/sra/docs/submitmeta/ for details)

From: Clare Thomas
Sent: 29 November 2021 09:37
To: [redacted]@wh.iov.cn
Subject: RE: RE: Matters Arising regarding your Nature paper

Dear Zhengli,
Thank you very much.
All the best,
Clare

From: [redacted]@wh.iov.cn <[redacted]@wh.iov.cn>
Sent: 29 November 2021 09:07
To: Clare Thomas <[redacted]@nature.com>
Subject: Re: RE: Matters Arising regarding your Nature paper

[External - Use Caution]

Dear Clare,

Please see our answers as follows:
The reasons for the low bacterial reads in the raw sequencing data of RaTG13 could be:
1) The sample is anal swab, not a fecal pellet.
2) We used the High Pure Viral RNA Kit for the RNA extraction.
3) The sequencing depth was not high.

For the 5'race done in September 2020, we used the viral RNA previously extracted from that anal swab sample.

Best regards,
Zhengli,

[redacted]@wh.iov.cn

From: Clare Thomas
Date: 2021-11-24 19:51
To: [redacted]@wh.iov.cn
Subject: RE: Matters Arising regarding your Nature paper

[redacted]

Dear Zhengli,

Thanks again for providing very helpful responses to the Matters Arising. We do have an obligation to look into any comments about papers that we publish, particularly if they relate to concerns about insufficient methodological detail etc. I just wanted to ask you about a two more things, about the sample source, for the sake of completeness.

The Matters Arising author points to a preprint that claims the raw data contain lower levels of bacterial reads than would be expected from a fecal swab. I cannot see from the methods anywhere that the nature of the sample was described. Was it a fecal swab? If so, is there an explanation for the low bacterial reads, if indeed that claim is true?

And along the same lines, what was the sample used for the sequencing of the 5'end done in September 2020?

Thanks in advance for clarifying these details, which do seem pertinent to the methods described in our paper and therefore we do have to ask.

Once again I'm very sorry for having to trouble you on so many occasions with these queries.

With best wishes,

Clare

From: [redacted]@wh.iov.cn <[redacted]@wh.iov.cn>
Sent: 24 November 2021 09:10
To: Clare Thomas <[redacted]@nature.com>
Subject: Re: Matters Arising regarding your Nature paper

[External - Use Caution]

Dear Clare,

I'm sorry that you continue to recieve such emails. It's a pity that there are someone who is contining to doute and scru etine our work. This person has been interrupting me and my colleagues and want to find evidence to show that the SARS-CoV-2 is a lab leak. I don't think I should answer his unreasonable questions and crazy ideas. But for your refrence, I would like to send you more details although I think they are not whinth the duty of you and neither the scope of my publication in your journal.

Best regards,
Zhengli,

[redacted]@wh.iov.cn

From: Clare Thomas
Date: 2021-11-19 02:09
To: 石正丽
Subject: Matters Arising regarding your Nature paper

Dear Zhengli,

I hope you're well. I'm afraid we've been contacted by a scientist who has submitted a Matters Arising to the journal, regarding your 2020 Nature paper. I've attached the MA here.

One of the points raised is something we already discussed, which is why there is a difference in sequence identity between SARS-CoV and RaTG13 and SARS-CoV and the virus labelled Ra4991-Yunnan in the thesis which appeared online. You already responded to a journalist's query about this, and told us that the difference was due to different bioinformatics approaches.

The other concerns seem to be points that have not been raised with us before. The author notes that the original Nature paper did not contain any information about how the RaTG13 genome was assembled and has some concerns regarding the timeline of the sequencing and assembly as well as missing methods (e.g. primer sequences). The addendum touched on the timing of the sequencing, but not the methods, and the author has some concerns regarding the timeline and asks for further details to clarify how the full RaTG13 sequence was obtained.

Would you please be able to send us a response to these new concerns so that we can discuss how to proceed? If you could return a response within one week that would be greatly appreciated.

With best wishes,

[redacted]

Released by Chairman Rand Paul

Clare

Clare Thomas
Senior Editor
Nature

From: 石正丽 <[redacted]@wh.iov.cn>
Sent: 29 June 2021 00:13
To: Clare Thomas <[redacted]@nature.com>
Subject: Re: RE: RE: A question about the addendum to your Nature paper

[External - Use Caution]

Dear Clare,

Thank you for your information. I'm fine with the passing to the journalist on the information I told you.

Best regards,

Zhengli,

-----原始邮件-----
发件人:"Clare Thomas" <[redacted]@nature.com>
发送时间:2021-06-29 04:39:21 (星期二)
收件人: "[redacted]@wh.iov.cn" <[redacted]@wh.iov.cn>
抄送:
主题: RE: RE: A question about the addendum to your Nature paper
Dear Zhengli,

Thanks again for replying to my question about the discrepancy highlighted to us. We've received some queries about it from journalists. Conversations between editors and authors are confidential but I wanted to ask you if you would have any objection to our passing on the information that you have told us? Would you be willing for us to tell the journalists that you have told us that the bioinformatics approaches used to analyse the genome sequences in the Nature paper and the thesis were different? We are considering how to respond and wonder whether this might help dampen the speculation. Please could you let me know?

All the best,

Clare

From: [redacted]@wh.iov.cn <[redacted]@wh.iov.cn>
Sent: 27 June 2021 03:48
To: Clare Thomas <[redacted]@nature.com>
Subject: Re: RE: A question about the addendum to your Nature paper

[External - Use Caution]

Dear Clare,

I'm sorry for replying you late.

This kind of speculation by the anonymous person is damging the science. I thought it's not necessary to clarify the question when I received your email. But I did carefully check with my colleagues who did the sequence analyses. First, there is no doubt that the TG13 and 4991 are the same sample and also the only one we found in the past 17 years and show the closest relative to SARS-CoV-2. Second, the resason of the discrepancy come from different comparison strategy with different softwares. The data we published in Nature was produced by blastp in NCBI between TG13 and SARS-CoV Tor. The data in the thesis of our graduate student as indicated in the request email was produced by alignment of mutiple sequences using Mafft software followed by cauculation of identity by Bioedit.

[redacted]

Released by Chairman Rand Paul

In addition, the thesis of our graduate student is currently embargo becuase of knowledge property protection and we don't know why this thesis was uploded in the google drive and misused by the consparicy people.

I hope I clarify your concern.

Best regards,
Zhengli,

[redacted]@wh.iov.cn

From: Clare Thomas
Date: 2021-06-25 02:09
To: [redacted]@wh.iov.cn
Subject: RE: A question about the addendum to your Nature paper

Dear Zhengli,

I wonder whether you have had a chance to consider my email below? I am sorry to bug you about it, but we do have an obligation to look into any queries that we receive about any Nature paper that we publish. I can imagine that you must be quite frustrated with these sorts of queries, but if there is an explanation for the apparent discrepancy highlighted to us then it would be great if you could please let us know.

Many thanks in advance and all the best,

Clare

From: Clare Thomas
Sent: 23 June 2021 17:07
To: [redacted]@wh.iov.cn' <[redacted]@wh.iov.cn>
Subject: A question about the addendum to your Nature paper

Dear Zhengli,

I hope you're well. We have been contacted by someone who claims that a thesis from the Wuhan Institute of Virology contains information that seemingly questions the relationship of RaTG13 to the sample originally named 4991. You can see the correspondence that we've received below. We have not clicked on these links, so have not looked at the thesis itself, but would you please be able to provide some clarification about these claims? I believe the concern is that if Ra4991 and RaTG13 are the same virus, as claimed in the addendum, then their identity to SARS-CoV should be the same and the table pasted below indicates that they differ to some extent in the spike gene.

Thanks in advance and best wishes,

Clare

Clare Thomas
Senior Editor
Nature

A Dissertation submitted to The University of Chinese Academy of Sciences in 2019 by Yu Ping at the Wuhan institute of Virology has recently surfaced online.

Original: https://drive.google.com/drive/folders/1cJBYAkjkZX9KbNfHCaeaaMhNDgff1elg

English translation: https://docs.google.com/document/d/15U2uE7Eru0QxRbf8QVRPRMpssCoYhGvT/edit

The document has been uploaded by an anonymous user on Twitter, and contains potentially new information the RATG13 virus sequence and its relationship to bat sample 4991.

The RATG13 sequence was first mentioned in the article "A pneumonia outbreak associated with a new coronavirus of probable bat origin» published by Nature. In the addendum to this article, that was published

[redacted]

Released by Chairman Rand Paul

November last year, the authors clarify that RATG13 sequence is the full virus sequence collected from bat sample 4991.

However, the newly uncovered thesis by Ping, raises new questions on the raw data in regards to the RATG13 sequence and its relationship to the 4991 sample. In the thesis the full sequence of bat sample 4991 is shown to be 75,4% identical in the spike gene compared to SARs-CoV Tor2.

Table 3.2 Comparison of ORF amino acid identities between bat SARSr-CoVs and human SARS-CoV Tor2.

CoV	ORF1a	S	ORF3	E	M	ORF6	ORF7	ORF8	N
LYRa11/Yunnan	95.8	89.2	90.8	98.6	97.7	95.2	94.2	15.4	97.8
WIV16/Yunnan	98.0	96.8	97.0	100.0	98.1	92.0	95.0	16.1	99.5
WIV1/Yunnan	97.9	92.1	96.7	100.0	98.1	93.6	95.0	16.9	99.7
Rs4084/Yunnan	97.9	89.8	97.0	98.6	98.1	96.8	95.9	85.9	99.5
Anlong-103/Guizhou	98.1	79.4	89.7	100.0	98.6	96.8	95.0	31.8	98.3
Rp3/Guangxi	96.5	78.5	83.5	100.0	97.2	92.0	95.0	15.4	97.8
HKU3-7/Guangdong	94.0	78.1	82.8	98.6	97.2	92.0	93.4	15.4	98.1
HKU3-1/Hong Kong	94.1	77.9	81.7	100.0	98.6	93.6	94.2	14.7	96.4
Rf1/Hubei	94.0	76.6	86.1	96.0	97.7	93.6	91.8	23.9	95.4
Jiyuan-84/Henan	94.0	76.8	86.8	96.0	97.7	92.0	94.2	25.3	96.2
Rp/Shaanxi	95.4	79.0	82.4	97.3	96.8	92.0	92.6	15.4	97.8
HeB2013/Hebei	94.1	76.8	87.2	96.0	97.7	93.6	93.4	25.3	96.2
JL2012/Jilin	93.2	74.6	86.1	97.3	97.2	87.3	90.1	NA	95.7
Ra4991_Yunnan	80.0	75.4	73.8	94.7	90.9	66.6	83.6	12.6	90.5
Rs5725_Yunnan	98.2	94.8	97.0	100.0	100.0	100.0	95.9	31.1	NC
Rs8561_Guangdong	80.4	75.2	70.5	94.7	89.6	68.2	83.6	12.6	92.8
Rs141456_Guangxi	96.1	78.6	83.5	98.6	98.6	88.8	94.2	16.3	98.1
BM48-31/Bulgaria	80.8	74.7	69.0	92.1	88.5	49.2	56.5	NP	87.2

NA, not available; NP, not present; NC, not complete.

This indicates that bat sample 4991 is not fully identical to RATG13 across the genome, as the RATG13 Spike is shown to be 76.59 percent identical to SARS-CoV Tor2 in the spike gene, thereby deviating by 1.1 percent.

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Released by Chairman Rand Paul

From: [redacted]@wh.iov.cn <[redacted]@wh.iov.cn>
Sent: Monday, March 14, 2022 12:53 AM EDT
To: Peter Daszak <[redacted]@ecohealthalliance.org>
CC: zlshi <[redacted]@wh.iov.cn>; huben <[redacted]@wh.iov.cn>; Hongying Li <[redacted]@ecohealthalliance.org>; Aleksei Chmura <[redacted]@ecohealthalliance.org>
Subject: Re: RaTG13 sequence?

Thanks Peter, our true friend !

---- 回复的原邮件 ----

发件人	Peter Daszak<[redacted]@ecohealthalliance.org>
日期	2022年03月14日 10:07
收件人	石正丽<[redacted]@wh.iov.cn>
抄送至	胡犇<[redacted]@wh.iov.cn>、周鹏<p[redacted]@wh.iov.cn>、Hongying Li<[redacted]@ecohealthalliance.org>、Aleksei Chmura<[redacted]@ecohealthalliance.org>
主题	RE: Re: RaTG13 sequence?

I don’t know him personally, and don’t know if he’s a good scientist or not, but anyone who looks at the evidence on whether COVID-19 came from a lab or from the wildlife markets, and still thinks it came from the lab, cannot be a good, logical scientist.

Additionally, some of his comments online suggest that he holds a deep-seated view that Chinese scientists do not have the same standards as Western scientists. I find that to be racist, and unacceptable.

Cheers,

Peter

Peter Daszak
President

EcoHealth Alliance
520 Eighth Avenue, Suite 1200
New York, NY 10018-6507
USA

Tel.: [redacted]
Website: www.ecohealthalliance.org
Twitter: @PeterDaszak

EcoHealth Alliance develops science-based solutions to prevent pandemics and promote conservation

From: 石正丽 <[redacted]@wh.iov.cn>
Sent: Sunday, March 13, 2022 9:48 PM
To: Peter Daszak <[redacted]@ecohealthalliance.org>
Cc: 胡犇 <[redacted]@wh.iov.cn>; 周鹏 <[redacted]@wh.iov.cn>; 李泓萤 <[redacted]@ecohealthalliance.org>; Aleksei Chmura <[redacted]@ecohealthalliance.org>
Subject: Re: Re: RaTG13 sequence?

Thanks, Peter. No response to him any more. I just appreciate that he is a good scientist and I can persuade him. I realize that it an effort with nothing.

> -----原始邮件-----
> **发件人:**"Peter Daszak" <[redacted]@ecohealthalliance.org>
> **发送时间:**2022-03-13 20:49:51 (星期日)
> **收件人:** "石正丽" <[redacted]@wh.iov.cn>
> **抄送:** "胡犇" <[redacted]@wh.iov.cn>, "周鹏" <[redacted]@wh.iov.cn>, "李泓萤" <[redacted]@ecohealthalliance.org>, "Aleksei Chmura"

[redacted]

Released by Chairman Rand Paul

<[redacted]@ecohealthalliance.org>
主题: Re: RaTG13 sequence?

Dear zhengli,

I strongly recommend you don't answer more questions from Jesse bloom. The questions may seem harmless, like he is trying to find out more about basic information, but his goals are to continue attacking you, the WIV, and our collaboration. He has already asked me about the RaTG13 information separately, and I responded with a single sentence to tell him the sequence is incomplete at the end of the genome. In other words he already knew the answer but wrote to you separately anyway, I believe he is trying to see if one of us says a different response so h Evan accuse us of lying.

With someone like this, if you give home more than a short response, he will use the information against you. He has done this with us in the past by making public statements about things we've said in emails to him and criticizing us.

For example, if you tell him that you've done other recombinant virus work - he will now tell other people and journalists could now write a story that accuses us of continuing our NIH work even after being told to stop. This is not true and it is unfair, but that is how the press are working here.

Obviously what you've said to him is not a problem, but I strongly advise not to continue the conversation if he keeps coming back with more questions.

Also I really appreciate you copying me into the email chain - I am tracking his accusations online and it's important to see what he's up to.

Cheers,

Peter

Peter Daszak

President
EcoHealth Alliance

520 8th Avenue, New York, NY10018-6507, USA

www.EcoHealthAlliance.org

On Mar 12, 2022, at 11:07 PM, 石正丽 <[redacted]@wh.iov.cn> wrote:

We have tried many oral samples and never found coronavirus positive. I believe, like most of animal coronaviruses, bat coronaviruses are intestinal tropism and are transmitted through fecal to oral route. But I cann't exclude the possibility of transit replication in the respiratory tract.

> -----原始邮件-----
> **发件人:**"Bloom PhD, Jesse D" <[redacted]@fredhutch.org>
> **发送时间:**2022-03-13 11:44:18 (星期日)
> **收件人:** "石正丽" <[redacted]@wh.iov.cn>
> **抄送:** "胡犇" <[redacted]@wh.iov.cn>, "周鹏" <[redacted]@wh.iov.cn>, "李泓萤" <[redacted]@ecohealthalliance.org>, "Peter Daszak" <[redacted]@ecohealthalliance.org>
> **主题:** Re: Re: Re: RaTG13 sequence?
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> Jesse Bloom
> Professor, Fred Hutchinson Cancer Research Center
> Investigator, Howard Hughes Medical Institute
>
> ---
>
> **From:** 石正丽 <[redacted]@wh.iov.cn>
> **Date:** Saturday, March 12, 2022 at 7:28 PM
> **To:** Bloom PhD, Jesse D <[redacted]@fredhutch.org>

[redacted]

Released by Chairman Rand Paul

Cc: 胡犇 <[redacted]@wh.iov.cn>, 周鹏 <[redacted]@wh.iov.cn>, 李泓萤 <[redacted]@ecohealthalliance.org>, Peter Daszak <[redacted]@ecohealthalliance.org>
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收件人: "[redacted]@wh.iov.cn" <[redacted]@wh.iov.cn>, "[redacted]@wh.iov.cn" <[redacted]@wh.iov.cn>
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From: [redacted]@wh.iov.cn <[redacted]@wh.iov.cn>
Sent: Sunday, March 13, 2022 7:36 PM EDT
To: jbloom <[redacted]@fredhutch.org>
CC: zlshi <[redacted]@wh.iov.cn>; huben <[redacted]@wh.iov.cn>; Hongying Li <[redacted]@ecohealthalliance.org>; Peter Daszak <[redacted]@ecohealthalliance.org>
Subject: Re: RaTG13 sequence?

No. I still believe it is naturally weak ACE2-usage, reflecting a trend of evolution.

---- 回复的原邮件 ----

发件人	Bloom PhD, Jesse D<[redacted]@fredhutch.org>
日期	2022年03月13日 21:44
收件人	[redacted]@wh.iov.cn<[redacted]@wh.iov.cn>
抄送至	zlshi<[redacted]@wh.iov.cn>、huben<[redacted]@wh.iov.cn>、Hongying Li<[redacted]@ecohealthalliance.org>、Peter Daszak<[redacted]@ecohealthalliance.org>
主题	Re: RaTG13 sequence?

Hi Peng,

In terms of the other receptor, do you mean the receptor for the RBD clade containing viruses like Rf1 and HKU3? (The ones shown in orange in Figure 1 here?) I obviously agree finding the receptor for that clade is important. But since RaTG13 phylogenetically clusters far more closely with other ACE2-binding viruses and does have modest ACE2 affinity for some ACE2s (like human and mouse), then I'd be very surprised if it isn't ACE2-utilizing.

Or do you mean maybe there is some unknown secondary receptor even among strong ACE2 binding viruses not in the Rf1 / HKU3 clade?

--Jesse

--
Jesse Bloom
Professor, Fred Hutchinson Cancer Research Center
Investigator, Howard Hughes Medical Institute

From: [redacted]@wh.iov.cn <[redacted]@wh.iov.cn>
Date: Saturday, March 12, 2022 at 9:04 PM
To: Bloom PhD, Jesse D <[redacted]@fredhutch.org>
Cc: zlshi <[redacted]@wh.iov.cn>, huben <[redacted]@wh.iov.cn>, Hongying Li <[redacted]@ecohealthalliance.org>, Peter Daszak <[redacted]@ecohealthalliance.org>
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主题	Re: Re: Re: RaTG13 sequence?

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[redacted]

Released by Chairman Rand Paul

From: "Sizemore, Christine (NIH/FIC) [E]" <[redacted]@nih.gov>
To: "Spiro, David (NIH/FIC) [E]" <[redacted]@nih.gov>
Subject: RE: Did you see this petition?
Date: Thu, 20 Jul 2023 10:29:32 -0400
Importance: Normal
Inline-Images: image001.png

Wow – I did not know all of this!
For me its all about scientific elitism and the few at the top pulling strings. I agree, there is no evidence that Fauci orchestrated this but then again, I am not sure about this either.
I am not sure about anything any more … all I can say is that the upper crust at NIH and in the global research arena does pull strings and control messages.

From: Spiro, David (NIH/FIC) [E] [redacted]@nih.gov>
Sent: Thursday, July 20, 2023 10:23 AM
To: Sizemore, Christine (NIH/FIC) [E] [redacted]@nih.gov>
Subject: RE: Did you see this petition?

Yes, I did and I also watched portions of the hearing with Andersen and Garry. The House report is a skewed and doesn't take into account some of the details revealed in the hearing. After watching the hearing, I think Fauci and Collins were involved, I am not convinced that this was orchestrated by Fauci. Jeremy Farrar was the initiator of the article and Fauci sat in on a call. Andersen said that Fauci played a minimal role in the talks and that they changed their point of view based on analysis of the data. Given my review of the genomic data, this seems reasonable. I think the paper is most likely an honest assessment of data. Quickly done, no doubt but there was an emergency situation.
What confuses me is why Fauci publicly pretended that he didn't know the investigators and I wonder if this is because he placed his thumb on the post-peer review process leading to an award of CREID centers for Garry and Andersen. The peer review took place in November, but the grants weren't awarded until April I believe. After the call for proximal origin. Andersen said that the peer review couldn't possibly have been tampered with, but you and I both know that awarding large cooperative agreements goes beyond peer review and the NIAID OD could have weighed in. The other strange thing was awarding a CREID center to Dascak after Trump specifically blocked an earlier grant to EcoHealth alliance.

From: Sizemore, Christine (NIH/FIC) [E] [redacted]@nih.gov>
Sent: Thursday, July 20, 2023 9:20 AM
To: Spiro, David (NIH/FIC) [E] [redacted]@nih.gov>
Subject: RE: Did you see this petition?

Have you read that report from the committee that I sent recently? I would have agreed with you until I saw the actual emails and Slack channel conversations… I am still siding with you that it should not be retracted, also because that sets precedence. But what went on behind the scenes is pretty bad.

From: Spiro, David (NIH/FIC) [E] [redacted]@nih.gov>
Sent: Thursday, July 20, 2023 9:01 AM
To: Sizemore, Christine (NIH/FIC) [E] [redacted]@nih.gov>
Subject: RE: Did you see this petition?

Hi,
I don't agree with the petition.
I think it is an important first analysis of the data available at the time and is part of a series of investigations by the authors and collaborators attempting to find the origin through genomic and epi analysis.

Released by Chairman Rand Paul

The problem came with how the Dems and NIH leadership used it as a weapon to silence scientific debate. It is also an important historical record at this point.

From: Sizemore, Christine (NIH/FIC) [E] [redacted]@nih.gov>
Sent: Thursday, July 20, 2023 8:29 AM
To: Spiro, David (NIH/FIC) [E] [redacted]@nih.gov>
Subject: Did you see this petition?

Petition to withdraw the Proximal Origins paper…
What do you think? I am a bit torn here…. On one hand, if this were a paper that summarizes the state of knowledge about SARS-CoV2 as of Feb 2020 and speculates what the origins may be, and then it turns out, as is part of science, that there is more to it, I would not have a problem with the paper. But now that is has been shown that it was not a full accounting of how the authors felt about potential origins, but clearly drove a specific narrative, I am not sure what to think any more. I know that scientific publications will never be able to present all possible scenarios and of course show the conclusions of the authors (and not also list other conclusions by other scientists)… so in that sense, the paper is not any different there.

https://mailchi.mp/biosafetynow/retract-proximal-origins?e=4bbd46214d

Christine

Christine F. Sizemore, Ph.D.
Director, Division of International Relations

[redacted]

Fogarty International Center
National Institutes of Health, USA

31 Center Drive, B2C11
Bethesda, Maryland 20892

People take different roads seeking fulfillment and happiness. Just because they're not on your road doesn't mean they've gotten lost. --- *H. Jackson Brown, Jr.*

Released by Chairman Rand Paul

From: "Spiro, David (NIH/FIC) [E]" <[redacted]@nih.gov>
To: "Sizemore, Christine (NIH/FIC) [E]" <[redacted]@nih.gov>
Subject: RE: Did you see this petition?
Date: Thu, 20 Jul 2023 10:23:03 -0400
Importance: Normal
Inline-Images: image001.png

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Released by Chairman Rand Paul

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https://mailchi.mp/biosafetynow/retract-proximal-origins?e=4bbd46214d

Christine

Christine F. Sizemore, Ph.D.
Director, Division of International Relations

[redacted]

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Released by Chairman Rand Paul

To: "Ford, Andrew (NIH/NIAID) [E]" <[redacted]@nih.gov>
Cc: "Erbelding, Emily (NIH/NIAID) [E]" <[redacted]@nih.gov>, "Lyon, Rickie (NIH/NIAID) [C]" <[redacted]@niaid.nih.gov>, "Post, Diane (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Ison, Michael (NIH/NIAID) [E]" <[redacted]@nih.gov>
Subject: RE: Please advise by COB today 3/21: Additional questions related to SRG review of EHA grant
Date: Tue, 21 Mar 2023 14:44:34 -0400
Importance: Normal
Attachments: Summary_Statements_Media_Statement_es.docx

Hi Andrew,
See attached. Let me know if there are any other questions.
Thanks!
Erik

From: Ford, Andrew (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Tuesday, March 21, 2023 10:52 AM
To: Stemmy, Erik (NIH/NIAID) [E] [redacted]@nih.gov>
Cc: Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Ford, Andrew (NIH/NIAID) [E] [redacted]@nih.gov>; Lyon, Rickie (NIH/NIAID) [C] [redacted]@niaid.nih.gov>; Post, Diane (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Ison, Michael (NIH/NIAID) [E] [redacted]@nih.gov>
Subject: FW: Please advise by COB today 3/21: Additional questions related to SRG review of EHA grant
Importance: High

Hey Erik,

Per Sara's email below, documents related to the SRG review of the EHA award are likely to be provided to the congressional requestors later this week. Attached is a media statement (third attachment) drafted by OLPA that notes a few potential vulnerabilities from comments in the summary statements. Could you please review attached media statement **and** the questions bolded below and send to me any edits/comments/responses by **COB today, Tuesday, March 21, 2023.**

Thanks,
Andrew

From: Sara Selgrade <[redacted]@nih.gov>
Date: Tuesday, March 21, 2023 at 10:37 AM
To: NIAID BUGS [redacted]@niaid.nih.gov>, NIAID DEA DART <[redacted]@mail.nih.gov>, "Linde, Emily (NIH/NIAID) [E]" [redacted]@mail.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>, "Auchincloss, Hugh (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Harper, Jill (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Billet, Courtney (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, Emily Erbelding <[redacted]@nih.gov>, "Poe, Kelly (NIH/NIAID) [E]" [redacted]@nih.gov>, "Gilles, Sharon (NIH/NIAID) [E]" [redacted]@nih.gov>
Subject: Please advise by COB today 3/21: Additional questions related to SRG review of EHA grant

Good morning,

Background

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As you recall, NIH OLPA reached out recently to make us aware of congressional requests for documents related to Scientific Review Group (SRG) review of the original and renewal EHA award. NIH OLPA has indicated that HHS is likely to provide these to the congressional requestors later this week.

NIH OLPA has drafted the attached "media statement" that notes a few potential vulnerabilities from comments in the summary statements. They have asked us if we have additional information on these points (bolded questions below):

Vulnerabilities:

1. In the 2013 review, critique number 3 mentions that a potential overlap with PREDICT was noted. **Does NIAID have additional information that we could share about how it was determined this was not double billing?**
2. In the same critique, there is a note that the potential risk to human subjects is not fully addressed. **Did NIAID work with the grantee to address these concerns before funding?**
3. In the 2019 review, critique number 2 mentions that the letters from the two Chinese institutions were identical. **Do you know if there was follow-up regarding this?**

Action Item
By COB today, Tuesday March 21, please review the "media statement" document and provide any edits or comments. Please also provide any information responsive to the bolded questions above. If these questions are better referred to OER or other NIH components, please let us know.

Thanks,
Sara

From: Selgrade, Sara (NIH/NIAID) [E] [redacted]@nih.gov>
Sent: Wednesday, March 8, 2023 2:17 PM
To: NIAID BUGS [redacted]@niaid.nih.gov>; NIAID DEA DART [redacted]@mail.nih.gov>; Linde, Emily (NIH/NIAID) [E] [redacted]@mail.nih.gov>
Cc: NIAID OCGR Leg [redacted]@mail.nih.gov>; Auchincloss, Hugh (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Harper, Jill (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Billet, Courtney (NIH/NIAID) [E] [redacted]@niaid.nih.gov>; Erbelding, Emily (NIH/NIAID) [E] [redacted]@nih.gov>; Poe, Kelly (NIH/NIAID) [E] [redacted]@nih.gov>; Gilles, Sharon (NIH/NIAID) [E] [redacted]@nih.gov>
Subject: Please advise by 10am tomorrow: Documents for congressional requests related to EHA grant
Importance: High

Hello all,

Background
As you may be aware, the House Select Subcommittee on the Coronavirus Pandemic, as well as the House Energy and Commerce Committee, have requested documents related to EcoHealth Alliance's NIH grants.

NIH OLPA has been working with NIH OER and others to provide documents responsive to the two requests outlined below. Please note the highlighted requests from NIH OLPA outlined below regarding these document productions.

Action Item
Please let us know by 10am tomorrow, Thursday March 9, if you know of any additional documentation or have any concerns to flag as requested by NIH OLPA.

1. Congressional Request: All documents related to the Scientific Review Group (SRG) review of the initial R01 grant.

Note from OCGR-Leg: NIH OLPA/NIH OER has identified the two attached documents below responsive to this request. Please note that we suggested that OLPA should also consult with the Center for Scientific Review.

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<< File: December 18 2013 Summary Statement (1).pdf >> << File: February 14 2019 Type 2 Summary Statement.pdf >>

NIH OLPA questions related to these documents:

1. If you know of any additional documentation from the SRG review we could share with Congress, please flag for OLPA. We have asked OER/OPERA to confirm as well. [note from OCGR-Leg: please advise if NIAID would have responsive documents. If so, we can assist with keywords and individuals for a CIT search for documents]
2. Are there any sensitivities you would like to flag? OLPA will work with OGC to redact personally identifiable information before transmission to Congress.

2. Energy & Commerce Committee Request (Follow up to prior document production consisting of Type 5 Checklists from the initial R01):

Questions from the congressional staff, with proposed responses from NIH OER in red:
Following up on the production of the Type 5 checklist documents, we noticed there was not an Award Worksheet Report for Year 6 of the EcoHealth award or Year 1 of the EcoHealth R02 award (depending on how you look at it).

Based on this HHS OIG report (see excerpt below), the NIH may have closeout documentation for the EcoHealth R01 award.
https://oig.hhs.gov/oei/reports/oei-07-11-00190.pdf. However, we would like clarification on the following: When a grant award is renewed, do NIH staff complete closeout documentation for the R01 grant in lieu of the Award Worksheet Report? NIH Response: No.

If not, do NIH staff complete an Award Worksheet Report for Year 6 (the Year 1 for the R02 award)? NIH Response: Yes.
If there is closeout documentation for the EcoHealth R01, please provide these materials as responsive to the request for the grant file. NIH Response: There is no closeout documentation at this time, because the award continued with the renewal (Type 2).
If instead there is no closeout documentation and there is an Award Worksheet Report, please provide the Year 6 Award Worksheet Report and any other subsequent Award Worksheet Reports. NIH Response: The Year 6 Award Worksheet Reports are attached.

<< File: AWS4298904 9.28.22.pdf >> << File: AWS3993758 9.15.21.pdf >> << File: AWS3672471 7.15.20.pdf >>
<< File: AWS3602757 4.27.20.pdf >> << File: AWS3438397 8.5.19.pdf >> << File: AWS3424934 7.24.19.pdf >>

For background - OER/OPERA Response:
Thanks to our OPERA colleagues, we can offer the following explanation. There are actually 6 award worksheets for the Type 2 due to the actions outlined below:

- 7-24-19: initial award
- 8-5-19: budget adjustment
- 4-27-20: termination—award zero'd out
- 7-15-20: award reinstated
- 9-15-21: award extended (mid-budget period)
- 9-28-22: WIV termination; budget renegotiated to remove aims involving WIV

NIH OLPA questions related to these responses/documents:
Please let us know if you have any concerns or flags

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Sara Selgrade, Ph.D.
Section Chief for Legislative Activities
Legislative Affairs and Correspondence Management Branch
Office of Communications and Government Relations
NIAID/NIH/DHHS
Bldg. 31, Room 7A17, MSC 2520
Bethesda, MD 20892-2520
Phone: [redacted]
[redacted]@mail.nih.gov

Disclaimer:
The information in this e mail and any of its attachments is confidential and may contain sensitive information. It should not be used by anyone who is not the original intended recipient. If you have received this e-mail in error please inform the sender and delete it from your mailbox or any other storage devices. National Institute of Allergy and Infectious Diseases shall not accept liability for any statements made that are sender's own and not expressly made on behalf of the NIAID by one of its representatives.

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Information to share with OCPL

Background:

The attached summary statements are from the Scientific Review Group, also known as peer review, of the initial application (review conducted in 2013) and the review of the renewal application (review conducted in 2019). The summary statement is the official record of these reviews. NIH peer reviewers use a 9-point scale for scoring NIH grant applications. A score of 1 means exceptional and 9 means poor, with 5 considered an average score. Impact scores run from 10 to 90 and are based on the normalized average of all reviewer impact/priority scores. Generally speaking, impact scores of 10 to 30 are most likely to be funded; scores between 31 and 45 might be funded; and scores greater than 46 are rarely funded.

The review panel roster is posted publicly on the NIH website. These two rosters can be found:
https://public.era.nih.gov/pubroster/preRosIndex.era?AGENDA=265100&CID=102597

https://public.era.nih.gov/pubroster/preRosIndex.era?AGENDA=356932&CID=102597

Tough Q/As:

Did the NIH grant to EcoHealth Alliance with a subaward to WIV support ePPP research?

- As these reviews show the research proposed in the grant application sought to understand how bat coronaviruses evolve naturally in the environment to become transmissible to the human population. This included studying viral diversity in bat reservoirs, surveying people who work in live animal markets or other jobs with high exposure to wildlife for evidence of bat-coronavirus infection and analyzing data to predict which newly discovered viruses pose the greatest threat to human health.
- NIH did not approve funding for research proposing to enhance SARS-CoV transmissibility or virulence in humans in China or elsewhere.
- The body of science produced under the grant, including the bat coronavirus sequences identified by the researchers and published in the scientific literature, showed that the viruses studied were evolutionarily quite distant from SARS-CoV-2 and could not have been the source of SARS-CoV-2.

Vulnerabilities:

- In the 2013 review, critique number 3 mentions that a potential overlap with PREDICT was noted.
- In the same critique, there is a note that the potential risk to human subjects is not fully addressed and therefore, raises concerns.
- In the 2019 review, critique number 2 mentions that the letters from the two Chinese institutions were identical.

Commented [SE([1]: Suggest adding a bullet that reviewer comments including risk to human subjects and potential overlap were address prior to award being made. This was documented in the 2014 Checklist for R01AI110964-01.
Erik Stemmy
2023-03-21 14:30:00

Commented [SE([2]: Overlap was addressed via JIT: fieldwork for the PREDICT program ended in June 2014 and PREDICT fully ended in September 2014. This award was funded 5/27/2014.
Erik Stemmy [2]
2023-03-21 14:27:00

Commented [SE([3]: It needs to be noted that the "risk" evaluated in the human subjects section is in no way related to the chimeric virus work. This section evaluates whether the risk of the research activities to be performed directly on the human subjects is adequately addressed. In this case it was the blood draws/sample collection and interview questions and did not involve any of the chimeric viruses. The risk noted was the potential financial risk to subjects that may have been involved in illegal wildlife trade potentially losing their source of income. See link below for reviewer guidelines for HS protections:
https://grants.nih.gov/grants/peer/guidelines_general/Guidelines_for_the_Review_of_the_Human_Subjects.pdf

This risk was addressed in the JIT submission.
Erik Stemmy [3]
2023-03-21 14:19:00

Commented [SE([4]: The same general language was used for the two letters of support, but the scientific details of the roles of each institution were appropriately included in the other sections of the application.
Erik Stemmy [4]
2023-03-21 14:42:00

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From: "Ranganathan, Rajesh (NIH/OD) [C]" [redacted]@nih.gov>
To: "Hudson, Kathy (NIH/OD) [E]" [redacted]@nih.gov>, "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Subject: FW: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)
Date: Thu, 18 Nov 2010 21:30:16 -0500
Importance: Normal

This is what I wrote back...I hope it strikes the right tone...

R
------ Forwarded Message
From: "Ranganathan, Rajesh (NIH/OD) [C]" [redacted]@nih.gov
Date: Thu, 18 Nov 2010 21:29:23 -0500
To: "Hatchett, Richard J." [redacted]@nss.eop.gov
Cc: "Burrus-Shaw, Cyndi (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: Re: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)

Richard:

We have discussed this internally amongst a subset of the exec. Team and the consensus is that it is too early for us to have a conversation about CAN, not yet having implemented anything related to CAN. Furthermore, I have only been here 2+ weeks and hence would be out of my depth with respect to MCMI. The main concern is that we would be wasting Ms. Avery's time. It would be unfortunate to risk any dampening of enthusiasm around what CAN could achieve by having a briefing at this high level prematurely.

Would it be possible at this point to diplomatically request that the meeting with Ms. Avery be postponed to a later date, when we are in fact ready to brief her in a substantive way?

And given that you are about to move to BARDA, would it make sense for you and I to chat once you get settled in that new role? However, if you feel that there would still be value in us talking now, I would be happy to come over on Monday to meet 1 on 1 with you.

Please let me know what you think.

Rajesh

On 11/18/10 8:51 AM, "Hatchett, Richard J." [redacted]@nss.eop.gov wrote:

> Rajesh,

> Sorry, I should have clarified that in our initial exchanges, as I assumed that was the context in which JJ spoke with you. We have an overlapping (and
> in fact prior) interest in CAN because of the President's biodefense initiative, and I was taking advantage of JJ's intro to contact you on MCMI (I

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> hadn't heard that you'd been selected for the position before JJ contacted me).
>
I'm actually in the late stages of negotiating a move to BARDA (the Biomedical
> Advanced Research & Development Authority) as deputy director and I don't think JJ knew this when he spoke with you. It will be good to be coordinated
> with you in that regard as well.

> With respect to Heidi, she comes from the intelligence community so doesn't have a scientific or pharmaceutical background, but as you'll see she is a
> very quick study. She oversaw White House coordination of the response to the pandemic and has been acutely sensitized to the deficiencies of our
> countermeasures development efforts. I think she'll be most interested to hear about your and Dr. Collins's vision for CAN and how it will facilitate
> translational efforts at NIH.

> It's probably worth your reviewing the HHS Medical Countermeasures Enterprise Review document just to get your head in the game. For the better part of a
> decade, our efforts on MCMs have focused on traditional government approaches to financing technology development (R&D funds for academia, advanced
> development contracts for industry, and procurement contracts serving as the main "reward") with some twiddling of other pull incentives, with only
> marginal success against threats we can define and not much progress in developing true rapid response capabilities.
>
The main conceptual novelty of MCMI is the focus on adjusting the cost side of
> the equation by making strategic investments at what we've been calling the "chokepoints" of product development - the places where projects are failing
> or dying on the vine for reasons other than lack of safety or efficacy. The overarching goal of MCMI is to change the nature of the public-private
> partnership governing product development efforts in this area, changing the role of government from one of "funder" to active strategic collaboration.
> This is where I think what we are doing will be of interest to you: we are using the national security imperative to maintain focus and drive budgets but
> adopting an approach which ought to be fungible to other areas where our translational efforts are faltering. Heidi's goal won't be to co-opt CAN but
> to think strategically with you about how what we are doing might serve to enhance our drug development efforts more broadly (and hopefully preserve the
> competitiveness of the US biopharmaceutical industry in the process).

> Happy to chat further but I think that's the kernel of what she'll be interested in discussing with you.
>
Do you have a brief bio you could send over by any chance?
>
Best regards, and I look forward to meeting you on Monday -
> Richard

> Best,
Richard
>

> ----- Original Message -----
From: Ranganathan, Rajesh (NIH/OD) [C] [redacted]@nih.gov
> To: Hatchett, Richard J.
Sent: Wed Nov 17 21:02:12 2010
> Subject: Re: Discussion about Cures Acceleration Network and the President's

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> Medical Countermeasures Initiative (MCMI)

>

> Rajesh

> On 11/17/10 5:55 PM, "Hatchett, Richard J."
[redacted]@nss.eop.gov wrote:
>
Cyndi, Rajesh --
>>
Thanks for being flexible. Ms. Avery was very interested in joining the
>> discussion. We'll meet in her office (EEOB 426) but why don't you come a few
minutes early and meet me in 421?
>>
Best,
>> Richard

>> -----Original Message-----
From: Burrus-Shaw, Cyndi (NIH/OD) [E] [mailto [redacted]@nih.gov]
>> Sent: Wednesday, November 17, 2010 5:50 PM
To: Hatchett, Richard J.
>> Cc: Ranganathan, Rajesh (NIH/OD) [C]
Subject: RE: Discussion about Cures Acceleration Network and the President's
>> Medical Countermeasures Initiative (MCMI)

>> Yes - that is fine. Dr. Ranganathan will be there on 11/22 at 12:00 pm.
Please confirm that the location is still the same (EEOB, 421). Many thanks.
>>
Best,
>> Cyndi

>> -----Original Message-----
From: Hatchett, Richard J. [mailto [redacted]@nss.eop.gov]
>> Sent: Wednesday, November 17, 2010 5:46 PM
To: Burrus-Shaw, Cyndi (NIH/OD) [E]
>> Subject: RE: Discussion about Cures Acceleration Network and the President's
Medical Countermeasures Initiative (MCMI)
>>
Cyndi,
>>
Ms. Avery (Deputy Homeland Security Adviser to the President) can do 12:00p
>> on
Monday, but not 11:00a. Would this work for Dr. Ranganathan?
>>
Thanks,
>> Richard

------ End of Forwarded Message

Released by Chairman Rand Paul

From: "Ranganathan, Rajesh (NIH/OD) [C]" [redacted]@nih.gov>
To: "Hudson, Kathy (NIH/OD) [E]" [redacted]@nih.gov>
Cc: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Subject: Re: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)
Date: Thu, 18 Nov 2010 21:17:50 -0500
Importance: Normal

Ok, thanks. Will deflect. I was not asking to be involved in this stuff - it was just meant to be a casual conversation with one of our detailees...

Rajesh

On 11/18/10 9:14 PM, "Hudson, Kathy (NIH/OD) [E]" [redacted]@nih.gov wrote:

> Thanks for asking. My knee jerk reaction is to support your misgivings. I think it is a bad idea for a whole bunch of reasons. JJ erred in pointing you to the white house. Protocol dictates that we don't talk to the white house without going through hhs. It would be okay to yak with one of our detailees but this has taken a turn. Plus, I suspect you know next to nothing about biosecurity and BARDA. This is not really your domain and frankly, not a central issue to NCTS at the outset. It IS the domain of other NIH staff who would probably be a little miffed about why you are suddenly in the middle of their "space." NIAID has programs in this arena and you should learn about them but they ain't coming into to ncts at the get go and the politics around biosecurity is complex.
>
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> From: Ranganathan, Rajesh (NIH/OD) [C]
> Sent: Thursday, November 18, 2010 6:51 PM
> To: Hudson, Kathy (NIH/OD) [E]
> Cc: Tabak, Lawrence (NIH/OD) [E]
> Subject: FW: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)
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> Date: Thu, 18 Nov 2010 08:51:35 -0500
To: "Ranganathan, Rajesh (NIH/OD) [C]" [redacted]@nih.gov
> Subject: Re: Discussion about Cures Acceleration Network and the President's
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> Date: Wed, 17 Nov 2010 20:50:57 -0500
To: "Hatchett, Richard J." [redacted]@nss.eop.gov
> Subject: Re: Discussion about Cures Acceleration Network and the President's
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To: "Hudson, Kathy (NIH/OD) [E]" [redacted]@nih.gov>
Cc: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Subject: FW: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)
Date: Thu, 18 Nov 2010 18:51:28 -0500
Importance: Normal

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To: Hatchett, Richard J.
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Subject: RE: Discussion about Cures Acceleration Network and the President's
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From: "Kawazoe, Robin (NIH/OD) [E]" [redacted]@mail.nih.gov>
To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Subject: Re: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)
Date: Thu, 18 Nov 2010 22:30:37 -0500
Importance: Normal

Larry,

Do you know what Raj means when he said he would "deflect?" Does that mean postpone the meeting?

Robin

----- Original Message -----
From: Tabak, Lawrence (NIH/OD) [E]
To: Ranganathan, Rajesh (NIH/OD) [C]; Hudson, Kathy (NIH/OD) [E]
Cc: Burrus-Shaw, Cyndi (NIH/OD) [E]
Sent: Thu Nov 18 21:27:59 2010
Subject: RE: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)

Agree
Thanks
larry

-----Original Message-----
From: Ranganathan, Rajesh (NIH/OD) [C]
Sent: Thursday, November 18, 2010 9:18 PM
To: Hudson, Kathy (NIH/OD) [E]
Cc: Tabak, Lawrence (NIH/OD) [E]
Subject: Re: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)

Ok, thanks. Will deflect. I was not asking to be involved in this stuff - it
was just meant to be a casual conversation with one of our detailees...

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Date: Thu, 18 Nov 2010 22:46:32 -0500
Importance: Normal

Yes! Thank you.

Robin

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From: Tabak, Lawrence (NIH/OD) [E]
To: Kawazoe, Robin (NIH/OD) [E]
Sent: Thu Nov 18 22:33:02 2010
Subject: Re: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)

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> contacted me).

> I'm actually in the late stages of negotiating a move to BARDA (the Biomedical Advanced Research & Development Authority) as deputy director and
> I don't think JJ knew this when he spoke with you. It will be good to be coordinated with you in that regard as well.
>
With respect to Heidi, she comes from the intelligence community so doesn't
> have a scientific or pharmaceutical background, but as you'll see she is a very quick study. She oversaw White House coordination of the response to
> the pandemic and has been acutely sensitized to the deficiencies of our countermeasures development efforts. I think she'll be most interested to
> hear about your and Dr. Collins's vision for CAN and how it will facilitate translational efforts at NIH.
>
It's probably worth your reviewing the HHS Medical Countermeasures
> Enterprise Review document just to get your head in the game. For the better part of a decade, our efforts on MCMs have focused on traditional
> government approaches to financing technology development (R&D funds for academia, advanced development contracts for industry, and procurement
> contracts serving as the main "reward") with some twiddling of other pull incentives, with only marginal success against threats we can define and not
> much progress in developing true rapid response capabilities.

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> the "chokepoints" of product development - the places where projects are failing or dying on the vine for reasons other than lack of safety or
> efficacy. The overarching goal of MCMI is to change the nature of the public-private partnership governing product development efforts in this
> area, changing the role of government from one of "funder" to active strategic collaboration. This is where I think what we are doing will be of
> interest to you: we are using the national security imperative to maintain focus and drive budgets but adopting an approach which ought to be fungible
> to other areas where our translational efforts are faltering. Heidi's goal won't be to co-opt CAN but to think strategically with you about how what we
> are doing might serve to enhance our drug development efforts more broadly (and hopefully preserve the competitiveness of the US biopharmaceutical
> industry in the process).

Released by Chairman Rand Paul

>
Happy to chat further but I think that's the kernel of what she'll be
> interested in discussing with you.

> Do you have a brief bio you could send over by any chance?

> Best regards, and I look forward to meeting you on Monday -
Richard
>
Best,
> Richard

> ------ Forwarded Message
From: "Ranganathan, Rajesh (NIH/OD) [C]" [redacted]@nih.gov
> Date: Wed, 17 Nov 2010 20:50:57 -0500
To: "Hatchett, Richard J." [redacted]@nss.eop.gov
> Subject: Re: Discussion about Cures Acceleration Network and the President's
Medical Countermeasures Initiative (MCMI)
>
Richard:
>
Can you give me some background on what Ms. Avery is likely to be interested
> in hearing about. Is there anything I should know about MCMI to be
appropriately prepared?
>
On 11/17/10 5:55 PM, "Hatchett, Richard J."
> <[redacted]@nss.eop.gov> wrote:

>> Cyndi, Rajesh --

>> Thanks for being flexible. Ms. Avery was very interested in joining the
discussion. We'll meet in her office (EEOB 426) but why don't you come a few
>> minutes early and meet me in 421?

>> Best,
Richard
>>
-----Original Message-----
>> From: Burrus-Shaw, Cyndi (NIH/OD) [E] [mailto [redacted]@nih.gov]
Sent: Wednesday, November 17, 2010 5:50 PM
>> To: Hatchett, Richard J.
Cc: Ranganathan, Rajesh (NIH/OD) [C]
>> Subject: RE: Discussion about Cures Acceleration Network and the President's
Medical Countermeasures Initiative (MCMI)
>>
Yes - that is fine. Dr. Ranganathan will be there on 11/22 at 12:00 pm.
>> Please confirm that the location is still the same (EEOB, 421). Many thanks.

>> Best,
Cyndi
>>
-----Original Message-----
>> From: Hatchett, Richard J. [mailto [redacted]@nss.eop.gov]
Sent: Wednesday, November 17, 2010 5:46 PM
>> To: Burrus-Shaw, Cyndi (NIH/OD) [E]
Subject: RE: Discussion about Cures Acceleration Network and the President's
>> Medical Countermeasures Initiative (MCMI)

Released by Chairman Rand Paul

>>
Cyndi,
>>
Ms. Avery (Deputy Homeland Security Adviser to the President) can do 12:00p
>> on
Monday, but not 11:00a. Would this work for Dr. Ranganathan?
>>
Thanks,
>> Richard

>
------ End of Forwarded Message
>

Released by Chairman Rand Paul

From: "Hudson, Kathy (NIH/OD) [E]" [redacted]@nih.gov>
To: "Ranganathan, Rajesh (NIH/OD) [C]" [redacted]@nih.gov>
Cc: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Subject: RE: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)
Date: Thu, 18 Nov 2010 21:14:33 -0500
Importance: Normal

Thanks for asking. My knee jerk reaction is to support your misgivings. I think it is a bad idea for a whole bunch of reasons. JJ erred in pointing you to the white house. Protocol dictates that we don't talk to the white house without going through hhs. It would be okay to yak with one of our detailees but this has taken a turn. Plus, I suspect you know next to nothing about biosecurity and BARDA. This is not really your domain and frankly, not a central issue to NCTS at the outset. It IS the domain of other NIH staff who would probably be a little miffed about why you are suddenly in the middle of their "space." NIAID has programs in this arena and you should learn about them but they ain't coming into to ncts at the get go and the politics around biosecurity is complex.

I would suggest to Richard that the meeting be "delayed" until you have a better understanding of what Francis has in mind, yadda yadda.

-----Original Message-----
From: Ranganathan, Rajesh (NIH/OD) [C]
Sent: Thursday, November 18, 2010 6:51 PM
To: Hudson, Kathy (NIH/OD) [E]
Cc: Tabak, Lawrence (NIH/OD) [E]
Subject: FW: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)

Kathy:

Some background for you (I was able to tell Larry in person)..Tony sent me to JJ McGowan, who thought that Richard Hatchett, currently on detail to the White House is someone I should talk to because he might have the skill set to help with NCTS. I checked in with Larry and we agreed that I should certainly meet such people and hear them out. So, when Richard reached out, I agreed to go down to the EEOB to meet him. He appears to have mentioned that he is meeting me to Ms. Heidi Avery (Deputy Homeland Security Adviser to the President), who now wants to join in and the meeting got moved to Monday to accommodate her schedule. Please see below for what Richard thinks Ms. Avery wants to know.

Two issues: a) there is not much I can say about CAN or anything else re: NCTS on Monday, and b) as a contractor, I should not be reprenseting the NIH externally. Larry has arranged from Robin from DPCPSI to go with me to ensure that the NIH is represented by an employee.

But I am wondering if this meeting with Ms. Avery should even happen - feels too early in the process Please advise on the ramifications of cancelling/postponing on her vs. taking the meeting and not saying anything

Released by Chairman Rand Paul

substantive... Thanks.

Rajesh

------ Forwarded Message
From: "Hatchett, Richard J." [redacted]@nss.eop.gov
Date: Thu, 18 Nov 2010 08:51:35 -0500
To: "Ranganathan, Rajesh (NIH/OD) [C]" [redacted]@nih.gov
Subject: Re: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)

Rajesh,

Sorry, I should have clarified that in our initial exchanges, as I assumed that was the context in which JJ spoke with you. We have an overlapping (and in fact prior) interest in CAN because of the President's biodefense initiative, and I was taking advantage of JJ's intro to contact you on MCMI (I hadn't heard that you'd been selected for the position before JJ contacted me).

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Released by Chairman Rand Paul

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Do you have a brief bio you could send over by any chance?

Best regards, and I look forward to meeting you on Monday -
Richard

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Richard:

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<[redacted]@nss.eop.gov> wrote:

> Cyndi, Rajesh --
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> Best,
> Richard

> -----Original Message-----
> From: Burrus-Shaw, Cyndi (NIH/OD) [E] [mailto [redacted]@nih.gov]
> Sent: Wednesday, November 17, 2010 5:50 PM
> To: Hatchett, Richard J.
> Cc: Ranganathan, Rajesh (NIH/OD) [C]
> Subject: RE: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)

> Yes - that is fine. Dr. Ranganathan will be there on 11/22 at 12:00 pm. Please confirm that the location is still the same (EEOB, 421). Many thanks.
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> Best,
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> Sent: Wednesday, November 17, 2010 5:46 PM
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> Subject: RE: Discussion about Cures Acceleration Network and the President's Medical Countermeasures Initiative (MCMI)

Released by Chairman Rand Paul

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Cyndi,
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Ms. Avery (Deputy Homeland Security Adviser to the President) can do 12:00p on
> Monday, but not 11:00a. Would this work for Dr. Ranganathan?

> Thanks,
Richard

------ End of Forwarded Message

Released by Chairman Rand Paul

From: "Jahrling, Peter (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Lane, Cliff (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Coe, Linda (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: FW: Heads-up!!!!!!FW: NICBR Coordination Cell (UNCLASSIFIED)
Date: Thu, 15 Oct 2009 20:05:02 -0400
Importance: Normal
Attachments: CV09-09.doc; [redacted]_2-page_CV_09.doc

Cliff,

I have mixed feeling about both of these people. You will remember [redacted] as Kevin Anderson's predecessor at NBACC. At leasthe knows where the bodies are burried and felt the USAG was less than fair with NBACC as well. [redacted] is a DOD insider, I recall her activities as the de facto XO ar RIID during some trying times; I rather like her. We should discuss when we meent next week.

Peter

_____
From: Jewett, Mike Mr CIV USA MEDCOM USAG [redacted]
Sent: Thursday, October 15, 2009 2:16 PM
To: Coe, Linda (NIH/NIAID) [E]; Jahrling, Peter (NIH/NIAID) [E]
Subject: Heads-up!!!!!!FW: NICBR Coordination Cell (UNCLASSIFIED)

Classification: UNCLASSIFIED
Caveats: NONE

FYI....this note went to Dr. Lane and [redacted].

-----Original Message-----
From: [redacted]@taurigroup.com]
Sent: Thursday, October 15, 2009 1:38 PM
To: Gilman, James K MG MIL USA MEDCOM USAMRMC; Gilman, James K MG MIL USA MEDCOM USAMRMC; cliff.lane@nih.hhs.gov
Cc: [redacted]
Subject: NICBR Coordination Cell

MG Gilman & Dr Lane:
Forgive my forwardness, but I wanted to pass along CVs for myself and [redacted] based upon information we received regarding your initiative to establish a coordination cell for the NICBR at Fort Detrick. Dr [redacted] and I heard of this last week and are very interested in obtaining more information regarding this much-needed initiative. We also feel that we and several of our colleagues in the Tauri Group could be instrumental in its success because of our experience and relationships with many of the players.

Please feel free to pass our CVs to your lead for this project so we can initiate a dialog.

MG Gilman, I know you are on travel this week and believe you are traveling with Dr. [redacted] who knows me well and can attest to my previous work.

Released by Chairman Rand Paul

Thank you for your time and attention; I apologize for the boldness, but wanted to capitalize on what little information we have.

Regards,

[redacted]

[redacted] DVM, PhD, MS

Tauri Group

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

Classification: UNCLASSIFIED
Caveats: NONE

Released by Chairman Rand Paul

From: "Kerr, Lawrence D." [redacted]@ostp.eop.gov>
To: "Fauci, Anthony (NIH/NIAID)" <AFAUCI@niaid.nih.gov>
Subject: RE: New Scientist: US develops lethal new viruses
Date: Thu, 30 Oct 2003 15:57:45 -0500
Importance: Normal

Thank you. We had a very good talk with Mark and St. Louis University's communications team. I articulated the points you made and they were planning to have talking points ready for Mark when he spoke to the AP person. Kathryn Harrington here in OSTP was going to call the editor of the New Scientist and discuss the lop-sided nature of their piece and see if they would print a correction. I guess we'll see how the news reports look tomorrow.

Larry

-----Original Message-----
From: Fauci, Anthony (NIH/NIAID) [mailto:AFAUCI@niaid.nih.gov]
Sent: Thursday, October 30, 2003 3:52 PM
To: Kerr, Lawrence D.
Subject: FW: New Scientist: US develops lethal new viruses

Larry:
FYI.
Tony
-----Original Message-----
From: Fauci, Anthony (NIH/NIAID)
Sent: Thursday, October 30, 2003 3:37 PM
To: 'Falkenrath, Richard'
Subject: RE: New Scientist: US develops lethal new viruses

Richard:
The study of making a mouse poxvirus that has a mouse IL-4 gene inserted was funded through an NIAID contract to the investigator Mark Buller. The contact was let to evaluate vaccine and antiviral candidates. The purpose of the work in question was to confirm the already published study by the Australians and to develop an animal model to determine ways to counter the heightened virulence of the mouse poxvirus - mouse IL-4 construct. This could be done by antivirals or by neutralizing the effect of the IL-4 gene, which is the culprit that causes the immune suppression.
Tony

-----Original Message-----
From: Falkenrath, Richard [mailto:[redacted]@who.eop.gov]
Sent: Thursday, October 30, 2003 8:58 AM
To: Fauci, Anthony (NIH/NIAID)
Subject: FW: New Scientist: US develops lethal new viruses

Tony: Do you happen to know if this is independent research or if it's USG sponsored? RAF

US develops lethal new viruses
19:00 29 October 03 Exclusive from New Scientist Print Edition.

A scientist funded by the US government has deliberately created an extremely deadly form of mousepox, a relative of the smallpox virus, through genetic engineering.

The new virus kills all mice even if they have been given antiviral drugs as well as a vaccine that would normally protect them.

The work has not stopped there. The cowpox virus, which infects a range of animals including humans, has been genetically altered in a similar way.

[redacted]

Released by Chairman Rand Paul

The new virus, which is about to be tested on animals, should be lethal only to mice, Mark Buller of the University of St Louis told New Scientist. He says his work is necessary to explore what bioterrorists might do.

But the research brings closer the prospect of pox viruses that cause only mild infections in humans being turned into diseases lethal even to people who have been vaccinated.

And vaccines are currently our main defence against smallpox and its relatives, such as the monkeypox that reached the US this year. Some researchers think the latest research is risky and unnecessary.

"I have great concern about doing this in a pox virus that can cross species," said Ian Ramshaw of the Australian National University in Canberra on being told of Buller's work.

Ramshaw was a member of the team that accidentally discovered how to make mousepox more deadly (New Scientist, 13 January 2001). But the modified mousepox his team created was not as deadly as Buller's.

No rebound

Since then, Ramshaw told New Scientist, his team has also created more deadly forms of mousepox, and has used the same method to engineer a more deadly rabbitpox virus.

But this research revealed that the modified pox viruses are not contagious, he says. That is good news in the sense that these viruses could not cause ecological havoc by wiping out mouse or rabbit populations around the world if they escaped from a lab.

However, this discovery also means some bioterrorists might be more tempted to use the same trick to modify a pox virus that infects humans. Such a disease, like anthrax, would infect only those directly exposed to it. It would not spread around the world and rebound on the attackers. But there is no guarantee that other pox viruses modified in a similar way would also be non-contagious.

Ramshaw's team made its initial discovery while developing contraceptive vaccines for sterilising mice and rabbits without killing them. The researchers modified the mousepox virus by adding a gene for a natural immunosuppressant called IL-4, expecting this would boost antibody production.

Instead, the modified mousepox virus was far more lethal, killing 60 per cent of vaccinated mice. The addition of IL-4 seems to switch off a key part of the immune system called the cell-mediated response.

Maximised production

Now Buller has engineered a mousepox strain that kills 100 per cent of vaccinated mice, even when they were also treated with the antiviral drug cidofovir. A monoclonal antibody that mops up IL-4 did save some, however.

His team "optimised" the virus by placing the IL-4 gene in a different part of the viral genome and adding a promoter sequence to maximise production of the IL-4 protein, he told a biosecurity conference in Geneva last week.

Buller has also constructed a cowpox virus containing the mouse IL-4 gene, which is about to be tested on mice at the US Army Medical Research Institute of Infectious Diseases at Fort Detrick, Maryland.

Cowpox infects people, but Buller says the IL-4 protein is species-specific and would not affect the human immune system. The experiments are being done at the second-highest level of biological containment.

Ramshaw says there is no reason to do the cowpox experiments, as his group's work on rabbits has already shown the method works for other pox viruses. While viruses containing mouse IL-4 should not be lethal to humans, recombinant viruses can have unexpected effects, he says. "You'd hope the combination remains mouse-specific."

Why his group's engineered viruses are not contagious is a mystery, he says. It is not, for instance, because the host dies faster than usual, taking the virus with it. But his findings could explain why pox viruses containing IL-4 have never evolved naturally, even though the viruses frequently pick up genes that affect their host's immunity.

Released by Chairman Rand Paul

Despite the concerns, work on lethal new pox viruses seems likely to continue in the US. When members of the audience in Geneva questioned the need for such experiments, an American voice in the back boomed out: "Nine-eleven". There were murmurs of agreement.

Debora MacKenzie, Geneva

[redacted]

Released by Chairman Rand Paul

From: "McInnes, Pamela (NIH/NIAID)" </O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=PMCINNES>
To: "Fauci, Anthony (NIH/NIAID)" <AFAUCI@niaid.nih.gov>
Cc: "Gruber, Robin (NIH/NIAID)" <[redacted]@niaid.nih.gov>, "Heilman, Carole (NIH/NIAID)" [redacted]@niaid.nih.gov>
Subject: Buller - funding source
Date: Thu, 30 Oct 2003 15:16:40 -0500
Importance: Normal

Tony:

- Buller never told Program about his cowpox-IL4 work with Jahrling until last week.
- Consequently contract funding approval was neither sought nor received.
- Jahrling did not fund his work.
- He has a grant with us which is not for this work either.
- By default, contract resources were used for the work.
- Apparently he viewed this as an extension of his work with ectromelia
- Effective tomorrow morning, the Virology Branch will have initiated a documented standard approval process for contract expenditure on any study under the animal model contracts. Appropriate technical review of concepts is under discussion.

Pamela

[redacted]

Released by Chairman Rand Paul

From: "McInnes, Pamela (NIH/NIAID)" </O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=PMCINNES>
To: "Fauci, Anthony (NIH/NIAID)" <AFAUCI@niaid.nih.gov>
Cc: "Gruber, Robin (NIH/NIAID)" <[redacted]@niaid.nih.gov>, "Heilman, Carole (NIH/NIAID)" <[redacted]@niaid.nih.gov>
Subject: More on Buller
Date: Thu, 30 Oct 2003 14:37:26 -0500
Importance: Normal

Tony:

- Mark Buller has an animal model contract from us to evaluate vaccine and antiviral candidates. He mostly utilizes rabbits (rabbit pox) and mice (ectromelia).
- He has not made a vaccinia virus IL-4 recombinant and will not do so without our permission.
- At Jahrling's request Buller has made a cowpox virus mouse IL-4 recombinant which he transferred to USAMRIID (Jahrling). Buller has no plans to work with it at his own institution. Still awaiting confirmation on source of funding for making the construct. Jahrling has not used the construct in any experiment. It is secured at USAMRIID.
- Back to my earlier note, the identity of the US person who expressed concern was Richard Hatchett.

Pamela

[redacted]

Released by Chairman Rand Paul

From: "Gruber, Robin (NIH/NIAID)" </O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=RGRUBER>
To: "Fauci, Anthony (NIH/NIAID)" <AFAUCI@niaid.nih.gov>
Subject: Mark Buller and so called US develops lethal new viruses
Date: Thu, 30 Oct 2003 13:51:49 -0500
Importance: High

Summary:

- Yes, NIAID is funding Dr. Mark Buller's research under a contract.
- Dr. Buller's experiments have been limited to validating the already published Australian data.
- Dr. Buller research to date has been on engineered ectromelia, which does not infect humans.
- Jim Meegan has instructed Dr. Buller not to begin any research on cowpox or vaccinia without express permission from NIAID.
- I am awaiting a summary of Barney Graham's research (due by 4:00 today)

R

[redacted]

Released by Chairman Rand Paul

From: "Kerr, Lawrence D." <[redacted]@ostp.eop.gov>
To: [redacted]@hhs.gov, "Fauci, Anthony (NIH/NIAID)" <AFAUCI@niaid.nih.gov>, [redacted]@hhs.gov, "Bernard, Kenneth" [redacted]@who.eop.gov>, "Tavel, Jorge " <[redacted]@ovp.eop.gov>, "Dale, Shana L." <[redacted]@ostp.eop.gov>
Cc: "Green, Terry M. (NIH/NIAID)" <[redacted]@niaid.nih.gov>, "Harrington, Kathryn M." <[redacted]@ostp.eop.gov>
Subject: FW: New Scientist: US develops lethal new viruses
Date: Thu, 30 Oct 2003 08:53:48 -0500
Importance: Normal

Good morning,

Dr. Marburger and General Gordon met this morning to discuss this news release. I had been over the scientific presentation that Mark Buller gave in Geneva with Dr. Marburger so he knows that the news article doesn't reflect the true nature of the science and the development of countermeasures (anti-IL-4 mAb) that Mark has worked on. None-the-less there are some serious concerns that this raises and they have asked that we solicit Dr. Fauci's and HHS's opinion on this work and the proper response (if any) that we should be prepared to give.

Coincidently, Mark Buller just called and we had a good talk. He is quite upset with the tone of the article. I made a couple of requests to him- First, that he contact St. Louis University's public relations department and fill them in on his scientific work. Kathryn I offered your contact information should they want to talk to someone here. Secondly, I ask him to review some talking points and Q&As for me. I am preparing a non-scientific version of his observations, balanced with the work he has done to develop prophylactic countermeasures. I am working on Q&As for Mark McClellan should they be needed. I will share all of this with you as they are prepared and ask for your comments. Mark is sending me his ppt from Geneva (I only have the handouts currently).

More to come....

Larry

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[redacted]

Released by Chairman Rand Paul

No rebound

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Now Buller has engineered a mousepox strain that kills 100 per cent of vaccinated mice, even when they were also treated with the antiviral drug cidofovir. A monoclonal antibody that mops up IL-4 did save some, however.

His team "optimised" the virus by placing the IL-4 gene in a different part of the viral genome and adding a promoter sequence to maximise production of the IL-4 protein, he told a biosecurity conference in Geneva last week.

Buller has also constructed a cowpox virus containing the mouse IL-4 gene, which is about to be tested on mice at the US Army Medical Research Institute of Infectious Diseases at Fort Detrick, Maryland.

Cowpox infects people, but Buller says the IL-4 protein is species-specific and would not affect the human immune system. The experiments are being done at the second-highest level of biological containment.

Ramshaw says there is no reason to do the cowpox experiments, as his group's work on rabbits has already shown the method works for other pox viruses. While viruses containing mouse IL-4 should not be lethal to humans, recombinant viruses can have unexpected effects, he says. "You'd hope the combination remains mouse-specific."

Why his group's engineered viruses are not contagious is a mystery, he says. It is not, for instance, because the host dies faster than usual, taking the virus with it. But his findings could explain why pox viruses containing IL-4 have never evolved naturally, even though the viruses frequently pick up genes that affect their host's immunity.

Despite the concerns, work on lethal new pox viruses seems likely to continue in the US. When members of the audience in Geneva questioned the need for such experiments, an American voice in the back boomed out: "Nine-eleven". There were murmurs of agreement.

Debora MacKenzie, Geneva

Released by Chairman Rand Paul

From: "Graham, Barney (NIH/VRC)" <[redacted]@mail.nih.gov>
To: "Gruber, Robin (NIH/NIAID)" <[redacted]@niaid.nih.gov>, "Anthony S. Fauci (E-mail)" <af10r@nih.gov>
Cc: "McInnes, Pamela (NIH/NIAID)" <[redacted]@niaid.nih.gov>, "Heilman, Carole (NIH/NIAID)" <[redacted]@niaid.nih.gov>
Subject: RE: Vaccinia Virus Mouse IL-4 Construct
Date: Thu, 30 Oct 2003 15:00:31 -0500
Importance: Normal
Attachments: ICAAC_2003_MVA_-_final.psd

We made a vaccinia-IL-4 virus construct in 1996 for studies of how IL-4 modulates the effector function of CD8+ T cells. Several papers have been published on the use of this construct in mice.

Aung S, Tang YW, **Graham BS**. IL-4 inhibits induction of cytotoxic T lymphocyte activity in mice infected with recombinant vaccinia virus expressing respiratory syncytial virus M2 protein. Journal of Virology 1999; 73:8944-8949.

Aung S, **Graham BS.** Differential regulation of perforin- and FasL-mediated cytotoxicity by IL-4. Journal of Immunology 2000;164:3487-3493.

Johnson TR, Fischer JE, **Graham BS.** Construction and characterization of recombinant vaccinia viruses co-expressing a respiratory syncytial virus protein and a cytokine. Journal of General Virology 2001; 82:2107-2116.

We used the vaccinia-IL-4 construct to challenge mice immunized with MVA. Either one or two doses of MVA protects mice from lethal infection with vaccinia-IL-4 intranasal challenge. They MVA protection is effective even in mice that have been depleted of CD4 or CD8 T cells prior to challenge, or in mice that cannot make functional antibody responses. This work was presented as an abstract at the recent ICAAC meeting in Chicago and the poster is attached.

Let me know if you would like any additional information.

Barney

****

Barney S. Graham, M.D., Ph.D.
Chief, Viral Pathogenesis Laboratory and Clinical Trials Core
VRC/NIAID/NIH
[redacted]
Bethesda, MD 20892-3017
Phone: [redacted]
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-----Original Message-----
From: Gruber, Robin (NIH/NIAID)
Sent: Thursday, October 30, 2003 1:47 PM
To: Graham, Barney (NIH/VRC)
Cc: McInnes, Pamela (NIH/NIAID); Heilman, Carole (NIH/NIAID)
Subject: Vaccinia Virus Mouse IL-4 Construct

Dr. Graham-

[redacted]

Released by Chairman Rand Paul

Dr. Fauci has received and inquiry from the White House regarding NIAID funding of Dr. Mark Buller's research on engineered ectromelia. Dr. Buller is proposing to work on cowpox and vaccinia next, but has not received authorization from NIAID to do so. Since you are already working on a vaccinia virus mouse IL-4 construct, Dr. Fauci would like you to prepare a brief summary of your research and findings to date for him by 4:00 today. You can either send to me or to him directly. If you send to him directly, please cc me.

If you have any questions or concerns, please do not hesitate to call me.

Thank you.

Robin

Robin L. Gruber, MPS
Special Assistant to the Director
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Phone: [redacted]
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Released by Chairman Rand Paul

From: "McInnes, Pamela (NIH/NIAID)" </O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=PMCINNES>
To: "Fauci, Anthony (NIH/NIAID)" <AFAUCI@niaid.nih.gov>
Cc: "Gruber, Robin (NIH/NIAID)" <[redacted]@niaid.nih.gov>, "Heilman, Carole (NIH/NIAID)" [redacted]@niaid.nih.gov>
Subject: Mark Buller and so called US develops lethal new viruses
Date: Thu, 30 Oct 2003 13:09:33 -0500
Importance: High
Embedded: unnamed

Tony:

Background on Mark Buller presentation in Geneva re so-called US development of lethal new viruses

In 2000, Australian investigators, while pursuing a contraceptive development program for controlling mice, serendipitously discovered that by engineering ectromelia (mousepox) to include mouse IL-4, the new virus was more virulent and could evade normally protective vaccination (Dryvax). These data were published (Jackson RJ, et al. J Virol. 2001 Feb;75(3):1205-10. Expression of mouse interleukin-4 by a recombinant ectromelia virus suppresses cytolytic lymphocyte responses and overcomes genetic resistance to mousepox.) The data created some disturbance in the poxvirus research community, in the national security community and in the press because of the possible implications for engineering a smallpox virus with human IL-4.

Given that the data were in the public domain and the study design was not optimal from a virologic perspective, it was felt to be both important and appropriate to verify these data and to explore ways to control this new virulent virus, utilizing either a vaccine or a therapeutic.

Under Contract N01-AI-15436, Dr. Mark Buller of St. Louis University implemented a study in mice utilizing a mouse pox virus engineered with mouse IL-4. (Carole sent you the attached e-mail 7/16/2002 informing you of progress on the study.) The **MOUSE** part of each component is critical and adds two levels of safety. Both the virus and the IL-4 used were mouse species specific. This study confirmed the Australian findings and Dr. Buller has presented these data in several forums including the International Poxvirus Meeting held in Lake Placid in summer 2002, and down at DHHS.

Shift to Geneva. Last week a meeting organized by Acambis was held in Geneva. DA was prominently involved in the meeting and honored at a dinner. Larry Kerr (DHS) , Bernie Moss, Peter Jahrling, Jim Meegan, Mark Challberg were among other meeting attendees. Mark Buller had been assigned the topic of "The Potential Use of Genetic Engineering to Enhance Orthopoxviruses as Bioweapons". Jim Meegan reports that in the first half of Mark's talk, he discussed hypothetical scenaria and tried to show that these would not add to the general body of knowledge in a meaningful way; e.g. engineering monkey pox. In the second half of his talk, he presented his data that confirmed the Australian findings with engineered ectromelia. The only new data presented were partial protection against the engineered virus with antivirals (cidofovir). He acknowledged funding of the work from NIAID. At the end of his talk, Buller said that in partnership with Jahrling, he was going to create a cowpox virus mouse IL-4 construct and a vaccinia virus mouse IL-4 construct for testing of antivirals in the mouse system.

Following his talk, Jim Meegan immediately jumped up and stressed that the Australian data were already published, that it was important to confirm them, that safety issues had been fully considered and embraced in the design of the experiment, and no aspect of the study had been covert.

The next individual to comment from the audience (US person, unknown name) expressed relief that Dr. Meegan had clarified those issues because that eased his concerns re the experiment and the data and the chance that we were "giving terrorists a recipe for a bioweapon."

At the end of the session, Dr. Meegan instructed Dr. Buller not to initiate work on the cowpox virus mouse IL-4 or vaccinia virus mouse IL-4 construct experiment without discussion and express permission if NIAID money was proposed for use. The reason for his concern obviously was that one of the two safety barriers (cowpox and vaccinia can infect humans) would not be in place for such an experiment. Dr. Buller yesterday sent an e-mail to Dr. Meegan asking for clarification on this. Dr. Meegan has not yet responded.

However, within the last 24 hours we have discovered that Barney Graham has already created and tested a vaccinia virus mouse IL-4 construct. (There is some similar work published almost a decade ago.) We hear that this virus was also more

[redacted]

Released by Chairman Rand Paul

From: "Carole Heilman" </O=NIH/OU=NIAID/CN=RECIPIENTS/CN=CHEILMAN>

To: "Fauci, Anthony (NIH/NIAID)" <AFAUCI@niaid.nih.gov>, "La Montagne, John (NIH/NIAID)" <[redacted]@niaid.nih.gov>, "Killen, Jack (NIH/NCCAM)" <[redacted]@mail.nih.gov>

Cc: "McInnes, Pamela (NIH/NIAID)" <[redacted]@niaid.nih.gov>

Subject: Ectromelia/IL-4 - repeat

Date: Tue, 16 Jul 2002 16:14:20 -0400

Importance: Normal

Tony:

Mark Buller has been working on repeating the Australian experiment that demonstrated that insertion of the IL4 gene in ectromelia resulted in a more virulent form. I wanted to update you with respect to these results.

- He has successfully repeated these studies
- Prior vaccination with an ectromelia vaccine, however, protected the mice equally well from this new virulent virus when compared to WT ectromelia..
- However, prior vaccination with the related orthopox virus, vaccinia, protected only against ectromelia challenge and NOT against the ectromelia-IL4 construct.
- The mechanism of the break-through immunity associated with the IL-4 insert is being further evaluated but appears to be mediated through the IL4 receptor, as Balb-C-IL-4 knockout mice appear to be protected under the heterologous challenge scenario

Carole

[redacted]

Released by Chairman Rand Paul

UNIVERSITY OF MINNESOTA

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April 12, 2012

Amy P. Patterson, M.D.
Associate Director for Science Policy
National Institutes of Health
Office of Science Policy, OD, NIH
Building 1, Room 103
9000 Rockville Pike
Bethesda, MD 20892

Dear Amy,

We all realize that the National Science Advisory Board for Biosecurity (NSABB) is currently in "uncharted scientific and public policy waters" with the request by the United States Government (USG) to review and make recommendations regarding publication of manuscripts from Dr. Ron Fouchier and colleagues and Dr. Yoshihiro Kawaoka and colleagues reporting their respective research methods and results related to the transmissibility of H5N1 in mammals. As a member of the NSABB, I appreciate the extensive efforts by the Board over the past six months to provide this comprehensive review and to make recommendations based on the previous extensive work of the Board to define dual-use research of concern (DURC.) It has been a gratifying professional and personal experience for me to work with such a dedicated group of scientific and policy leaders with a common purpose of both enabling the ongoing critical life science research that provides answers to some our most challenging health and environmental issues and at the same time protecting the world from potential catastrophic outcomes resulting from similar research.

It has been two weeks since the NSABB meeting of March 29-30 where the Board was requested by the USG to reconsider our previous decision recommending the redaction of both the above referenced manuscripts before publication. During this time I have given considerable thought to the way the meeting was conducted and the subsequent decision by the NSABB to change its recommendation to full publication of both manuscripts without redaction. While we all realize any effort by the NSABB members and staff to arrive at a "Solomon-like" decision regarding the dissemination of the methods and results included in these manuscripts will be questioned by those who do not agree with the outcome, there is also a critical consideration for establishing precedence for how the NSABB will move forward with similar complex issues in the future. It is for this reason I share this letter with the NSABB members and the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA) staff that support the Board's work. The views in this letter are mine and mine alone; I have not communicated with members of the NSABB or staff since the meeting. I write this letter in the spirit of moving forward and with an understanding of how the recent events related to the H5N1 influenza manuscript review informs us on why the USG-NSABB process for evaluating DURC issues must fundamentally change to

Released by Chairman Rand Paul

both protect life science research and the risk to the public of such research. For the record, I voted at the meeting to approve the full publication of the Kawaoka manuscript and the continued requirement of redaction of the Fouchier manuscript.

First, I believe that the agenda and speakers for the March 29 and 30th NSABB meeting as determined by the OBA staff and other USG officials was designed to produce the outcome that occurred. It represented a very "one sided" picture of the risk-benefit of the dissemination of the information in these manuscripts. The agenda was not designed to promote a balanced reconsideration of the manuscripts. While I don't suggest that there was a sinister motive by the USG with regard to either the agenda or invited speakers, I believe there was a bias toward finding a solution that was a lot less about a robust science- and policy-based risk-benefit analysis and more about how to get us out of this difficult situation. I also believe that this same approach in the future will mean all of us, including life science researchers, journal editors and government policy makers, will just continue to "kick the can down the road" without coming to grips with the very difficult task of managing DURC and the dissemination of potentially harmful information to those who might intentionally or unintentionally use that information in a way that risks public safety. Merely providing a "minority report" in the final findings and recommendations of the meeting does nothing to address the fundamental issues of how the risk and benefits were determined, described, and considered at the meeting. For example we heard from Dr. Fouchier that he has already identified an additional mutation (not included in his current manuscript) that results in ferret-to-ferret transmission (mammalian transmission) without the need for repeated passage of the virus in ferrets. This work, which may have been supported by NIH funds, surely must be considered as a candidate for the next manuscript to be before the NSABB for review. What scientific and policy issues will differ with this "incrementally changed manuscript" compared with the issues we just considered? If such work represents only incremental changes in results from previously approved work, will the Board ever find a bright line for redacting publication and all the issues that go with that decision?

For you to better understand my concerns, I will detail specific examples of how I believe the agenda and selected speakers resulted in the one-sided risk-benefit analysis that I described above. I will use in part the general considerations and conclusions in the April 11th draft NSABB findings and recommendations document as the framework for these points.

The data in the newly revised manuscripts are immediately and directly enabling.

There was no objective review provided by a disinterested subject matter expert that addressed the current state of the art regarding the proliferation and use of reverse genetics technology that can incorporate the methods and results presented in the current manuscripts to allow those who would not have the ready expertise or resources to more easily repeat these experiments. The implications of doing such work, even by well-meaning scientists who do not have adequate biosafety measures in place, should have been reviewed. The subject matter experts that addressed this issue at the meeting have a real conflict of interest in that their laboratories are involved in this same type of work and the results of our deliberations directly affect them, too. The same can be said about the attendees and outcome of the February World Health Organization consultation. In short, it was the "involved influenza research community" telling us what they should and shouldn't be allowed to do based on their interested perspective. Such a

Released by Chairman Rand Paul

perspective is very important and should be included in this discussion, but it shouldn't be the only voice.

As director of one of the five NIH-supported centers of excellence in influenza research and surveillance, I can speak with firsthand knowledge and experience that the voice of an important group of senior influenza researchers not doing similar mutation/transmission work was not heard regarding this issue. I personally tried to have their voices represented at the meeting. They were not invited. One of them wrote me a very clear and compelling comment on the potential for the information in one of the manuscripts to be immediately and directly enabling. He stated;

> "I am an influenza virologist myself, and we routinely create viral mutants in my lab using reverse genetics, so I have a good sense of the technical issues involved. As such, I can recognize that some outspoken researchers in our field have been under-representing the increased risk that would be entailed by full publication of the specific mutations versus the current situation where only the general outline of the ferret-passage scheme is known. A ferret-passage experiment is expensive and technically demanding, and could only be done by a handful of labs in the world. Once the mutations are public, individuals in my lab (or many other labs) could generate the mutants in a few weeks given several thousand dollars for gene synthesis.
>
> I remain agnostic about what is the best policy going forward. I recognize that there also important potential benefits from this research, and think that research along these lines does have valid scientific and public-health justifications. But these benefits need to be carefully weighed against the real risks, and I am definitely concerned that there has been a rush to judgment for full publication within our own research community."

I have talked with many similarly minded influenza researchers from around the world who agree with the above statement. Yet these voices were notably absent in the NSABB deliberations.

The data may benefit public health and surveillance efforts.

The Board received no formal or informal presentation from those on the front lines of H5N1 animal surveillance and control. Specifically, no one with H5N1 virus surveillance and control expertise from either the Food and Agriculture Organization (FAO) or the World Organization for Animal Health (OIE) were invited to participate. I have discussed with officials from both organizations the implications of sharing the mutation data; the general response indicated that such information without major new resources and government commitment to active animal surveillance and control would not fundamentally change current surveillance and control practices in most of the endemic H5N1 countries. Yet, there was a series of very general and unsubstantiated statements made by others invited to the meeting who are not involved in the day-to-day animal surveillance activities in the H5N1 endemic countries (including the authors) as to the benefits of making the mutational data available for this purpose.

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Our NIH-supported center of excellence is supporting surveillance for H5N1 virus in domestic animals in one of the H5N1 endemic countries; our surveillance researchers have told us that the finding of an H5N1 virus with specific mutational changes in poultry would not result in widespread culling activities unless the birds are sick. Immediate culling is supposed to be the standard protocol now for the control of H5N1 virus, but resources for a number of the H5N1 endemic countries are often lacking to detect the virus or support programs. The voice of these and similar on-the-ground experts was missing from our discussion regarding the benefit of making these mutation data general available.

Setting aside the fact that surveillance experts noted above were not invited as subject matter experts, it is notable that current news sections in both *Science* and *Nature* have published a series of articles on the controversy of using the H5N1 virus mutation information for surveillance and control purposes. Several of these stories were well researched, with numerous interviews with some of the experts I noted above. Their conclusions were consistent with my comments above regarding the utility of making the mutation data from these studies generally available and the impact on the control of H5N1 infection in poultry. None of these news stories were referenced in the meeting (except by me) or provided as important background information leading to a more complete risk-benefit analysis. There was no discussion as to the limited number (and time from sampling to testing) of H5N1 viruses sequenced from endemic countries or how to improve that situation in the endemic countries before the release of the mutation data could yield even remote benefit.

The most important aspect of the results in these two studies on surveillance and control has already been accomplished; namely alerting the world to the possibility that H5N1 influenza virus surely can become a mammalian-transmitted virus and poses real pandemic potential. We must be much better prepared to respond to a possible H5N1 influenza pandemic than we are today. Publication of the full study methods and result of either manuscript will not enhance this conclusion.

Finally, I believe it was unfortunate that Dr. Smith was able to present the work on the population-based mutational changes in H5N1 viruses without an opportunity for others in the influenza field to provide commentary. Since Dr. Fouchier was a coauthor of the work, it hardly represented an unbiased view of H5N1 virus genetics. Was the manuscript that Dr. Smith presented peer-reviewed? While I appreciate that he is a leading influenza researcher, for the sake of balance others without a primary interest in these manuscripts should have led this discussion.

Security considerations and the risk of malevolent applications of the mutation data.

One of the most disturbing aspects of the meeting was the security briefing on the evening of March 29th. It was one of them most incomplete and, dare I say, useless classified security briefings I've ever attended. For the past 20 years, I have held security clearances in my work with international and national bioterrorism, including a top secret clearance in my role as a special assistant to HHS Secretary Tommy Thompson from 2001 to 2004. I have served as a briefer for some of our leading government officials during that time. I do understand threat assessment and the limitations and strengths of intelligence.

Released by Chairman Rand Paul

I realize I'm limited in to what I can share here because of the classified nature of the briefing, but in short the briefing we received can be summed up by saying "We don't know much about anyone wanting to use this information for malevolent reasons, so it's probably not a risk." I would agree that few persons in the terrorism and intelligence worlds see this as a primary or even secondary weapon of choice for international terrorism for all the obvious reasons. But the absence of any discussions regarding international or national rogue scientists or irresponsible researchers not using adequate biosafety to conduct "now enabled work" was a major flaw in the briefing. These types of scientists are exactly the ones who would benefit immensely in conducting work of serious concern with the recipe and methods defined in fully published manuscripts. There was no discussion of eco-terrorists whose single purpose is to disrupt animal production activities. A release of a mammalian-transmitted H5N1 virus in swine would devastate that industry even if limited illness occurred because of the public relations issue of "killer bird flu virus in pigs." I can't think of a worse scenario than having H5N1 virus circulating widely in swine with a critical reassortment likely to occur and human transmission not far off.

The briefing (or the meeting as a whole) did not cover the historical perspective of why influenza virus is truly different than any Class A pathogen we worry about because of it the consequences of its accidental release and our inability to stop transmission once it occurs in the community. As bad as an accidental release of variola virus, *Bacillus anthracis*, *Yersinia pestis*, or SARS virus might be, we could—based on agent transmissibility, incubation period, clinical recognition and countermeasures—effectively stop a global pandemic from occurring. We can't do that with influenza virus. There is no margin for error. We need look no further than the reemergence of H1N1 in 1977, after a 20-year absence from global circulation. Our group has been actively investigating the return of H1N1 in 1977, and based on that work we are convinced it leaked out of a Russian lab that was working on a live-attenuated H1N1 virus vaccine. Again, none of this information was addressed in the risk assessment overview.

I am particularly concerned about this aspect of the two days of deliberations, because I heard several members remark how the security briefing had a substantial impact on their decision of how to vote.

The use of the mutation data to enhance countermeasure preparedness.

Although this issue came up several times in terms of the importance for sharing the mutation data for the development of countermeasures (vaccines and antiviral drugs), there were no data-related presentations addressing this issue. Again the *Science* and *Nature* news stories of the previous three months did an outstanding job of researching the claim that the mutation data were critical in developing and deploying H5N1 countermeasures. The authors of the articles interviewed a number of global experts in the area of influenza countermeasures; they concluded there was no immediate benefit to countermeasure development or production as a result of the availability of the mutation data. At no time was this information presented to the Board by a disinterested expert.

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A previous decision.

Throughout the discussion of the current review of the two manuscripts, the issue surrounding the NSABB's approval of publication of the 1918 H1N1 virus paper in 2005 has been raised as precedence for how we might proceed in this situation. I want for the record to be clear that I firmly believe we made a mistake in approving the publication of the 1918 virus paper. At the time I was one of the supporters of publication. We reasoned that the 1918 H1N1 virus, if it were to accidently escape or be intentionally released, would cause little public health consequence because of the previous circulation of H1N1 influenza virus prior to 1958 and again since 1977. We believed that the vast majority of the world's population would have sufficient cross-protective immunity to prevent any kind of H1N1 influenza pandemic as experienced in 1918. Well, with the appearance of A(H1N1)pdm09, we now realize there was virtually no population-based immunity to either the new H1N1 virus or the closely related virus, the 1918 H1N1 strain. The exception was for those who had experienced H1N1 infection prior to the early 1950's when those circulating strains in humans did provide cross protection.

Had someone taken the published data on the 1918 virus mutations, they could have created a virus that, had it been even accidently released, could have caused a pandemic much as the A(H1N1)pdm09 virus did. I share this observation not to be critical of the 2005 NSABB decision, as I was part of that decision. Rather, it's to remind us that you can't unring a bell. Any decisions that the NSABB makes with regard to the influenza issue may possibly have far-reaching and yet unrecognized implications, like the 1918 virus situation.

Summary

In short, the NSABB March meeting should be a very important learning experience for the USG, the journal editors, and life scientists in general as to the need for a much more effective system to address DURC issues. One primary lesson that I believe is critical: The Board must involve disinterested subject matter experts to provide technical advice. I believe that the relative lack of subject matter expert input from those without a direct interest in the Board's decision be viewed critically by the larger policy and life science communities as the decision is debated over the upcoming days.

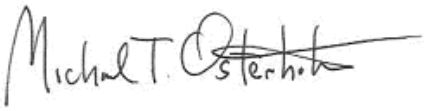
As I stated before, I believe our recent experience is just the beginning, not the end of this type of scientific and policy conflict. As a said to Dr. Collins toward the conclusion of the March meeting, I wouldn't want to be in his shoes sitting before a Congressional hearing trying to explain why the NSABB and likely the USG supported the full Fouchier publication when we heard at the meeting that he has done more work and found one additional mutation that now confers H5N1 transmissibility between mammals without ferret passage. How will we justify one more "incremental finding paper" that now is a pretty complete cookbook when we didn't recommend redaction for the vast body of his work? If we believe redaction of the current manuscript is problematic in terms of international agreements, I think the next mutation paper will prove to be the straw that breaks the camel's back. It is unfortunate that the current NSABB action just kicked the can down the road to the next manuscript.

I hope these comments are helpful as the NSABB moves forward. As someone who will soon be rotating off the Board after 7 years of service, I believe now, more than ever, of its importance.

Released by Chairman Rand Paul

Thank you for the honor and opportunity to participate.

Sincerely,



Michael T. Osterholm, PhD, MPH
Director, Center for Infectious Disease Research and Policy
Director, Minnesota Center of Excellence for Influenza Research and Surveillance
Professor, Division of Environmental Health Sciences, School of Public Health
Adjunct Professor, Medical School

Cc: NSABB Members
NSABB Staff

Released by Chairman Rand Paul

MEMORANDUM OF UNDERSTANDING
Between
UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
NATIONAL INSTITUTES OF HEALTH And
THE UNITED STATES MARSHALS SERVICE

I. PARTIES

This Memorandum of Understanding (MOU) sets forth the understanding of the obligations and goals of the United States Department of Health and Human Services (HHS), National Institutes of Health (NIH), and the United States Marshals Service (USMS) relating to protective services for Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases prior to and after his retirement from federal service.

II. PURPOSE

The purpose of this MOU is to define the roles, responsibilities, and actions necessary to secure and protect Dr. Anthony Fauci under this MOU and the fiscal year Reimbursable Agreement (RA).

III. AUTHORITY

For USMS:

1. 28 United States Code (U.S.C.) §§ 561(b), 566(e)(1)
2. 28 Code of Federal Regulation (C.F.R.) § 0.111(e)
3. USMS Directive 10.1, Judicial Security

For HHS NIH:

1. 42 U.S.C. § 282
2. 15 U.S.C. § 1535

IV. FUNDING AND REIMBURSEMENT

Funds transferred to the USMS by HHS NIH will be utilized for the sole purpose of the protective services provided to Dr. Anthony Fauci and will include, but not be limited to, the following:

1. Salaries and benefits for assigned Deputy United States Marshals (DUSM) and administrative support personnel, including reasonable and necessary overtime pay.
2. Reasonable and necessary travel costs for Temporary Duty personnel.
3. One leased and equipped limousine and follow car used for the transportation and security of Dr. Anthony Fauci.
4. Leased vehicle and fuel for one vehicle for each DUSM assigned to the protective detail.
5. Necessary law enforcement equipment for operational use.

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6. Other ancillary costs as identified, documented by USMS, and mutually agreed upon in advance by HHS NIH and the USMS.

The RA accompanying this MOU identifies the actual cost of the services to be provided. All expenses incurred by USMS related to this agreement must be reasonable, necessary, mission related, and documented.

Funding for the following items will be paid for directly by HHS NIH:

1. All travel and per diem expenses for permanent security detail members related to the protective mission will be paid for by HHS NIH.
2. Other ancillary costs as identified, documented by USMS, and mutually agreed upon in advance by HHS NIH and the USMS.

V. USMS PROTECTIVE SERVICES PROVIDED

1. The protective services provided will continue upon the execution of this MOU and the effective transfer of funds as stipulated in the accompanying RA, as well as future fiscal year RAs, subject to periodic assessment as outlined below. The number of reimbursable positions and other costs identified in the RAs are based on USMS protective service requirements, experience and methodology, in addition to USMS operational requirements at the HHS NIH. At least each fiscal year hereafter, and as frequently as the USMS deems appropriate, the USMS will conduct a threat assessment to determine, in its discretion, whether USMS authorities allow for continued protection and, if so, future protective requirements, if any. HHS NIH will be consulted and provide recommendations regarding protective requirements, but the USMS retains final authority regarding the extent of protective requirements and the continuing need and authority for protective services. Permanent security detail members are not HHS NIH employees and at all times during the term of this MOU will remain USMS personnel and operate under the supervision of the USMS.
2. Personal Security briefing, including occasional threat-based briefings, will be provided by a USMS Chief Inspector DUSM or designee assigned to HHS NIH. The initial briefing on USMS protective services will include, but not be limited to, USMS protective service policy 10.1 and 28 USC 566(e)(I)(A). The initial briefing will be provided to Dr. Anthony Fauci and his immediate family. Dr. Anthony Fauci and his immediate family will be given a copy of USMS Publication #94 (Offsite Security Handbook).
3. Protective services will be provided for Dr. Anthony Fauci. The level of support will be based on the USMS assessment. At any time, threat-based circumstances exist, additional personnel may be added to or removed from the protective detail as agreed upon by the Deputy Director for Management, NIH (or their designee) and the USMS.
4. The USMS will monitor and mitigate threats against Dr. Anthony Fauci. This includes access to, and use of, the USMS Office of Protective Intelligence, Threat Management Center, and other USMS protective investigations resources as required. The USMS Detail Chief Inspector will meet regularly with the Deputy Director for Management, NIH (or their designee) to discuss security services and threat management.

Released by Chairman Rand Paul

5. USMS technical protective support (Tactical Operations Division – Office of Strategic Technology) will be provided as needed and agreed upon by the USMS Chief Inspector and the HHS NIH designee.

VI. DURATION OF AGREEMENT AND ADMINISTRATION

This MOU will be effective on January 1, 2023. This MOU shall remain in effect through September 20, 2023, subject to the availability of funds as detailed in the RA. This MOU may be extended or renewed for future fiscal years by the mutual, written consent of both parties. This MOU may be modified by the mutual, written consent of both parties. This MOU may be terminated by either party at any time; however, terminating party must provide written notice to the other party at least 2 months (60 days) in advance of the effective date of the termination. It is further established that the terms and conditions stipulated herein are subject to modification, upon written notice, by the parties as they may mutually agree. Upon termination of this agreement, all USMS records as they relate to the security detail, are proprietary and will remain the property of the USMS. Specific information contained in USMS records will be disclosed and provided to appropriate party upon any Congressional inquiry in accordance with USMS policy.

The fiscal year RA amount will be binding for any specific fiscal year and may be adjusted by USMS or HHS NIH to account for increase or decrease in the actual costs of services provided, as deemed reasonable by both parties and subject to the availability of funds. A projected fiscal year cost will accompany the RA. Each RA will be signed and returned expeditiously so that neither agency falls into a non-compliant situation. Any unused funds will be de-obligated at the end of the period of availability of the appropriation.

VII. APPROVALS

The parties have entered into this Memorandum of Understanding by signatures of their authorized representatives.

_____ _____

Roberto I. Robinson
Deputy Director
U.S. Marshals Service

Date

[redacted]

_____ _____

Alfred C. Johnson, Ph.D.
Deputy Director for Management
National Institutes of Health
U.S. Department of Health
and Human Services

Date

Released by Chairman Rand Paul

From: "Erbelding, Emily (NIH/NIAID) [E]" <[redacted]@nih.gov>
To: "Schmaljohn, Connie (NIH/NIAID) [E]" <[redacted]@nih.gov>
Cc: "Cassetti, Cristina (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Bryant, Paula (NIH/NIAID) [E]" <[redacted]@nih.gov>, "Hewitt, Judith (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Subject: NHPs at IRF and DMID collaboration
Date: Sat, 28 Mar 2020 09:01:57 -0400
Importance: Normal

Connie,
I learned yesterday that investigators on the IRF team weren't clear that the early NHP experiments done in collaboration with David O'Connor were related to the Moderna mRNA vaccine. If you didn't know this, it is a critical failure in communication on our part and we need to immediately address it.

We think that the rate-limiting step in taking the Moderna vaccine into Ph2 trials by May/June, will be proving to the FDA that vaccine related enhancement won't be an added risk to participants. So starting these experiments at a basic level (and not doing refined natural history studies first) is NIAID's highest priority for these animals. I believe that Barney Graham has started doing the experiments in Ralph Baric's mouse model. The FDA has signaled that data from a second species of animals will be necessary.

There wasn't time in the division directors meeting yesterday to get to this item on the agenda so I wanted to follow up now.

To reiterate--getting the Moderna vaccine into Phase 2 trials is the highest priority for the vaccine effort (Quote from Tony Fauci to me this week: "I hope that you feel like my foot is on your neck right now to get this done.")

Let me know if you want to discuss further.

regards,
Emily

Emily Erbelding, M.D., M.P.H.
[redacted]
Office: [redacted]
E-mail: [redacted]

Released by Chairman Rand Paul

From: "Hudgings, Carole (NIH/NIAID) [V]" <[redacted]@niaid.nih.gov>
To: "Lane, Cliff (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Cc: "Hudgings, Carole (NIH/NIAID) [V]" <[redacted]@niaid.nih.gov>
Subject: FW: DMID IAA
Date: Wed, 12 Dec 2018 16:13:22 -0500
Importance: Normal
Attachments: AAI18027_(Countersigned_7600AB)_Fully_signed_REVISED_AMOUNT.pdf; AAI18027-001-00000_DHS-NIAID_Signed.pdf

---

Cliff –
See the SOW on the **Pages 14-16 of the Signed PDF** document (not the revised amount document).

Thanks, Carole

From: Meaney, Tammy (NIH/NIAID) [E] <[redacted]@nih.gov>
Sent: Wednesday, December 12, 2018 9:43 AM
To: Hudgings, Carole (NIH/NIAID) [V] <[redacted]@niaid.nih.gov>
Subject: RE: DMID IAA

Hi Carole,

The amount that this agreement was executed was $2,454,590.49. I have attached the documents for your reference.

Thanks-

Tammy Meaney
Administrative Officer
NIH/NIAID/OAS/EAMB
[redacted], MD [redacted] Office
[redacted]@nih.gov

Disclaimer:

The information in this e-mail and any of its attachments is confidential and may contain sensitive information. It should not be used by anyone who is not the original intended recipient. If you have received this e mail in error please inform the sender and delete it from your mailbox or any other storage devices. National Institute of Allergy and Infectious Diseases shall not accept liability for any statements made that are sender's own and not expressly made on behalf of the NIAID by one of its representatives.

From: Hudgings, Carole (NIH/NIAID) [V] <[redacted]@niaid.nih.gov>
Sent: Wednesday, December 12, 2018 9:12 AM
To: Meaney, Tammy (NIH/NIAID) [E] [redacted]y@nih.gov>
Cc: Hudgings, Carole (NIH/NIAID) [V] <[redacted]@niaid.nih.gov>
Subject: DMID IAA

FYI DMID has provided the below background information about the agreement:

The IAA was signed on August 15th 2018 and runs until August 14th 2019. The title is "The Influence of Aerodynamic Particle Size on the Virulence of Aerosolized Ebola Virus." The purpose of this study is to further understand the disease caused by aerosolized Ebola virus in a relevant animal model.

From the document:

Scope of Work: NIAID is developing Medical Countermeasures (MCMs) to protect against Ebola virus disease. Therefore, NIAID needs to understand differences in disease when Ebola virus infection occurs by different routes and to ensure that MCMs under development are effective in these different scenarios. The purpose of this study is to further understand the disease caused by aerosolized Ebola virus in a relevant animal model. This study has been developed jointly by NIAID and the National Biological Threat Characterization Center (NBTCC) in coordination with DHS/S&T BTCP. NBTCC shall perform work on a non-interference basis with DHS/S&T priorities and the NBACC Annual Plan.

Under this work plan, the NBTCC with guidance from the BTCP shall:

(1) NBTCC shall conduct pre-execution activities to obtain all necessary approvals to conduct the Project

(2) NBTCC shall provide NIAID and BTCP a draft study protocol for the *in vitro* study and a final study protocol following incorporation of NIAID and BTCP input. NBTCC shall first assess their inhalation exposure system with Ebola virus and optimize aerosol generation, sampling, and assay methodologies. The target median aerodynamic particle sizes will be 1-3 μm, to allow comparison to previously published studies with aerosolized filoviruses which utilized small particle aerosols to facilitate penetration to the deep lung, and 10-12 μm, to facilitate deposition in the oronasal region of the upper respiratory tract.

(3) NBTCC shall provide NIAID *[note from Sarah formatting error in the original]*

(4) and BTCP a draft study protocol for the small particle study and a final study protocol following incorporation of NIAID and BTCP input. Conduct studies to determine the influence of Ebola virus aerodynamic 1-3 μm particle sizes on the median lethal dose and disease presentation in a nonhuman primate (NHP) model of inhalational Ebola virus disease (EVD). They shall assess the median lethal dose of Ebola virus small particle aerosols in NHPs using a modified up-and-down methodology. NBTCC estimates that approximately 24 NHPs will be required for each experiment.

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UNITED STATES GOVERNMENT
INTERAGENCY AGREEMENT (IAA)
Agreement Between Federal Agencies
General Terms & Conditions (GT&C) Section

BUREAU OF THE Fiscal Service
LEAD. TRANSFORM. DELIVER.

IAA Number AAI18027 (GT&C #) 001 (Order #) 00000 (Amendment # / Mod #)

DEPARTMENT AND/OR AGENCY		
1.	**Requesting Agency of Products / Services**	**Servicing Agency Providing Products / Sevices**
Name	HHS/NIH/NIAID	Department of Homeland Security Science and Technology Directorate
Address	[redacted] MD [redacted]	[redacted] Washington, D.C. [redacted]

2. Servicing Agency Tracking Number (Optional) : _____

3. Assisted Acquisition Agreement ☑ **Yes** ☐ **No**

4. GT&C Action (Check action being taken)

☑ **New**

☐ **Amendment** - Complete only the GT&C blocks being changed and explain the changes being made.

☐ **Cancellation** - Provide a brief explanation for the IAA cancellation and complete the effective End Date.

5. Agreement Period Start Date 08/15/2018 (MM-DD-YYYY) End Date 08/14/2019 (MM-DD-YYYY) of IAA or effective cancellation date

6. Recurring Agreement (Check One) A Recurring Agreement will continue, unless a notice to discontinue is received

☐ Yes If **Yes**, this is an: Annual Renewal ☐ Other Renewal ☐ State the other renewal period: _____

☑ No

7. Agreement Type (Check One) ☑ Single Order IAA ☐ Multiple Order IAA

8. Are Advance Payments Allowed for this IAA (Check One) ☐ Yes ☑ No

If **Yes** is checked, enter Requesting Agency's Statutory Authority Title and Citation

Note: Specific advance amounts will be captured on each related order.

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9. Estimated Agreement Amount (The Servicing Agency completes all information for the estimated agreement amount)

(Optional for assisted Acquisitions)

Direct Cost	$2,454,590.49	Provide a general explanation of the Overhead Fees and Charges
Overhead Fees & Charges		
Total Estimated Amount	$2,454,590.49	

10. STATUTORY AUTHORITY

a. Requesting Agency's Authority (Check One)

Franchise Fund	Revolving Fund	Working Capital Fund	Economy Act (31 U.S.C. 1535 / FAR 17.5)	Other Authority
☐	☐	☐	☑	☐

Fill in Statutory Authority Title and Citation for Franchise Fund, Revolving Fund, Working Capital Fund, or Other Authority

b. Servicing Agency's Authority (Check One)

Franchise Fund	Revolving Fund	Working Capital Fund	Economy Act (31 U.S.C. 1535 / FAR 17.5)	Other Authority
☐	☐	☐	☑	☐

Fill in Statutory Authority Title and Citation for Franchise Fund, Revolving Fund, Working Capital Fund, or Other Authority

11. Requesting Agency's Scope (State and/or List Attachments that support Requesting Agency's Scope.)

12. Roles and Responsibilities for the Requesting Agency and the Servicing Agency (State and/or list attachments for the roles and responsibilities for the Requesting Agency and the Servicing Agency)

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13. Restrictions (Optional) (State and/or attach unique requirements and/or mission specific restrictions specific to this IAA).

14. Assisted Acquisition Small Business Credit Clause (The Servicing Agency will allocate the socio-economic credit to the Requesting Agency for any contract actions it has executed on behalf of the Requesting Agency).

15. Disputes: Disputes related to this IAA shall be resolved in accordance with instructions provided in the Treasury Financial Manual (TFM) Volume I, Part 2, Chapter 4700, Appendix 10; Intragovernmental Transaction (IGT) Guide.

16. Termination (Insert the number of days that this IAA may be terminated by written notice by either the Requesting or Servicing Agency.) 180 days

If this agreement is cancelled, any implementing contract/order may also be canceled. If the IAA is terminated, the agencies shall agree to the terms of the termination, including costs attributable to each party and the disposition of awarded and pending actions.
If the Servicing Agency incurs costs due to the Requesting Agency's failure to give the requisite notice of its intent to terminate the IAA, the Requesting Agency shall pay any actual costs incurred by the Servicing Agency as a result of the delay in notification, provided such costs are directly attributable to the failure to give notice.

17. Assisted Acquisition Agreements - Requesting Agency's Organizations Authorized to Request Acquisition Assistance for this IAA (State or attach a list of Requesting Agency's organizations authorized to request acquistion assistance for this IAA.

18. Assisted Acquisition Agreements - Servicing Agency's Organizations Authorized to Request Acquisition Assistance for this IAA (State or attach a list of Servicing Agency's organizations authorized to request acquistion assistance for this IAA.)

19. Requesting Agency Clause(s) (Optional) (State and/or attach any additional Requesting Agency clauses.)

20. Servicing Agency Clause(s) (Optional) (State and/or attach any additional Servicing Agency clauses.)

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21. Additional Requesting Agency and/or Servicing Agency Attachments (Optional) (State and/or attach any additional Requesting Agency and/or Servicing Agency Attachments)

22. Annual Review of IAA
By signing this agreement, the parties agree to annually review the IAA if the agreement period exceeds one year. Appropriate changes will be made by amendment to the GT&C and/or modification to any affected Order(s).

AGENCY OFFICIAL

The Agency Official is the highest level accepting authority or official as designated by the Requesting Agency and Servicing Agency to sign this agreement. Each Agency Official must ensure that the general terms and conditions are properly defined, including the stated statutory authorities, and, that the scope of work can be fulfilled as per the agreement.

The Agreement Period Start Date (Block 5) must be the same as or later than the signature dates.

Actual work for this IAA may NOT begin until an Order has been signed by the appropriate individuals, as stated in the Instructions for Blocks 37 and 38.

23.	Requesting Agency	Servicing Agency
Name	John J. McGowan, Ph.D.	Sandra Cover
Title	Deputy Director for Science Mgmt & Operations	Director, Interagency Agreements Financial B
Telephone Number(s)	[redacted]	[redacted]
Fax Number	[redacted]	
Email Address	[redacted]@niaid.nih.gov	[redacted]a/C[redacted]@hq.dhs.gov
SIGNATURE	Jill K. Harper	Sandra Cover
Approval Date	UserName: JILL Harper Title: Associate Director for Science Mgmt. Date: Tuesday, 07 August 2018, 04:01 PM Eastern Daylight Time Warning: I have reviewed and approve the contents of the document in question.	8-14-2018

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UNITED STATES GOVERNMENT INTERAGENCY AGREEMENT (IAA)

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PRIMARY ORGANIZATION/OFFICE INFORMATION

24.	Requesting Agency	Servicing Agency
Primary Organization / Office Name	HHS/NIH/NIAID	Department of Homeland Security Science and Technology Directorate
Responsible Organization / Office Address	[redacted], MD [redacted]	[redacted] Washington, D.C. [redacted]

ORDER REQUIREMENTS INFORMATION

25. Order Action (Check One)

☑ **New**

☐ **Modification** (Mod) - List affected Order blocks being changed and explain the changes being made. For Example: for a performance period mod, state the new performance period for this Order in Block 27. **Fill out the Funding Modification Summary by Line** (Block 26) if the mod involves adding, deleting, or changing **Funding for an Order Line**.

☐ **Cancellation** - Provide a brief explanation for Order cancellation and fill in the Performance Period End Date for the effective cancellation date.

26. Funding Modification Summary by Line	Line #	Line #	Line #	Total of All Other Lines (attach funding details)	Total
Original Line Funding	$2,454,590.49				$2,454,590.49
Cumulative Funding Changes From Prior Mods [addition (+) or reduction (-)]					$0.00
Funding Change for This Mod					$0.00
TOTAL Modified Obligation	$2,454,590.49		$0.00	$0.00	$2,454,590.49
$0.00 Total Advance Amount	(-)				$0.00
Net Modified Amount Due	$2,454,590.49	$0.00	$0.00	$0.00	$2,454,590.49

27. Performance Period
For a performance period mod, insert the start and end dates that reflect the new performance period.

Start Date 08/15/2018 (MM-DD-YYYY) End Date 08/14/2019 (MM-DD-YYYY)

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28. Order Line / Funding Information									Line Number							
	Requesting Agency Funding Information								Servicing Agency Funding Information							
ALC	75-08-0031								70-08-1513							
Component	SP	ATA	AID	BPOA	EPOA	A	MAIN	SUB	SP	ATA	AID	BPOA	EPOA	A	MAIN	SUB
TAS (required by 10/1/2014)			075	2018	2018		0885	000								
and/or current TAS format	075-18-0885								070 18/20 0803							
BETC	DISB								COLL							
Object Class Code (Optional)	2538								6162							
BPN	927645168								967796496							
BPN + 4 (Optional)																
Additional Accounting Classification / Information (Optional)	8470051 8470038															
Requesting Agency Funding Expiration Date 09/30/2018 MM-DD-YYYY									Requesting Agency Funding Cancellation Date 09/30/2023 MM-DD-YYYY							

Project Number & Title The Influence of Aerodynamic Particle Size on the Virulence of Aerosolized Ebola Virus

Description of Products and/or Service, including the Bona Fide Need for this Order (State or attach a description of products/services, including the Bona Fide need for this Order.)
See attached

North American Industry Classification System (NCAIS) Number (Optional)

Breakdown of Reimbursable Line Costs and/or Breakdown of Assisted Acquisition Line Cost:

Unit of Measure			Contract Cost	
Quantity	Unit Price	**Total**	Servicing Fees	
1	$2,454590.49	$2,454,590.49	Total Obligated Cost	$0.00
Overhead Fees and Charges			Advance for Line (-)	
Total Line Amount Obligated		$2,454,590.49	Net Total Cost	$0.00
Advance Line Amount (-)			Assisted Acquisition Servicing Fees Explanation	
Net Line Amount Due		$2,454,590.49		

Type of Service Requirements

(●) Severable Service ( ) Non-Severable Service ( ) Not Applicable

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UNITED STATES GOVERNMENT INTERAGENCY AGREEMENT (IAA)
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29. Advance Information (Complete Block 29 if the Advance Payment for Products/Services was checked "Yes" on the GT&C)

Total Advance Amount for the Order _____ [All Order Line Advance amounts (Block 28) must sum to this total.]

Revenue Recognition Methodology (according to SFFAS 7)(Identify the Revenue Recognition Methodology that will be used to account for the Requesting Agency's expense and the Servicing Agency's revenue.)

☐ Straight-Line — Provide amount to be accrued _____ and Number of Months _____

☐ Accrual Per Work Completed — Identify the accounting post period:

☐ Monthly per work completed & invoiced

☐ Other — Explain other regular period (bimonthly, quarterly, etc.) for posting accruals and how the accrual amounts will be communicated if other than billed.

30. Total Net Order Amount: $2,454,590.49
[All Order Line Net Amounts Due for reimbursable agreements and Net Total Costs for Assisted Acquisition Agreements (Block 28) must sum to this total]

31. Attachments (State or list attachments)

☐ Key Project and/or acquisition milestones (Optional except for Assisted Acquisition Agreements)

☐ Other Attachments (Optional)

BILLING AND PAYMENT INFORMATION

32. Payment Method (Check One) **[Intra-governmental Payment and Collection (IPAC)** is the Preferred Method.]

☐ Requesting Agency Initiated IPAC
☑ Servicing Agency Initiated IPAC
☐ Credit Card
☐ Other — Explain other payment method and reasoning: _____

33. Billing Frequency (Check One)
[An invoice must be submitted by the Servicing Agency and accepted by the Requesting Agency BEFORE funds are reimbursed (i.e., via IPAC transaction)]

☐ Monthly ☐ Quarterly ☑ Other Billing Frequency (include explanation): Upon IPAC notification

34. Payment Terms (Check One)

☐ 7 Days ☑ Other Payment Terms (include explanation): Upon IPAC notification

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35. Funding Clauses / Instructions (Optional) (State and/or list funding clauses/instructions)
Subject to the Availability of Funds

36. Delivery / Shipping Information for Products (Optional)

Agency Name	
Point of Contact (POC) Name & Title	
POC Email Address	
Delivery Address / Room Number	
POC Telephone Number	
Special Shipping Information	

APPROVALS AND CONTACT INFORMATION

37. Program Officials
The Program Officials, as identified by the Requesting Agency and Servicing Agency, must ensure that the scope of work is properly defined and can be fulfilled for this Order. The Program Official may or may not be the Contracting Officer depending on each agency's IAA business process.

	Requesting Agency	Servicing Agency
Name	John J. McGowan, Ph.D.	Lloyd Hough
Title	Deputy Director for Science Mgmt & Operations	Program Manager
Telephone Number	[redacted]	[redacted]
Fax Number	[redacted]	
Email Address	[redacted]@niaid.nih.gov	[redacted]@hq.dhs.gov
SIGNATURE	[signature] Title: Associate Director for Science Mgmt Date: Tuesday, 07 August 2018, 04:01 PM Eastern Daylight Time Meaning: I have reviewed and approve the contents of the document in question	LLOYD P HOUGH Digitally signed by LLOYD P HOUGH Date: 2018.08.08 22:19:33 -04'00'
Date Signed		8/8/2018

38. Funding Officials — The Funds Approving Officials, as identified by the Requesting Agency and Servicing Agency, certify that the funds are accurately cited and can be properly accounted for per the purposes set forth in the Order. The Requesting Agency Funding Official signs to obligate funds. The Servicing Agency Funding Official signs to start the work, and to bill, collect, and properly account for funds from the Requesting Agency, in accordance with the agreement.

	Requesting Agency	Servicing Agency
Name	Wayne Crum	Sandra Cover
Title	Financial Management Officer, NIAID	Director, Interagency Agreements Fina
Telephone Number	[redacted]	[redacted]
Fax Number	[redacted]	
Email Address	[redacted]@niaid.nih.gov	[redacted]hq.dhs.gov
SIGNATURE	[signature] Title: Acting Director, OR/FM Date: Tuesday, 07 August 2018, 02:01 PM Eastern Daylight Time Meaning: I have reviewed and approve the contents of the document in question	[signature]
Date Signed		08/14/2018

Released by Chairman Rand Paul

UNITED STATES GOVERNMENT INTERAGENCY AGREEMENT (IAA)

Agreement Between Federal Agencies
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BUREAU OF THE Fiscal Service
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CONTACT INFORMATION

39. FINANCE OFFICE Points of Contact (POCs)

	Requesting Agency (Payment Office)	Servicing Agency (Billing Office)
Name	Tammy Meaney	James Conklin
Title	Administrative Officer	Sr. Financial Analyst
Office Address	[redacted], MD [redacted]	[redacted] Washington, D.C. [redacted]
Telephone Number	[redacted]	[redacted]
Fax Number		
Email Address	[redacted]@nih.gov	[redacted]@hq.dhs.gov
Signature & Date (Optional)		

40. ADDITIONAL Points of Contact (POCs) (as determined by each Agency)
This may include CONTRACTING Office Points of Contact (POCs).

	Requesting Agency	Servicing Agency
Name	Adele Bartha	Alexandria H. Davidson
Title	Administrative Technician	Interagency Agreements Specialist
Office Address	[redacted], MD [redacted]	[redacted] Washington, D.C. [redacted]
Telephone Number	[redacted]	[redacted]
Fax Number		
Email Address	[redacted]@nih.gov	[redacted]e@hq.dhs.gov
Signature & Date (Optional)		
Name	William Dowling	
Title	Program Officer	
Office Address	[redacted], MD [redacted]	
Telephone Number	[redacted]	
Fax Number		
Email Address	[redacted]@nih.gov	
Signature & Date (Optional)		
Name		
Title		
Office Address		
Telephone Number		
Fax Number		
Email Address		
Signature & Date (Optional)		

Released by Chairman Rand Paul

UNITED STATES GOVERNMENT
INTERAGENCY AGREEMENT (IAA)
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IAA Number AAI18027 (GT&C #) 001 (Order #) 00000 (Amendment # / Mod #)

DEPARTMENT AND/OR AGENCY		
1.	**Requesting Agency of Products / Services**	**Servicing Agency Providing Products / Sevices**
Name	HHS/NIH/NIAID	Department of Homeland Security Science and Technology Directorate
Address	[redacted], MD [redacted]	[redacted] Washington, D.C. [redacted]

2. Servicing Agency Tracking Number (Optional) : _____

3. Assisted Acquisition Agreement ☑ **Yes** ☐ **No**

4. GT&C Action (Check action being taken)

☑ **New**

☐ **Amendment** - Complete only the GT&C blocks being changed and explain the changes being made.

☐ **Cancellation** - Provide a brief explanation for the IAA cancellation and complete the effective End Date.

5. Agreement Period Start Date 08/15/2018 (MM-DD-YYYY) End Date 08/14/2019 (MM-DD-YYYY) of IAA or effective cancellation date

6. Recurring Agreement (Check One) A Recurring Agreement will continue, unless a notice to discontinue is received

☐ Yes If **Yes**, this is an: Annual Renewal ☐ Other Renewal ☐ State the other renewal period: _____

☑ No

7. Agreement Type (Check One) ☑ Single Order IAA ☐ Multiple Order IAA

8. Are Advance Payments Allowed for this IAA (Check One) ☐ Yes ☑ No

If **Yes** is checked, enter Requesting Agency's Statutory Authority Title and Citation

Note: Specific advance amounts will be captured on each related order.

Released by Chairman Rand Paul

UNITED STATES GOVERNMENT
INTERAGENCY AGREEMENT (IAA)
Agreement Between Federal Agencies
General Terms & Conditions (GT&C) Section

BUREAU OF THE Fiscal Service
LEAD. TRANSFORM. DELIVER.

IAA Number AAI18027 (GT&C #) 001 (Order #) 00000 (Amendment # / Mod #)

9. Estimated Agreement Amount (The Servicing Agency completes all information for the estimated agreement amount)

(Optional for assisted Acquisitions)

Direct Cost $2,508,000.00

Overhead Fees & Charges

Total Estimated Amount $2,508,000.00

Provide a general explanation of the Overhead Fees and Charges

10. STATUTORY AUTHORITY

a. Requesting Agency's Authority (Check One)

Franchise Fund	Revolving Fund	Working Capital Fund	Economy Act (31 U.S.C. 1535 / FAR 17.5)	Other Authority
☐	☐	☐	☑	☐

Fill in Statutory Authority Title and Citation for Franchise Fund, Revolving Fund, Working Capital Fund, or Other Authority

b. Servicing Agency's Authority (Check One)

Franchise Fund	Revolving Fund	Working Capital Fund	Economy Act (31 U.S.C. 1535 / FAR 17.5)	Other Authority
☐	☐	☐	☑	☐

Fill in Statutory Authority Title and Citation for Franchise Fund, Revolving Fund, Working Capital Fund, or Other Authority

11. Requesting Agency's Scope (State and/or List Attachments that support Requesting Agency's Scope.)

12. Roles and Responsibilities for the Requesting Agency and the Servicing Agency (State and/or list attachments for the roles and responsibilities for the Requesting Agency and the Servicing Agency)

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UNITED STATES GOVERNMENT
INTERAGENCY AGREEMENT (IAA)
Agreement Between Federal Agencies
General Terms & Conditions (GT&C) Section

BUREAU OF THE Fiscal Service
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IAA Number AAI18027 (GT&C #) 001 (Order #) 00000 (Amendment # / Mod #)

13. Restrictions (Optional) (State and/or attach unique requirements and/or mission specific restrictions specific to this IAA).

14. Assisted Acquisition Small Business Credit Clause (The Servicing Agency will allocate the socio-economic credit to the Requesting Agency for any contract actions it has executed on behalf of the Requesting Agency).

15. Disputes: Disputes related to this IAA shall be resolved in accordance with instructions provided in the Treasury Financial Manual (TFM) Volume I, Part 2, Chapter 4700, Appendix 10; Intragovernmental Transaction (IGT) Guide.

16. Termination (Insert the number of days that this IAA may be terminated by written notice by either the Requesting or Servicing Agency.) 180 days

If this agreement is cancelled, any implementing contract/order may also be canceled. If the IAA is terminated, the agencies shall agree to the terms of the termination, including costs attributable to each party and the disposition of awarded and pending actions.
If the Servicing Agency incurs costs due to the Requesting Agency's failure to give the requisite notice of its intent to terminate the IAA, the Requesting Agency shall pay any actual costs incurred by the Servicing Agency as a result of the delay in notification, provided such costs are directly attributable to the failure to give notice.

17. Assisted Acquisition Agreements - Requesting Agency's Organizations Authorized to Request Acquisition Assistance for this IAA (State or attach a list of Requesting Agency's organizations authorized to request acquistion assistance for this IAA.

18. Assisted Acquisition Agreements - Servicing Agency's Organizations Authorized to Request Acquisition Assistance for this IAA (State or attach a list of Servicing Agency's organizations authorized to request acquistion assistance for this IAA.)

19. Requesting Agency Clause(s) (Optional) (State and/or attach any additional Requesting Agency clauses.)

20. Servicing Agency Clause(s) (Optional) (State and/or attach any additional Servicing Agency clauses.)

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UNITED STATES GOVERNMENT
INTERAGENCY AGREEMENT (IAA)
Agreement Between Federal Agencies
General Terms & Conditions (GT&C) Section

BUREAU OF THE Fiscal Service
LEAD. TRANSFORM. DELIVER.

IAA Number AAI18027 (GT&C #) _____ (Order #) 00000 (Amendment # / Mod #)

21. Additional Requesting Agency and/or Servicing Agency Attachments (Optional) (State and/or attach any additional Requesting Agency and/or Servicing Agency Attachments)

22. Annual Review of IAA
By signing this agreement, the parties agree to annually review the IAA if the agreement period exceeds one year. Appropriate changes will be made by amendment to the GT&C and/or modification to any affected Order(s).

AGENCY OFFICIAL

The Agency Official is the highest level accepting authority or official as designated by the Requesting Agency and Servicing Agency to sign this agreement. Each Agency Official must ensure that the general terms and conditions are properly defined, including the stated statutory authorities, and, that the scope of work can be fulfilled as per the agreement.

The Agreement Period Start Date (Block 5) must be the same as or later than the signature dates.

Actual work for this IAA may NOT begin until an Order has been signed by the appropriate individuals, as stated in the Instructions for Blocks 37 and 38.

23.	Requesting Agency	Servicing Agency
Name	John J. McGowan, Ph.D.	
Title		
Telephone Number(s)	[redacted]	[redacted]
Fax Number	[redacted]	
Email Address	[redacted]@niaid.nih.gov	[redacted]@hq.dhs.gov
SIGNATURE	Jill R. Harper UserName: JILL Harper Title: Associate Director for Science Mgmt. Date: Tuesday, 07 August 2018, 04:01 PM Eastern Daylight Time Meaning: I have reviewed and approve the contents of the document in question.	
Approval Date		

Released by Chairman Rand Paul

UNITED STATES GOVERNMENT INTERAGENCY AGREEMENT (IAA)

Agreement Between Federal Agencies
Order Requirements and Funding Information (Order) Section

BUREAU OF THE Fiscal Service
LEAD. TRANSFORM. DELIVER.

IAA Number AAI18027 (GT&C #) | 001 (Order #) | 00000 (Amendment # / Mod #) | Servicing Agency's Agreement Tracking Number (Optional)

PRIMARY ORGANIZATION/OFFICE INFORMATION

24.	Requesting Agency	Servicing Agency
Primary Organization / Office Name	HHS/NIH/NIAID	Department of Homeland Security Science and Technology Directorate
Responsible Organization / Office Address	[redacted] MD [redacted]	[redacted] Washington, D.C. [redacted]

ORDER REQUIREMENTS INFORMATION

25. Order Action (Check One)

☑ **New**

☐ **Modification** (Mod) - List affected Order blocks being changed and explain the changes being made. For Example: for a performance period mod, state the new performance period for this Order in Block 27. **Fill out the Funding Modification Summary by Line** (Block 26) if the mod involves adding, deleting, or changing **Funding for an Order Line**.

☐ **Cancellation** - Provide a brief explanation for Order cancellation and fill in the Performance Period End Date for the effective cancellation date.

26. Funding Modification Summary by Line	Line #	Line #	Line #	Total of All Other Lines (attach funding details)	Total
Original Line Funding	$2,508,000.00				$2,508,000.00
Cumulative Funding Changes From Prior Mods [addition (+) or reduction (-)]					$0.00
Funding Change for This Mod					$0.00
TOTAL Modified Obligation	$2,508,000.00	$0.00	$0.00	$0.00	$2,508,000.00
Total Advance Amount (-)					$0.00
Net Modified Amount Due	$2,508,000.00	$0.00	$0.00	$0.00	$2,508,000.00

27. Performance Period
For a performance period mod, insert the start and end dates that reflect the new performance period.

Start Date 08/15/2018 (MM-DD-YYYY) End Date 08/14/2019 (MM-DD-YYYY)

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UNITED STATES GOVERNMENT INTERAGENCY AGREEMENT (IAA)

Agreement Between Federal Agencies
Order Requirements and Funding Information (Order) Section

BUREAU OF THE Fiscal Service
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IAA Number AAI18027 (GT&C #) | 001 (Order #) | 00000 (Amendment # / Mod #) | Servicing Agency's Agreement Tracking Number (Optional)

28. Order Line / Funding Information									Line Number							
	Requesting Agency Funding Information								Servicing Agency Funding Information							
ALC	75-08-0031								70-08-1513							
Component	SP	ATA	AID	BPOA	EPOA	A	MAIN	SUB	SP	ATA	AID	BPOA	EPOA	A	MAIN	SUB
TAS (required by 10/1/2014)			075	2018	2018		0885	000								
and/or current TAS format	075-18-0885								070 18 0800							
BETC	DISB								COLL							
Object Class Code (Optional)	2538								6162							
BPN	927645168								967796496							
BPN + 4 (Optional)																
Additional Accounting Classification / Information (Optional)	8470051 8470038															

Requesting Agency Funding Expiration Date	Requesting Agency Funding Cancellation Date
09/30/2018 MM-DD-YYYY	09/30/2023 MM-DD-YYYY

Project Number & Title The Influence of Aerodynamic Particle Size on the Virulence of Aerosolized Ebola Virus

Description of Products and/or Service, including the Bona Fide Need for this Order (State or attach a description of products/services, including the Bona Fide need for this Order.)
See attached

North American Industry Classification System (NCAIS) Number (Optional)

Breakdown of Reimbursable Line Costs and/or Breakdown of Assisted Acquisition Line Cost:

Unit of Measure			Contract Cost	
Quantity	Unit Price	**Total**	Servicing Fees	
1	$2,508,000.00	$2,508,000.00	Total Obligated Cost	$0.00
Overhead Fees and Charges			Advance for Line (-)	
Total Line Amount Obligated		$2,508,000.00	Net Total Cost	$0.00
Advance Line Amount (-)			Assisted Acquisition Servicing Fees Explanation	
Net Line Amount Due		$2,508,000.00		

Type of Service Requirements

(●) Severable Service ( ) Non-Severable Service ( ) Not Applicable

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UNITED STATES GOVERNMENT INTERAGENCY AGREEMENT (IAA)
Agreement Between Federal Agencies
Order Requirements and Funding Information (Order) Section

BUREAU OF THE Fiscal Service
LEAD. TRANSFORM. DELIVER.

IAA Number AAI18027 (GT&C #) | 001 (Order #) | 00000 (Amendment # / Mod #) | Servicing Agency's Agreement Tracking Number (Optional) _____

29. Advance Information (Complete Block 29 if the Advance Payment for Products/Services was checked "Yes" on the GT&C)

Total Advance Amount for the Order _____ [All Order Line Advance amounts (Block 28) must sum to this total.]

Revenue Recognition Methodology (according to SFFAS 7)(Identify the Revenue Recognition Methodology that will be used to account for the Requesting Agency's expense and the Servicing Agency's revenue.)

☐ Straight-Line — Provide amount to be accrued _____ and Number of Months _____

☐ Accrual Per Work Completed — Identify the accounting post period:

☐ Monthly per work completed & invoiced

☐ Other — Explain other regular period (bimonthly, quarterly, etc.) for posting accruals and how the accrual amounts will be communicated if other than billed.

30. Total Net Order Amount: $2,508,000.00
[All Order Line Net Amounts Due for reimbursable agreements and Net Total Costs for Assisted Acquisition Agreements (Block 28) must sum to this total]

31. Attachments (State or list attachments)

☐ Key Project and/or acquisition milestones (Optional except for Assisted Acquisition Agreements)

☐ Other Attachments (Optional)

BILLING AND PAYMENT INFORMATION

32. Payment Method (Check One) **[Intra-governmental Payment and Collection (IPAC)** is the Preferred Method.]

☐ Requesting Agency Initiated IPAC
☑ Servicing Agency Initiated IPAC
☐ Credit Card
☐ Other — Explain other payment method and reasoning: _____

33. Billing Frequency (Check One)
[An Invoice must be submitted by the Servicing Agency and accepted by the Requesting Agency BEFORE funds are reimbursed (i.e., via IPAC transaction)]

☐ Monthly ☐ Quarterly ☑ Other Billing Frequency (include explanation): Upon IPAC notification

34. Payment Terms (Check One)

☐ 7 Days ☑ Other Payment Terms (include explanation): Upon IPAC notification

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UNITED STATES GOVERNMENT INTERAGENCY AGREEMENT (IAA)

Agreement Between Federal Agencies
Order Requirements and Funding Information (Order) Section

BUREAU OF THE Fiscal Service
LEAD. TRANSFORM. DELIVER.

IAA Number _____ GT&C # | 001 Order # | 00000 Amendment # / Mod # | Servicing Agency's Agreement Tracking Number (Optional) _____

35. Funding Clauses / Instructions (Optional) (State and/or list funding clauses/instructions)
Subject to the Availability of Funds

36. Delivery / Shipping Information for Products (Optional)

Agency Name	
Point of Contact (POC) Name & Title	
POC Email Address	
Delivery Address / Room Number	
POC Telephone Number	
Special Shipping Information	

APPROVALS AND CONTACT INFORMATION

37. Program Officials
The Program Officials, as identified by the Requesting Agency and Servicing Agency, must ensure that the scope of work is properly defined and can be fulfilled for this Order. The Program Official may or may not be the Contracting Officer depending on each agency's IAA business process.

	Requesting Agency	Servicing Agency
Name	John J. McGowan, Ph.D.	
Title	Deputy Director for Science Mgmt & Operations	
Telephone Number	[redacted]	[redacted]
Fax Number	[redacted]	
Email Address	[redacted]	[redacted]@hq.dhs.gov
SIGNATURE	Jill R. Harper	
Date Signed		

38. Funding Officials — The Funds Approving Officials, as identified by the Requesting Agency and Servicing Agency, certify that the funds are accurately cited and can be properly accounted for per the purposes set forth in the Order. The Requesting Agency Funding Official signs to obligate funds. The Servicing Agency Funding Official signs to start the work, and to bill, collect, and properly account for funds from the Requesting Agency, in accordance with the agreement.

	Requesting Agency	Servicing Agency
Name	Wayne Crum	Sandra Cover
Title	Financial Management Officer, NIAID	
Telephone Number	[redacted]	[redacted]
Fax Number	[redacted]	
Email Address	[redacted]	[redacted]@hq.dhs.gov
SIGNATURE	UserName:D:\WAYNE Crum Title: Acting Director, OMIFM Date: Tuesday, 07 August 2018, 02:01 PM Eastern Daylight Time Meaning: I have reviewed and approve the contents of the document in question.	
Date Signed		

Released by Chairman Rand Paul

UNITED STATES GOVERNMENT INTERAGENCY AGREEMENT (IAA)
Agreement Between Federal Agencies
Order Requirements and Funding Information (Order) Section

BUREAU OF THE Fiscal Service
LEAD. TRANSFORM. DELIVER.

IAA Number _____ (GT&C #) 001 (Order #) _____ (Amendment # / Mod #) Servicing Agency's Agreement Tracking Number (Optional) _____

CONTACT INFORMATION

39. FINANCE OFFICE Points of Contact (POCs)

	Requesting Agency (Payment Office)	Servicing Agency (Billing Office)
Name	Tammy Meaney	James Conklin
Title	Administrative Officer	
Office Address	[redacted]	[redacted] Washington, D.C. [redacted]
Telephone Number	[redacted]	[redacted]
Fax Number		
Email Address	[redacted]@nih.gov	[redacted]@hq.dhs.gov
Signature & Date (Optional)		

40. ADDITIONAL Points of Contact (POCs) (as determined by each Agency)

This may include CONTRACTING Office Points of Contact (POCs).

	Requesting Agency	Servicing Agency
Name	Adele Bartha	Alexandria H. Davidson
Title		
Office Address	[redacted] MD [redacted]	[redacted] Washington, D.C. 20528
Telephone Number	[redacted]	[redacted]
Fax Number		
Email Address	[redacted]@nih.gov	[redacted]@hq.dhs.gov
Signature & Date (Optional)		
Name		
Title	Program Officer	
Office Address	[redacted] MD [redacted]	
Telephone Number	[redacted]	
Fax Number		
Email Address	[redacted]	
Signature & Date (Optional)		
Name		
Title		
Office Address		
Telephone Number		
Fax Number		
Email Address		
Signature & Date (Optional)		

Released by Chairman Rand Paul

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

http://www.niaid.nih.gov/

National Institutes of Health (NIH)
National Institute of Allergy and Infectious Diseases (NIAID)
Office of Acquisitions, DEA
6700B Rockledge Drive, Room 3214
Bethesda, MD 20892-7612

DETERMINATION AND FINDINGS

AUTHORITY TO ENTER INTO AN INTERAGENCY AGREEMENT UNDER THE ECONOMY ACT FAR 17.502-2 and HHSAR 317.5

I HEREBY FIND THAT:

The NIAID proposes to enter into an Interagency Agreement (IAA) with DHS S&T Directorate to support a project entitled

Assessment of the Influence of Aerodynamic Particle Size on the Virulence of Aerosolized Ebo.

The proposed IAA Number is AAI18027-001-00000.

The estimated cost of the proposed agreement is $ 2,508,000 for a period of 2.8 years (08/06/2018 through 06/06/2021).

Use of this IAA is in the best interest of the Government because:

1) The supplies or services cannot be obtained as conveniently or economically by contracting directly with a private source and;

2) A contract action is required by the servicing Agency in order to meet the needs of the NIAID and (***please check at least one***):

   ☐ The acquisition will appropriately be made under an existing contract of the servicing agency, entered into before placement of the order, to meet the requirements of the NIAID for the same or similar supplies or services, and/or;

   ☑ The servicing agency has the capability or expertise to enter into a contract for such supplies or services which is not available within the NIAID, and/or;

   ☐ The servicing agency is specifically authorized by law or regulation to purchase such supplies or services on behalf of other agencies.

3) Servicing organization(s) contemplated (the assigned HHS contracting office shall be one of the servicing organizations contemplated);

   NIAID Office of Acquisitions, DHS Science and Technology Directorate/ Biological Threat Characterization Program (BTCP)

Released by Chairman Rand Paul

4) Organization(s) and alternative approach(es) contemplated, the anticipated benefits to the NIAID; the anticipated costs, including associated fees or other compensation; and the contract/order placement timeframe and;

The alternative approach considered was issuing a task order under DMID's "Animal Models of Infectious Diseases" IDIQ contract. Using this IAA will be faster due to the lead time required for a new task order combined with limited availability of non-human primate space (NHP) at other Biosafety Level 4 (BSL4) laboratories. Unlike BSL4 labs accessible via the IDIQ, the DHS lab has current available capacity to perform studies. In addition, DHS has unique expertise in generation, analysis and delivery of aerosolized pathogens.

5) Tradeoffs (cost, schedule, performance) among the approaches considered and;

The main factors in favor of this IAA are schedule and performance. DHS has the ability to begin these studies in FY18, faster than could be accessed through a task order. The equipment , systems and expertise to perform complex aerosol studies is already in place.

6) Conclusion that the contract to be awarded by the selected servicing organization is the most advantageous alternative to the Government, notwithstanding fees and the increased risk associated with assisted contracting; and:

This is the most advantageous alternative to get studies initiated in FY18. For the studies to be performed with NHPs at DHS, this mechanism will be faster than a task order due to the lead time required for a new task order combined with limited availability of NHP space at other Biosafety Level 4 (BSL4) labs. DHS has available capacity to initiate studies in FY18 combined with required expertise in aerosol generation, analysis and delivery.

7) Steps taken to ensure that contract funding will comply with the bona fide needs rule and the Anti-Deficiency Act.

There is a current bona fide need to assess the impact of aerosol particle size on Ebola virus disease in NHPs.

Released by Chairman Rand Paul

I HEREBY DETERMINE THAT:

On the basis of the above findings and in accordance with FAR Subpart 17.502-2 and HHSAR Subpart 317.5 use of an IAA to fulfill the NIAID's requirement is in the best interest of the Government. Authority exists under The Economy Act of 1932, as amended, 31 U.S.C. 1535 and P.L. 92-218 for the Department of Health and Human Services (DHHS), National Institutes of Health (NIH), National Institute of Allergy and Infectious Diseases to enter into an Interagency Agreement with DHS S&T.

UserName: GEORGE Kennedy
Title: Contracting Officer
Date: Tuesday, 07 August 2018, 09:10 AM Eastern Daylight Time
Meaning: I have reviewed and approve the contents of the document in question.

Date

George W Kennedy

Contracting Officer

Released by Chairman Rand Paul

Interagency Agreement AAI18027-001-00000
Between the National Institute of Allergy and Infectious Disease (NIAID)
And Department of Homeland Security Science and Technology Directorate (DHS/S&T) Biological Threat Characterization Program (BTCP)
In Accordance with Memorandum of Agreement between NIAID and DHS S&T signed 5-21-2018

Work Plan Title: The Influence of Aerodynamic Particle Size on the Virulence of Aerosolized Ebola Virus

NIAID Plan Point of Contact:	**William Dowling, PhD**	**Tel:** [redacted]
DHS/S&T BTCP Point of Contact:	**Lloyd Hough, PhD**	**Tel:** [redacted]

Incorporation: This agreement is in accordance with provisions of the Memorandum of Agreement (MOA) between NIAID and DHS/S&T and upon signature becomes a subordinate Annex to that MOA. The signatories to this Annex agree to the terms of that over-arching MOA as relevant to conducting the work specified in this Annex.

Authority: The authorities for NIAID and DHS/S&T BTCP to enter into this agreement are:

1. The Economy Act, 31 U.S.C. § 1535, which provides that an agency may place an order with a major organizational unit within the same agency or another agency for goods or services if:
   A. amounts are available;
   B. the ordering Agency decides the order is in the best interest of the United States Government;
   C. the Agency to fill the order is able to provide or get by contract the ordered goods or services; and
   D. the Agency decides ordered goods or services cannot be provided by contract as conveniently or cheaply by a commercial enterprise (payments must be made on the basis of the actual cost of goods or services provided).

2. Sections 301, 405, and 446 of the Public Health Service Act (42 U.S.C. § 241, § 284, and § 285f).
3. Homeland Security Act of 2002, 6 U.S.C. §§ 182(13) and 188(c).

Economy Act Findings: According to the "Determinations and Findings Pursuant to 48 CFR 17.503," NIAID represents that sufficient funding amounts are available, that this agreement is in the best interest of the United States Government, and that the services requested cannot be provided by contract as conveniently or cheaply by a commercial enterprise.

NIAID represents that the servicing Agency has capabilities or expertise to enter into a contract for such supplies or services that is not available within the Requesting Agency.

DHS/S&T BTCP warrants that it is able to provide the requested services. DHS/S&T BTCP also warrants that it has adequate statutory authority for the contractual action and will comply fully with the competition requirements of part 6 of the Federal Acquisition Regulations as well as all other legal or regulatory requirements applicable to the contract.

Released by Chairman Rand Paul

Scope of Work: NIAID is developing Medical Countermeasures (MCMs) to protect against Ebola virus disease. Therefore, NIAID needs to understand differences in disease when Ebola virus infection occurs by different routes and to ensure that MCMs under development are effective in these different scenarios. The purpose of this study is to further understand the disease caused by aerosolized Ebola virus in a relevant animal model. This study has been developed jointly by NIAID and the National Biological Threat Characterization Center (NBTCC) in coordination with DHS/S&T BTCP. NBTCC shall perform work on a non-interference basis with DHS/S&T priorities and the NBACC Annual Plan.

Under this work plan, the NBTCC with guidance from the BTCP shall:

(1) NBTCC shall conduct pre-execution activities to obtain all necessary approvals to conduct the project
(2) NBTCC shall provide NIAID and BTCP a draft study protocol for the *in vitro* study and a final study protocol following incorporation of NIAID and BTCP input. NBTCC shall first assess their inhalation exposure system with Ebola virus and optimize aerosol generation, sampling, and assay methodologies. The target median aerodynamic particle sizes will be 1-3 µm, to allow comparison to previously published studies with aerosolized filoviruses which utilized small particle aerosols to facilitate penetration to the deep lung, and 10-12 µm, to facilitate deposition in the oronasal region of the upper respiratory tract.
(3) NBTCC shall provide NIAID
(4) and BTCP a draft study protocol for the small particle study and a final study protocol following incorporation of NIAID and BTCP input. Conduct studies to determine the influence of Ebola virus aerodynamic 1-3 µm particle sizes on the median lethal dose and disease presentation in a nonhuman primate (NHP) model of inhalational Ebola virus disease (EVD). They shall assess the median lethal dose of Ebola virus small particle aerosols in NHPs using a modified up-and-down methodology. NBTCC estimates that approximately 24 NHPs will be required for each experiment.
(5) NBTCC shall provide NIAID and BTCP a draft study protocol for the large particle study and a final study protocol following incorporation of NIAID and BTCP input. Conduct studies to determine the influence of Ebola virus aerodynamic 10-12 µm particle sizes on the median lethal dose and disease presentation in a nonhuman primate (NHP) model of inhalational Ebola virus disease (EVD). They shall assess the median lethal dose of Ebola virus small particle aerosols in NHPs using a modified up-and-down methodology. NBTCC estimates that approximately 24 NHPs will be required for each experiment.
(6) NBTCC shall provide NIAID and BTCP a draft study report, host a NIAID and BTCP audit and then provide a final report addressing and incorporating NIAID and BTCP comments and feedback

Under this work plan, NIAID will:

- Fund this work. NIAID personnel will provide feedback on draft study protocols for NBTCC to incorporate into final study protocols. NIAID personnel will also review the study report and perform an audit of the draft study report and raw data.

Released by Chairman Rand Paul

Timeline/Milestones for Work:

Task/Subtask Number and Name	Milestones/Deliverables	Due Date or Completion Date
1.0 Pre-Execution Activities	Completion of internal and external pre-execution activities	Completion due by six (6) months after Task Order Award
2.1 Study Protocol (Draft)	Delivery of draft Study Protocol for in vitro study	Completion due by one (1) month after Task Order Award
2.2 Study Protocol (Final)	Delivery of final Study Protocol for in vitro study	Completion due by two (2) months after Task Order Award
2.3 Characterization of inhalation system with Ebola virus	Completion on inhalation system performance with both small and large particle aerosols containing Ebola virus	Completion due by six (6) months after Task Order Award
2.4 Go/No-Go	Meet with BTCP and NIAID sponsors review deliverables form subtask 2 and make Go/No-Go determination	Completion due by six (6) months after Task Order Award
3.1 Study Protocol (Draft)	Delivery of Draft Study Protocol for Small Particle Aerosol in vivo study	Completion due by four (4) months after Task Order Award
3.2 Study Protocol (Final)	Delivery of Final Study Protocol for Small Particle Aerosol in vivo study	Completion due by four (5) months after Task Order Award
3.3 Estimation of median lethal dose of small particle aerosols	Completion of the estimation of the medial lethal dose of small particle aerosols containing Ebola virus in nonhuman primates	Completion due by eighteen (18) months after Task Order Award
3.4 Go/No-Go	Meet with BTCP and NIAID sponsors review deliverables form subtask 3 and make Go/No-Go determination	Completion due by eighteen (18) months after Task Order Award
4.1 Study Protocol (Draft)	Delivery of Draft Study Protocol for Large Particle Aerosol in vivo study	Completion due by eleven (11) months after Task Order Award
4.2 Study Protocol (Final)	Delivery of Final Study Protocol for Large Particle Aerosol in vivo study	Completion due by twelve (12) months after Task Order Award
4.3 Estimation of median lethal dose of large particle aerosols	Completion of the estimation of the medial lethal dose of large particle aerosols containing Ebola virus in nonhuman primates	Completion due by twenty-six (26) months after Task Order Award

Released by Chairman Rand Paul

Task/Subtask Number and Name	Milestones/Deliverables	Due Date or Completion Date
5.1 Final Report (Draft)	Draft Final Report delivered to sponsor	Completion due by twenty-nine (29) months after Task Order Award
5.2 Sponsor Audit	Sponsor Audit of raw data	Completion due by thirty-one (31) months after Task Order Award
5.3 Final Report	Final Report delivered to sponsor	Completion due by thirty-four (34) months after Task Order Award

Reporting Requirements: Monthly progress meeting with NIAID and BTCP including updated Microsoft Project schedule; Draft and final study protocols; Draft and final study reports

Budget: NIAID will fully fund the cost of the work, for a total to DHS/S&T of $2,508,000.00 over a period of performance of 34 months from the date of IAA Award. Indirect costs associated with this project represent a flat indirect rate based upon historical and projected Facilities General and Administrative (FG&A), bear a relationship to this project, and are not covered by other funds. Direct labor is not already paid through annual appropriation to this agency and is included only for staff working on this project directly.

Governance: The identified NIAID project officer/point of contact and the DHS/S&T BTCP Program Manager shall monitor the progress of activities conducted under this agreement and solve problems that arise. Unresolved issues will be referred to the Director Office of National Labs at DHS/S&T and the Director of the Division of Microbiology and Infectious Diseases, NIAID for resolution.

Publications; Press Releases: Abstracts, manuscripts and other public presentations based on the results of research conducted under this IAA shall conform to the current publication policies of the agencies. If the agencies' publication policies conflict with each other, security considerations will take precedent and the respective POCs for each agency will resolve any additional differences. Individuals employed by either agency, as well as individuals employed by third parties, who meet the customary criteria for authorship, will be included as authors on publications that result from this collaborative effort. The agencies agree that prior to submission for publication, copies of abstracts, manuscripts and presentation materials will be provided to POCs to allow thirty (30) days to review any proposed manuscripts and publication materials and 3 days to review proposed abstracts. The submitting authors will take into consideration any comments from the reviewers.

Each agency shall provide a copy of any proposed press release related to the work described in this IAA to the other agency for review and comment at least five (5) business days in advance of the proposed publication date.

Intellectual Property: The agencies intend as follows with respect to inventions:

The rights to all intellectual property arising from the projects under this agreement will be governed by Federal law. Inventions made by the employees of an Agency should be administered in accordance with the policies of that Agency. The agencies intend to coordinate the licensing of any jointly-owned inventions arising under this agreement.

Released by Chairman Rand Paul

Safety and Biohazards:
To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Servicing Agency shall comply with all Federal, State and local laws and regulations applicable to the work being performed under this contract. In addition, recommended guidelines for use in developing and implementing health and safety operating procedures and practices for both personnel and facilities may be located in the current version of Biosafety in Microbiological and Biomedical Laboratories (http://www.cdc.gov/biosafety/publications/bmbl5/).

NBTCC shall maintain an accurate record of, and promptly report to NIAID within 5 business days all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; damage to property incidental to work performed under the contract; and all violations for which NBTCC has been cited by any Federal, State or local regulatory/enforcement agency. If NBTCC fails or refuses to comply with the Federal, State or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), NIAID may move to delay or terminate this IAA unless satisfactory corrective action (as approved by the Federal, State or local regulatory/enforcement agencies) has been taken and documented to NIAID. No part of the time lost due to any delay in work shall be subject to a claim for extension of time or costs or damages by NBTCC.

Funding Information and Estimated Cost: NIAID will provide $2,508,000 appropriated funds to DHS/S&T. DHS/S&T should send an SF-1080 to the following address for payment:

Division of Accounting Operations
National Institutes of Health
[redacted]
MD [redacted]

Billing in the form of an SF-1080 will be accomplished using the following accounting data:

	From	To
Agency	**NIAID/NIH**	**DHS/S&T BTCP**
Appropriation	**75-18-0885**	**----------**
Agency Location Code (ALC)	**75-08-0031**	
Common Account Number	**8-8470038 $1,618,000**	
	8-8470051 $890,000	
Amount	**$ 2,508,000**	
Agreement number	**AAI18027-001-00000**	

NIAID Annex Point of Contact:
William Dowling
Program Officer, NIAID/NIH
[redacted], MD, [redacted]
[redacted]@nih.gov

NIAID Administrative Contact:
Tammy Meaney
Administrative Officer, NIAID/NIH
[redacted], MD
Tel: [redacted]
[redacted]@nih.gov

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DHS S&T Point of Contact:
Lloyd Hough
Program Manager, Biological Threat Characterization
DHS S&T

[redacted]@hq.dhs.gov

DHS S&T Administrative Contact:
Lewis Brown
NBACC Lab Operations Program Manager
DHS S&T

[redacted]@hq.dhs.gov

Released by Chairman Rand Paul

From: "Barstow, Kevin (HHS/IOS)" <[redacted]@hhs.gov>
To: "Tabak, Lawrence (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: RE: IC 90-Day Review
Date: Mon, 28 Jun 2021 18:08:13 -0400
Importance: Normal

Please include everyone you mentioned, including Steve Sherry. The first step will be to have an internal conversation about what data and information might be relevant to share with ODNI and then it sounds like ODNI would be interested in a meeting between subject matter experts. However, we can take it one step at a time and discuss internally first. Thanks so much.

From: Tabak, Lawrence (NIH/OD) [E] <[redacted]@nih.gov>
Sent: Monday, June 28, 2021 6:03 PM
To: Barstow, Kevin (HHS/IOS) <[redacted]@hhs.gov>
Subject: Re: IC 90-Day Review

Kevin,

Pleased to speak with them. As you no doubt noted during today's meeting there are several NIH staff who are more knowledgeable than I am, and I would like to include them – Alan Embry and Elodie Gedlin to start. Also, If there is an interest in what we have in NCBI data bases I would include Steve Sherry.
May I reach out to them sharing the contents of your note to engage them in this?

Thanks, and best wishes,
Larry

From: "Barstow, Kevin (HHS/IOS)" <[redacted]@hhs.gov>
Date: Monday, June 28, 2021 at 5:51 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: IC 90-Day Review

Dr. Tabak:
As you know, President Biden has asked the Intelligence Community to collect and analyze information regarding the origins of COVID-19. As part of this review, the Office of the Director of National Intelligence (ODNI) has asked HHS to share any data and information that may be relevant to this inquiry. HHS supports this review by the Intelligence Community and is cooperating with ODNI's request.

As an initial step, we would like to set-up a time to talk to you about what potential relevant data and information NIH might possess to share with the Intelligence Community. We'll have a few people from the Office of the Secretary on and you should feel free to include others from NIH. Ideally, we could all talk by Wednesday at the latest. Yvette Hubert, the Executive Assistant in our office, will be reaching out to coordinate schedules.

In the meantime, if you have any questions or would like to discuss further, please let me know. You can also reach me at [redacted] Thank you.

Kevin Barstow
Senior Counsel
Office of the Deputy Secretary
U.S. Department of Health and Human Services

Released by Chairman Rand Paul

Released by Chairman Rand Paul

From: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
To: "Ghedin, Elodie (NIH/NIAID) [E]" <[redacted]@nih.gov>
Cc: "Embry, Alan (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: Re: IC 90-Day Review
Date: Mon, 28 Jun 2021 18:20:15 -0400
Importance: Normal

Thanks.
Larry

From: "Ghedin, Elodie (NIH/NIAID) [E]" <[redacted]@nih.gov>
Date: Monday, June 28, 2021 at 6:19 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <[redacted]@nih.gov>
Cc: "Embry, Alan (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Subject: Re: IC 90-Day Review

Thank you, Larry.
I am happy to participate. (Just one caveat is that I will be on a train on Wednesday afternoon and would likely not be able to join then)

From: "Tabak, Lawrence (NIH/OD) [E]" <[redacted]@nih.gov>
Date: Monday, June 28, 2021 at 6:13 PM
To: "Embry, Alan (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Ghedin, Elodie (NIH/NIAID) [E]" <[redacted]@nih.gov>, "Sherry, Steve (NIH/NLM/NCBI) [E]" <[redacted]@ncbi.nlm.nih.gov>
Cc: "Collins, Francis (NIH/OD) [E]" <[redacted]@od.nih.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Brennan, Patti (NIH/NLM) [E]" <[redacted]@nih.gov>
Subject: IC 90-Day Review

I would appreciate your presence at this meeting with HHS, likely to be held in the next couple of days. Just giving you a heads up about the pending request.

Parenthetically, everyone was very appreciative of your contributions Alan and Elodie at today's meeting.

Best wishes,
Larry

From: "Barstow, Kevin (HHS/IOS)" <[redacted]@hhs.gov>
Date: Monday, June 28, 2021 at 5:51 PM
To: "Tabak, Lawrence (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: IC 90-Day Review

Dr. Tabak:
As you know, President Biden has asked the Intelligence Community to collect and analyze information regarding the origins of COVID-19. As part of this review, the Office of the Director of National Intelligence (ODNI) has asked HHS to share any data and information that may be relevant to this inquiry. HHS supports this review by the Intelligence Community and is cooperating with ODNI's request.

Released by Chairman Rand Paul

As an initial step, we would like to set-up a time to talk to you about what potential relevant data and information NIH might possess to share with the Intelligence Community. We'll have a few people from the Office of the Secretary on and you should feel free to include others from NIH. Ideally, we could all talk by Wednesday at the latest. Yvette Hubert, the Executive Assistant in our office, will be reaching out to coordinate schedules.

In the meantime, if you have any questions or would like to discuss further, please let me know. You can also reach me at [redacted]. Thank you.

Kevin Barstow
Senior Counsel
Office of the Deputy Secretary
U.S. Department of Health and Human Services

Released by Chairman Rand Paul

From: "Sherry, Steve (NIH/NLM/NCBI) [E]" <[redacted]@ncbi.nlm.nih.gov>
To: "Tabak, Lawrence (NIH/OD) [E]" <[redacted]@nih.gov>, "Ghedin, Elodie (NIH/NIAID) [E]" <[redacted]@nih.gov>, "Embry, Alan (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Cc: "Collins, Francis (NIH/OD) [E]" <[redacted]@od.nih.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Brennan, Patti (NIH/NLM) [E]" <[redacted]@nih.gov>
Subject: Re: IC 90-Day Review
Date: Mon, 28 Jun 2021 19:27:18 -0400
Importance: Normal

Larry, likewise I am happy to join as well.

cheers,
Steve

From: Embry, Alan (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>
Sent: Monday, June 28, 2021 7:05:06 PM
To: Tabak, Lawrence (NIH/OD) [E] <[redacted]@nih.gov>; Ghedin, Elodie (NIH/NIAID) [E] <[redacted]@nih.gov>; Sherry, Steve (NIH/NLM/NCBI) [E] <[redacted]@ncbi.nlm.nih.gov>
Cc: Collins, Francis (NIH/OD) [E] <[redacted]@od.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>; Brennan, Patti (NIH/NLM) [E] <[redacted]@nih.gov>
Subject: RE: IC 90-Day Review

Larry,

Sure, happy to join.

Thanks,
Alan

From: Tabak, Lawrence (NIH/OD) [E] <[redacted]@nih.gov>
Sent: Monday, June 28, 2021 6:13 PM
To: Embry, Alan (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>; Ghedin, Elodie (NIH/NIAID) [E] <[redacted]@nih.gov>; Sherry, Steve (NIH/NLM/NCBI) [E] <[redacted]@ncbi.nlm.nih.gov>
Cc: Collins, Francis (NIH/OD) [E] <[redacted]@od.nih.gov>; Fauci, Anthony (NIH/NIAID) [E] <[redacted]@niaid.nih.gov>; Brennan, Patti (NIH/NLM) [E] <[redacted]@nih.gov>
Subject: IC 90-Day Review
Importance: High

I would appreciate your presence at this meeting with HHS, likely to be held in the next couple of days. Just giving you a heads up about the pending request.

Parenthetically, everyone was very appreciative of your contributions Alan and Elodie at today's meeting.

Best wishes,
Larry

From: "Barstow, Kevin (HHS/IOS)" <[redacted]@hhs.gov>
Date: Monday, June 28, 2021 at 5:51 PM

Released by Chairman Rand Paul

To: "Tabak, Lawrence (NIH/OD) [E]" [redacted]@nih.gov>
Subject: IC 90-Day Review

Dr. Tabak:
As you know, President Biden has asked the Intelligence Community to collect and analyze information regarding the origins of COVID-19. As part of this review, the Office of the Director of National Intelligence (ODNI) has asked HHS to share any data and information that may be relevant to this inquiry. HHS supports this review by the Intelligence Community and is cooperating with ODNI's request.

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In the meantime, if you have any questions or would like to discuss further, please let me know. You can also reach me at [redacted] Thank you.

Kevin Barstow
Senior Counsel
Office of the Deputy Secretary
U.S. Department of Health and Human Services

Released by Chairman Rand Paul

From: "Tabak, Lawrence (NIH/OD) [E]" <[redacted]@nih.gov>
To: "Chan, Leighton (NIH/CC/RMD) [E]" <[redacted]@cc.nih.gov>
Subject: Re: ODNI Meeting Request- on AHI
Date: Fri, 01 Oct 2021 09:35:29 -0400
Importance: Normal

Unfortunately I can't make a meeting at that time – it conflicts with the NIH Leadership Forum that I run for Francis.

I spoke with David, the ball was in their court; he reached out and they said they would get back to him quickly.

From: "Chan, Leighton (NIH/CC/RMD) [E]" <[redacted]@cc.nih.gov>
Date: Friday, October 1, 2021 at 9:32 AM
To: "Tabak, Lawrence (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: ODNI Meeting Request- on AHI

Hi Larry- Would you like to join this meeting with ODNI? I assume the topic is related to the call you took this week. One of the central issues here is that no one from NIH OGC has a security clearance that will allow them into the SCIF. That has slowed this process.

LC

_____

Leighton Chan, MD, MPH
Chief, Rehabilitation Medicine Department, Clinical Center, National Institutes of Health
[redacted], MD [redacted]

Phone: [redacted]
Fax: [redacted]
Email: [redacted]@cc.nih.gov <mailto:[redacted]@cc.nih.gov>

From: Cullen, William (NIH/OD/ORS) [E]
Sent: Friday, October 1, 2021 8:48 AM
To: Hollie, Leslie (IOS/ONS) <[redacted]@hhs.gov>
Cc: Chan, Leighton (NIH/CC/RMD) [E] <[redacted]@cc.nih.gov>
Subject: Fwd: ODNI Meeting Request- on AHI

Les we think Dr. Leighton Chan and his colleague Dr. French from across the street are the correct POCs. Dr.Chan is copied to ensure we have identified the right people for the discussion. V/r Bill

---

From: "Southers, Jordan (NIH/OD/ORS) [E]" <[redacted]@od.nih.gov>
Date: Thursday, September 30, 2021 at 1:39:58 PM
To: "Cullen, William (NIH/OD/ORS) [E]" <[redacted]@mail.nih.gov>
Subject: RE: ODNI Meeting Request- on AHI

Louis French, he's with DHA/Walter Reed.

Jordan Southers

Released by Chairman Rand Paul

From: Hollie, Leslie (IOS/ONS) <[redacted]@hhs.gov>
Sent: Thursday, September 30, 2021 10:31 AM
To: Cullen, William (NIH/OD/ORS) [E] <[redacted]@mail.nih.gov>; Reed, Paul (HHS/OASH) [redacted]@hhs.gov>; Boateng, Sarah (HHS/OASH) <[redacted]@hhs.gov>
Cc: Aguirre, Lisa (IOS/ONS) <[redacted]@hhs.gov>; Barstow, Kevin (HHS/IOS) <[redacted]@hhs.gov>; Maycock, Brett (OS/ONS) <[redacted]@hhs.gov>
Subject: ODNI Meeting Request- on AHI

All,

ODNI is interested in speaking with the appropriate HHS team on topic. Checking your availability for Thursday -7 October @ 1330 to 1430 for a SCIF meeting. Please let me know if this date and time works for you. Bill, I don't recall the name of the two NIH SMEs off hand but please pass along this invite because they are critical to the conversation.

Best,
Les

Leslie W. Hollie
National Security Advisor to the Secretary(A)
USDHHS-Office of National Security
[redacted]@hhs.gov
[redacted](Desk)

Released by Chairman Rand Paul

From: "Tabak, Lawrence (NIH/OD) [E]" <[redacted]@nih.gov>
To: "Chan, Leighton (NIH/CC/RMD) [E]" <[redacted]@cc.nih.gov>
Subject: Re: briefing for DNI Haines
Date: Tue, 07 Dec 2021 09:24:26 -0500
Importance: Normal

Ok; will ask Dina to set up.

From: "Chan, Leighton (NIH/CC/RMD) [E]" <[redacted]@cc.nih.gov>
Date: Tuesday, December 7, 2021 at 9:24 AM
To: "Tabak, Lawrence (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: RE: briefing for DNI Haines

Don't think so. I can come to your office.

LC

_____

Leighton Chan, MD, MPH
Chief, Rehabilitation Medicine Department, Clinical Center, National Institutes of Health
[redacted], MD [redacted]

Phone: [redacted]
Fax: [redacted]
Email: [redacted]@cc.nih.gov <mailto:[redacted]@cc.nih.gov>

From: Tabak, Lawrence (NIH/OD) [E]
Sent: Tuesday, December 7, 2021 9:23 AM
To: Chan, Leighton (NIH/CC/RMD) [E] <[redacted]@cc.nih.gov>
Subject: Re: briefing for DNI [redacted]

Does the meeting need to be in the SCIF?

From: "Chan, Leighton (NIH/CC/RMD) [E]" <[redacted]@cc.nih.gov>
Date: Tuesday, December 7, 2021 at 9:19 AM
To: "Tabak, Lawrence (NIH/OD) [E]" <[redacted]@nih.gov>
Subject: FW: briefing for DNI Haines

Hi Larry-

I think it's time for another face to face meeting with you. Last week we had a large meeting of clinicians at Hopkins. We presented some of our findings and it has caused a bit of a stir. The Director of ODNI has asked for a brief next week and I wanted to clear the meeting with you and get some feedback on the things I might tell her.

They have set the meeting for next Wed in McLean. I have not responded yet.

Released by Chairman Rand Paul

I have time during the rest of this week and Monday also looks good. We will need about an hour.

Best,

LC

_____

Leighton Chan, MD, MPH
Chief, Rehabilitation Medicine Department, Clinical Center, National Institutes of Health
[redacted], MD [redacted]

Phone: [redacted]
Fax: [redacted]
Email: [redacted]@cc.nih.gov <mailto:[redacted]@cc.nih.gov>

From: Benjamin M. Sandler <[redacted]@dni.gov>
Sent: Tuesday, December 7, 2021 8:01 AM
To: Chan, Leighton (NIH/CC/RMD) [E] <[redacted]@cc.nih.gov>
Cc: 'Hollie, Leslie (IOS/ONS)' <[redacted]@hhs.gov>; Joseph G Morosco <[redacted]@dni.gov>; Sandrea I. Hwang <[redacted]@dni.gov>
Subject: [EXTERNAL] briefing for DNI Haines

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dr. Chan-

Good morning. You may recall that in October, myself and Joe Morosco from the ODNI's National Counterintelligence and Security Center briefed you and and other HHS/NIH personnel.

DNI Avril Haines has heard that you and other medical professionals recently gathered in Maryland (as we have heard, dubbed the "Maryland Summit") to discuss medical aspects of AHI. DNI Haines would like to receive a back-brief of that meeting. Due to her limited availability, her staff has already scheduled that meeting for next Wednesday, 15 December, from 1-2pm. Would you be able to meet with DNI Haines that date/time at her McLean, VA office?

Cheers,
Ben

Released by Chairman Rand Paul

From: "Fauci, Anthony (NIH/NIAID) [E]" </O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=AFAUCI>
To: "Kurilla, Michael (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Subject: RE: December Interagency EGB Meeting - Follow Up
Date: Wed, 16 Dec 2009 18:36:00 -0500
Importance: Normal

Can you call now? Am in the office at [redacted]

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
[redacted]
National Institutes of Health
Bethesda, MD 20892-2520
Phone: [redacted]
FAX: [redacted]
E-mail: afauci@niaid.nih.gov
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From: Kurilla, Michael (NIH/NIAID) [E]
Sent: Wednesday, December 16, 2009 6:35 PM
To: Fauci, Anthony (NIH/NIAID) [E]
Subject: RE: December Interagency EGB Meeting - Follow Up

I'm free until 11AM.

AM okay?

Michael G Kurilla, MD-PhD

Director, Office of BioDefense Research Affairs

Associate Director for BioDefense Product Development

DMID, NIAID, NIH, DHHS

6610 Rockledge Dr. Rm. 3510

Bethesda, MD 20892-6604

[redacted]
(F) [redacted]

We're all puppets, ... I'm just a puppet who can see the strings.
- Jon Osterman

From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Wednesday, December 16, 2009 6:33 PM
To: Kurilla, Michael (NIH/NIAID) [E]
Cc: Conrad, Patricia (NIH/NIAID) [E]
Subject: RE: December Interagency EGB Meeting - Follow Up

Released by Chairman Rand Paul

Mike:

Please give me a call tomorrow regarding the conversation that I had with Heidi Avery tonight. I will explain.

Thanks,

ASF

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
[redacted]
National Institutes of Health
Bethesda, MD 20892-2520
Phone: [redacted]
FAX: [redacted]
E-mail: afauci@niaid.nih.gov
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From: Kurilla, Michael (NIH/NIAID) [E]
Sent: Wednesday, December 16, 2009 5:27 PM
To: Fauci, Anthony (NIH/NIAID) [E]
Subject: RE: December Interagency EGB Meeting - Follow Up

Yes

Michael G Kurilla, MD-PhD

Director, Office of BioDefense Research Affairs

Associate Director for BioDefense Product Development

DMID, NIAID, NIH, DHHS

[redacted]

Bethesda, MD 20892-6604

[redacted]

(F) [redacted]

We're all puppets, ... I'm just a puppet who can see the strings.
- Jon Osterman

From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Wednesday, December 16, 2009 4:24 PM
To: Kurilla, Michael (NIH/NIAID) [E]
Cc: Conrad, Patricia (NIH/NIAID) [E]; Folkers, Greg (NIH/NIAID) [E]
Subject: FW: December Interagency EGB Meeting - Follow Up
Importance: High

Are you taking care of this?

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
[redacted]

Released by Chairman Rand Paul

National Institutes of Health
Bethesda, MD 20892-2520
Phone: [redacted]
FAX: [redacted]
E-mail: afauci@niaid.nih.gov
The information in this e-mail and any of its attachments is confidential and may contain sensitive information. It should not be used by anyone who is not the original intended recipient. If you have received this e-mail in error please inform the sender and delete it from your mailbox or any other storage devices. The National Institute of Allergy and Infectious Diseases (NIAID) shall not accept liability for any statements made that are the sender's own and not expressly made on behalf of the NIAID by one of its representatives.

From: Wright, Casey (OS)
Sent: Wednesday, December 16, 2009 12:30 PM
To: Bar-Shalom, Tali; Casscells, Ward; Emanuel, Peter A.; Hopkins, Tom; Kevin Hanretta; Verga, Peter; Lurie, Nicole (OS); Collins, Francis (NIH/OD) [E]; Hamburg, Margaret A (FDA); Frieden, Thomas (CDC); Turman, Richard (OS); Cade, David (OS); Palm, Andrea (OS); Embrey, Ellen, DASD/Force Health Protection and Readiness, OASD(HA); [redacted]@HQ.DHS.GOV; [redacted]@ostp.eop.gov; [redacted]@gmail.com; Kurilla, Michael (NIH/NIAID) [E]; Lushniak, Boris D (FDA); Sosin, Daniel M. (CDC); [redacted]@ha.osd.mil; [redacted]@ha.osd.mil; [redacted]@dhs.gov; Korch, George (OS); Parker, Gerald (OS); Robinson, Robin (OS); Pillai, Segaran ; Lushniak, Boris; [redacted]@va.gov
Cc: Lucas, John ; Alston, Ibn (NIH/OD) [E]; Conrad, Patricia (NIH/NIAID) [E]; Flowers, Susan (NIH/OD) [E]; Holt, Yolonde P. (CDC); Johnson, Eilse; Lee, Barbara D (OS); Mansoura, Monique (OS); Mercadel, Acesa (CDC); Minor, Eloise (OS); Palmer, Kelly L (FDA); Payne, Matthew (OS); Payne, Pamela (OS); Petillo, Jay (OS); Pisner, Pamela E (FDA); Prasher, Joanna (OS); Stancil, Audrey A (OS); Williams, Judith A. (CDC); Fauci, Anthony (NIH/NIAID) [E]; Linden, Carol (OS); Mazanec, Mary (OS); Yeskey, Kevin (OS); Deborah Jermunson; DeVeny, John; Hemer, Mary; Jaffe, Richard; Jean Kelley; John Hancock; Kotra, Diane (CDC osd.mil); Randy Zeller; Karen Soto; Terri Cheshire; Trevino, David; OS Berry, Diane; Garufi, Marc; Hottenstein, Omar ; Jaffe, Richard, CTR, OSD-ATL; Lucas, John ; Reed, Jean; Vesely, Keith; Wallace, Katherine S. ; Timmens, Eric, LCDR, OASD(HA)/TMA; Lucas, John, CIV, OASD(HA); Zaza, Stephanie (CDC); Cochran, Norris (OS); Sherman, Susan (OS); McCurdy, Erica (OS); Annelli, Joseph; Moss, Marcille (OS); Koch, Michala (OS); Johnson, Elise E (FDA); Powell, Shunetta (NIH/OD) [E]; Mercadel, Acesa (CDC); [redacted]@dhs.gov; Karen Soto; Verga, Pete, CIV, OSD-POLICY; Shapiro, Jonathan (OS); Pillai, Segaran (PSC); Colacicco, Christopher, LTC, OASD(HA)/TMA; O'Toole, Tara; Hamburg, Margaret; McCurdy, Erica (OS); Fowler, Erin (OS); Novak, Ben (OS); Burel, William G. (CDC); [redacted]@dhs.gov
Subject: December Interagency EGB Meeting - Follow Up
Importance: High

All,

Thank you for the thoughtful discussion today about the Enterprise Review. There are two follow up activities for which your help is required.

First, please forward to Erica McCurdy [redacted]@hhs.gov) a lead point of contact and alternate for further follow up on the Review.

Second, your support to white paper development will be most helpful. To add some further detail to today's conversation, Dr. Lurie recognizes a great deal of analysis has already taken place that is directly and indirectly related to our problem statement. She plans to commission a few white papers to synthesize all of this work and to tee up key issues. In addition to analyses about how our current strategy has served us well and how it hasn't, she is interested in an exploration of economic and market incentives for all stages of the Enterprise, how to get the right players to the table with the right economics and incentives, what is the best model to the get the science done and pay for the science and how do we optimize programs and investments across the federal government. These white papers will serve as the foundation for a few workshops in February.

While our conversation this morning is fresh in your minds, please forward key questions you think these white papers should address/answer to me and Monique Mansoura by 1000 tomorrow.

Thanks and please let me now if you have any questions.

R/Casey

From: Wright, Casey (HHS/ASPR/OPSP)
Sent: Tuesday, December 15, 2009 4:17 PM

Released by Chairman Rand Paul

From: "Kurilla, Michael (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" <AFAUCI@niaid.nih.gov>
Cc: "Auchincloss, Hugh (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: update on the status of the HHS Countermeasure review
Date: Thu, 14 Jan 2010 13:58:00 -0500
Importance: Normal

Tony,

Just a quick update on the HHS review (which precipitated your conversation with Heidi Avery). Bear in mind that this review has very ambitious turnaround time with a final report due 3/31/10.

There will be an IOM Workshop (Feb 11-12) that will provide some input on a subset of the overall objectives. The agenda is still being fleshed out, but will likely examine possible regulatory reforms (specifically to address rapidly emerging public health threats), business incentives, and alternative organizational models (this is Heidi's interests). Gail Cassell is involved from the IOM side.

Hugh needs to be aware that there will be a series of National Biodefense Science Board meetings (both telecons and actual meetings) from next month and through March to sort through a series of white papers on various topics being prepared by a contractor for HHS as well as to review the IOM Workshop output.

Finally, I wanted to let you know that I learned, part of Heidi's receptivity was due to a series of briefings that Heidi has been receiving from Richard Hatchett and James Lawler (both detailed to the WH for H1N1 issues).

Michael G Kurilla, MD-PhD
Director, Office of BioDefense Research Affairs
Associate Director for BioDefense Product Development
DMID, NIAID, NIH, DHHS
[redacted]
(F) [redacted]

I am interested in how to live in a world we don't understand very well –in other words, while most human thought (particularly since the enlightenment) has focused us on how to turn knowledge into decisions, I am interested in how to turn lack of information, lack of understanding, and lack of "knowledge" into decisions
- Nassim Nicholas Taleb

Released by Chairman Rand Paul

From: "Heilman, Carole (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
To: NIAID BUGS <[redacted]@niaid.nih.gov>
Subject: Fw: Not much happened while you were in Mali/Paris
Date: Sat, 16 Jan 2010 06:54:09 -0500
Importance: Normal

Fyi

From: Kurilla, Michael (NIH/NIAID) [E]
To: Heilman, Carole (NIH/NIAID) [E]
Sent: Fri Jan 15 18:41:30 2010
Subject: Not much happened while you were in Mali/Paris

Carole,

The Sebelius review is in full steam (and likely to just as easily crash). There is an extremely tight timeline (report due 3/31). Gail Cassell and I have been engaged for the planning for the IOM Workshop. The National Biodefense Science Board is also engaged with multiple telecons and meetings scheduled between now and the end of March. Hugh is our ex officio member, but you may get pinged to fill in. The Board is suppose to distill the output of a series of 'white papers' that HHS is hiring a contractor to write as well as the IOM Workshop output into a series of recommendations for the report to Sebelius.

Finally, you may recall ASF's lunch with Heidi Avery down at the white house. This has advanced such that Tony and I are going downtown on Tuesday to discuss the concept (along with HHS and CDC). Tony needs a one-pager that is essentially a distilled version of our 2007 BioD Strategy update. These along with CDC and HHS will be further gisted to be included in the upcoming state of the union address as part of some grand vision of global health security strategy.

Michael G Kurilla, MD-PhD
Director, Office of BioDefense Research Affairs
Associate Director for BioDefense Product Development
DMID, NIAID, NIH, DHHS
[redacted]
(F) [redacted]

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Released by Chairman Rand Paul

From: "Fauci, Anthony (NIH/NIAID) [E]" </O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=AFAUCI>

To: "Korch, George (OS)" [redacted]@hhs.gov>

Cc: "Kurilla, Michael (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Folkers, Greg (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <AFAUCI@niaid.nih.gov>

Subject: RE: Reminder about inputs for the potential White House Briefing on Sustainable Systems approach to MCM's

Date: Mon, 18 Jan 2010 08:26:02 -0500

Importance: Normal

Attachments: NIH_-_R_and_D_for_Health_threats_-_1-pager_-_FINAL.docx

---

George:
I am attaching our 1-pager as requested. Please let me know if you have any questons.
Thanks,
Tony

-----Original Message-----
From: Korch, George (OS)
Sent: Monday, January 18, 2010 7:52 AM
To: Fauci, Anthony (NIH/NIAID) [E]; Robinson, Robin (OS)
Subject: Reminder about inputs for the potential White House Briefing on Sustainable Systems approach to MCM's

Gentlemen:

I will be assembling the information received on how to augment and improve the medical countermeasure enterprise from each of the partners to present to Heidi Avery and others on the NSC staff sometime tomorrow. Thanks in advance for sending your inputs to me so that I can craft a document to redistribute to all concerned.

V/r,

George

A Research and Development (R & D) Strategy for Future Health Threats – The NIH Approach - 2010

GOAL: The nation must be prepared to protect its citizens and preserve national security with safe and effective medical interventions that can prevent, diagnose, and treat existing biological threats as well as respond rapidly and effectively to newly emerging threats that are either naturally occurring or deliberately propagated.

TRADITIONAL STRATEGY: While the traditional medical countermeasure development approach is a sound and appropriate strategy for mitigation of known biological threats, time and resources limit the ability of this "one bug – one drug – one vaccine" approach to achieve a rapid and effective response to all possible threats. As a result NIH has been transitioning to a new paradigm with three "broad spectrum" strategies (*products, platforms, and technology*) that will underpin a more flexible and responsive medical countermeasure capability.

FUTURE STRATEGY: *Broad Spectrum Products*: Existing anti-infective products possess narrow activity across the wide range of potential pathogens. a) Vaccines. Using Influenza as an example, vaccines are exquisitely targeted such that a new influenza vaccine is required annually. Cross protective vaccine concepts offer the potential for a universal influenza vaccine such that annual vaccinations would be eliminated and pandemic protection would already be pre-existing. b) Drugs. Given the virtually limitless number of organisms that can constitute public health threats, it is essential to pursue the broad spectrum approach towards therapeutics. In addition to a small number of drugs replacing a medicine cabinet of pathogen specific drugs, drug resistance would be less likely to develop. Truly broad spectrum products offer the potential not only to address the vast, existing infectious disease spectrum, but allow for effective countermeasures for emerging diseases that could not even be predicted.

Broad Spectrum Platforms: The concept of new platforms pertains most readily to vaccines. Standardized recombinant DNA technologies must be made available for immediate application in the context of emerging infectious diseases. Standardized methods offer the potential to significantly reduce the complexity, time, and cost required to bring medical countermeasures to general use. Platforms can be expanded to other aspects of the overall product development process such as diagnostic screening. Multiplexed platform diagnostics systems offer the capability to test for a wide array of potential pathogens, while at the same time, offering a simple and straightforward path for introduction of new tests as novel pathogens evolve or emerge.

Broad Spectrum Technology: Technological enhancements offer greater capabilities in storage, dispersal, and utilization of countermeasures. NIH has focused on temperature stabilization and alternative delivery for vaccines as ancillary technologies with potential applicability to existing as well as future vaccines. Temperature stabilization allows for room temperature stockpiling which reduces storage and shipment costs as well as extending the shelf life of the vaccine. The potential to improve the vaccination effectiveness in the 3rd world where cold chain capability can be limited is enormous.

Taken together, this new R & D strategy will position us well to address existing health threats as well as the challenge of new and emerging threats.

Released by Chairman Rand Paul

From: "Korch, George (HHS/ASPR/IO)" [redacted]@hhs.gov>

To: "Fauci, Anthony (NIH/NIAID) [E]" <Anthony.Fauci@nih.hhs.gov>

Cc: "Kurilla, Michael (NIH/NIAID) [E]" [redacted]@nih.hhs.gov>, "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@nih.hhs.gov>, "Folkers, Greg (NIH/NIAID) [E]" [redacted]@nih.hhs.gov>, "Lurie, Nicole (HHS/ASPR/IO)" [redacted]@hhs.gov>, "Mansoura, Monique (HHS/ASPR/BARDA)" [redacted]@hhs.gov>

Subject: RE: Reminder about inputs for the potential White House Briefing on Sustainable Systems approach to MCM's

Date: Mon, 18 Jan 2010 08:26:46 -0500

Importance: Normal

Thanks very much Tony ! I will send back a consolidated version sometime before early afternoon for everyone's edits.

George

-----Original Message-----
From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Mon 1/18/2010 8:26 AM
To: Korch, George (HHS/ASPR/IO)
Cc: Kurilla, Michael (NIH/NIAID) [E]; Conrad, Patricia (NIH/NIAID) [E]; Folkers, Greg (NIH/NIAID) [E]; Fauci, Anthony (NIH/NIAID) [E]
Subject: RE: Reminder about inputs for the potential White House Briefing on Sustainable Systems approach to MCM's

George:
I am attaching our 1-pager as requested. Please let me know if you have any questons.
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Tony

-----Original Message-----
From: Korch, George (OS)
Sent: Monday, January 18, 2010 7:52 AM
To: Fauci, Anthony (NIH/NIAID) [E]; Robinson, Robin (OS)
Subject: Reminder about inputs for the potential White House Briefing on Sustainable Systems approach to MCM's

Gentlemen:

I will be assembling the information received on how to augment and improve the medical countermeasure enterprise from each of the partners to present to Heidi Avery and others on the NSC staff sometime tomorrow. Thanks in advance for sending your inputs to me so that I can craft a document to redistribute to all concerned.

V/r,

George

Released by Chairman Rand Paul

From: "Korch, George (HHS/ASPR/IO)" [redacted]@hhs.gov>
To: "Frieden, Thomas (Tom) (CDC/OD)" [redacted]@cdc.gov>, "Hamburg, Margaret A. (FDA)" [redacted]@fda.hhs.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <Anthony.Fauci@nih.hhs.gov>, "Goodman, Jesse L. (FDA)" [redacted]@cber.fda.gov>
Cc: "Sosin, Dan (CDC/COTPER/OD)" [redacted]@CDC.GOV>, "Kurilla, Michael (NIH/NIAID) [E]" [redacted]@nih.hhs.gov>, "Robinson, Robin (HHS/ASPR/BARDA)" [redacted]@HHS.GOV>, "Khabbaz, Rima (CDC/CCID/NCPDCID)" [redacted]@CDC.GOV>, "Parker, Gerald (HHS/ASPR/IO)" [redacted]@hhs.gov>
Subject: Sustainable systems for PHEMCE products (v8 0 NL)RM jl edits.doc
Date: Tue, 19 Jan 2010 16:31:19 -0500
Importance: Normal
Attachments: Sustainable_systems_for_PHEMCE_products_(v8_0_NL)RM_jl_edits.doc

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Drs Frieden, Hamburg, Fauci and Goodman:

Attached, please find the final version of the paper on the PHEMCE enterprise for discussion this evening with Ms. Heidi Avery and the NSS. Dr. Lurie has also asked that I have available the more fully developed texts that you all provided earlier to further inform the White House staff.

V/r,

George

George W. Korch, Jr.
Senior Science Advisor
ASPR

Released by Chairman Rand Paul

Information Paper on Developing a Systems Approach for Managing the Public Health Emergency Medical Countermeasure Enterprise

A. BACKGROUND

- Despite significant effort and research expenditure to develop public health emergency medical countermeasures (vaccines, drugs, diagnostics, devices) there are insufficient products in the current development pipeline to address these natural or man-made threats.

- The current pathway for product development involves multiple steps which include: defining product characteristics, discovery, advanced development, manufacturing, procurement, storage, distribution, and patient administration.

- What we currently lack is a 'systems" or end-to-end approach for product development

B. AIM

We require a unified management approach for this product pipeline, potentially under a single decision authority, that incorporates metrics for success and continually monitors the progress of products through a sustainable, long-range and properly-structured enterprise.

We propose to improve the current system by focusing on four components of the countermeasure development process: 1). science and technology investments, 2). advanced development and manufacturing capability, 3). regulatory science, laws and regulations and 4). product use and improvement

In addressing these components, we anticipate 1) advancing science and technology, for national and global health security, 2) improving our preparedness and ability to respond to natural and man-made disasters, 3) aligning financial and market incentives for these products 4) creating public-private partnerships (government, academia and industry) for cutting edge, scientifically-based manufacturing, which 5) creates substantial job opportunity for a highly-skilled workforce.

1. SCIENCE AND TECHNOLOGY INVESTMENTS

An integrated, systems approach begins with a science and technology effort that keep the end-users in mind, and builds a target product profile based on those needs. This ultimately contributes to the best "return on investment". At a minimum, we require rapid, facile point of care and multiplexed diagnostics; new broad-spectrum antimicrobial drugs and vaccines; user-expedient vaccine delivery methods; room temperature long term stability and field-friendly equipment that improves management of life support. The NIH has been transitioning to a new paradigm to address these types of needs with three "broad spectrum" strategies (products, platforms, and technology) to achieve a more flexible and responsive medical countermeasure capability that moves beyond the traditional medical countermeasure approach of "one bug – one drug – one vaccine". The goal is for

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these science and technology investments to be able to translate products more effectively into the advanced development process.

A. Broad Spectrum Products: Existing anti-infective products possess narrow activity across the wide range of potential pathogens, a) **Vaccines**. Using Influenza as an example, vaccines are exquisitely targeted such that a new influenza vaccine is required annually. Cross-protective vaccine concepts offer the potential for a universal influenza vaccine, eliminating annual vaccines and essentially providing pre-existing pandemic protection, b) **Drugs**. Given the virtually limitless number of natural and potential organisms that could constitute public health threats, it is essential to pursue the broad spectrum approach towards therapeutics. Truly broad spectrum products offer the potential not only to address the vast, existing and emerging infectious disease spectrum, but to produce effective countermeasures for 'unpredictable' diseases, c) **Diagnostics**. Highly multiplexed methods that take advantage of the specificity in nucleic acid, antibody and other protein signatures are well recognized as the approaches needed to develop rapid, sensitive and specific diagnostic tools, but challenges lie in miniaturization, cost, computational analysis of multiplexed information and signal to noise issues.

B. Broad Spectrum Platforms: The concept of new platforms pertains most readily to vaccines and other biologics. Standardized recombinant DNA technologies must be developed for immediate application in the context of emerging infectious diseases. Standardized methods offer the potential to significantly reduce the complexity, time, and cost required to bring medical countermeasures to general use. In addition, multiplexed platform diagnostics systems offer the capability to test for a wide array of pathogens that are already recognized, while at the same time, offering a simple and straightforward path for diagnosis as novel pathogens evolve or emerge.

C. Broad Spectrum Technology: Technological enhancements offer greater capabilities in storage, dispersal, and utilization of countermeasures. NIH has focused on temperature stabilization and alternative delivery for vaccines as ancillary technologies with potential applicability to existing as well as future vaccines. This focus reflects the end-user needs for products that are less reliant on cold chain, and can be self administered with a single dose. For example, temperature stabilization allows for room temperature stockpiling which reduces storage and shipment costs as well as extending the shelf life of the vaccine. The potential to improve the vaccination effectiveness in the 3rd world where cold chain capability can be limited is enormous.

2. ADVANCED DEVELOPMENT AND MANUFACTURING CAPABILITY

Successful efforts at the bench prove their worth in the advanced development stages of candidate product development. Platform technologies must succeed against the increasing levels of regulatory scrutiny during the scale up and testing process, and ultimately must produce a specific vaccine, drug or diagnostic, and not just a general demonstration of technology feasibility. Currently, challenges to advanced development include lack of product and manufacturing expertise among innovative sponsors which are often small biotech companies, strong reliance on animal models for efficacy data in lieu of trials in humans, insufficient methods to address safety and discard those products likely to cause unacceptable toxicity in human trials, or to ensure product reliability and stability, and lack of flexible capacity to surge or dampen manufacturing capacity based on population and market needs. Early alignment of the biotechnology / innovator

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communities with skilled advanced developers from the larger pharmaceutical organizations appears to be the best strategy to accomplishing this end goal.

Opportunities to enhance successful delivery of approved products through advanced development will require:

- Fostering broader spectrum indications to increase market attractiveness
- Offering long-term (≥ 10 years) product acquisition contracts with minimum warm-base manufacturing to guarantee markets
- Establishing government/private sector-sponsored facilities for advanced development, and domestic pilot lot and commercial scale manufacturing;
- Creating more domestic fill-finish capability
- Building more flexible and robust high-level biocontainment facilities to conduct regulated animal challenge studies for safety and efficacy testing.

3 . REGULATORY SCIENCE, LAWS AND REGULATIONS

There is an urgent need to invest in applied regulatory science (ARS) and to strengthen the underlying research contributing to a more robust and agile regulatory process. This is necessary to ensure that the potential benefits of these public health medical countermeasure candidates translate into approved products. Such science is distinct from basic discovery research, typically done in academia with NIH support, or industry research intended to develop one specific product. ARS can improve the likelihood of success for a product at all stages from preclinical studies through stockpile, distribution and dispensing. Other areas may include revisiting regulations pertaining to the Animal Rule (AR) and Emergency Use Authorization (EUA). Finally, there may be a benefit to exploring alternate regulatory paradigms and pathways for these specific products for public health emergencies.

Applied regulatory science can assist on issues such as:

- Using biomarkers and more predictive animal models to increase indicators of efficacy.
- Using “adaptive” and other flexible clinical trial designs and current information technology sciences to modernize clinical trial design, performance and analysis, reduce costs, and decrease development time
- Facilitating more rapid scale up of production
- Improving stability of products
- Developing quality measurements, assays and standards for novel technologies such as stem cells and engineered tissues
- Developing better or faster testing technologies like rapid microbial testing for vaccines to identify accidental or deliberate contaminants.

4. PRODUCT USE AND IMPROVEMENTS

When new threats to population health appear, we must be able to rapidly recognize them from the noise of routine health-related activities. Highly flexible diagnostic technologies, such as the multi-array platforms described above, are needed to optimize detection and speed characterization of

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threats so that effective response actions can be initiated. The approaches taken for broad-spectrum applications and platforms in advanced development could expand into technologies or capabilities for surveillance needs. Performance of these surveillance and diagnostic technologies centers must filter back to the material developers to permit continuous improvement in these technologies.

Once an etiology is identified, we must respond with highly effective deployment of the Emergency Public Health Supplies (vaccines, diagnostic tests, drugs and other medical devices and treatments such as ECMO) from publicly held stockpiles, or through enhanced supply mechanisms. Feedback on the success and failures in these deployments must translate back to the appropriate level of this product development enterprise to solve identified issues – thus recalibrating the product for optimized end use.

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From: "Korch, George (HHS/ASPR/IO)" [redacted]@hhs.gov>
To: Jesse Goodman [redacted]@fda.hhs.gov>, "Frieden, Thomas (Tom) (CDC/OD)" [redacted]@cdc.gov>, "Hamburg, Margaret A. (FDA)" [redacted]@fda.hhs.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <Anthony.Fauci@nih.hhs.gov>
Cc: "Sosin, Dan (CDC/COTPER/OD)" [redacted]@CDC.GOV>, "Kurilla, Michael (NIH/NIAID) [E]" [redacted]@nih.hhs.gov>, "Robinson, Robin (HHS/ASPR/BARDA)" [redacted]@HHS.GOV>, "Khabbaz, Rima (CDC/CCID/NCPDCID)" [redacted]@CDC.GOV>, "Parker, Gerald (HHS/ASPR/IO)" [redacted]@hhs.gov>
Subject: RE: Sustainable systems for PHEMCE products (v8 0 NL)RM jl edits.doc
Date: Tue, 19 Jan 2010 16:54:41 -0500
Importance: Normal

Outstanding points Jesse, and ones to keep in mind in our extended discussion with the White House this evening, and in general during this review and its outcomes.

Thanks very much,

George

George W. Korch Jr., Ph.D.
Senior Science Advisor
Principal Deputy Assistant Secretary for Preparedness & Response
Department of Health and Human Services
Washington, D.C.
[redacted] (FAX)

Disclaimer:
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From: Jesse Goodman
Sent: Tuesday, January 19, 2010 4:46 PM
To: Korch, George (HHS/ASPR/IO); Frieden, Thomas (Tom) (CDC/OD); Hamburg, Margaret A. (FDA); Fauci, Anthony (NIH/NIAID) [E]
Cc: Sosin, Dan (CDC/COTPER/OD); Kurilla, Michael (NIH/NIAID) [E]; Robinson, Robin (HHS/ASPR/BARDA); Khabbaz, Rima (CDC/CCID/NCPDCID); Parker, Gerald (HHS/ASPR/IO)
Subject: RE: Sustainable systems for PHEMCE products (v8 0 NL)RM jl edits.doc

Thanks for all the efforts on this. It looks good. Two quick comments I would make are:

1- that the potential positive implications for neglected diseases seem to have somewhat fallen out. While I think we do not want to oversell that, it is a plus and a dual use and ties in with a lot of outside interest and our humanitarian goals.

and

2- broad spectrum has a medical meaning that we need to keep in mind, as all are aware, but needs care w the non-scientists we are engaging here. I understand here we are talking about both multipathogen (e.g. broadly acting antimicrobials or, as in flu example, vaccines) and platform technologies that could be generalized to multiple pathogens or threats. Issues with focusing too much attention on "broad spectrum" in terms of broad activity may include the following - a) that such accomplishments may be difficult to achieve scientifically and b) that we will face the challenge we face with

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commercially usable drugs, the tension between broad use leading to resistance development, vs.. preserving for resistance and MCM needs. Of interest, perhaps somewhat in between, and in some cases more realistic than truly broad spectrum, are interventions that may be dual or multi-use but not truly "broad spectrum" , such as an antibiotic that might be active both against terrorism threats and against specific resistant organisms in the health care setting. Or a radiation injury treatment that might be useful in cancer therapy, marrow transplantation and in radiation injury. I know this is what is intended by all of us but wanted to emphasize for discussions.

One way to discuss for non-medical audiences might be that beyond a single only emergency use, dual use, multiuse and broad spectrum agents and platforms can be part of a more technologically advanced and strategic continuum that can increase economic incentives, US competitiveness, preparedness and health benefits.

Thanks

Jesse

From: Korch, George (HHS/ASPR/IO) [mailto:[redacted]@hhs.gov]
Sent: Tuesday, January 19, 2010 4:31 PM
To: Frieden, Thomas (CDC); Commissioner FDA; Fauci, Anthony S (NIH); Goodman, Jesse
Cc: Sosin, Daniel M. (CDC); Kurilla, Michael G (NIH); Robinson, Robin (OS); Khabbaz, Rima F. (CDC); Parker, Gerald (OS)
Subject: Sustainable systems for PHEMCE products (v8 0 NL)RM jl edits.doc

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Attached, please find the final version of the paper on the PHEMCE enterprise for discussion this evening with Ms. Heidi Avery and the NSS. Dr. Lurie has also asked that I have available the more fully developed texts that you all provided earlier to further inform the White House staff.

V/r,

George

George W. Korch, Jr.
Senior Science Advisor
ASPR

Released by Chairman Rand Paul

From: "Kurilla, Michael (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: NIAID BUGS [redacted]@niaid.nih.gov>, "Heilman, Carole (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
Subject: One pager and its integration into the HHS package
Date: Tue, 19 Jan 2010 16:52:41 -0500
Importance: Normal
Attachments: Sustainable_systems_for_PHEMCE_products_(v8_0_NL)RM_jl_edits.doc; NIH_-_R_and_D_for_Health_threats_-_1-pager_-_FINAL.docx

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Attached you'll find a one pager that NIAID assembled over the weekend as part of an HHS document to be presented to Heidi Avery (National Security Council Deputy Assistant to the President) this evening. The larger document is the "shortened" version of the HHS package (there is a 10 page version as well).

Michael G Kurilla, MD-PhD
Director, Office of BioDefense Research Affairs
Associate Director for BioDefense Product Development
[redacted]
Bethesda, MD 20892-6604
[redacted]
(F) [redacted]

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Information Paper on Developing a Systems Approach for Managing the Public Health Emergency Medical Countermeasure Enterprise

A. BACKGROUND

- Despite significant effort and research expenditure to develop public health emergency medical countermeasures (vaccines, drugs, diagnostics, devices) there are insufficient products in the current development pipeline to address these natural or man-made threats.

- The current pathway for product development involves multiple steps which include: defining product characteristics, discovery, advanced development, manufacturing, procurement, storage, distribution, and patient administration.

- What we currently lack is a 'systems" or end-to-end approach for product development

B. AIM

We require a unified management approach for this product pipeline, potentially under a single decision authority, that incorporates metrics for success and continually monitors the progress of products through a sustainable, long-range and properly-structured enterprise.

We propose to improve the current system by focusing on four components of the countermeasure development process: 1). science and technology investments, 2). advanced development and manufacturing capability, 3). regulatory science, laws and regulations and 4). product use and improvement

In addressing these components, we anticipate 1) advancing science and technology, for national and global health security, 2) improving our preparedness and ability to respond to natural and man-made disasters, 3) aligning financial and market incentives for these products 4) creating public-private partnerships (government, academia and industry) for cutting edge, scientifically-based manufacturing, which 5) creates substantial job opportunity for a highly-skilled workforce.

1. SCIENCE AND TECHNOLOGY INVESTMENTS

An integrated, systems approach begins with a science and technology effort that keep the end-users in mind, and builds a target product profile based on those needs. This ultimately contributes to the best "return on investment". At a minimum, we require rapid, facile point of care and multiplexed diagnostics; new broad-spectrum antimicrobial drugs and vaccines; user-expedient vaccine delivery methods; room temperature long term stability and field-friendly equipment that improves management of life support. The NIH has been transitioning to a new paradigm to address these types of needs with three "broad spectrum" strategies (products, platforms, and technology) to achieve a more flexible and responsive medical countermeasure capability that moves beyond the traditional medical countermeasure approach of "one bug – one drug – one vaccine". The goal is for

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these science and technology investments to be able to translate products more effectively into the advanced development process.

A. Broad Spectrum Products: Existing anti-infective products possess narrow activity across the wide range of potential pathogens, a) **Vaccines**. Using Influenza as an example, vaccines are exquisitely targeted such that a new influenza vaccine is required annually. Cross-protective vaccine concepts offer the potential for a universal influenza vaccine, eliminating annual vaccines and essentially providing pre-existing pandemic protection, b) **Drugs**. Given the virtually limitless number of natural and potential organisms that could constitute public health threats, it is essential to pursue the broad spectrum approach towards therapeutics. Truly broad spectrum products offer the potential not only to address the vast, existing and emerging infectious disease spectrum, but to produce effective countermeasures for 'unpredictable' diseases, c) **Diagnostics**. Highly multiplexed methods that take advantage of the specificity in nucleic acid, antibody and other protein signatures are well recognized as the approaches needed to develop rapid, sensitive and specific diagnostic tools, but challenges lie in miniaturization, cost, computational analysis of multiplexed information and signal to noise issues.

B. Broad Spectrum Platforms: The concept of new platforms pertains most readily to vaccines and other biologics. Standardized recombinant DNA technologies must be developed for immediate application in the context of emerging infectious diseases. Standardized methods offer the potential to significantly reduce the complexity, time, and cost required to bring medical countermeasures to general use. In addition, multiplexed platform diagnostics systems offer the capability to test for a wide array of pathogens that are already recognized, while at the same time, offering a simple and straightforward path for diagnosis as novel pathogens evolve or emerge.

C. Broad Spectrum Technology: Technological enhancements offer greater capabilities in storage, dispersal, and utilization of countermeasures. NIH has focused on temperature stabilization and alternative delivery for vaccines as ancillary technologies with potential applicability to existing as well as future vaccines. This focus reflects the end-user needs for products that are less reliant on cold chain, and can be self administered with a single dose. For example, temperature stabilization allows for room temperature stockpiling which reduces storage and shipment costs as well as extending the shelf life of the vaccine. The potential to improve the vaccination effectiveness in the 3rd world where cold chain capability can be limited is enormous.

2. ADVANCED DEVELOPMENT AND MANUFACTURING CAPABILITY

Successful efforts at the bench prove their worth in the advanced development stages of candidate product development. Platform technologies must succeed against the increasing levels of regulatory scrutiny during the scale up and testing process, and ultimately must produce a specific vaccine, drug or diagnostic, and not just a general demonstration of technology feasibility. Currently, challenges to advanced development include lack of product and manufacturing expertise among innovative sponsors which are often small biotech companies, strong reliance on animal models for efficacy data in lieu of trials in humans, insufficient methods to address safety and discard those products likely to cause unacceptable toxicity in human trials, or to ensure product reliability and stability, and lack of flexible capacity to surge or dampen manufacturing capacity based on population and market needs. Early alignment of the biotechnology / innovator

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communities with skilled advanced developers from the larger pharmaceutical organizations appears to be the best strategy to accomplishing this end goal.

Opportunities to enhance successful delivery of approved products through advanced development will require:

- Fostering broader spectrum indications to increase market attractiveness
- Offering long-term (≥ 10 years) product acquisition contracts with minimum warm-base manufacturing to guarantee markets
- Establishing government/private sector-sponsored facilities for advanced development, and domestic pilot lot and commercial scale manufacturing;
- Creating more domestic fill-finish capability
- Building more flexible and robust high-level biocontainment facilities to conduct regulated animal challenge studies for safety and efficacy testing.

3 . REGULATORY SCIENCE, LAWS AND REGULATIONS

There is an urgent need to invest in applied regulatory science (ARS) and to strengthen the underlying research contributing to a more robust and agile regulatory process. This is necessary to ensure that the potential benefits of these public health medical countermeasure candidates translate into approved products. Such science is distinct from basic discovery research, typically done in academia with NIH support, or industry research intended to develop one specific product. ARS can improve the likelihood of success for a product at all stages from preclinical studies through stockpile, distribution and dispensing. Other areas may include revisiting regulations pertaining to the Animal Rule (AR) and Emergency Use Authorization (EUA). Finally, there may be a benefit to exploring alternate regulatory paradigms and pathways for these specific products for public health emergencies.

Applied regulatory science can assist on issues such as:

- Using biomarkers and more predictive animal models to increase indicators of efficacy.
- Using “adaptive” and other flexible clinical trial designs and current information technology sciences to modernize clinical trial design, performance and analysis, reduce costs, and decrease development time
- Facilitating more rapid scale up of production
- Improving stability of products
- Developing quality measurements, assays and standards for novel technologies such as stem cells and engineered tissues
- Developing better or faster testing technologies like rapid microbial testing for vaccines to identify accidental or deliberate contaminants.

4. PRODUCT USE AND IMPROVEMENTS

When new threats to population health appear, we must be able to rapidly recognize them from the noise of routine health-related activities. Highly flexible diagnostic technologies, such as the multi-array platforms described above, are needed to optimize detection and speed characterization of

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threats so that effective response actions can be initiated. The approaches taken for broad-spectrum applications and platforms in advanced development could expand into technologies or capabilities for surveillance needs. Performance of these surveillance and diagnostic technologies centers must filter back to the material developers to permit continuous improvement in these technologies.

Once an etiology is identified, we must respond with highly effective deployment of the Emergency Public Health Supplies (vaccines, diagnostic tests, drugs and other medical devices and treatments such as ECMO) from publicly held stockpiles, or through enhanced supply mechanisms. Feedback on the success and failures in these deployments must translate back to the appropriate level of this product development enterprise to solve identified issues – thus recalibrating the product for optimized end use.

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From: "Conrad, Patricia (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" <AFAUCI@niaid.nih.gov>
Subject: FYI OMB Meeting
Date: Wed, 27 Jan 2010 10:12:15 -0500
Importance: Normal

This is on for Friday from 1-2 pm downtown– will you need any prep? Interesting…Nicki is not one of the attendees "thus far"!!

The attendees of the meeting thus far are:

[redacted] Merck
[redacted], Novartis
[redacted], NKT Therapeutics
[redacted], Hecker and Associates
Tony Fauci, NIAID
[redacted] GSK
Heidi Avery, NSC
Richard Hatchett, NSC
Zeke Emanuel, OMB

A brief agenda from Zeke is:

1) Introductions
2) Introduction of new initiative
3) Discussion of specific changes in Govt policy to facilitate drug and vaccine development
   a) Regulations
   b) Research support
   c) Manufacturing

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From: "Goldie, Chrisy (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" <AFAUCI@niaid.nih.gov>
Subject: FW: Details for Friday's Meeting
Date: Wed, 27 Jan 2010 11:14:28 -0500
Importance: Normal
Attachments: Reinventing_the_Countermeasure_Enterprise_26Jan10.pdf

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Chrisy Goldie
[redacted]
FAX: [redacted]

From: Bafford, Elizabeth A. [mailto:[redacted]@omb.eop.gov]
Sent: January 27, 2010 11:11 AM
To: Bafford, Elizabeth A.; [redacted]@gsk.com; Ruth, Lois Ann; Sandy Hecker; [redacted]@novartis.com; Goldie, Chrisy (NIH/NIAID) [E]; Robert Mashal; Korch, George (OS); Merchant, Raina (HHS/ASPR)
Cc: Severn, Deborah; Emanuel, Ezekiel J.
Subject: RE: Details for Friday's Meeting

Zeke asked me to share the attached ahead of Friday's meeting. Please review, but keep close hold.

Thank you,
Beth

From: Bafford, Elizabeth A.
Sent: Tuesday, January 26, 2010 4:54 PM
To: [redacted]@gsk.com'; 'Ruth, Lois Ann'; 'Sandy Hecker'; '[redacted]@novartis.com'; '[redacted]@niaid.nih.gov'; 'Robert Mashal'
Cc: Severn, Deborah; Emanuel, Ezekiel J.
Subject: Details for Friday's Meeting

Hi everyone,

I have been getting a lot of questions, so I thought it might be easiest to put everything in one place.

This meeting will be held in the Eisenhower Executive Office Building, in the White House complex from **1-2pm on Friday, January 29th**. The room is TBD, and I will let you know as soon as I have that information.

We are located at 1650 Pennsylvania Ave, NW, but the entrance to the building is at 17th and State Place (see map attached). I need all attendees to send me their **full name, date of birth, and social security number** so I can clear them into the building.

The attendees of the meeting thus far are:

[redacted] Merck
[redacted], Novartis
[redacted], NKT Therapeutics
[redacted], Hecker and Associates
Tony Fauci, NIAID
[redacted], GSK

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Heidi Avery, NSC
Richard Hatchett, NSC
Zeke Emanuel, OMB

A brief agenda from Zeke is:

1) Introductions
2) Introduction of new initiative
3) Discussion of specific changes in Govt policy to facilitate drug and vaccine development
   a) Regulations
   b) Research support
   c) Manufacturing

Thank you and we look forward to seeing you on Friday!

Best,
Beth

Beth Bafford
Office of Management and Budget
Eisenhower Executive Office Building, [redacted]
[redacted] (o)
(m)

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PROTECTING AGAINST WMD AND OTHER PUBLIC HEALTH THREATS

The accelerated development of effective drugs, vaccines, and diagnostics is a national security imperative. Our approach to the development and procurement of these medical "countermeasures" against biological weapons and other WMD threats, as well as emerging infectious diseases and pandemics has not produced the results we demand. Our results reflect in part the state of the pharmaceutical industry as a whole. As a nation, we are spending more time and money in research and development of pharmaceuticals, but fewer licensed products are emerging from the pipeline. As the array of public health threats expands, we can and must do better.

Recognizing this need, the Obama Administration is launching an initiative aimed at responding faster and more effectively to public health threats. Health and Human Services Secretary Kathleen Sebelius took an important first step on December 1, 2009 when she announced a review of medical countermeasure development efforts. Pursuant to this review, President Obama is calling to action key U.S. Government leaders to re-design our medical countermeasure enterprise to protect Americans and advance global health efforts.

The goal is a national capability for the rapid, reliable, and affordable production of an array of medical countermeasures against public health threats. Prior government efforts have been mostly unable to counter market forces driving private industry toward more profitable products outside of key public health needs. Our new approach will turn this around. We will pursue a business model that leverages market forces and reduces risk to attract pharmaceutical and biotechnology industry collaboration with the U.S. Government.

Four principles will guide this initiative: (1) a concerted, enterprise approach to medical countermeasure development that is goal-oriented and mission-driven; (2) a focus on multi-use products and flexible, platform-based capabilities; (3) an emphasis on innovation and disruptive technologies; and (4) the establishment of new and more effective public-private partnerships based on common interests to mitigate risks and reduce costs.

The initiative will apply these guiding principles in four focus areas:

- **Research and Discovery** - Re-aligning programs to support systems-biology approaches, mission-driven research for multi-use products and platform-based solutions, translation of basic discovery into clinical application, and improved data sharing to enhance discovery.
- **Regulatory Science and Innovation** - Modernizing our regulatory process to create licensure pathways that are more predictable, transparent, and faster; in particular, advancing the emerging field of regulatory science to improve efficiency of product development and evaluation while enhancing confidence in safety and effectiveness.
- **Industrial Process Improvement** - Partnering with industry to improve development and manufacturing processes, share best practices, and identify solutions.
- **Markets and Financing** – Designing programs in which public and private financing collaborate to foster innovation and harness market forces to develop multi-use biodefense products with durable markets appealing to private investment.

This initiative will include: (1) A concerted effort to advance regulatory science and practice by engaging our vast national scientific resources to evolve, evaluate, and validate new tools and approaches for biomedical product development; (2) government-facilitated collaborations to leverage opportunities for innovation in applied biotechnology, advanced development, and manufacturing; and (3) the provision of approaches to meet core services needs and lower barriers to entry, reduce opportunity costs, enhance innovation, and clarify regulatory requirements for safety and effectiveness.

A successful model created for this purpose can be applied more broadly to the urgent need for novel medical countermeasures in global health, provide a pathway toward more affordable and effective pharmaceuticals here at home, and ensure that the United States remains at the forefront of the global biotechnology revolution. We must commit ourselves fully to this effort now - there is no higher priority than our public health and security.

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From: "Korch, George (HHS/ASPR/IO)" [redacted]@hhs.gov>

To: [redacted]@who.eop.gov, [redacted]@who.eop.gov, "Emanuel, Ezekiel (NIH/CC/BEP) [E]" [redacted]@nih.hhs.gov>, "Ezekiel Emanuel" [redacted]@omb.eop.gov>, "Lurie, Nicole (HHS/ASPR/IO)" [redacted]@hhs.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <Anthony.Fauci@nih.hhs.gov>, "Robinson, Robin (HHS/ASPR/BARDA)" [redacted]@HHS.GOV>, "Merchant, Raina (HHS/ASPR)" [redacted]@hhs.gov>, "Borio, Luciana L. (FDA)" [redacted]@fda.hhs.gov>

Cc: "Korch, George (HHS/ASPR/IO)" [redacted]@hhs.gov>

Subject: Synopsis of Conversation with Pharma/Bio Reps 29 Jan 2010

Date: Sat, 30 Jan 2010 13:57:49 -0500

Importance: Normal

Attachments: Synopsis_of_Meeting_with_Pharma_and_Biotech_VP's_at_EEOB_on_29_Jan.doc

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Heidi, et al.:

I have summarized the conversation with the VP's and representatives from the pharmaceutical / biotechnology industries regarding incentives promoting greater participation by industry in our public health emergency medical countermeasure enterprise. Where possible, I identify follow-on actions that derive directly from the conversation. There are still important conversations to continue with our commercial partners. Please feel free to modify or add information or perspectives that I did not adequately capture. Also, I did not quote by name the discussions offered by our industrial partners.

Best regards
George

George W. Korch Jr.
Senior Science Advisor
Assistant Secretary for Preparedness and Response
Department of Health & Human Services

[redacted]

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Summary of meeting with VP's of pharmaceutical and biotechnology companies
29 January 2010
Eisenhower Executive Office Building

Dr. Zeke Emanuel opened the meeting with a problem definition statement that we as a nation need medical countermeasures for public health emergency events ranging from biodefense to emerging infectious diseases, but after years of investment, we still have not been successful in meeting these needs. He indicated that to a certain degree, there is a sense that the big pharmaceutical companies have opted out of assisting in this endeavor, and while there are smaller, biotechnology companies attempting to fill the gap, they lack the experience to complete the task. Ms. Heidi Avery added that this was not to single out big pharma, but that the USG recognizes that it may not have created the best conditions for being a good partner as well. She pointed out that the industry itself has recently struggled with producing approved medical products for more highly valued commercial products. The bottom line is that the President is seriously committed to this problem and this was highlighted in his State of the Union message.

This meeting was being held therefore to start a dialogue with industrial partners (big pharma and the biotechnology sector) to gain their perspectives on what government actions can we take to lower the barrier to entry and to increase the attractiveness of partnership, because without big pharma specifically, the whole thing will not work. We need to hear their ideas.

Merck started by reminding folks that they had in fact bid on the contract award for the cell culture derived smallpox vaccine, but had not been successful.

Merck then indicated that there are three areas of concern that must be addressed to attract companies like theirs to the program:

1. **Need to assure an adequate market**
2. **Need to make the regulatory path much more viable**
3. **Need to reduce legal liabilities (e.g. tort claims)**

Markets

On the issue of adequate markets, this allows both big pharma and the biotechnology companies to gauge issues on such things as return on investment, infrastructure and operations costs, etc. Even if the market is destined just to be standard replacement of a strategic stockpile, that constitutes a defined market need. NKT Therapeutics, representing the biotechnology sector indicated that ability to define an adequate market is a key variable for their ability as a small company to secure investment funding. (Note: I interpret the relative order of these three items to actually be in a sort of priority order for big pharma).

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An issue that was cited as an example for how markets might be improved for these products was the use of the Priority Review Voucher System applied to biodefense products as is now afforded to industry for orphan products under the Orphan Drug Act. **If a system could be developed wherein the voucher was transferable or saleable to another industry partner, it would represent a value proposition that could be understood by the investor community as a potential opportunity for return on investment.** There was discussion regarding the theoretical vs. practical aspect of this advantage for priority review, but agreement that another feature regarding 3 months of granted exclusivity on review would be of value.

Regulatory Approval Pathway

On the issue of better defining the pathway to regulatory approval of the product, a general description of the preferred process is that the FDA should be very specific in the requirements that a company is expected to demonstrate for a candidate study, rather than the current system where a company provides data for a study, and is then told whether it meets the reviewers' approval. Dr. Zeke Emanuel pressed for more specificity on the steps where this pathway could be made more transparent. <u>This is an action item for the industry to be further defined with more dialogue.</u>

One concrete example of how better understanding of a path to approval would affected a company's effectiveness in producing countermeasures was given by Novartis regarding use of an adjuvant to increase immunogenicity of a vaccine. Adjuvants stimulate an immune response at a lower antigen concentration, and potentially produce a broadened response profile to similar antigens, thus increasing the manufacturing yield per unit of production. "In general, you can have more product produced if the material is more potent" was the phrase used to define this issue. In Europe, this pathway to use of adjuvant through their regulatory agency permitted the use of adjuvants in influenza vaccine, so what is the reason that the U.S. cannot seem to provide a reasonable pathway to accomplish a similar allowance ? **There is a need for harmonization of the regulatory pathway with the EMEA** (the European Medicines Agency) on issues such as this. It would also permit global companies more opportunity for accessing larger markets. Zeke Emanuel pointed out that the issue of adjuvants had to also account for the perceptions of safety by the U.S. population and must be factored into the market issues concerning this approach.

Merck added an example regarding lack of a clear understanding of the regulatory path to have an anthrax lethal factor inhibitor approved.

- Action item: identify what steps or processes are needed for international harmonization in regulatory pathways, with adjuvants as an exemplar
- Action item: industry needs to be more specific in what steps should be taken to improve the FDA's study review process (prospective vs. retrospective feedback).

Liability

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It was noted by Merck that adequate liability is afforded to the industry on childhood vaccines (National Childhood Vaccine Injury Act), but that similar liability protections are not provided for adult vaccines. Dr. George Korch asked for clarification regarding whether protections under the PREP Act were not sufficient for the industry concerns regarding liability of products for biodefense and pandemic disease threats. There was no further discussion of liability issues at this time, and a due out to industry would be more definition of the nature of liability concerns that remain. (Note regarding the Prep Act: "Passed primarily to address the pandemic influenza threat, the PREP Act provides liability protections after a Secretarial declaration of covered countermeasures for any disease or health condition that the Secretary views as constituting a public health emergency, either presently or in the future. Liability protections cover the manufacture, testing, development, distribution, or use of the designated covered countermeasure absent willful misconduct", source: http://www.hrsa.gov/countermeasurescomp/prep_act.htm as accessed on 30 January 2010)

- An action item would be to have industry better define the nature of liability concerns that remain

Partnering

GSK commented on an issue regarding partnership models, and cited their ability to partner with the Defense Threat Reduction Agency as an example of how they are able to further progress on anti-infectives that may have dual utility for biodefense and for overall infectious disease markets. Another partnership example was the Wellcome Trust as a good example of effective partnership abilities. In this example, the company is covering costs of production of a malaria product, with an allowance for a small profit that is being turned back into research for additional malaria products. On a negative partnership experience, NKT pharmaceuticals described two examples of an inability to have easy access to National Institute of Health experts on an influenza antibody product and on an assay development (replacement of RBCs needed in hemagglutination assay) that took a great deal of time and paperwork to process and ultimately was resulted in no access. Someone pointed out one possible attributable factor is the stringent requirements by the NIH to avoid conflict of interest by employees.

Novartis provided a suggestion on an tax credit incentive that would be viewed as favorable by big pharma and would stimulate partnerships with biotechnology companies. If the USG had a program where $ 40 M were available as tax credit to the company for partnering with biotechnology organizations to advance a promising technology or product within the biotech's inventory, then it would serve in a similar way to a grant, but would have other advantages. For the USG, it would be a cost neutral opportunity to stimulate added partnerships, with potential spin off in licensing and access to technology.

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Manufacturing Capacity

Big pharma did not express a concern about a lack of manufacturing capacity per se, but did indicate that rapid turn-around of production to a new product was difficult due to the regulatory approval of products that are site / locality specific. Merck said that it actually has excess capacity in some localities. The biotechnology sector said that they would love to have a manufacturing capacity issue. Merck indicated that overall, it would be happy to provide advice to the USG regarding manufacturing facility designs, etc. It was also understood that new facilities would have greater value if they were on U.S. soil.

Small biotechnology Issues

The disadvantage of the biodefense or public health emergency countermeasure market is that investors have no ability now to predict cost, return on investment, or timeline to return. Thus the biotechnology firms are looking for multiple ways to reduce the hurdles, with some examples pertaining to access to government and academia partners mentioned above.

The SBIR program that would provide funding for small companies requires that the company not be more than 50% investor owned. It was suggested that this is set to change in legislation, but that the legislation is being held up waiting for health care legislation to proceed.

At a programming level, lots of money was spent early on for very mature products to achieve approval, but there is less of an investment in early stage platform technologies to move them into position for scale-up and maturation. Many of the disruptive technologies come from the more risk-accepting smaller biotechnology companies, and there is not enough investment in the funds to realize gains faster.

There needs to be more transparency on which scientists or investigators within the DoD and NIH programs are working on specific intramural programs to create a chance for more partnering with industry.

Platform Technologies

Dr. Tony Fauci asked about whether big pharma anticipates, or is pursuing any role in advancing platform technologies which would be transformative in the ability to realize dual marketing potential for products related both to public health emergency needs and to more commercially viable products. It would be preferable to share risk with big pharmaceutical companies in developing these platforms. Dr. George Korch also asked about prospects for host-based therapeutic targets for infectious agents vs. strictly pathogen based targets. Merck acknowledged the interest in host-based technologies,

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but in general there was no vibrant discussion of the platform approaches being considered by the industry at this meeting.

There was a quick question as to whether stimulus funding should be applied to these broad-based platform technologies

- Action item would be to expand inquiry regarding this approach to other companies, or to hold more one-on-one conversations with individual companies if there was a reluctance to disclose possible technologies now being addressed by these companies.

- Another action item would be to determine what specific platform technologies would be estimated by industry as offering best return on investment.

Other areas

Regarding clinical studies, a suggestion was made that FDA should be allowed to explore less parametric and more Bayesian approaches to analysis of clinical trials data with a hope that it would allow for faster approval of products.

The approaches for using the Animal Efficacy Rule were quickly discussed as needing much greater clarity from the FDA on how to accomplish approval under the rules. It was felt that there was a great deal of expertise in the DoD and NIH that would also contribute to industry's needs.

Regarding approval of medical products in general for public health emergency applications, one must account for the risk/benefit ratio of these products, relative to everyday products used for standard medical conditions and ask whether there needs to be some other lower threshold for approval of products that would be used under these higher risk scenarios.

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From: "Emanuel, Ezekiel (NIH/CC/BEP) [E]" [redacted]@cc.nih.gov>

To: "Korch, George (OS)" [redacted]@hhs.gov>, "[redacted]@who.eop.gov" [redacted]@who.eop.gov>, [redacted]@who.eop.gov" <[redacted]@who.eop.gov>, Ezekiel Emanuel <[redacted]@omb.eop.gov>, "Lurie, Nicole (OS)" [redacted]@hhs.gov>, "Fauci, Anthony (NIH/NIAID) [E]" <AFAUCI@niaid.nih.gov>, "Robinson, Robin (OS)" [redacted]@HHS.GOV>, "Merchant, Raina (HHS/ASPR)" [redacted]@hhs.gov>, "Borio, Luciana L (FDA)" [redacted]@fda.hhs.gov>

Subject: RE: Synopsis of Conversation with Pharma/Bio Reps 29 Jan 2010

Date: Sat, 30 Jan 2010 14:48:01 -0500

Importance: Normal

Thanks for this summary.

From my perspective there were three main concrete suggestions/ issues:

1) Regulatory reform--"We need FDA to tell us up front what it will take to pass the hurdles and get to licensure." This is an issue--clarity bout the types of studies and levels of outcomes necessary for approval. There was also a call to use Bayesian statistics in this area and the need to have prompt FDA response to queries--being able to have a person with authority assigned to the development process.

2) Fostering Biotech-Pharma collaboration--the idea was to shift some money from SBIR or grants to a tax credit that big Pharma would get for investing in promising biotech for countermeasures. This would 1) give big Pharma a stake in developing a biotech product, 2) use big Pharma's ability to assess the promise of technologies, and 3) have the added advantage of attracting more investors in biotech since there would be big Pharma partners earlier in the process. So every dollar could be leveraged.

3) Liability reform--What I heard is that they wanted something like the National Childhood Vaccine Injury Act for countermeasures. Recent court case about FDA approval not serving as liability protection made this more important to big Pharma.

I thought the market issue was important but that in this area the Pharma companies were willing to have a lower ROI--it is a matter of positive PR for them so the actual return could be lower as long as they were not losing money by doing it.

Ezekiel J. Emanuel, M.D., Ph.D.

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-----Original Message-----

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From: Korch, George (OS)
Sent: Saturday, January 30, 2010 1:58 PM
To: [redacted]@who.eop.gov; [redacted]@who.eop.gov; Emanuel, Ezekiel (NIH/CC/BEP) [E]; Ezekiel Emanuel; Lurie, Nicole (OS); Fauci, Anthony (NIH/NIAID) [E]; Robinson, Robin (OS); Merchant, Raina (HHS/ASPR); Borio, Luciana L (FDA)
Cc: Korch, George (OS)
Subject: Synopsis of Conversation with Pharma/Bio Reps 29 Jan 2010

Heidi, et al.:

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Best regards
George

George W. Korch Jr.
Senior Science Advisor
Assistant Secretary for Preparedness and Response
Department of Health & Human Services

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From: "Emanuel, Ezekiel (NIH/CC/BEP) [E]" [redacted]@cc.nih.gov>
To: "Lurie, Nicole (OS)" [redacted]@hhs.gov>
Cc: "Hatchett, Richard J." [redacted]@who.eop.gov>, "Merchant, Raina (HHS/ASPR)" <[redacted]@hhs.gov>, "Robinson, Robin (OS)" [redacted]@HHS.GOV>, "Fauci, Anthony (NIH/NIAID) [E]" <AFAUCI@niaid.nih.gov>, "Borio, Luciana L (FDA)" [redacted]@fda.hhs.gov>, "Avery, Heidi E." <[redacted]@who.eop.gov>, "Korch, George (OS)" [redacted]@hhs.gov>
Subject: RE: Synopsis of Conversation with Pharma/Bio Reps 29 Jan 2010
Date: Mon, 01 Feb 2010 08:49:47 -0500
Importance: Normal

I am not taking it off the table only think it is very limited. If we want to solve the problem we should not think small pieces will work. Furthermore, things that require some govt official to make a determination always count for less among private companies because they cannot be sure the govt official will rule the right way and in a timely manner. If we want the private sector to have confidence to allocate tens if not hundreds of millions then we need to give them some strong assurances and this does not seem to me to do it.

Ezekiel J. Emanuel, M.D., Ph.D.

Department of Bioethics
The Clinical Center
National Institutes of Health
and
Office of Management and Budget
Executive Office of the President

	Phone	Fax
NIH OMB	[redacted]	[redacted]

Cell [redacted]
Private [redacted]

-----Original Message-----
From: Lurie, Nicole (OS)
Sent: Sunday, January 31, 2010 9:37 PM
To: Emanuel, Ezekiel (NIH/CC/BEP) [E]
Cc: Hatchett, Richard J.; Merchant, Raina (HHS/ASPR); Robinson, Robin (OS); Fauci, Anthony (NIH/NIAID) [E]; Borio, Luciana L (FDA); Avery, Heidi E.; Korch, George (OS)
Subject: RE: Synopsis of Conversation with Pharma/Bio Reps 29 Jan 2010

Out of curiosity, why would you take PRV off the table as a part of a package of incentives--agree that it cant work alone--n

Nicole Lurie, MD, MSPH
Assistant Secretary for Preparedness and Response
Rear Admiral, US Public Health Service
Department of Health and Human Services
[redacted]
Washington, DC
[redacted]

Released by Chairman Rand Paul

-----Original Message-----
From: Emanuel, Ezekiel (NIH/CC/BEP) [E]
Sent: Saturday, January 30, 2010 9:49 PM
To: Borio, Luciana L. (FDA); Korch, George (HHS/ASPR/IO); [redacted]@who.eop.gov; [redacted]@who.eop.gov; Ezekiel Emanuel; Lurie, Nicole (HHS/ASPR/IO); Fauci, Anthony (NIH/NIAID) [E]; Robinson, Robin (HHS/ASPR/BARDA); Merchant, Raina (HHS/ASPR); Goodman, Jesse L. (FDA)
Cc: Korch, George (HHS/ASPR/IO)
Subject: RE: Synopsis of Conversation with Pharma/Bio Reps 29 Jan 2010

Very interesting but probably would not work for say Anthrax drug or drug for botulism toxin.

Ezekiel J. Emanuel, M.D., Ph.D.

Department of Bioethics
The Clinical Center
National Institutes of Health
Bethesda, Maryland 20892-1156
and
Special Advisor for Health Policy
Office of Management and Budget

	Tel.	Fax
NIH	[redacted]	[redacted]
OMB		

Cell--NIH [redacted]
Cell-Personal [redacted]

-----Original Message-----
From: Borio, Luciana L (FDA)
Sent: Saturday, January 30, 2010 6:06 PM
To: Korch, George (OS); [redacted]@who.eop.gov; [redacted]@who.eop.gov; Emanuel, Ezekiel (NIH/CC/BEP) [E]; Ezekiel Emanuel; Lurie, Nicole (OS); Fauci, Anthony (NIH/NIAID) [E]; Robinson, Robin (OS); Merchant, Raina (HHS/ASPR); Goodman, Jesse L (FDA)
Cc: Korch, George (OS)
Subject: RE: Synopsis of Conversation with Pharma/Bio Reps 29 Jan 2010

I would like to clarify one point in George's excellent summary with respect to "markets."

Section 524 of the FD&C Act authorizes the Secretary to issue a priority review voucher (PRV) to the sponsor of a tropical disease product application that entitles the holder of such voucher to priority review (6 months) of another single human drug application.

According to the Act, the recipient of a PRV may transfer (including by sale) the entitlement to such voucher to another sponsor.

The Act lists the eligible tropical infectious diseases, and also allows the Secretary to designate "any other infectious disease for which there is no significant market in developed nations and that disproportionately affects poor and marginalized populations."

FDA issued its 1st PRV to Novartis for the development of Coartem Tablets to treat malaria in April 2009.

Released by Chairman Rand Paul

-----Original Message-----
From: Korch, George (HHS/ASPR/IO) [mailto[redacted]@hhs.gov]
Sent: Saturday, January 30, 2010 1:58 PM
To: [redacted]@who.eop.gov; [redacted]@who.eop.gov; Emanuel, Ezekiel J (NIH); Ezekiel Emanuel; Lurie, Nicole (OS); Fauci, Anthony S (NIH); Robinson, Robin (OS); Merchant, Raina (HHS/ASPR); Borio, Luciana
Cc: Korch, George (OS)
Subject: Synopsis of Conversation with Pharma/Bio Reps 29 Jan 2010

Heidi, et al.:

I have summarized the conversation with the VP's and representatives from the pharmaceutical / biotechnology industries regarding incentives promoting greater participation by industry in our public health emergency medical countermeasure enterprise. Where possible, I identify follow-on actions that derive directly from the conversation. There are still important conversations to continue with our commercial partners. Please feel free to modify or add information or perspectives that I did not adequately capture. Also, I did not quote by name the discussions offered by our industrial partners.

Best regards
George

George W. Korch Jr.
Senior Science Advisor
Assistant Secretary for Preparedness and Response
Department of Health & Human Services

[redacted]

Released by Chairman Rand Paul

From: "Hatchett, Richard (NIH/NIAID) [E]" [redacted]@niaid.nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" <AFAUCI@niaid.nih.gov>
Subject: RE: Draft Strategy
Date: Thu, 11 Feb 2010 20:49:38 -0500
Importance: Normal

Tony,

Thanks for turning this around so quickly and for the nuanced edits. We got them into the version going to the President.

Richard

From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Thursday, February 11, 2010 8:15 PM
To: 'Avery, Heidi E.'
Cc: Hatchett, Richard (NIH/NIAID) [E]
Subject: FW: Draft Strategy

Heidi:
I spoke to Richard a little while ago and he asked me to focus mainly on the Introduction and the Multi-Use Principle, which I have done. I will leave it to others to examine their components in order to get this back to you quickly since I know that you have to prepare something tonight for the POTUS. The document looks quite good. I have made a few changes that are tracked and have explained why I have done this. Please let me know if you have any questions or if you need to speak with me later. I am available. You were an amazing model of flexibility today. I hope that my comments on the phone call helped.
Best regards,
Tony

From: Avery, Heidi E. [mailto:[redacted]@who.eop.gov]
Sent: Thursday, February 11, 2010 6:58 PM
To: [redacted]@hhs.gov; AFAUCI@niaid.nih.gov; [redacted]@fda.hhs.gov; [redacted]@osd.mil; [redacted]@cdc.gov; [redacted]@hhs.gov; [redacted]@niaid.nih.gov; [redacted]@fda.hhs.gov; [redacted]@hhs.gov; [redacted]@osd.mil; Emanuel, Ezekiel J.; Holdren, John P.; Petrou, Laura (OS)
Cc: Hatchett, Richard J.; Lawler, James V.
Subject: Draft Strategy

Attached is the revised draft strategy. Hunting typos, but thought it would be useful to see sooner than later.

Heidi E. Avery
Deputy Assistant to the President
for Homeland Security
The White House
[redacted]

From: Avery, Heidi E.
Sent: Thursday, February 11, 2010 4:26 PM
To: [redacted]@hhs.gov'; 'AFAUCI@niaid.nih.gov'; [redacted]@fda.hhs.gov'; [redacted]@osd.mil'; [redacted]@cdc.gov'; [redacted]@hhs.gov'; [redacted]@niaid.nih.gov'; [redacted]@fda.hhs.gov'; [redacted]@hhs.gov'; [redacted]@osd.mil'; Emanuel, Ezekiel J.; Holdren, John P.; 'Petrou, Laura (HHS/OS)'
Cc: Hatchett, Richard J.; Lawler, James V.; Severn, Deborah; [redacted]@hhs.gov'; [redacted]@fda.hhs.gov';

Released by Chairman Rand Paul

[redacted]@cdc.gov'; Bafford, Elizabeth A.; McLaughlin, Patricia M.; [redacted]@niaid.nih.gov'
Subject: Conference Call Today at 6pm

Greetings – Believe it would be useful for us to talk briefly today at 6pm. Our meeting with the President remains scheduled for 2pm tomorrow in the WHSR. During the call we will clarify the meeting intent, discuss any concerns, and generally seek to set all of us up for success.

Meanwhile, we will have a new version of the draft strategy to you soon. Appreciate all of the very good comments. And, to be clear, we expect the draft strategy will be further adjusted based on consultations. The ongoing MCM review, PCAST study, and talks with industry will be critical to further shape the way forward. We remain early in the process. Thanks, Heidi

BRIDGE NUMBER: [redacted]

CONFEREE PASSCODE: [redacted]

Heidi E. Avery
Deputy Assistant to the President
for Homeland Security
The White House
[redacted]

Released by Chairman Rand Paul

From: "Fauci, Anthony (NIH/NIAID) [E]" </O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=AFAUCI>
To: "Kurilla, Michael (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Subject: FW: Draft Strategy
Date: Thu, 11 Feb 2010 20:59:57 -0500
Importance: Normal
Attachments: iPHEMCE_Strategy_v11_2-11-10.doc

From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Thursday, February 11, 2010 8:15 PM
To: 'Avery, Heidi E.'
Cc: Hatchett, Richard (NIH/NIAID) [E]
Subject: FW: Draft Strategy

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Tony

From: Avery, Heidi E. [mailto:[redacted]@who.eop.gov]
Sent: Thursday, February 11, 2010 6:58 PM
To: [redacted]@hhs.gov; [redacted]@niaid.nih.gov; [redacted]@fda.hhs.gov; [redacted]@osd.mil; [redacted]@cdc.gov; [redacted]@hhs.gov; [redacted]@niaid.nih.gov; [redacted]@fda.hhs.gov; [redacted]@hhs.gov; [redacted]@osd.mil; Emanuel, Ezekiel J.; Holdren, John P.; Petrou, Laura (OS)
Cc: Hatchett, Richard J.; Lawler, James V.
Subject: Draft Strategy

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Heidi E. Avery
Deputy Assistant to the President
for Homeland Security
The White House
[redacted]

From: Avery, Heidi E.
Sent: Thursday, February 11, 2010 4:26 PM
To: [redacted]@hhs.gov'; [redacted]@niaid.nih.gov'; [redacted]@fda.hhs.gov'; [redacted]@osd.mil'; [redacted]@cdc.gov'; [redacted]@hhs.gov'; [redacted]@niaid.nih.gov'; [redacted]@fda.hhs.gov'; [redacted]@hhs.gov'; [redacted]@osd.mil'; Emanuel, Ezekiel J.; Holdren, John P.; 'Petrou, Laura (HHS/OS)'
Cc: Hatchett, Richard J.; Lawler, James V.; Severn, Deborah; [redacted]@hhs.gov'; [redacted]@fda.hhs.gov'; [redacted]@cdc.gov'; Bafford, Elizabeth A.; McLaughlin, Patricia M.; [redacted]@niaid.nih.gov'
Subject: Conference Call Today at 6pm

Released by Chairman Rand Paul

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BRIDGE NUMBER: [redacted]

CONFEREE PASSCODE: [redacted]

Heidi E. Avery
Deputy Assistant to the President
for Homeland Security
The White House
[redacted]

Released by Chairman Rand Paul

Draft

Strategy for Reinventing the
Integrated Public Health Emergency Medical Countermeasures Enterprise

The U.S. Government's Integrated Public Health Emergency Medical Countermeasures Enterprise (iPHEMCE) has struggled for almost a decade to develop drugs, diagnostics, and vaccines ("countermeasures") against naturally occurring pandemics and other infectious diseases, and deliberately propagated bioterrorism and other public health threats. Despite significant investment, our National efforts have yielded only a modest number of new countermeasures. We recognize that our current approach is not sustainable over the long term, will not provide us with the comprehensive protection we require against both known and emerging threats, and that recent advances in the biological sciences and pharmaceutical industry create scientific opportunities that must be pursued. (Excellent!)

To reduce our vulnerability to public health threats and safeguard the health and safety of the American people, we must pursue immediately a ~~very~~ different approach to novel medical countermeasures development and acquisition. To that end, and as announced during the President's State of the Union address on January 27, 2010, the Obama Administration is launching a transformative initiative. The goal is to develop a national capability for the rapid, reliable, robust, and affordable production of an array of medical countermeasures against public health threats. This document lays out the broad strategy to achieve this goal.

Commented [a1]: I inserted the word "broad" to alleviate the anxiety that this is final and to suggest by the wording that there are still specifics to be ironed out.
afauci
2010-02-11 19:37:00

In creating a transformed iPHEMCE, it is useful to understand the obstacles that have limited its success to date. In pursuing new biodefense countermeasures over the last eight years, the Federal Government has experimented with a variety of "push" and "pull" incentives for the pharmaceutical industry, a critical partner in the development of countermeasures. These incentives, including the creation of a $5.6B Special Reserve Fund for Project BioShield, have not resulted in the desired flow of new and next-generation medical countermeasures because they have not addressed the real problem, which is the barriers that the pharmaceutical industry perceives to return on investment in this area.

These barriers include:

- Complex, burdensome, and uncertain path to licensure of countermeasures;
- Rapid and unpredictable pace of new requirements for novel countermeasures;
- Small markets and/or low profit margins for the products the USG has indicated it requires;
- High cost of drug development under any circumstances;
- High costs associated with scale-up and manufacturing;
- Limited in-house subject matter expertise;
- Lack of expertise and experience in negotiating the U.S. Food and Drug Administration (FDA) "animal rule" pathway to product licensure;
- Complex policy environment;
- Complex funding environment; and
- High risk of failure.

After assessing the high opportunity cost and financial risk of working in the domain of developing countermeasures for bioterror threats, and considering the high transaction costs associated with government contracts, capable large pharmaceutical firms have uniformly elected to focus their

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efforts and resources on the development of more commercially viable products~~elsewhere~~. The innovative small biotechnology firms that have been attracted to countermeasure development against bioterror and pandemic threats generally do not possess the inherent expertise or capabilities that enable larger firms to complete development and industrialization projects. The result for the U.S. Government has been an inconsistent return on its investments to date.

The Administration's initiative is aimed at transforming how investments are made in the countermeasure enterprise and at enhancing performance of the enterprise through highly engaged end-to-end support and management. Greater productivity from such investments will be achieved primarily by reducing or eliminating the barriers that impede progress. By reducing these barriers, the U.S. Government can change the calculus that results in an unacceptable return on investment and thus offer private sector partners a more favorable value proposition. As a complement to ~~Complementing~~ this approach of attacking the barriers, incentives external to the drug development process will also be employed in more creative ways.

The new U.S. Government strategy comprises five principles or "pillars" necessary to transform IPHEMCE. The first is the adoption of the multi-use principle as a high priority and governing principle for future investments. The second through fifth pillars are collectively aimed at fundamentally altering the conduct and management of public-private partnerships in the area of countermeasure development against public health threats.

These pillars will be pursued in tandem and as an Enterprise-wide initiative. Implementing individual~~the~~ pillars alone or in isolation will not effect the comprehensive transformation that is required or ensure greater productivity for our efforts and investment. The principles must be enacted and implemented together as a composite initiative if their full benefit is to be realized. The goal is to markedly increase the return on the U.S. Government's investment in medical countermeasures against public health threats. Achieving this breakthrough will yield a new template for government support of private sector drug development in areas where progress has been impeded by apparent market failures.

I. The Multi-Use Principle

Orthodox opinion holds that the U.S. Government is the only customer for biodefense and pandemic countermeasures and that viable commercial markets for these products do not exist. This received wisdom has inhibited efforts on the part of government program managers to find and leverage the market forces that will attract private sector partners to invest in projects that address our requirements. For far too long, the U.S. Government has attempted to counter market forces that drive potential private sector partners toward lower-risk investments in other areas. As our track record in countermeasure programs demonstrates quite clearly, however, ignoring market realities makes a difficult process even more challenging.

The easiest way to enlist the aid of market forces is by developing specific countermeasures that have legitimate markets. Such was the case with our pandemic influenza program that successfully engaged several pharmaceutical companies and that resulted ultimately in a safe and highly effective vaccine. The success of our pandemic influenza program illustrates this principle in a dramatic way. In other cases, the solution has been to focus on "multi-use" products that address many threats simultaneously or that among a wider range of indications demonstrate efficacy against specified threats. Where therapeutics and diagnostics are concerned, leveraging market

Commented [a2]: I know that I have read this many times and have not changed it. However, it just struck me that the use of the pandemic influenza program as a "success" story might decrease our credibility since the USG got an "F" for this and this has embarrassed the POTUS. Thus, I have changed the wording somewhat.
afauci
2010-02-11 20:10:00

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forces by investing in multi-use products is straightforward. Diagnostic platforms and multiplex technologies can address biodefense needs while simultaneously seeking access to durable and well-defined commercial markets. Many pathways and strategies for finding dual utility exist for therapeutics and these need not be enumerated here.

While it is true that some required products (e.g., vaccines, antitoxins) have inherently circumscribed uses, it does not follow that market forces cannot be leveraged to support their development. One way to leverage market forces is to reduce the risk and costs of development and manufacturing to such an extent that the existing, circumscribed market becomes a sufficient incentive in itself to drive development. A more sustainable strategy, however, is to support the development of limited-use products by investing in enabling, "multi-use" platforms and technologies that reduce the complexity, time, and cost of developing the desired product. These platforms and technologies can then be turned to other commercial applications that will provide the return on investment that private sector partners seek while also providing our chief defense against newly emerging threats. The U.S. Government has already made substantial investments in such platforms and technologies through the Transformational Medical Technologies Initiative Program supported by the Department of Defense (DoD) and numerous investments at the National Institutes of Health (NIH).

To lower cost and risk in pursuing novel multi-use products and platforms, the U.S. Department of Health and Human Services (HHS) and DoD can assist the pharmaceutical industry by providing scientific expertise, critical reagents, repositories of essential specimens and products, animal facilities, pilot lot manufacturing facilities, and clinical trial networks. The goal in so doing is not only to partner with industry and decrease their investment risk while facilitating the development of specific products needed for public health and national security, but also to foster and promote the development of multi-use products, platforms and technologies in which industry would otherwise not invest because of the prohibitive costs. Once developed, these technologies could be used by industry for the development of products that would attract a considerable commercial market outside of the realm of biodefense and pandemics. In turn, once up and running, these platforms and technologies could be adapted to the development of countermeasures against unpredictable threats to public health, either deliberate or naturally occurring.

The challenge is to accept that in general our guiding principle should be ~~we should~~to direct~~constrain~~ our investments to products and approaches that embrace the concept of multi-use. Over time, the cascading benefits of accepting this fundamental principle~~constraint~~ promise to be enormous. Focusing on multi-use products, platforms, and technologies that provide our private sector partners with access to legitimate commercial markets will accelerate and simplify medical countermeasure development, decrease our partners' dependency on direct government subsidies, assure ongoing manufacturing capability, and decrease aggregate cost and risk to the U.S. Government.

Perhaps the greatest benefit of adopting the multi-use principle is that it represents the only true path to long-term sustainability for the iPHEMCE. Under our current one-bug, one-drug, one-vaccine paradigm, the aggregate costs over time of discovery, development, procurement, stockpile maintenance, and securing ongoing access to surge manufacturing capability for each of the many countermeasures we require are prohibitive. And these costs are just for the threats we know about and can predict. By adopting the multi-use principle, and by sharing the costs of discovery and development with the private sector, which will have a vested interest in maintaining the multi-use

Released by Chairman Rand Paul

products and capabilities required to address our public health needs, the U.S. Government will reduce its fixed costs while providing itself with greater flexibility in stockpiling and enhanced agility in responding to unexpected threats.

Because multi-use approaches have the potential to yield commercially appealing products, industry already has an inherent motivation for exploring this space. Industry is currently constrained however, because such technological leaps are generally outside of the accepted risk portfolio for large pharmaceutical firms, and the smaller biotech companies (that drive much of the innovation in the life sciences) have difficulty in acquiring capital for such risky endeavors without a well-circumscribed end market. Therefore, we must also find ways to increase investment in such high-risk/high-reward approaches. The U.S. Government will assess whether incentives such as research and development tax credits and transferable priority review vouchers would increase collaborations between large pharmaceutical firms and smaller companies developing innovative technology. The U.S. Government will also consider establishing an independent, not-for-profit venture-capital entity that spurs innovation by providing critical early-stage investments in multi-use approaches.

A model for an entity that addresses national security needs while supporting the development of multi-use products already exists in the form of In-Q-Tel, which was launched by the Central Intelligence Agency (CIA) in 1999 as a private, independent, not-for-profit organization. Rather than seeking single-solution custom products, In-Q-Tel engages with companies that build successful technology solutions that can be sustained by the commercial market. Meeting the demands of the commercial market stimulates continued product development and enhancements with added value for the Intelligence Community (IC).[1]

Although~~Henceforward,~~ the U.S. Government will adopt credible multi-use capability as a high priority governing principle for future investments in medical countermeasures. ~~. In adopting multi-use as a high priority and governing principle, however~~, we will not jeopardize current success nor tie the hands of government to act in the best interests of the American people. Going forward, the extent to which we apply the principle to legacy programs and investments will be determined on a case-by-case basis.

Commented [a3]: I got rid of "Henceforth" since it sounds too much like a royal degree and will feed the current anxieties. I believe that we get the same effect with the way I have changed it. afauci
2010-02-11 20:09:00

II. Collaborations, Partnerships, and Cooperatives

The pharmaceutical industry too often relies on anachronistic technologies or practices because our regulatory paradigm and market forces present large costs and marginal returns for many innovations in the development and manufacturing process. It is often against the economic interest

[1] Analogous to corporate strategic funds such as those found at Intel Corporation, Motorola, and Disney, In-Q-Tel operates for the strategic – rather than financial – benefit of its customers in the IC. In-Q-Tel targets its technology engagements based on a deep understanding of the needs of its customers in the CIA and the IC. To best serve these customers, In-Q-Tel plays multiple roles, serving as:

- A technology accelerator, fostering development and introduction of technologies needed by the IC;
- A capabilities builder, helping nascent commercial technologies mature into commercial-off-the-shelf products the government can buy;
- An idea lab and forum for innovation, providing the IC with insight and access to both new technologies and leading innovators and thinkers; and
- A strategic investment firm, investing in companies and helping build businesses into reliable providers for the IC.

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of individual firms to make investments in newer approaches. One such example is the continued use of chicken eggs for the growth of influenza virus for use in vaccines.

In recent years, however, as biomedical research and drug development have become more expensive, biomedical research has become more of an information science, technical barriers to information sharing have declined, cultural shifts favoring large-scale collaborations have occurred, and biotechnology and pharmaceutical firms have explored new ways to partner with each other and with government to solve common problems and make the leap to new technology and practices. Such collaborations and partnerships are based on shared goals that are critical for progress but that cannot be monetized (i.e., exploited as stand-alone profit-making opportunities) and cannot feasibly be achieved by a single organization. In such circumstances, "precompetitive" collaborations and partnerships have been established to reduce cost and risk to individual partners while pursuing advances that benefit all participants.

Such collaborations and partnerships have a considerable track record. They have been used to develop new standards and tools, to generate or aggregate data, and to create new knowledge or develop products by accessing resources and capabilities across organizations. Consortia have been established to foster process innovation, to enable discovery, and to serve as innovation incubators. Pooling resources to invest in sector-wide process and technology improvements leverages the investments of and minimizes risk for individual partners while enabling downstream processes that create market value and unlock creative capital and dormant intellectual property.

A convergence of factors has also led to the emergence of more robust and innovative public-private partnerships in various domains of biomedicine. These factors include the flattening of NIH budgets in recent years, the declining productivity of freestanding research and development programs within the biotechnology and pharmaceutical industries, the escalating complexity of biomedical science, the challenges posed by regulatory processes, and the emergence of viable collaborative models. Precompetitive collaborations that have enhanced public-private partnerships include (among others) the Biomarkers Consortium, which is managed by the Foundation for NIH and includes NIH, FDA, CMS, PhRMA, BIO, non-profit organizations, and multiple biotechnology and pharmaceutical firms as partners, and the partnerships and consortia supported through FDA's Critical Path Initiative that engage NIH, patient organizations, academia, and multiple biotechnology and pharmaceutical firms to facilitate advances in regulatory science, including innovation in product development, safety assessment and clinical trials. These diverse efforts provide models of collaboration likely to be very helpful in advancing relevant biodefense and public health focused projects. Through existing U.S. Government networks and alliances here and abroad, such partnerships could be extended internationally, to include allied nations as well as overseas clinical trial sites and other valuable components of the product development pathway.

As a part of the initiative to transform our countermeasure enterprise, the U.S. Government will work with industry partners to leverage existing or to create new public-private partnerships to propel much-needed advancements in pharmaceutical product discovery, development, and manufacturing. Input from industry partners will focus the capabilities and operating concepts of these partnerships so that they meet the needs of all participants. These partnerships will foster advances in enabling science and technology that facilitate the development of countermeasures against public health threats, and they will be guided by the multi-use principle in concentrating resources on those that will have broader application for other products.

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III. Regulatory Innovation and Advancement of Regulatory Science

A very significant barrier to participation of capable large pharmaceutical firms in the development of countermeasures against public health threats is the complex, time-consuming, and uncertain path to approval. Novel countermeasures for public health threats face all of the challenges associated with traditional drug development plus the uncertainties associated with diseases that are difficult to study and the complexities of the FDA "animal rule" pathway to product approval. These uncertainties, and the challenges of developing suitable animal models (or alternative paths to approval), have created conditions of intolerable risk for pharmaceutical companies where biodefense and other public health products are concerned.

These challenges can be addressed in two ways, by advancing the regulatory science that governs the approval process and by ensuring that FDA has the resources and staff to be more responsive and accessible to industry partners at every stage of the development process. Modernizing and streamlining our regulatory process to create pathways to approval that are more predictable, transparent, and rapid than currently exist is an indispensable condition of participation for large pharmaceutical firms.

The best way to map out such pathways is collaboratively, in particular by advancing the emerging field of regulatory science. Working with industry partners to improve the efficiency of product development and evaluation, while simultaneously enhancing regulators' confidence in the safety and effectiveness of regulated products, will facilitate the path to approval, thereby reducing cost, risk, and uncertainty for our partners and accelerating the delivery of the medical countermeasures that we need. This type of close interaction, beginning very early in product development and continuing through and after approval, is of tremendous value to industry and a proven ingredient in those public health product development efforts that have been successful to date. In addition to smoothing the path to approval, such an approach identifies scientific gaps and potential product problems early, allowing them to be addressed more efficiently and effectively, or, if needed, supporting a need to change course.

To generate much-needed advancements in regulatory science, the FDA will establish and manage a regulatory science center. This program will evolve, evaluate, and validate new tools and practices that can facilitate biomedical product development, evaluation and manufacturing. The center will also examine and make recommendations for changes of regulatory policies where there is an opportunity to improve simplicity, transparency, speed, and effectiveness of regulatory oversight.

The FDA program will directly engage with the partnerships described in the section above to create opportunities to explore solutions that assist FDA and industry in improving speed and effectiveness in regulatory testing and evaluation. Pharmaceutical firms will be offered the opportunity to collaborate with each other and directly with FDA staff to address regulatory problems of common concern, advance regulatory science, and promote regulatory evolution. FDA will benefit by building core expertise in new regulatory technologies, predictive models, and approaches to statistical analysis. FDA and industry will both benefit from the earlier introduction of novel ideas and practices for regulatory scrutiny and troubleshooting. Finally, and most importantly, the public will benefit from the introduction of new technology into the medical product development process that lowers the time and cost of development, while simultaneously improving the quality of safety and efficacy assessment.

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The Center will initially focus on projects that have demonstrable value for all parties. Such projects could focus on:

- Comparatively advanced manufacturing platforms with which FDA already has some familiarity (e.g., monoclonal antibodies, therapeutics based on RNA interference (RNAi), various protein expression systems for vaccines and therapeutics, novel adjuvants, widely available automated high throughput diagnostic platforms for nucleic acids, proteins and antibodies);
- Good Laboratory Practice (GLP) animal-efficacy model development for new vaccines, antibiotics and antiviral medications;
- Validation of improved potency and rapid sterility assays; and
- New approaches to statistical analysis of clinical trials.

Over time, the Center could expand its focus to address other regulatory challenges, including:

- Development and validation of biomarkers for use as alternative clinical endpoints and to enhance prediction of safety;
- Cell culture and *in silico* modeling of efficacy;
- Non-animal toxicological and safety evaluation;
- Defining pathways for novel vaccine manufacturing platforms (e.g., virus-like particles and DNA vaccines targeted to novel antigens); and
- Defining pathways for point-of-care diagnostics with ability to subtype influenza or detect antimicrobial resistance.

IV. Product Development and Manufacturing Services

Advanced development and manufacturing account for a large proportion of the total cost of medical countermeasure development. These costs represent a substantial barrier to the participation of large pharmaceutical firms, which prefer a more favorable return on investment, and to the progress of smaller biotechnology firms, which typically lack the necessary capital and expertise required to succeed.

Compounding these problems, the Federal contracting mechanisms most often used to support advanced development and manufacturing can impose long lead times and significant transaction costs. Contracts may further impose a form of reverse moral hazard, in that the difficulty and publicity associated with their cancellation often lead program staff and government agencies to become more failure-averse. Federal contracting must be streamlined and accelerated, and future contracts to support the development of medical countermeasures against public health threats must be structured in a way that facilitates early down-selection of projects that are not making appropriate progress. Given the high attrition rates associated with drug development, government agencies must configure themselves to be highly tolerant of failure and to have mechanisms that allow projects, if they are to fail, to "fail fast and fail cheap."

Going forward, and as needs dictate, the U.S. Government will also employ other mechanisms, including service and cooperative agreements, other transaction authorities, and challenge grants to facilitate public-private partnerships and expedite countermeasure development and manufacturing. Such mechanisms will augment the more traditional contracting processes currently used to support advanced development and manufacturing activities, enabling the Enterprise to be more flexible,

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adaptive, and responsive in engaging with industry to promote medical countermeasure development.

The opportunity costs and risk assumed by private sector partners can be lowered substantially through the direct provision of advanced product development and manufacturing services. To provide such services, the U.S. Government must work with industry to establish prioritized access to advanced development and manufacturing capabilities for these countermeasure products. The capabilities specified and prioritized by the U.S. Government would build on an existing domestic infrastructure composed of an integrated network of industrial facilities able to provide assistance in product development or in manufacturing clinical investigational lots or commercial scale lots of countermeasure products.

Components of this advanced product development and manufacturing services capability could be assembled in multiple, non-exclusive ways by establishing contract partnerships with academia, contract research and manufacturing organizations, and industry, or by establishing Manufacturing and Development Centers of Excellence or a non-profit, Federally Funded Research & Development Center or Centers. In whatever form the capability is established, it would provide a full range of pre-clinical and advanced product development services[2] (including animal-efficacy model development and validation) as well as dedicated scale-up, validation, and production capabilities using flexible manufacturing technologies. Technical expertise in scale up and manufacturing process development as well as commercial scale manufacturing will be provided by Biodefense Advanced Research and Development Authority (BARDA) to industry partners in need of these skills. The infrastructure required to provide this end-to-end range of services would be operated by industry under U.S. Government oversight. Important downstream benefits of establishing this capability are that it will make life cycle management and replenishment of needed countermeasures more cost effective and provide expanded domestic emergency manufacturing capacity.

One of the core product development services the U.S. Government will provide is identifying and addressing regulatory challenges prospectively and providing assistance with regulatory filings. Regulatory officers from NIH, BARDA, and DoD with deep knowledge of the "animal rule" and FDA concerns will provide expert support to private-sector partners and facilitate and participate in formal and informal interactions with FDA.

By providing subject matter and animal model expertise, developing and validating screening and GLP animal models, anticipating and addressing regulatory challenges prospectively, and establishing an advanced development and manufacturing capability, the U.S. Government will drastically reduce the opportunity costs and other barriers that limit investment by the pharmaceutical and biotechnology industries in public health countermeasure projects. This intensive and direct support by the U.S. Government will reduce the absolute investment of company resources in particular projects and fundamentally alter the calculus of return on investment. A much more favorable return on investment will, in turn, enable pharmaceutical and

[2] For example, Good Laboratory Practice (GLP) toxicology and safety pharmacology studies, formulation methodology, current Good Manufacturing Practice (cGMP) manufacturing support, stability studies, non-pivotal screening and efficacy evaluations, GLP pivotal efficacy studies in validated animal models, and support for Phase I clinical safety and pharmacokinetic studies.

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biotechnology firms to pursue the development of products that meet our national security and overall public health needs.

While the capital outlay necessary to establish this advanced development and manufacturing capability will be substantial, the benefits in terms of increased research and development productivity will more than justify the cost. Implementation of the multi-use principle will substantially reduce the costs associated with individual projects since multi-use value will enhance access to private capital markets, justify independent development, and reduce the need for advanced development and manufacturing support.[3]

V. End-to-end Multidisciplinary Project Management

U.S. Government support for the development of countermeasures against deliberately released and naturally occurring health threats is parceled out across numerous departments and agencies, and the release of requests for proposals and other targeted solicitations across this bureaucratic space is not well synchronized. While there have been efforts to coordinate U.S. Government countermeasure investments in an "Integrated National Portfolio" approach, a unified approach to budgeting and governance has not been achieved. For many private-sector partners, unfortunately, the IPHEMCE remains a confusing welter of acronyms, agencies, and funding mechanisms. This complex funding and policy environment is exceptionally difficult to navigate, particularly for the smaller firms and academic start-ups that are the main engines for innovation. Coupling the challenges of negotiating this terrain with the challenges of product development and the quirks of the "animal rule" pathway to product licensure has created an environment that is inhospitable to the translation of promising basic-science discoveries into clinically useful products.

The U.S. Government will implement a new program of end-to-end multidisciplinary project management to mitigate the complexity of our current institutional arrangements, identify relevant funding opportunities, facilitate handoffs between different departments and agencies, and inform private-sector partners at every stage of product development about relevant policy and the path to product approval. Multidisciplinary project management teams will include program managers, subject matter experts from DoD, NIH, BARDA, and the Centers for Disease Control and Prevention (CDC), a liaison from FDA, and, as needed, regulatory officers from NIH and BARDA.

The role of these teams will be to serve as "Sherpas" to our academic and private sector partners. Sherpas, of course, are members of a people of Tibetan descent who in modern times have achieved renown as expert guides on Himalayan mountaineering expeditions. During such expeditions, each climber is assigned a Sherpa to carry his or her gear, cook food, and set up camp. The Sherpa's role is to make the climb as easy as possible for the person being guided. All the climber has to focus on is climbing. Experienced Sherpas also recognize when a climber is not going to make it and can take appropriate action. The multidisciplinary project management teams would play an analogous role for academic and private sector partners, providing strategic recommendations where appropriate, and helping them negotiate the bureaucratic, scientific, policy, and funding terrain. It will be the responsibility of the project management teams to ensure the coordinated transition of

[3] In the optimal case of an already licensed product with dual utility and a substantial human safety database, the costs of development will be limited to the costs of demonstrating efficacy in validated animal models and filing a supplemental New Drug Application (NDA).

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projects between departments and agencies and from stage to stage of product development and testing.

Conclusion

The development of drugs, diagnostics, and vaccines against naturally occurring pandemics and emerging infectious diseases, as well as against deliberately propagated bioterror and other threats, is a national security imperative. But the substantial U.S. Government investments made since 2002 have not succeeded in producing the desired flow of new and next-generation countermeasures. We now recognize that it is only by attacking the direct barriers to the development of countermeasures against public health threats that we will increase our prospects of success. To say this is not to belie the value of incentives external to the drug development process. It is merely to point out that external incentives by themselves are insufficient.

Going forward, the U.S. Government will change the way it defines its mission and role in supporting the development and acquisition of medical countermeasures against public health threats. We will pursue a strategy with five critical pillars for biodefense product development:

I. ***The Multi-Use Principle*** *– for individual products but also platforms and technologies*
II. ***Precompetitive Collaboration***
III. ***Regulatory Innovation and Advancement in Regulatory Science***
IV. ***Product Development and Manufacturing Services***
V. ***End-to-end Multidisciplinary Project Management***

By implementing these pillars rigorously and without delay, the U.S. Government can transform the nature of the public-private partnerships it supports in this area. Ultimately, these changes will create a new template for government partnership in the arena of private-sector drug development in all the many areas where progress has been impeded by apparent market failures, will increase the productivity of our investments in the life sciences, and will enhance U.S. competitiveness.

This approach is expected to provide the following clear advantages for biotechnology companies, large pharmaceutical firms, and the U.S. Government:

Advantages for biotechnology companies

- Increases speed and lowers risks in the development of countermeasures;
- Offloads downstream development activities where expertise is lacking and more difficult to obtain;
- Allows for greater focus on discovery translation and technology innovation; and
- Creates a more durable business model.

Advantages for large pharmaceutical firms

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- Increases speed and lowers risks in the development of countermeasures against public health threats;
- Enhances innovation by providing access to newer technologies sooner;
- Provides an incubator and test bed for new platforms and technologies for future use in the development of commercially desirable products; and
- Enables more productive engagement with the FDA

Advantages for the U.S. Government

- Increases speed and lowers costs and risks in the development of medical countermeasures;
- Ensures sustained domestic U.S. production capability;
- Enhances USG surge capacity available for emerging and reemerging diseases;
- Provides for a critical mass of technical expertise that is available for a more rapid response when needed;
- Enables more overall drug development effort due to lower investment cost;
- Raises the potential to partner with NGOs and others to address global health problems; and
- Establishes a model for drugs, diagnostics, and vaccines for any and all diseases, including in cases where commercial viability is doubtful.

The strategy outlined is a significant departure from the U.S. Government's previous approach. It is not without some risk. But to eschew the uncertain risk associated with establishing a new business model and continue with the certain risk of unacceptable return that our current model continues to demonstrate would be untenable. Even if we were better able to produce effective countermeasures with our current model, over time our one-bug, one-drug, one-vaccine approach will inevitably lead to a lack of sustainability for the Enterprise as a whole, as the costs of discovery, development, procurement, stockpile maintenance, and securing ongoing access to surge manufacturing capability are aggregated for each of the many countermeasures we require.

A critical factor for successful implementation of our new strategy is a holistic approach to knocking down barriers impeding progress. There currently exists pockets of effort attempting to address these barriers and adopt some of the pillars of the strategy outlined here, but an ad hoc and incomplete approach will not create the conditions for a breakthrough in establishing a successful, sustainable approach. Incremental improvements will not achieve our goals. Only by leaping forward, employing the outlined strategy pillars comprehensively and broadly, will we achieve the output for which many in the IPHEMCE have worked tirelessly.

Now is the time to establish an approach yielding dramatically improved return on investment. Our return will not be measured in dollars but in the protection of the safety and security of the American people. In pursuing this fundamental charge of the Federal government, it is abundantly clear that failure is not an option.

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From: "Kurilla, Michael (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Subject: Re: Draft Strategy
Date: Thu, 11 Feb 2010 21:16:34 -0500
Importance: Normal

Subtle, but demonstrably better in tone.

Good luck tomorrow.

Mike

Sent from my BlackBerry Wireless Handheld. Please excuse my typing; I suffer from blackberry thumb syndrome.

From: Fauci, Anthony (NIH/NIAID) [E]
To: Kurilla, Michael (NIH/NIAID) [E]
Sent: Thu Feb 11 20:59:57 2010
Subject: FW: Draft Strategy

From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Thursday, February 11, 2010 8:15 PM
To: 'Avery, Heidi E.'
Cc: Hatchett, Richard (NIH/NIAID) [E]
Subject: FW: Draft Strategy

Heidi:
I spoke to Richard a little while ago and he asked me to focus mainly on the Introduction and the Multi-Use Principle, which I have done. I will leave it to others to examine their components in order to get this back to you quickly since I know that you have to prepare something tonight for the POTUS. The document looks quite good. I have made a few changes that are tracked and have explained why I have done this. Please let me know if you have any questions or if you need to speak with me later. I am available. You were an amazing model of flexibility today. I hope that my comments on the phone call helped.
Best regards,
Tony

From: Avery, Heidi E. [mailto:[redacted]@who.eop.gov]
Sent: Thursday, February 11, 2010 6:58 PM
To: [redacted]@hhs.gov; [redacted]@niaid.nih.gov; [redacted]@fda.hhs.gov; [redacted]@osd.mil; [redacted]@cdc.gov; [redacted]@hhs.gov; [redacted]@niaid.nih.gov; [redacted]@fda.hhs.gov; [redacted]@hhs.gov; [redacted]@osd.mil; Emanuel, Ezekiel J.; Holdren, John P.; Petrou, Laura (OS)
Cc: Hatchett, Richard J.; Lawler, James V.
Subject: Draft Strategy

Attached is the revised draft strategy. Hunting typos, but thought it would be useful to see sooner than later.

Heidi E. Avery
Deputy Assistant to the President
for Homeland Security
The White House

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[redacted]

From: Avery, Heidi E.
Sent: Thursday, February 11, 2010 4:26 PM
To: [redacted]@hhs.gov'; [redacted]@niaid.nih.gov'; [redacted]@fda.hhs.gov'; [redacted]@osd.mil'; [redacted]@cdc.gov'; [redacted]@hhs.gov'; [redacted]@niaid.nih.gov'; [redacted]@fda.hhs.gov'; [redacted]@hhs.gov'; [redacted]@osd.mil'; Emanuel, Ezekiel J.; Holdren, John P.; 'Petrou, Laura (HHS/OS)'
Cc: Hatchett, Richard J.; Lawler, James V.; Severn, Deborah; [redacted]@hhs.gov'; [redacted]@fda.hhs.gov'; [redacted]@cdc.gov'; Bafford, Elizabeth A.; McLaughlin, Patricia M.; 'conradpa@niaid.nih.gov'
Subject: Conference Call Today at 6pm

Greetings – Believe it would be useful for us to talk briefly today at 6pm. Our meeting with the President remains scheduled for 2pm tomorrow in the WHSR. During the call we will clarify the meeting intent, discuss any concerns, and generally seek to set all of us up for success.

Meanwhile, we will have a new version of the draft strategy to you soon. Appreciate all of the very good comments. And, to be clear, we expect the draft strategy will be further adjusted based on consultations. The ongoing MCM review, PCAST study, and talks with industry will be critical to further shape the way forward. We remain early in the process. Thanks, Heidi

BRIDGE NUMBER: [redacted]

CONFEREE PASSCODE: [redacted]

Heidi E. Avery
Deputy Assistant to the President
for Homeland Security
The White House
[redacted]

Released by Chairman Rand Paul

From: "Fauci, Anthony (NIH/NIAID) [E]" </O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=AFAUCI>
To: "Collins, Francis (NIH/OD) [E]" <[redacted]@nih.gov>
Bcc: "Conrad, Patricia (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Folkers, Greg (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Subject: FW: Draft Strategy
Date: Thu, 11 Feb 2010 21:16:51 -0500
Importance: Normal
Attachments: iPHEMCE_Strategy_v11_2-11-10.doc

Francis:

As per our conversation yesterday, here is the document that we have been working on for several weeks with multiple revisions. You will see my final edits that I put into the document today. As mentioned to you over the phone, the exercise morphed over weeks from a consideration of how we can improve the process of the development of countermeasures against emerging infections and bioterror threats to a new "bold" strategy. This process has been driven by Heidi Avery, Deputy to John Brennan, in the Homeland Security component of the new National Security Council. The decision was made final this afternoon that we will meet with the POTUS tomorrow at 2:00 PM to present the draft strategy. Heidi Avery will present the strategy and I will be present as a subject matter expert to be available to answer questions on the scientific aspects if necessary. I will let you know how it went.

Best regards,

Tony

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From: "Collins, Francis (NIH/OD) [E]" <[redacted]@nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Subject: RE: Draft Strategy
Date: Fri, 12 Feb 2010 07:15:40 -0500
Importance: Normal

Thanks, Tony, please keep me posted.
FC

From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Thursday, February 11, 2010 9:17 PM
To: Collins, Francis (NIH/OD) [E]
Subject: FW: Draft Strategy

Francis:
As per our conversation yesterday, here is the document that we have been working on for several weeks with multiple revisions. You will see my final edits that I put into the document today. As mentioned to you over the phone, the exercise morphed over weeks from a consideration of how we can improve the process of the development of countermeasures against emerging infections and bioterror threats to a new "bold" strategy. This process has been driven by Heidi Avery, Deputy to John Brennan, in the Homeland Security component of the new National Security Council. The decision was made final this afternoon that we will meet with the POTUS tomorrow at 2:00 PM to present the draft strategy. Heidi Avery will present the strategy and I will be present as a subject matter expert to be available to answer questions on the scientific aspects if necessary. I will let you know how it went.
Best regards,
Tony

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From: [redacted]@niaid.nih.gov
To: Conrad Patty <[redacted]@niaid.nih.gov>, "Michael [E] Kurilla" <[redacted]@niaid.nih.gov>
Date: Wed, 03 Mar 2010 22:45:01 -0500
Importance: Normal

Let us discuss tomorrow the long conversation that I had tonight with Heidi Avery at 10:00pm. It is important.

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From: "Fauci, Anthony (NIH/NIAID) [E]" </O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=AFAUCI>
To: "Hudson, Kathy (NIH/OD) [E]" <[redacted]@nih.gov>
Cc: "Collins, Francis (NIH/OD) [E]" [redacted]@nih.gov>, "Kurilla, Michael (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Bcc: "Conrad, Patricia (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>, "Folkers, Greg (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Subject: RE: Heads up
Date: Sat, 10 Apr 2010 15:36:35 -0400
Importance: Normal

Kathy:
I believe that this is just the White House and OMB looking for ways to meet the President's wishes (this initiative is one of them) and at the same time not increase spending. There has been discussion of 2 sources of money for the program: 1) the "flu supplement" for 2010. This, however, is one year money with the possibility of getting converted to no year money. 2) The other source is to carve it out of the 2011 budget and also add it as truly new money into the 2012 budget. I have never heard serious discussion about using unexpended ARRA funding, but then again that does not mean that they are not talking about it at meetings that I have not attended.
Tony

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
[redacted]
National Institutes of Health
Bethesda, MD [redacted]
Phone: [redacted]
FAX: [redacted]
E-mail: [redacted]@niaid.nih.gov
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From: Hudson, Kathy (NIH/OD) [E]
Sent: Saturday, April 10, 2010 1:32 PM
To: Fauci, Anthony (NIH/NIAID) [E]
Cc: Collins, Francis (NIH/OD) [E]
Subject: RE: Heads up

Thanks Tony. I got a phone call from Zeke about this a couple of days ago and he said that Rahm had suggested in a brfing that this program be partially funded by NIH ARRA remainders. Have you heard anything like that? I had Colleen develop a table that shows ARRA obligations, commitments and planned obligations in order to show that we have a balance of something on the order of $1.57.

From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Saturday, April 10, 2010 11:27 AM
To: Collins, Francis (NIH/OD) [E]
Cc: Hudson, Kathy (NIH/OD) [E]; Kurilla, Michael (NIH/NIAID) [E]; Heilman, Carole (NIH/NIAID) [E]; Conrad, Patricia (NIH/NIAID) [E]; Folkers, Greg (NIH/NIAID) [E]; Auchincloss, Hugh (NIH/NIAID) [E]; McGowan, John J. (NIH/NIAID) [E]
Subject: Heads up

Released by Chairman Rand Paul

Francis:

First, I hope that things have improved greatly with your daughter's illness. Second, I want to give you a heads up that I have called your office to arrange for me to brief you on how things have been progressing with our weekly White House meetings with Heidi Avery of the National Security Staff (NSS). As you may know she is John Brennan's Deputy and is intensively interested in "transforming" how we respond to deliberate and naturally occurring biological threats through the development of medical countermeasures (MCM). She has been making a number of proposals that have been discussed at length at these meetings and have undergone a continual series of modifications based on comments from the participants. The "Program" has now matured to the point of including 4 elements: 1) boosting regulatory science; 2) developing Transformational Centers of Excellence for Advanced Development and Manufacturing of MCM; 3) establishing an independent strategic investment firm (i.e. a government venture capital-like organization) for innovation in MCM; 4) and finally an idea that she got from what NIAID has been doing for some time on a relatively small scale – the development of a "concept exploitation focus" to help stimulate discovery and translation. What we have been doing is playing an active role from the time a grantee makes a discovery, but has no experience in pushing it into translation. NIAID has served as a "sherpa" or chaperone for the investigators by providing them with NIAID assets (reagents, animal models, connection to the regulatory process, etc.) to begin the process of translation. This is totally compatible with your interest in translational research on a broader scale including the CTSAs , particularly in light of the Cures Acceleration Network Initiative. The reason that I want to brief you is that Heidi is starting now to push OMB for real, new money for all these initiatives and this could be an opportunity for us to put some flesh on the whole Translational Research approach. I propose having a meeting at the end of next week (your office said that this was the best for your schedule) in which I together with my program person, Mike Kurilla, brief you on the entire MCM initiative as well as the role that they propose NIAID/NIH play. In addition, I can fill you in on the interesting dynamics between the White House and HHS.

Best regards,

Tony

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
[redacted]
National Institutes of Health
Bethesda, MD [redacted]
Phone: [redacted]
FAX: [redacted]
E-mail: [redacted]@niaid.nih.gov

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From: "Kurilla, Michael (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Subject: Fw: Heads up
Date: Sat, 10 Apr 2010 20:29:29 -0400
Importance: Normal

Tony,

I'll add on on slide with 4 bullets summarizing the WH activity.

Mike

Sent from my BlackBerry Wireless Handheld. Please excuse my typing; I suffer from blackberry thumb syndrome.

From: Collins, Francis (NIH/OD) [E]
To: Fauci, Anthony (NIH/NIAID) [E]
Cc: Hudson, Kathy (NIH/OD) [E]; Kurilla, Michael (NIH/NIAID) [E]; Heilman, Carole (NIH/NIAID) [E]; Conrad, Patricia (NIH/NIAID) [E]; Folkers, Greg (NIH/NIAID) [E]; Auchincloss, Hugh (NIH/NIAID) [E]; McGowan, John J. (NIH/NIAID) [E]; Wood, Gretchen (NIH/OD) [E]; Flowers, Susan (NIH/OD) [E]
Sent: Sat Apr 10 17:15:09 2010
Subject: RE: Heads up

Hi Tony,

Thanks for this heads up. I would very much like to hear more about how this MCM initiative is shaping up. Perhaps Friday morning April 16 would work, but I am ccing Gretchen and Sus to encourage them to find the right time.

Francis

From: Fauci, Anthony (NIH/NIAID) [E]
Sent: Saturday, April 10, 2010 11:27 AM
To: Collins, Francis (NIH/OD) [E]
Cc: Hudson, Kathy (NIH/OD) [E]; Kurilla, Michael (NIH/NIAID) [E]; Heilman, Carole (NIH/NIAID) [E]; Conrad, Patricia (NIH/NIAID) [E]; Folkers, Greg (NIH/NIAID) [E]; Auchincloss, Hugh (NIH/NIAID) [E]; McGowan, John J. (NIH/NIAID) [E]
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Released by Chairman Rand Paul

Acceleration Network Initiative. The reason that I want to brief you is that Heidi is starting now to push OMB for real, new money for all these initiatives and this could be an opportunity for us to put some flesh on the whole Translational Research approach. I propose having a meeting at the end of next week (your office said that this was the best for your schedule) in which I together with my program person, Mike Kurilla, brief you on the entire MCM initiative as well as the role that they propose NIAID/NIH play. In addition, I can fill you in on the interesting dynamics between the White House and HHS.

Best regards,

Tony

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
[redacted]
National Institutes of Health
Bethesda, MD [redacted]
Phone: [redacted]
FAX: [redacted]
E-mail: [redacted]@niaid.nih.gov

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From: "Fauci, Anthony (NIH/NIAID) [E]"
</O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=AFAUCI>
To: "Heilman, Carole (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Subject: RE: Heads up
Date: Sat, 10 Apr 2010 12:56:08 -0400
Importance: Normal

Thanks for the note. Mike has been "amazing" on all this.

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
[redacted]
National Institutes of Health
Bethesda, MD [redacted]
Phone: [redacted]
FAX: [redacted]
E-mail: [redacted]@niaid.nih.gov
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From: Heilman, Carole (NIH/NIAID) [E]
Sent: Saturday, April 10, 2010 12:19 PM
To: Fauci, Anthony (NIH/NIAID) [E]
Subject: Re: Heads up

This is really starting to come together - thanks for all the energy you are putting into this.

From: Fauci, Anthony (NIH/NIAID) [E]
To: Collins, Francis (NIH/OD) [E]
Cc: Hudson, Kathy (NIH/OD) [E]; Kurilla, Michael (NIH/NIAID) [E]; Heilman, Carole (NIH/NIAID) [E]; Conrad, Patricia (NIH/NIAID) [E]; Folkers, Greg (NIH/NIAID) [E]; Auchincloss, Hugh (NIH/NIAID) [E]; McGowan, John J. (NIH/NIAID) [E]
Sent: Sat Apr 10 11:26:35 2010
Subject: Heads up

Francis:

First, I hope that things have improved greatly with your daughter's illness. Second, I want to give you a heads up that I have called your office to arrange for me to brief you on how things have been progressing with our weekly White House meetings with Heidi Avery of the National Security Staff (NSS). As you may know she is John Brennan's Deputy and is intensively interested in "transforming" how we respond to deliberate and naturally occurring biological threats through the development of medical countermeasures (MCM). She has been making a number of proposals that have been discussed at length at these meetings and have undergone a continual series of modifications based on comments from the participants. The "Program" has now matured to the point of including 4 elements: 1) boosting regulatory science; 2) developing Transformational Centers of Excellence for Advanced Development and Manufacturing of MCM; 3) establishing an independent strategic investment firm (i.e. a government venture capital-like organization) for innovation in MCM; 4) and finally an idea that she got from what NIAID has been doing for some time on a relatively small scale – the development of a "concept exploitation focus" to help stimulate discovery and translation. What we have been doing is playing an active role from the time a grantee makes a discovery, but has no experience in pushing it into translation. NIAID has served as a "sherpa" or chaperone for the investigators by providing them with NIAID assets (reagents, animal models, connection to the regulatory process, etc.) to begin the process of translation. This is totally compatible with

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your interest in translational research on a broader scale including the CTSAs , particularly in light of the Cures Acceleration Network Initiative. The reason that I want to brief you is that Heidi is starting now to push OMB for real, new money for all these initiatives and this could be an opportunity for us to put some flesh on the whole Translational Research approach. I propose having a meeting at the end of next week (your office said that this was the best for your schedule) in which I together with my program person, Mike Kurilla, brief you on the entire MCM initiative as well as the role that they propose NIAID/NIH play. In addition, I can fill you in on the interesting dynamics between the White House and HHS.

Best regards,

Tony

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
[redacted]
National Institutes of Health
Bethesda, MD [redacted]
Phone: [redacted]
FAX: [redacted]
E-mail: [redacted]@niaid.nih.gov

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From: "Conrad, Patricia (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
To: "Fauci, Anthony (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Subject: FW: Meeting Material request -- 4/16 Briefing with Dr. A. Fauci, Dr. M. Kurilla and Dr. Patterson re: MCM
Date: Thu, 15 Apr 2010 09:01:54 -0400
Importance: Normal
Attachments: Meeting_request_--_4.16_MCM.docx; MCM_Briefing_Paper.docx

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Okay doc....let her rip on the second document...I look forward to all your red!

Patricia Conrad
Special Assistant to the Director
[redacted] office

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From: Dicrosta, Nicholas (NIH/OD) [E]
Sent: Wednesday, April 14, 2010 12:23 PM
To: Conrad, Patricia (NIH/NIAID) [E]
Subject: Meeting Material request -- 4/16 Briefing with Dr. A. Fauci, Dr. M. Kurilla and Dr. Patterson re: MCM

Good afternoon Ms. Conrad,

Are there further materials you and Dr. Fauci will be submitting to the ES in regard to this meeting? If so, please use the attached template and return to me at your earliest convenience.

Thank you!

Nick DiCrosta
Management Intern, Class of 2011
Currently on rotation with the NIH Executive Secretariat
(p) [redacted]
[redacted]@mail.nih.gov

Released by Chairman Rand Paul

Good afternoon Ms. Conrad

As you know, Dr. Collins will be meeting with Dr. Fauci regarding Medical Countermeasures. You have been assigned the lead in preparing briefing information for this meeting. Please prepare the material for this meeting using the outline below and submit this material electronically to me as soon as possible.

BACKGROUND INFORMATION
Name of Meeting
Date of Meeting
Time

ACTION REQUIRED BY THE DIRECTOR:

PURPOSE OF MEETING (one sentence):

BACKGROUND (short summary, 3-4 sentences):

PARTICIPANTS:

DISCUSSION POINTS/TALKING POINTS (using concise/to the point bullets):

Attachments:

- Bios
- Relevant correspondence
- Supplemental Information
- Etc.

Thank you,

Nicholas DiCrosta
Management Intern currently on rotation with the NIH Executive Secretariat

Released by Chairman Rand Paul

BACKGROUND INFORMATION
HHS/White House Medical Countermeasure Initiative (MCM) Briefing
Friday, April 16, 2010
9:00 am – 10:00 am

ACTION REQUIRED BY THE DIRECTOR: None

PURPOSE OF MEETING:
The purpose of the meeting is to brief you on NIAID's role in the HHS/White House Medical Countermeasure (MCM) Initiative.

BACKGROUND:
NIAID has participated in weekly meetings with The White House (National Security Staff - NSS) and HHS staff to create a "transforming" initiative on how the US government responds to deliberate and naturally occurring biological threats through the development of medical countermeasures (MCM). NSS Staff will soon seek new money from OMB to support this new initiative.

The "Program" includes 4 elements: 1) boosting regulatory science; 2) developing Transformational Centers of Excellence for Advanced Development and Manufacturing of MCM; 3) establishing an independent strategic investment firm (i.e. a government venture capital-like organization) for innovation in MCM; 4) the development of a "concept exploitation focus" to help stimulate discovery and translation.

PARTICIPANTS:
Anthony S. Fauci, MD, Director, NIAID

Michael G Kurilla, MD-PhD
Director, Office of BioDefense Research Affairs
Associate Director for BioDefense Product Development , NIAID

DISCUSSION POINTS/TALKING POINTS (using concise/to the point bullets):

Attachments:

- Bios
- Relevant correspondence
- Supplemental Information
- Etc.

Thank you,

Nicholas DiCrosta
Management Intern currently on rotation with the NIH Executive Secretariat

Released by Chairman Rand Paul

Released by Chairman Rand Paul

From: "Fauci, Anthony (NIH/NIAID) [E]" </O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=AFAUCI>
To: "Conrad, Patricia (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Subject: FW: Meeting Material request -- 4/16 Briefing with Dr. A. Fauci, Dr. M. Kurilla and Dr. Patterson re: MCM
Date: Thu, 15 Apr 2010 09:36:09 -0400
Importance: Normal
Attachments: Meeting_request_--_4.16_MCM.docx; MCM_Briefing_Paper.docx

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Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
[redacted]
National Institutes of Health
Bethesda, MD [redacted]
Phone: [redacted]
FAX: [redacted]
E-mail: [redacted]@niaid.nih.gov
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From: Conrad, Patricia (NIH/NIAID) [E]
Sent: Thursday, April 15, 2010 9:02 AM
To: Fauci, Anthony (NIH/NIAID) [E]
Subject: FW: Meeting Material request -- 4/16 Briefing with Dr. A. Fauci, Dr. M. Kurilla and Dr. Patterson re: MCM

Okay doc....let her rip on the second document...I look forward to all your red!

Patricia Conrad
Special Assistant to the Director
[redacted] office

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From: Dicrosta, Nicholas (NIH/OD) [E]
Sent: Wednesday, April 14, 2010 12:23 PM
To: Conrad, Patricia (NIH/NIAID) [E]
Subject: Meeting Material request -- 4/16 Briefing with Dr. A. Fauci, Dr. M. Kurilla and Dr. Patterson re: MCM

Good afternoon Ms. Conrad,

Are there further materials you and Dr. Fauci will be submitting to the ES in regard to this meeting? If so, please use the attached template and return to me at your earliest convenience.

Released by Chairman Rand Paul

Thank you!

Nick DiCrosta
Management Intern, Class of 2011
Currently on rotation with the NIH Executive Secretariat
(p) [redacted]
[redacted]@mail.nih.gov

Released by Chairman Rand Paul

Good afternoon Ms. Conrad

As you know, Dr. Collins will be meeting with Dr. Fauci regarding Medical Countermeasures. You have been assigned the lead in preparing briefing information for this meeting. Please prepare the material for this meeting using the outline below and submit this material electronically to me as soon as possible.

BACKGROUND INFORMATION
Name of Meeting
Date of Meeting
Time

ACTION REQUIRED BY THE DIRECTOR:

PURPOSE OF MEETING (one sentence):

BACKGROUND (short summary, 3-4 sentences):

PARTICIPANTS:

DISCUSSION POINTS/TALKING POINTS (using concise/to the point bullets):

Attachments:

- Bios
- Relevant correspondence
- Supplemental Information
- Etc.

Thank you,

Nicholas DiCrosta
Management Intern currently on rotation with the NIH Executive Secretariat

Released by Chairman Rand Paul

BACKGROUND INFORMATION
HHS/White House Medical Countermeasure Initiative (MCM) Briefing
Friday, April 16, 2010
9:00 am – 10:00 am

ACTION REQUIRED BY THE DIRECTOR: None

PURPOSE OF MEETING:
The purpose of the meeting is to brief NIH Director on NIAID's role in the HHS/White House Medical Countermeasure (MCM) Initiative.

BACKGROUND:
NIAID has participated in weekly meetings with The White House (National Security Staff - NSS) and HHS staff to create a "transforming" initiative on how the US government responds to deliberate and naturally occurring biological threats through the development of medical countermeasures (MCM). The initiative was driven predominantly by Heidi Avery (Deputy to John Brennan) and NSS Staff who will soon seek new money from OMB to support this new initiative.

The "Program" includes 4 elements: 1) boosting regulatory science; 2) developing Transformational Centers of Excellence for Advanced Development and Manufacturing of MCM; 3) establishing an independent strategic investment firm (i.e. a government venture capital-like organization) for innovation in MCM; 4) the development of a "concept exploitation focus" to help stimulate discovery and translation.

PARTICIPANTS:
Anthony S. Fauci, MD, Director, NIAID

Michael G Kurilla, MD-PhD
Director, Office of BioDefense Research Affairs
Associate Director for BioDefense Product Development , NIAID

DISCUSSION POINTS/TALKING POINTS (using concise/to the point bullets):

Attachments:

- Bios
- Relevant correspondence
- Supplemental Information
- Etc.

Thank you,

Nicholas DiCrosta

Released by Chairman Rand Paul

Management Intern currently on rotation with the NIH Executive Secretariat

Released by Chairman Rand Paul

From: "Fauci, Anthony (NIH/NIAID) [E]" </O=NIH/OU=NIHEXCHANGE/CN=NIAID/CN=AFAUCI>
To: "Goldie, Chrisy (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Cc: "Conrad, Patricia (NIH/NIAID) [E]" <[redacted]@niaid.nih.gov>
Subject: MCM meeting at White House
Date: Tue, 11 May 2010 17:17:00 -0400
Importance: Normal

Chrisy:
Heidi Avery's office called and there is now a White House MCM meeting on Thursday, May 13 at 5:00 PM in the Situation Room. Please cancel EXCOM and put the WH meeting on the calendar. Also, allow me 1 hour (4:00 to 5:00 PM) to travel to the White House.
Thank,
ASF

Anthony S. Fauci, MD
Director
National Institute of Allergy and Infectious Diseases
[redacted]
National Institutes of Health
Bethesda, MD [redacted]
Phone: [redacted]
FAX: [redacted]
E-mail: [redacted]@niaid.nih.gov
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