From: Embry, Alan (NIH/NIAID) [E]
Sent: Thu, 8 Jul 2021 17:41:56 +0000
To: Haskins, Melinda (NIH/NIAID) [E];Selgrade, Sara (NIH/NIAID) [E];Barasch, Kimberly (NIH/NIAID) [E];Conrad, Patricia (NIH/NIAID) [E]
Subject: 3pm materials
Attachments: Key questions 7.8.21 combined ae2.docx, Flow charts.pptx

Attached are materials for the 3pm prep session.

Kim, would you be able to help print copies for people who will be attending in person?

I am leaving momentarily to help set up, etc.

Thanks,
Alan

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From: Haskins, Melinda (NIH/NIAID) [E]
Sent: Wed, 7 Jul 2021 21:56:08 +0000
To: Embry, Alan (NIH/NIAID) [E]
Cc: Selgrade, Sara (NIH/NIAID) [E]
Subject: CB Edits attached
Attachments: Key Questions 7.7.21 CB.docx

From: Billet, Courtney (NIH/NIAID) [E] (b)(6)
Sent: Wednesday, July 7, 2021 5:54 PM
To: Embry, Alan (NIH/NIAID) [E] (b)(6); Selgrade, Sara (NIH/NIAID) [E] (b)(6); Haskins, Melinda (NIH/NIAID) [E] (b)(6)
Cc: Folkers, Greg (NIH/NIAID) [E] (b)(6)
Subject: RE: prep

Some suggestions from me.

From: Embry, Alan (NIH/NIAID) [E] (b)(6)
Sent: Wednesday, July 7, 2021 4:26 PM
To: Selgrade, Sara (NIH/NIAID) [E] (b)(6); Haskins, Melinda (NIH/NIAID) [E] (b)(6); Billet, Courtney (NIH/NIAID) [E] (b)(6)
Cc: Folkers, Greg (NIH/NIAID) [E] (b)(6)
Subject: prep

Hi All,

Sending an updated version of the TPs for tomorrow's prep discussion. I would like multiple eyes to help review/refine. Do you want to send through BUGS or have me work directly with DMID?

I'm still tweaking things (and adding Q&As) but wanted to keep things moving.

Let me know if you want to discuss.

Thanks,
Alan

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TITLE

2017 PLOS Pathogens Paper

The research in this paper **is NOT gain-of-function** because the work did not result in any viruses with increased pathogenicity or transmissibility via the respiratory route in mammals.

- To understand the potential of bat coronaviruses to infect human cells, the researchers put a small piece of newly identified bat coronaviruses (spike) into a larger portion of a well characterized bat coronavirus (WIV1) that has never been demonstrated to infect humans
- Of the 8 viruses they tested, only three were able to be rescued, underscoring that inserting divergent spike proteins into viral model systems (chimeras) is not an inherently risky approach.
- The viruses created did not replicate more efficiently than the wild-type WIV1.
- The WIV-1 backbone and other bat coronaviruses characterized in this study could not have been the source of SARS-CoV-2.
    - WIV1 >6700 nucleotides different (72%) than SARS-CoV-2; other viruses also ~72%
- First study to find all building blocks of SARS-CoV in a single bat population.

TITLE

From: Embry, Alan (NIH/NIAID) [E]
Sent: Thu, 8 Jul 2021 13:15:17 +0000
To: NIAID OD COVID Coord
Subject: FW: combined edits
Attachments: Key questions 7.8.21 combined.docx

Draft

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From: Ford, Andrew (NIH/NIAID) [E]
Sent: Thu, 22 Jul 2021 21:45:32 +0000
To: Stemmy, Erik (NIH/NIAID) [E];Hauguel, Teresa (NIH/NIAID) [E]
Cc: NIAID BUGS;Embry, Alan (NIH/NIAID) [E]
Subject: FW: For review again: Response to GoF inquiry from FactCheck.org
Attachments: Response to FactCheck JR ed ae cb AQF clean_ss ae AQF.docx
Importance: High

Hey Erik and Teresa,

Attached for another round of review is the response to FactChecker. Note, in response to Alan's comment, I attempted to provide alternative language; it appears that additional language about the research under the grant was provided and an attempt to tie this new language to that about why the research was not GoF. Please do send your thoughts as soon as possible.

Thanks and apologies,
Andrew

From: "Embry, Alan (NIH/NIAID) [E]" (b)(6)
Date: Thursday, July 22, 2021 at 5:16 PM
To: "Billet, Courtney (NIH/NIAID) [E]" (b)(6), "Routh, Jennifer (NIH/NIAID) [E]" (b)(6) Sara Selgrade (b)(6) 'Deatrick, Elizabeth (NIH/NIAID) [E]" (b)(6) "Ford, Andrew (NIH/NIAID) [E]" (b)(6) NIAID BUGS (b)(6)
Cc: NIAID OCGR NSWB (b)(6), NIAID Media Inquiries (b)(6), "Haskins, Melinda (NIH/NIAID) [E]" (b)(6)
Subject: RE: For review again: Response to GoF inquiry from FactCheck.org

This language needs revision. Please work with DMID to fix.

From: Billet, Courtney (NIH/NIAID) [E] (b)(6)
Sent: Thursday, July 22, 2021 5:05 PM
To: Routh, Jennifer (NIH/NIAID) [E] (b)(6) Selgrade, Sara (NIH/NIAID) [E] (b)(6) Deatrick, Elizabeth (NIH/NIAID) [E] (b)(6); Embry, Alan (NIH/NIAID) [E] (b)(6); Ford, Andrew (NIH/NIAID) [E] (b)(6) NIAID BUGS (b)(6)
Cc: NIAID OCGR NSWB (b)(6); NIAID Media Inquiries (b)(6); Haskins, Melinda (NIH/NIAID) [E] (b)(6)
Subject: RE: For review again: Response to GoF inquiry from FactCheck.org

It's ok with me, with the caveat that I defer to Alan's expertise. Alan, OK with you?

From: Routh, Jennifer (NIH/NIAID) [E] (b)(6)
Sent: Thursday, July 22, 2021 4:55 PM
To: Selgrade, Sara (NIH/NIAID) [E] (b)(6) Deatrick, Elizabeth (NIH/NIAID) [E]

(b)(6) Embry, Alan (NIH/NIAID) [E] (b)(6); Ford, Andrew (NIH/NIAID) [E] (b)(6); Billet, Courtney (NIH/NIAID) [E] (b)(6); NIAID BUGS (b)(6)
Cc: NIAID OCGR NSWB (b)(6); NIAID Media Inquiries (b)(6); Haskins, Melinda (NIH/NIAID) [E] (b)(6)
Subject: RE: For review again: Response to GoF inquiry from FactCheck.org
Importance: High

I am adding BUGS, Andrew and Courtney to this thread so we are all on the same thread. The original response pulled from cleared language. I'd like to get this finalized ASAP. We really need to move this forward.

Jennifer Routh [E]
News and Science Writing Branch
Office of Communications and Government Relations
National Institute of Allergy and Infectious Diseases (NIAID)
NIH/HHS
31 Center Drive Room 7A17C
Bethesda, MD 20892
Direct: (b)(6)
(b)(6)

From: Selgrade, Sara (NIH/NIAID) [E] (b)(6)
Sent: Thursday, July 22, 2021 4:49 PM
To: Deatrick, Elizabeth (NIH/NIAID) [E] (b)(6); Embry, Alan (NIH/NIAID) [E] (b)(6)
Cc: NIAID OCGR NSWB (b)(6); NIAID Media Inquiries (b)(6); Haskins, Melinda (NIH/NIAID) [E] (b)(6)
Subject: RE: For review again: Response to GoF inquiry from FactCheck.org

Thanks Elizabeth. Some edits for your consideration in the attached. I'm copying Melinda as well for her review.

Defer to Alan on whether DMID should review again.

From: Deatrick, Elizabeth (NIH/NIAID) [E] (b)(6)
Sent: Thursday, July 22, 2021 4:33 PM
To: Embry, Alan (NIH/NIAID) [E] (b)(6); Selgrade, Sara (NIH/NIAID) [E] (b)(6)
Cc: NIAID OCGR NSWB (b)(6); NIAID Media Inquiries (b)(6)
Subject: For review again: Response to GoF inquiry from FactCheck.org

Good afternoon,

DMID has reviewed our response to FactCheck.org on GoF research, but recommended that we run the copy past you one more time before moving it forward in the clearance process. Please let me know if you have any notes on the attached clean document.

Best,

Elizabeth Deatrick
Technical Writer-Editor
Office of Communications and Government Relations
National Institute of Allergy and Infectious Diseases (NIAID)
(b)(6)

Please note that I am not a spokesperson for NIAID and should not be quoted as such.

Inquiry: “Would you be able to provide more information specifically about the 2017 paper Paul cited and why that research would not be considered gain-of-function by the NIH/NIAID? In 2014, the Obama White House said the pause in GOF research would apply to: “gain-of-function research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.” Does the 2017 paper not meet that definition because of the "respiratory route" specification, or is it that the experiments were not anticipated to generate viruses with increased transmissibility to mammals/humans?”

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From: Myles, Renate (NIH/OD) [E]
Sent: Mon, 24 May 2021 18:17:31 +0000
To: Tucker, Jessica (NIH/OD) [E];Embry, Alan (NIH/NIAID) [E]
Cc: Fine, Amanda (NIH/OD) [E];Wojtowicz, Emma (NIH/OD) [E];Billet, Courtney (NIH/NIAID) [E];Stover, Kathy (NIH/NIAID) [E];Routh, Jennifer (NIH/NIAID) [E]
Subject: PLEASE CONFIRM: Background/TPs/QAs
Attachments: 2-Backgrounder_GOF_WIV_5.24.2021.docx, 3-TPs_GOF_WIV_05.24.2021.docx
Importance: High

Hi Jessica and Alan:

I reviewed the backgrounder and TPs/QAs based on what we changed in the actual media QAs last week to ensure consistency (b)(5) (b)(5) Would you take another quick look to see if you see anything that's a problem? Emma will send it as part of FC's briefing materials for the hearings tomorrow and Wednesday.

Alan: one thing I'm struggling with is (b)(5) (b)(5)

Thanks,
Renate

Renate Myles, MBA
Acting Associate Director for Communications and Public Liaison
Acting Director, Office of Communications and Public Liaison
National Institutes of Health
Tel: (b)(6)

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From: Embry, Alan (NIH/NIAID) [E]
Sent: Thu, 8 Jul 2021 16:28:39 +0000
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: Post, Diane (NIH/NIAID) [E];Ford, Andrew (NIH/NIAID) [E];Haskins, Melinda (NIH/NIAID) [E];Selgrade, Sara (NIH/NIAID) [E]
Subject: prep
Attachments: Key questions 7.8.21 combined ae2.docx
Importance: High

Hi Erik,

Attached is the most recent version of the Q&A document. I would really appreciate it if you could look carefully at the several questions that I flagged.

Thanks,
Alan

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From: Embry, Alan (NIH/NIAID) [E]
Sent: Tue, 13 Jul 2021 18:50:01 +0000
To: Arms, Erin (NIH/NIAID) [E]
Cc: NIAID OCGR Leg
Subject: RE: Alan: quick review requested - 2017 PLOS paper FLIP
Attachments: FLIP 2017 PLOS Paper_ss_EMA ae.docx

Hi Erin,

Comments attached.

Thanks
Alan

From: Arms, Erin (NIH/NIAID) [E] (b)(6)
Sent: Tuesday, July 13, 2021 2:40 PM
To: Embry, Alan (NIH/NIAID) [E] (b)(6)
Cc: NIAID OCGR Leg (b)(6)
Subject: Alan: quick review requested - 2017 PLOS paper FLIP

Hi Alan,

Sara and I reviewed the draft FLIP for the 2017 PLOS Paper and had some edits/comments (attached). We'd appreciate your quick review/take before we put it into the review pipeline.

Thanks,
Erin

Erin Arms, Ph.D.
Public Health Analyst
Legislative Affairs and Correspondence Management Branch
Office of Communications and Government Relations
NIAID/NIH/DHHS
31 Center Drive
Bldg. 31, Room 7A17H, MSC 2520
Bethesda, MD 20892-2080
(b)(6)

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From: Ford, Andrew (NIH/NIAID) [E]
Sent: Fri, 23 Jul 2021 01:47:48 +0000
To: Routh, Jennifer (NIH/NIAID) [E];Selgrade, Sara (NIH/NIAID) [E];Deatrick, Elizabeth (NIH/NIAID) [E];Embry, Alan (NIH/NIAID) [E];Billet, Courtney (NIH/NIAID) [E]
Cc: NIAID OCGR NSWB;NIAID Media Inquiries;NIAID BUGS;Haskins, Melinda (NIH/NIAID) [E]
Subject: Re: For review again: Response to GoF inquiry from FactCheck.org
Attachments: Response to FactCheck JR ed ae cb AQF clean_ss ae AQF_TH1 AQF es[2].docx

Dear All,

The attached version contains additional edits/comments from program staff.

Happy to discuss.

Thanks,
Andrew

From: "Routh, Jennifer (NIH/NIAID) [E]" (b)(6)
Date: Thursday, July 22, 2021 at 4:55 PM
To: Sara Selgrade (b)(6) "Deatrick, Elizabeth (NIH/NIAID) [E]" (b)(6), "Embry, Alan (NIH/NIAID) [E]" (b)(6), "Ford, Andrew (NIH/NIAID) [E]" (b)(6), "Billet, Courtney (NIH/NIAID) [E]" (b)(6) NIAID BUGS (b)(6)
Cc: NIAID OCGR NSWB (b)(6), NIAID Media Inquiries (b)(6) "Haskins, Melinda (NIH/NIAID) [E]" (b)(6)
Subject: RE: For review again: Response to GoF inquiry from FactCheck.org

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Jennifer Routh [E]
News and Science Writing Branch
Office of Communications and Government Relations
National Institute of Allergy and Infectious Diseases (NIAID)
NIH/HHS
31 Center Drive Room 7A17C
Bethesda, MD 20892
Direct: (b)(6)
(b)(6)

From: Selgrade, Sara (NIH/NIAID) [E] (b)(6)
Sent: Thursday, July 22, 2021 4:49 PM
To: Deatrick, Elizabeth (NIH/NIAID) [E] (b)(6) Embry, Alan (NIH/NIAID) [E] (b)(6)
Cc: NIAID OCGR NSWB (b)(6) NIAID Media Inquiries (b)(6) Haskins, Melinda (NIH/NIAID) [E] (b)(6)
Subject: RE: For review again: Response to GoF inquiry from FactCheck.org

Thanks Elizabeth. Some edits for your consideration in the attached. I'm copying Melinda as well for her review.

Defer to Alan on whether DMID should review again.

From: Deatrick, Elizabeth (NIH/NIAID) [E] (b)(6)
Sent: Thursday, July 22, 2021 4:33 PM
To: Embry, Alan (NIH/NIAID) [E] (b)(6) Selgrade, Sara (NIH/NIAID) [E] (b)(6)
Cc: NIAID OCGR NSWB (b)(6) NIAID Media Inquiries (b)(6)
Subject: For review again: Response to GoF inquiry from FactCheck.org

Good afternoon,

DMID has reviewed our response to FactCheck.org on GoF research, but recommended that we run the copy past you one more time before moving it forward in the clearance process. Please let me know if you have any notes on the attached clean document.

Best,
Elizabeth Deatrick
Technical Writer-Editor
Office of Communications and Government Relations
National Institute of Allergy and Infectious Diseases (NIAID)
(b)(6)

Please note that I am not a spokesperson for NIAID and should not be quoted as such.

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From: Routh, Jennifer (NIH/NIAID) [E]
Sent: Thu, 22 Jul 2021 20:55:06 +0000
To: Selgrade, Sara (NIH/NIAID) [E];Deatrick, Elizabeth (NIH/NIAID) [E];Embry, Alan (NIH/NIAID) [E];Ford, Andrew (NIH/NIAID) [E];Billet, Courtney (NIH/NIAID) [E];NIAID BUGS
Cc: NIAID OCGR NSWB;NIAID Media Inquiries;Haskins, Melinda (NIH/NIAID) [E]
Subject: RE: For review again: Response to GoF inquiry from FactCheck.org
Attachments: Response to FactCheck JR ed ae cb AQF clean_ss.docx
Importance: High

I am adding BUGS, Andrew and Courtney to this thread so we are all on the same thread. The original response pulled from cleared language. I'd like to get this finalized ASAP. We really need to move this forward.

Jennifer Routh [E]
News and Science Writing Branch
Office of Communications and Government Relations
National Institute of Allergy and Infectious Diseases (NIAID)
NIH/HHS
31 Center Drive Room 7A17C
Bethesda, MD 20892
Direct: (b)(6)
(b)(6)

From: Selgrade, Sara (NIH/NIAID) [E] <(b)(6)
Sent: Thursday, July 22, 2021 4:49 PM
To: Deatrick, Elizabeth (NIH/NIAID) [E] <(b)(6)>; Embry, Alan (NIH/NIAID) [E] (b)(6)
Cc: NIAID OCGR NSWB (b)(6) ; NIAID Media Inquiries (b)(6) ; Haskins, Melinda (NIH/NIAID) [E] (b)(6)
Subject: RE: For review again: Response to GoF inquiry from FactCheck.org

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Defer to Alan on whether DMID should review again.

From: Deatrick, Elizabeth (NIH/NIAID) [E] <(b)(6)
Sent: Thursday, July 22, 2021 4:33 PM
To: Embry, Alan (NIH/NIAID) [E] (b)(6) Selgrade, Sara (NIH/NIAID) [E] (b)(6)
Cc: NIAID OCGR NSWB <(b)(6) NIAID Media Inquiries (b)(6)
Subject: For review again: Response to GoF inquiry from FactCheck.org

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Technical Writer-Editor
Office of Communications and Government Relations
National Institute of Allergy and Infectious Diseases (NIAID)
(b)(6)

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From: Embry, Alan (NIH/NIAID) [E]
Sent: Thu, 22 Jul 2021 18:16:50 +0000
To: Billet, Courtney (NIH/NIAID) [E];Deatrick, Elizabeth (NIH/NIAID) [E];Stover, Kathy (NIH/NIAID) [E]
Cc: NIAID OCGR NSWB
Subject: RE: For review: GoF respond to FactCheck.org
Attachments: Response to FactCheck JR ed clean ae.docx

For consideration, in the attached is alternative language developed for responses on this topic.
Thanks,
Alan

From: Embry, Alan (NIH/NIAID) [E]
Sent: Thursday, July 22, 2021 1:46 PM
To: Billet, Courtney (NIH/NIAID) [E] (b)(6); Deatrick, Elizabeth (NIH/NIAID) [E] (b)(6); Stover, Kathy (NIH/NIAID) [E] (b)(6)
Cc: NIAID OCGR NSWB (b)(6)
Subject: RE: For review: GoF respond to FactCheck.org

Courtney, Elizabeth,

A couple of suggestions in the attached. For requests on this topic, I would suggest having BUGS review too.

Thanks,
Alan

From: Billet, Courtney (NIH/NIAID) [E] (b)(6)
Sent: Thursday, July 22, 2021 12:16 PM
To: Deatrick, Elizabeth (NIH/NIAID) [E] (b)(6); Stover, Kathy (NIH/NIAID) [E] (b)(6); Embry, Alan (NIH/NIAID) [E] (b)(6)
Cc: NIAID OCGR NSWB (b)(6)
Subject: RE: For review: GoF respond to FactCheck.org

I need to defer to Alan for the final word as the SME here.
I'd recommend adding a simple statement at the end.
(b)(5)

From: Deatrick, Elizabeth (NIH/NIAID) [E] (b)(6)
Sent: Thursday, July 22, 2021 10:42 AM
To: Stover, Kathy (NIH/NIAID) [E] (b)(6); Billet, Courtney (NIH/NIAID) [E] (b)(6); Embry, Alan (NIH/NIAID) [E] (b)(6)

Cc: NIAID OCGR NSWB <(b)(6)
Subject: For review: GoF respond to FactCheck.org

Good morning,

Yesterday, we received a media inquiry from FactCheck.org regarding the exchange that Dr. Fauci had with Sen. Paul, and asking specifically about the paper that Sen. Paul cited. We've drafted the attached response based on language from the Leg Team—would you be able to review this, please? If you recommend it, I will send for OCPL review before clearance.

The writer told us their deadline is noon today, but I've asked if they could extend it.

Best,
Elizabeth Deatrick
Technical Writer-Editor
Office of Communications and Government Relations
National Institute of Allergy and Infectious Diseases (NIAID)
(b)(6)

Please note that I am not a spokesperson for NIAID and should not be quoted as such.

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From: Myles, Renate (NIH/OD) [E]
Sent: Mon, 24 May 2021 21:18:24 +0000
To: Embry, Alan (NIH/NIAID) [E];Tucker, Jessica (NIH/OD) [E]
Cc: Fine, Amanda (NIH/OD) [E];Wojtowicz, Emma (NIH/OD) [E];Billet, Courtney (NIH/NIAID) [E];Stover, Kathy (NIH/NIAID) [E];Routh, Jennifer (NIH/NIAID) [E];Jorgenson, Lyric (NIH/OD) [E]
Subject: RE: PLEASE CONFIRM: Background/TPs/QAs
Attachments: 2-Backgrounder_GOF_WIV_5.24.2021.docx, 3-TPs_GOF_WIV_05.24.2021.docx

Okay, thanks Alan. Clean versions with changes are attached for everyone's reference. Please replace previous versions with the these.

From: Embry, Alan (NIH/NIAID) [E] <(b)(6)>
Sent: Monday, May 24, 2021 4:52 PM
To: Myles, Renate (NIH/OD) [E] <(b)(6)>; Tucker, Jessica (NIH/OD) [E] <(b)(6)>
Cc: Fine, Amanda (NIH/OD) [E] <(b)(6)>; Wojtowicz, Emma (NIH/OD) [E] <(b)(6)>; Billet, Courtney (NIH/NIAID) [E] <(b)(6)>; Stover, Kathy (NIH/NIAID) [E] <(b)(6)>; Routh, Jennifer (NIH/NIAID) [E] <(b)(6)>; Jorgenson, Lyric (NIH/OD) [E] <(b)(6)>
Subject: RE: PLEASE CONFIRM: Background/TPs/QAs

Hi Renate,

A minor point in first paragraph of backgrounder (b)(5)
(b)(5)

The two papers are similar, but not exactly the same. As stated, the Baric paper did not involve enhancing the transmissibility or virulence of a (missing an "a") coronavirus. The chimeric virus that was created (SHC014-MA-15) was less pathogenic than the MA15 mouse adapted SARS-CoV-1 parental virus. On that basis, NIAID determined it not to be subject to the pause. However, because the comparator was a mouse-adapted SARS-CoV-1 virus, using the same language as the 2017 paper (original virus) could cause confusion.

Let me know if easier to discuss.

Thanks,
Alan

From: Myles, Renate (NIH/OD) [E] <(b)(6)>
Sent: Monday, May 24, 2021 4:00 PM
To: Tucker, Jessica (NIH/OD) [E] <(b)(6)>; Embry, Alan (NIH/NIAID) [E] <(b)(6)>
Cc: Fine, Amanda (NIH/OD) [E] <(b)(6)>; Wojtowicz, Emma (NIH/OD) [E] <(b)(6)>; Billet, Courtney (NIH/NIAID) [E] <(b)(6)>; Stover, Kathy

(NIH/NIAID) [E] (b)(6) >; Routh, Jennifer (NIH/NIAID) [E] <(b)(6) >; Jorgenson, Lyric (NIH/OD) [E] <(b)(6)
Subject: RE: PLEASE CONFIRM: Background/TPs/QAs

Thanks, Jessica. Good catches on both parts. I made those updates.

Alan: hoping you can answer the question about the two papers. As is, it's a bit confusing.

From: Tucker, Jessica (NIH/OD) [E] (b)(6)
Sent: Monday, May 24, 2021 3:14 PM
To: Myles, Renate (NIH/OD) [E] (b)(6) >; Embry, Alan (NIH/NIAID) [E] (b)(6)
Cc: Fine, Amanda (NIH/OD) [E] (b)(6) Wojtowicz, Emma (NIH/OD) [E] (b)(6) ; Billet, Courtney (NIH/NIAID) [E] (b)(6) ; Stover, Kathy (NIH/NIAID) [E] <(b)(6) >; Routh, Jennifer (NIH/NIAID) [E] (b)(6) Jorgenson, Lyric (NIH/OD) [E] <(b)(6)
Subject: RE: PLEASE CONFIRM: Background/TPs/QAs

Renate,

Thanks. Only had a quick minute to review, but a couple little things I noticed were (both on item 2):

- I thought we ultimately changed this statement slightly after (b)(5) (b)(5)
- The date of the Director's statement is incorrect.

I didn't notice anything else.

Thanks,

Jessica

From: Myles, Renate (NIH/OD) [E] (b)(6)
Sent: Monday, May 24, 2021 2:18 PM
To: Tucker, Jessica (NIH/OD) [E] (b)(6) ; Embry, Alan (NIH/NIAID) [E] (b)(6)
Cc: Fine, Amanda (NIH/OD) [E] (b)(6) ; Wojtowicz, Emma (NIH/OD) [E] (b)(6) ; Billet, Courtney (NIH/NIAID) [E] (b)(6) ; Stover, Kathy (NIH/NIAID) [E] (b)(6) ; Routh, Jennifer (NIH/NIAID) [E] (b)(6)
Subject: PLEASE CONFIRM: Background/TPs/QAs
Importance: High

Hi Jessica and Alan:

I reviewed the backgrounder and TPs/QAs based on what we changed in the actual media QAs last week to ensure consistency (b)(5)
(b)(5) Would you take another quick look to see if you see anything that's a problem? Emma will send it as part of FC's briefing materials for the hearings tomorrow and Wednesday.

Alan: one thing I'm struggling with is (b)(5)
(b)(5)

Thanks,
Renate

Renate Myles, MBA
Acting Associate Director for Communications and Public Liaison
Acting Director, Office of Communications and Public Liaison
National Institutes of Health
Tel: (b)(6)

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From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Thu, 8 Jul 2021 18:14:26 +0000
To: Ford, Andrew (NIH/NIAID) [E];Embry, Alan (NIH/NIAID) [E]
Cc: Post, Diane (NIH/NIAID) [E];Haskins, Melinda (NIH/NIAID) [E];Selgrade, Sara (NIH/NIAID) [E]
Subject: RE: prep
Attachments: Key questions 7.8.21 combined ae2 es.docx

Hi Alan,
More comments from me in the attached version.

Erik

From: Ford, Andrew (NIH/NIAID) [E] (b)(6)
Sent: Thursday, July 8, 2021 1:46 PM
To: Embry, Alan (NIH/NIAID) [E] (b)(6) Stemmy, Erik (NIH/NIAID) [E] (b)(6)
Cc: Post, Diane (NIH/NIAID) [E] (b)(6) Haskins, Melinda (NIH/NIAID) [E] (b)(6); Selgrade, Sara (NIH/NIAID) [E] (b)(6) Ford, Andrew (NIH/NIAID) [E] (b)(6)
Subject: Re: prep

Hey Alan,

Not sure I was supposed to review, but incorporated into the attached version are some edits/responses regarding some of the policy and reporting comments you posed.

Thanks,
Andrew

From: "Embry, Alan (NIH/NIAID) [E]" (b)(6)
Date: Thursday, July 8, 2021 at 12:28 PM
To: "Stemmy, Erik (NIH/NIAID) [E]" (b)(6)
Cc: "Post, Diane (NIH/NIAID) [E]" Ford, Andrew (NIH/NIAID) [E]" (b)(6), "Haskins, Melinda (NIH/NIAID) [E]" (b)(6), Sara Selgrade (b)(6)
Subject: prep

Hi Erik,

Attached is the most recent version of the Q&A document. I would really appreciate it if you could look carefully at the several questions that I flagged.

Thanks,
Alan

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From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Fri, 14 May 2021 18:50:01 +0000
To: Embry, Alan (NIH/NIAID) [E];Hauguel, Teresa (NIH/NIAID) [E]
Subject: RE: Rebuttal to Ebright?

One other rebuttal is to highlight that no function was gained by the chimera. Rs4231 and Rs7237 both could already use human ACE2. https://www.nature.com/articles/s41564-020-0688-y (figure 3) and I don't see anything in the PLoS paper that suggests enhancement beyond WIV1.

From: Embry, Alan (NIH/NIAID) [E] (b)(6)
Sent: Friday, May 14, 2021 2:31 PM
To: Hauguel, Teresa (NIH/NIAID) [E] (b)(6); Stemmy, Erik (NIH/NIAID) [E] (b)(6)
Subject: FW: Rebuttal to Ebright?

fyi

From: Collins, Francis (NIH/OD) [E] (b)(6)
Sent: Friday, May 14, 2021 12:33 PM
To: Fauci, Anthony (NIH/NIAID) [E] (b)(6); Embry, Alan (NIH/NIAID) [E] (b)(6)
Cc: Hallett, Adrienne (NIH/OD) [E] (b)(6); Myles, Renate (NIH/OD) [E] (b)(6)
Subject: Rebuttal to Ebright?

Hi Tony and Alan,

In case I get asked about this latest National Review report, wherein Richard Ebright says that NIH did in fact support GoF research at WIV – what's the rebuttal to his citation of the PLoS Pathogens paper from 2017?

https://www.nationalreview.com/news/biosafety-expert-explains-why-faucis-nih-gain-of-function-testimony-was-demonstrably-false/

https://journals.plos.org/plospathogens/article?id=10.1371/journal.ppat.1006698#abstract0

FC

From: Embry, Alan (NIH/NIAID) [E]
Sent: Mon, 12 Jul 2021 22:50:47 +0000
To: Selgrade, Sara (NIH/NIAID) [E];Stemmy, Erik (NIH/NIAID) [E];Haskins, Melinda (NIH/NIAID) [E]
Subject: RE: Response to Nat Med Q
Attachments: FLIP 2015 Nature Med.docx, FLIP 2017 PLOS Paper.docx

Sara,

Sorry, just getting out of meetings. Attached is content that Erik and I put together on this and PLOS paper. I defer to you for messaging to this audience. (b)(5)
(b)(5)

Will move to others but can revisit as needed.

Thanks,
Alan

From: Selgrade, Sara (NIH/NIAID) [E] (b)(6)
Sent: Monday, July 12, 2021 6:34 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b)(6) ; Haskins, Melinda (NIH/NIAID) [E]
(b)(6)
Cc: Embry, Alan (NIH/NIAID) [E] (b)(6)
Subject: RE: Response to Nat Med Q

What about something like what is below – please correct if I have said something wrong. (b)(5)
(b)(5)

My thought was to explain how you would evaluate for GOF (b)(5)
(b)(5)

(b)(5)

(b)(5)

From: Stemmy, Erik (NIH/NIAID) [E] (b)(6)
Sent: Monday, July 12, 2021 11:39 AM
To: Haskins, Melinda (NIH/NIAID) [E] (b)(6); Selgrade, Sara (NIH/NIAID) [E] (b)(6)
Cc: Embry, Alan (NIH/NIAID) [E] (b)(6)
Subject: Response to Nat Med Q

Hi Melinda and Sara,
I took a stab at a few version of a short response to the Nat Med paper Q. Let me know if you think any of these work with what ASF has requested. Happy to combine or otherwise make any edits you think are needed.

Erik

Erik J. Stemmy, Ph.D.
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases
Phone: (b)(6)
Pronouns: He/Him/His

TITLE

2015 Baric Nature Medicine Paper

The research in this paper was carefully reviewed by experienced NIAID staff in 2015 and determined NOT to be gain-of-function:

- Dr. Baric's comment about a "gain in pathogenesis" refers to a comparison with another artificial chimeric virus that he created in the laboratory.
- This is an incorrect comparator when considering whether there is gain-of-function.
- In fact, both viruses (SHC014-MA15 and Urbani-MA15) are less pathogenic when correctly compared to the parental mouse-adapted SARS-CoV
    - All of the mice infected with SARS-CoV-MA15 died, but the SHC014-MA15 mice had much less lung damage and recovered. This is not a gain of function.
    - A small difference in replication in cells does not equate to a difference in pathogenicity in animals (frequently the case).
- Work was conducted at the University of North Carolina and was NOT supported by NIAID's award to EcoHealth Alliance.

TITLE

TITLE

2017 PLOS Pathogens Paper

The research in this paper **is NOT gain-of-function** because the work did not result in any viruses with increased pathogenicity or transmissibility via the respiratory route in mammals.

- To understand the potential of bat coronaviruses to infect human cells, the researchers put a small piece of newly identified bat coronaviruses (spike) into a larger portion of a well characterized bat coronavirus (WIV1) that has never been demonstrated to infect humans
- Of the 8 viruses they tested, only three were able to be rescued, underscoring that inserting divergent spike proteins into viral model systems (chimeras) is not an inherently risky approach.
- The viruses created did not replicate more efficiently than the wild-type WIV1.
- The WIV-1 backbone and other bat coronaviruses characterized in this study could not have been the source of SARS-CoV-2.
    - WIV1 >6700 nucleotides different (72%) than SARS-CoV-2; other viruses also ~72%
- First study to find all building blocks of SARS-CoV in a single bat population.

TITLE

From: Ghedin, Elodie (NIH/NIAID) [E]
Sent: Thu, 8 Jul 2021 03:02:47 +0000
To: Selgrade, Sara (NIH/NIAID) [E]
Cc: Embry, Alan (NIH/NIAID) [E]
Subject: Re: URGENT for ASF - ASAP: Review Hearing Prep Q&A
Attachments: Key Questions_070721_to Divisions_eg.docx

Hi Sara:
The section more pertinent for my input looked good as is. I added some minor comments in other sections.
Best,
Elodie

From: "Selgrade, Sara (NIH/NIAID) [E]" <(b)(6)
Date: Wednesday, July 7, 2021 at 7:30 PM
To: "Erbelding, Emily (NIH/NIAID) [E]" (b)(6) "Stemmy, Erik (NIH/NIAID) [E]" (b)(6), "Hauguel, Teresa (NIH/NIAID) [E]" (b)(6) "Mulach, Barbara (NIH/NIAID) [E]" (b)(6), "Ford, Andrew (NIH/NIAID) [E]" (b)(6) "Fenton, Matthew (NIH/NIAID) [E]" (b)(6) "Linde, Emily (NIH/NIAID) [E]" (b)(6) "Ghedin, Elodie (NIH/NIAID) [E]" (b)(6)
Cc: NIAID OCGR Leg (b)(6), "Embry, Alan (NIH/NIAID) [E]" (b)(6) "Billet, Courtney (NIH/NIAID) [E]" (b)(6), "Folkers, Greg (NIH/NIAID) [E]" (b)(6), NIAID BUGS (b)(6), NIAID DIR-OCGR (b)(6) "Holland, Steven (NIH/NIAID) [E]" (b)(6)
Subject: URGENT for ASF - ASAP: Review Hearing Prep Q&A

Hello all,

Background
As you are aware, Dr. Fauci will testify before a hearing of the Senate Health, Education, Labor, and Pensions (HELP) Committee on COVID-19 on July 20th. In preparation for this hearing, NIAID OD has assembled the attached Q&A for Dr. Fauci's reference.

Action Item
We would appreciate your review of the attached document for accuracy and completeness **ASAP.** Please note there are comments included for your consideration and input, where relevant. If there are areas where you feel information is duplicative, or other questions you think could be raised, please let us know.

Thank you for your help on this quick turnaround request for Dr. Fauci. Please let us know if you have any questions.

Thanks,

Sara

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From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Thu, 8 Jul 2021 00:50:58 +0000
To: Selgrade, Sara (NIH/NIAID) [E];Erbelding, Emily (NIH/NIAID) [E];Hauguel, Teresa (NIH/NIAID) [E];Mulach, Barbara (NIH/NIAID) [E];Ford, Andrew (NIH/NIAID) [E];Fenton, Matthew (NIH/NIAID) [E];Linde, Emily (NIH/NIAID) [E];Ghedin, Elodie (NIH/NIAID) [E]
Cc: NIAID OCGR Leg;Embry, Alan (NIH/NIAID) [E];Billet, Courtney (NIH/NIAID) [E];Folkers, Greg (NIH/NIAID) [E];NIAID BUGS;NIAID DIR-OCGR;Holland, Steven (NIH/NIAID) [E]
Subject: RE: URGENT for ASF - ASAP: Review Hearing Prep Q&A
Attachments: Key Questions_070721_to Divisions es.docx

Hi Sara,
Some suggested edits and comments from me in the attached version.

Erik

From: Selgrade, Sara (NIH/NIAID) [E] <(b)(6)
Sent: Wednesday, July 7, 2021 7:30 PM
To: Erbelding, Emily (NIH/NIAID) [E](b)(6); Stemmy, Erik (NIH/NIAID) [E] (b)(6) Hauguel, Teresa (NIH/NIAID) [E](b)(6); Mulach, Barbara (NIH/NIAID) [E](b)(6) Ford, Andrew (NIH/NIAID) [E](b)(6) Fenton, Matthew (NIH/NIAID) [E](b)(6); Linde, Emily (NIH/NIAID) [E] (b)(6); Ghedin, Elodie (NIH/NIAID) [E](b)(6)
Cc: NIAID OCGR Leg <(b)(6); Embry, Alan (NIH/NIAID) [E] (b)(6); Billet, Courtney (NIH/NIAID) [E](b)(6); Folkers, Greg (NIH/NIAID) [E](b)(6) NIAID BUGS <(b)(6)>; NIAID DIR-OCGR (b)(6) Holland, Steven (NIH/NIAID) [E](b)(6)
Subject: URGENT for ASF - ASAP: Review Hearing Prep Q&A
Importance: High

Hello all,

Background
As you are aware, Dr. Fauci will testify before a hearing of the Senate Health, Education, Labor, and Pensions (HELP) Committee on COVID-19 on July 20th. In preparation for this hearing, NIAID OD has assembled the attached Q&A for Dr. Fauci's reference.

Action Item
We would appreciate your review of the attached document for accuracy and completeness **ASAP.** Please note there are comments included for your consideration and input, where relevant. If there are areas where you feel information is duplicative, or other questions you think could be raised, please let us know.

Thank you for your help on this quick turnaround request for Dr. Fauci. Please let us know if you have any questions.

Thanks,

Sara

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From: Selgrade, Sara (NIH/NIAID) [E]
Sent: Wed, 7 Jul 2021 23:30:14 +0000
To: Erbelding, Emily (NIH/NIAID) [E];Stemmy, Erik (NIH/NIAID) [E];Hauguel, Teresa (NIH/NIAID) [E];Mulach, Barbara (NIH/NIAID) [E];Ford, Andrew (NIH/NIAID) [E];Fenton, Matthew (NIH/NIAID) [E];Linde, Emily (NIH/NIAID) [E];Ghedin, Elodie (NIH/NIAID) [E]
Cc: NIAID OCGR Leg;Embry, Alan (NIH/NIAID) [E];Billet, Courtney (NIH/NIAID) [E];Folkers, Greg (NIH/NIAID) [E];NIAID BUGS;NIAID DIR-OCGR;Holland, Steven (NIH/NIAID) [E]
Subject: URGENT for ASF - ASAP: Review Hearing Prep Q&A
Attachments: Key Questions_070721_to Divisions.docx
Importance: High

Hello all,

Background

As you are aware, Dr. Fauci will testify before a hearing of the Senate Health, Education, Labor, and Pensions (HELP) Committee on COVID-19 on July 20th. In preparation for this hearing, NIAID OD has assembled the attached Q&A for Dr. Fauci's reference.

Action Item

We would appreciate your review of the attached document for accuracy and completeness **ASAP.** Please note there are comments included for your consideration and input, where relevant. If there are areas where you feel information is duplicative, or other questions you think could be raised, please let us know.

Thank you for your help on this quick turnaround request for Dr. Fauci. Please let us know if you have any questions.

Thanks,
Sara

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Withheld pursuant to exemption

(b)(5)

of the Freedom of Information and Privacy Act

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Withheld pursuant to exemption

(b)(5)

of the Freedom of Information and Privacy Act

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Withheld pursuant to exemption

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of the Freedom of Information and Privacy Act

Page 200 of 226

Withheld pursuant to exemption

(b)(5)

of the Freedom of Information and Privacy Act

From:	Greer, Jenny (NIH/NIAID) [E]
To:	(b)(6) (b)(6)
Cc:	Stemmy, Erik (NIH/NIAID) [E]; Kirker, Mary (NIH/NIAID) [E]; Glowinski, Irene (NIH/NIAID) [E]; Ford, Andrew (NIH/NIAID) [E]
Subject:	Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER
Date:	Thursday, July 7, 2016 10:00:17 AM
Attachments:	110964 Daszak GoF Determination Letter 7-7-2016.pdf

Aleksei and Peter,

Please find attached a determination regarding your grant.

As always, don't hesitate to contact us with any questions.

All the best,

Jenny

Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
5601 Fishers Lane, Room 4E49, MSC 9833
Bethesda, MD 20892-9824
Phone: 240-669-2949
Email: (b)(6)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

July 7, 2016

Mr. Aleksei Chmura
Senior Coordinator of Operations
EcoHealth Alliance
460 W. 34th Street – 17th Floor
New York, NY 10001

RE: 5 R01AI110964-03

Dear Mr. Chmura:

Thank you for your correspondence of June 28th, 2016, regarding the October 17, 2014 White House announcement of a U.S. Government-wide pause on certain gain-of-function (GoF) experiments and its potential impact on your research (http://www.whitehouse.gov/blog/2014/10/17/doing-diligence-assess-risks-and-benefits-life-sciences-gain-function-research). The research funding pause pertains to GoF research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the resulting virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.

NIAID reviewed the original grant application, and the additional information provided by you, and made the following assessments regarding Aim 3 of the above-referenced grant:

- NIAID is in agreement that the work proposed under Aim 3 to generate MERS-like or SARS-like chimeric coronaviruses (CoVs) is not subject to the GoF research funding pause. This determination is based on the following: (1) the chimeras will contain only S glycoprotein genes from phylogenetically distant bat CoVs; and (2) recently published work demonstrating that similar chimeric viruses exhibited reduced pathogenicity. Therefore it is not reasonably anticipated that these chimeric viruses will have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.
- NIAID acknowledges that if any of the MERS-like or SARS-like chimeras generated under this grant show evidence of enhanced virus growth greater than 1 log over the parental backbone strain, Dr. Daszak will immediately stop all experiments with these viruses and provide the NIAID Program Officer and Grants Management Specialist, and Wuhan Institute of Virology Institutional Biosafety Committee, with the relevant data and information related to these unanticipated outcomes.

Please remember that the institution must comply in full with all terms and conditions placed on this grant. As indicated above, NIAID determinations are based on information from multiple sources, but primarily on our communication with you about the details of your proposed experiments and your research results. Should NIAID's determination change based on information obtained through the U.S. Government GoF deliberative process, described here http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf, you will be notified; however, until such time, or until the GoF research funding pause is lifted, NIAID's determination, indicated above, is final.

Please let us know if you have any questions, or if you require additional information.

Sincerely,

(b)(6)

Jenny Greer
Grants Management Specialist
NIAID/NIH/DHHS

(b)(6)

Erik J. Stemmy, Ph.D.
Program Officer
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

CC: Dr. Peter Daszak
Ms. Mary Kirker
Dr. Irene Glowinski
Dr. Andrew Ford

From: Peter Daszak
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: Greer, Jenny (NIH/NIAID) [E]; Aleksei Chmura
Subject: RE: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER
Date: Tuesday, June 28, 2016 8:02:47 AM
Importance: High

Sorry for not responding more quickly Erik – I've been at meetings for the last couple of weeks. You are correct to identify a mistake in our letter. UNC has no oversight of the chimera work, all of which will be conducted at the Wuhan Institute of Virology. This was a clerical error because we used some language that I asked Ralph Baric to give me because I wanted to make sure we followed an approach that has some precedence.

We will clarify tonight with Prof. Zhengli Shi exactly who will be notified if we see enhanced replication, and then amend and re-send the letter to you so it is clear. I will also confirm with Zhengli the make-up of the Wuhan Institute of Virology's Institutional Biosafety Committee. However, my understanding is that I will be notified straight away, as PI, and that I can then notify you at NIAID.

Apologies for the error!

Cheers,

Peter

Peter Daszak
President

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

From: Stemmy, Erik (NIH/NIAID) [E] (b)(6)
Sent: Monday, June 27, 2016 3:49 PM
To: Peter Daszak

Cc: Greer, Jenny (NIH/NIAID) [E]; Aleksei Chmura
Subject: RE: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Hi Peter,
Just wanted to follow up with you to see if you had a chance to look in to the IBC question I sent earlier this month. Please let us know.

Thanks,
Erik

Sent with Good (www.good.com)

-----Original Message-----
From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Friday, June 17, 2016 03:38 PM Eastern Standard Time
To: Dr. Peter Daszak
Cc: Greer, Jenny (NIH/NIAID) [E]; Aleksei Chmura
Subject: RE: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Hi Peter,
Thanks very much for providing the additional information. I did have a couple of follow up questions for you. Can you clarify where the work with the chimeric viruses will actually be performed? Your original application described the BSL3 facilities at the Wuhan Institute of Virology, but your response letter indicated that you would notify the UNC IBC if you observed enhanced replication with any of the proposed chimeras. Therefore it's not clear where the studies are being performed. Please also clarify whether EcoHealth Alliance has its own IBC, and how the UNC IBC would be involved in the oversight of this work.

Many thanks,
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
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Email: (b)(6)

From: Greer, Jenny (NIH/NIAID) [E]
Sent: Thursday, June 09, 2016 5:56 PM
To: Aleksei Chmura (b)(6)
Cc: Dr. Peter Daszak (b)(6) Stemmy, Erik (NIH/NIAID) [E] (b)(6)
Subject: RE: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Thank you for your quick response!

Jenny

Jenny Greer
Grants Management Specialist
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5601 Fishers Lane, Room 4E49, MSC 9833
Bethesda, MD 20892-9824
Phone: 240-669-2949
Email: (b)(6)

From: Aleksei Chmura [mailto (b)(6)
Sent: Thursday, June 09, 2016 5:43 PM
To: Greer, Jenny (NIH/NIAID) [E] (b)(6)
Cc: Dr. Peter Daszak (b)(6) ; Stemmy, Erik (NIH/NIAID) [E] (b)(6) ; Kirker, Mary (NIH/NIAID) [E] (b)(6) ; Glowinski, Irene (NIH/NIAID) [E] (b)(6) ; Ford, Andrew (NIH/NIAID) [E] (b)(6)
Subject: Re: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Dear Jenny,

I concur with the detailed response that Dr. Daszak just sent to you in response to the Gain of Function questions in your email from 28th May. Please let me know anytime, if you require

any further information.

Many thanks!

Aleksei Chmura
Authorized Organizational Representative &
Senior Coordinator of Operations

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(mobile)
Aleksei MacDurian (Skype)

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On Jun 9, 2016, at 17:37, Greer, Jenny (NIH/NIAID) [E] (b)(6) wrote:

Peter,

Thank you for providing this response. We will review it shortly. In the meantime, I look forward to receiving concurrence from your authorized business official.

Thanks again!

Jenny

Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
5601 Fishers Lane, Room 4E49, MSC 9833
Bethesda, MD 20892-9824
Phone: 240-669-2949
Email: (b)(6)

From: Peter Daszak (b)(6)
Sent: Thursday, June 09, 2016 5:23 PM

To: Greer, Jenny (NIH/NIAID) [E] (b)(6) ; Aleksei Chmura (b)(6)

Cc: Stemmy, Erik (NIH/NIAID) [E] (b)(6) >; Kirker, Mary (NIH/NIAID) [E] (b)(6) Glowinski, Irene (NIH/NIAID) [E] >; Ford, Andrew (NIH/NIAID) [E] (b)(6)

Subject: RE: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Importance: High

Dear Jenny and Erik,

Please find our response letter to your email below, attached. I really appreciate you giving us the chance to clarify these details and look forward to your decision on our proposed work. As stated clearly in the letter, we will not (of course) move forward with any of the proposed work in Specific Aim #3 until we hear back from you with directions.

Cheers,

Peter

Peter Daszak
President

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From: Greer, Jenny (NIH/NIAID) [E] (b)(6)
Sent: Saturday, May 28, 2016 5:15 PM
To: Aleksei Chmura
Cc: Stemmy, Erik (NIH/NIAID) [E]; Peter Daszak; Kirker, Mary (NIH/NIAID) [E]; Glowinski, Irene (NIH/NIAID) [E]; Ford, Andrew (NIH/NIAID) [E]
Subject: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Dear Mr. Chmura,

Please find attached an important message about this grant. Your immediate response will be much appreciated.

All the best,

Jenny

Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
5601 Fishers Lane, Room 4E49, MSC 9833
Bethesda, MD 20892-9824
Phone: 240-669-2949
Email: (b)(6)

"Effective October 1, 2014, NIH closeout policy has changed (see NOT-OD-14-084). In order to avoid unilateral closeout, final reports must be submitted in a timely manner. Failure to submit accurate final reports could result in enforcement actions such as revisions to NOA funding levels, or delay in future funding."

From: Aleksei Chmura
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: Dr. Peter Daszak; Greer, Jenny (NIH/NIAID) [E]
Subject: Re: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER
Date: Tuesday, June 28, 2016 11:58:13 PM
Attachments: Response to GoF letter, 5R01AI110964 - 03 DASZAK, PETER.pdf

---

Dear Erik,

Prof. Zhengli Shi has confirmed that the Wuhan Institute of Virology Institutional Biosafety Committee would be immediately notified as per Peter's comments below. Please find the updated letter attached.

If you require further details, let us know anytime.

Sincerely,

-Aleksei

Aleksei Chmura
Authorized Organizational Representative &
Senior Coordinator of Operations

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On Jun 28, 2016, at 11:22, Stemmy, Erik (NIH/NIAID) [E] (b)(6) wrote:

Thanks Peter! Please have Aleksei send us an updated letter once you have one.

Erik

Sent with Good (www.good.com)

-----Original Message-----
From: Peter Daszak (b)(6)
Sent: Tuesday, June 28, 2016 08:02 AM Eastern Standard Time

EcoHealth Alliance

Dear Drs. Greer and Stemmy,

June 8, 2016

We appreciate your rapid review of our proposed work for year 3 of our R01 (5R01AI110964-03). We have provided the details you requested, below, including alternative strategies if we remove work that could be deemed gain of function. We look forward to your response and will modify our workplan accordingly. In the meantime, please rest assured that none of the proposed work for Specific Aim #3 that you have requested information about will begin.

Determination as to whether the above research does or does not include GoF work subject to the funding pause. Please provide a detailed explanation for this determination, including, but not limited to, descriptions of the MERS and MERS-like chimeric CoVs that you propose to create, and detailed descriptions of the experiments you plan to conduct. Your determination should also include whether each chimeric virus is reasonably anticipated to exhibit enhanced pathogenicity and/or transmissibility in mammals via the respiratory route compared to wild type MERS-CoV.

Firstly, we would like to reiterate that this work is *proposed* for year 3, and none has been conducted to date. Furthermore, we will not proceed with any of this unless we are given the go-ahead by NIAID. The goal of our proposed work to construct MERS and MERS-like chimeric CoVs is to understand the potential origins of MERS-CoV in bats by studying bat MERS-like CoVs in detail. The chimeric viruses will be used to ascertain receptor usage and infectivity of bat MERS-related CoVs *in vitro* and in a mouse model. To achieve this purpose, our aim is to firstly construct a MERS-CoV infectious clone based on the genomic sequence of EMC2012 (GenBank no. NC_019843) and then chimeric CoVs with the replacement of the spike envelope genes from bat derived MERS-like CoVs. We have very recently discovered a small number (9 different strains) of bat MERS-like CoVs in 99 samples from bats in Guangxi, Guangdong, and Szechuan provinces. Phylogenetically, these bat viruses are not very close to MERS-CoV (only 63-66% homology to the S-protein of MERS-CoV).

We aim to test the chimeric viruses for receptor usage of DPP4 (the MERS-CoV receptor) in cells and then in DPP4 transgenic mice, to see if these bat viruses have any capacity to use the same receptor. That said, given the phylogenetic distance from MERS-CoV, we believe it is *highly unlikely* that these bat spike proteins attach to DPP4, and if so, that they would have any pathogenic potential. Finally, should any of these recombinants show evidence of enhanced virus growth >1 log in cells expressing the human, bat, mouse or other DPP4 receptor over wildtype parental backbone MERS-CoV strain or grow more efficiently in human airway epithelial cells, we will immediately: i) stop all experiments with the mutant, ii) inform our NIAID Program Officer and the Wuhan Institute of Virology IBC of these results and iii) participate in decision making trees to decide appropriate paths forward.

In addition, your progress report makes reference to two chimeric bat SARS-like CoVs constructed on a WIV-1 backbone.
NIAID requests additional information on these strains of SARS-like CoVs, including: the dates the strains were created; whether the chimeric viruses exhibit enhanced pathogenicity and/or transmissibility in

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mammals via the respiratory route compared to wild type SARS-CoV; and what research plans you have for these chimeric viruses.

These two chimeric bat-like CoVs were constructed on September 24, 2015. They use the backbone of a group 2b SARS-like bat CoV WIV1 and the spike proteins of two newly discovered bat SL-CoVs (Rs7327 and RsSHC014). The construction of these chimeric viruses aims to understand the receptor usage and infectivity of bat SL-CoVs that may be progenitors of SARS-CoV. We have not yet tested the pathogenicity of these viruses in animals.

We believe that this work would not be considered GoF because the pause specifically targeted experiments that altered the pathogenicity or transmissibility of SARS-CoV, MERS-CoV and any influenza virus. Our molecular clone is WIV1, which is a group 2b SARS-like bat coronavirus that has never been demonstrated to infect humans or cause human disease. It is about 10% different from SARS-CoV. Thus, we feel that introducing other group 2b SARS-like bat coronavirus spike glycoproteins into WIV1 is not subject to the pause. Moreover, we are introducing progressively more distant S glycoproteins into WIV1 (The RBD of Rs7327 differs from WIV1 in several amino acid residues while RsSHC014 is even more distantly related phylogenetically), so it seems progressively less likely that any of these viruses would be more pathogenic or transmissible than the SARS-CoV. This is further supported by the fact that Prof. Ralph Baric's group (Menacherya *et al*., 2015, Nature Medicine, 21 (12):1508-1512; Menacherya *et al*., 2016, PNAS, 113 (11): 3048-3053) took WIV1 spike and inserted it onto a SARS-CoV backbone and showed reduced pathogenicity in mice with human ACE-2 relative to SARS-CoV (mortality rates were much lower, therefore this is *loss-of-function*). This strongly suggests that the chimeric bat spike/bat backbone viruses should not have enhanced pathogenicity in animals.

Finally, as proposed above for the MERS-like viruses, should any of these recombinants show evidence of enhanced virus growth >1 log in cells expressing the human, bat, mouse or civet receptor over wildtype parental backbone SARS-CoV strain or grow more efficiently in human airway epithelial cells, we will immediately: i) stop all experiments with the mutant, ii) inform our NIAID Program Officer and the Wuhan Institute of Virology IBC of these results and iii) participate in decision making trees to decide appropriate paths forward.

If it is determined that the above research DOES include GoF work subject to the funding pause, provide detailed information on what research will remain viable with the removal of the GoF work and appropriate budget adjustments. Options include:

- For the specific aims that propose GoF work, provide a detailed description of changes that can be made to remove the GoF work but maintain the specific aim(s); or
- Remove the specific aims and experiments that are subject to the pause from the Research Plan and request to have the award budget renegotiated.

If these proposed activities within Specific Aim #3 are considered gain of function, we would propose changing them as follows:

1) Instead of the proposed work on MERS-like chimeric CoVs, we would
    a. model the 3-D structure of bat MERS-like CoV spike to assess its potential to bond to DPP4; and
    b. build pseudoviruses with MERS-like CoV spike to conduct experiments for DPP4 binding.

2) Instead of the proposed work on SARS-like chimeric bat CoVs, we would build pseudoviruses with the spike proteins from these viruses and assess receptor binding *in vitro*.

We look forward to your response to our letter and will not conduct any of this proposed work until we hear back from you.

Yours sincerely,

(b)(6)

Dr. Peter Daszak

PI
President and Chief Scientist
EcoHealth Alliance

Tel: (b)(6)
e-mail: (b)(6)

To: Stemmy, Erik (NIH/NIAID) [E]
Cc: Greer, Jenny (NIH/NIAID) [E]; Aleksei Chmura
Subject: RE: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Sorry for not responding more quickly Erik – I've been at meetings for the last couple of weeks. You are correct to identify a mistake in our letter. UNC has no oversight of the chimera work, all of which will be conducted at the Wuhan Institute of Virology. This was a clerical error because we used some language that I asked Ralph Baric to give me because I wanted to make sure we followed an approach that has some precedence.

We will clarify tonight with Prof. Zhengli Shi exactly who will be notified if we see enhanced replication, and then amend and re-send the letter to you so it is clear. I will also confirm with Zhengli the make-up of the Wuhan Institute of Virology's Institutional Biosafety Committee. However, my understanding is that I will be notified straight away, as PI, and that I can then notify you at NIAID.

Apologies for the error!

Cheers,

Peter

Peter Daszak
President

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From: Stemmy, Erik (NIH/NIAID) [E] (b)(6)
Sent: Monday, June 27, 2016 3:49 PM
To: Peter Daszak
Cc: Greer, Jenny (NIH/NIAID) [E]; Aleksei Chmura
Subject: RE: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Hi Peter,

Just wanted to follow up with you to see if you had a chance to look in to the IBC question I sent earlier this month. Please let us know.

Thanks,
Erik

Sent with Good (www.good.com)

-----Original Message-----
From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Friday, June 17, 2016 03:38 PM Eastern Standard Time
To: Dr. Peter Daszak
Cc: Greer, Jenny (NIH/NIAID) [E]; Aleksei Chmura
Subject: RE: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Hi Peter,
Thanks very much for providing the additional information. I did have a couple of follow up questions for you. Can you clarify where the work with the chimeric viruses will actually be performed? Your original application described the BSL3 facilities at the Wuhan Institute of Virology, but your response letter indicated that you would notify the UNC IBC if you observed enhanced replication with any of the proposed chimeras. Therefore it's not clear where the studies are being performed. Please also clarify whether EcoHealth Alliance has its own IBC, and how the UNC IBC would be involved in the oversight of this work.

Many thanks,
Erik

Erik J. Stemmy, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases NIAID/NIH/HHS
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Getting ready to publish? Share the good news with your program officer asap! NIAID may be able to help publicize your article. And, remember to list your NIAID grant or contract number in the publication.
****

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From: Greer, Jenny (NIH/NIAID) [E]
Sent: Thursday, June 09, 2016 5:56 PM
To: Aleksei Chmura (b)(6)
Cc: Dr. Peter Daszak (b)(6); Stemmy, Erik (NIH/NIAID) [E] (b)(6)
Subject: RE: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Thank you for your quick response!

Jenny

Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
5601 Fishers Lane, Room 4E49, MSC 9833
Bethesda, MD 20892-9824
Phone: 240-669-2949
Email: (b)(6)

From: Aleksei Chmura (b)(6)
Sent: Thursday, June 09, 2016 5:43 PM
To: Greer, Jenny (NIH/NIAID) [E] (b)(6)
Cc: Dr. Peter Daszak (b)(6); Stemmy, Erik (NIH/NIAID) [E] (b)(6) Kirker, Mary (NIH/NIAID) [E] (b)(6) Glowinski, Irene (NIH/NIAID) [E] (b)(6); Ford, Andrew (NIH/NIAID) [E] (b)(6)
Subject: Re: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Dear Jenny,

I concur with the detailed response that Dr. Daszak just sent to you in response to the Gain of Function questions in your email from 28th May. Please let me know

anytime, if you require any further information.

Many thanks!

Aleksei Chmura
Authorized Organizational Representative &
Senior Coordinator of Operations

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On Jun 9, 2016, at 17:37, Greer, Jenny (NIH/NIAID) [E]
(b)(6) > wrote:

Peter,

Thank you for providing this response. We will review it shortly. In the meantime, I look forward to receiving concurrence from your authorized business official.

Thanks again!

Jenny

Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
5601 Fishers Lane, Room 4E49, MSC 9833
Bethesda, MD 20892-9824
Phone: 240-669-2949
Email (b)(6)

From: Peter Daszak (b)(6)
Sent: Thursday, June 09, 2016 5:23 PM
To: Greer, Jenny (NIH/NIAID) [E] (b)(6); Aleksei Chmura (b)(6)
Cc: Stemmy, Erik (NIH/NIAID) [E] (b)(6); Kirker, Mary (NIH/NIAID) [E] (b)(6); Glowinski, Irene (NIH/NIAID) [E] (b)(6); Ford, Andrew (NIH/NIAID) [E] (b)(6)
Subject: RE: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER
Importance: High

Dear Jenny and Erik,

Please find our response letter to your email below, attached. I really appreciate you giving us the chance to clarify these details and look forward to your decision on our proposed work. As stated clearly in the letter, we will not (of course) move forward with any of the proposed work in Specific Aim #3 until we hear back from you with directions.

Cheers,

Peter

Peter Daszak
President

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

From: Greer, Jenny (NIH/NIAID) [E] (b)(6)
Sent: Saturday, May 28, 2016 5:15 PM
To: Aleksei Chmura

Cc: Stemmy, Erik (NIH/NIAID) [E]; Peter Daszak; Kirker, Mary (NIH/NIAID) [E]; Glowinski, Irene (NIH/NIAID) [E]; Ford, Andrew (NIH/NIAID) [E]
Subject: Grant Number: 5R01AI110964 - 03 PI Name: DASZAK, PETER

Dear Mr. Chmura,

Please find attached an important message about this grant. Your immediate response will be much appreciated.

All the best,

Jenny

Jenny Greer
Grants Management Specialist
DHHS/NIH/NIAID/DEA/GMP
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"Effective October 1, 2014, NIH closeout policy has changed (see NOT-OD-14-084). In order to avoid unilateral closeout, final reports must be submitted in a timely manner. Failure to submit accurate final reports could result in enforcement actions such as revisions to NOA funding levels, or delay in future funding."

EcoHealth Alliance

Dear Drs. Greer and Stemmy,

June 8, 2016

We appreciate your rapid review of our proposed work for year 3 of our R01 (5R01AI110964-03). We have provided the details you requested, below, including alternative strategies if we remove work that could be deemed gain of function. We look forward to your response and will modify our workplan accordingly. In the meantime, please rest assured that none of the proposed work for Specific Aim #3 that you have requested information about will begin.

Determination as to whether the above research does or does not include GoF work subject to the funding pause. Please provide a detailed explanation for this determination, including, but not limited to, descriptions of the MERS and MERS-like chimeric CoVs that you propose to create, and detailed descriptions of the experiments you plan to conduct. Your determination should also include whether each chimeric virus is reasonably anticipated to exhibit enhanced pathogenicity and/or transmissibility in mammals via the respiratory route compared to wild type MERS-CoV.

Firstly, we would like to reiterate that this work is *proposed* for year 3, and none has been conducted to date. Furthermore, we will not proceed with any of this unless we are given the go-ahead by NIAID. The goal of our proposed work to construct MERS and MERS-like chimeric CoVs is to understand the potential origins of MERS-CoV in bats by studying bat MERS-like CoVs in detail. The chimeric viruses will be used to ascertain receptor usage and infectivity of bat MERS-related CoVs *in vitro* and in a mouse model. To achieve this purpose, our aim is to firstly construct a MERS-CoV infectious clone based on the genomic sequence of EMC2012 (GenBank no. NC_019843) and then chimeric CoVs with the replacement of the spike envelope genes from bat derived MERS-like CoVs. We have very recently discovered a small number (9 different strains) of bat MERS-like CoVs in 99 samples from bats in Guangxi, Guangdong, and Szechuan provinces. Phylogenetically, these bat viruses are not very close to MERS-CoV (only 63-66% homology to the S-protein of MERS-CoV).

We aim to test the chimeric viruses for receptor usage of DPP4 (the MERS-CoV receptor) in cells and then in DPP4 transgenic mice, to see if these bat viruses have any capacity to use the same receptor. That said, given the phylogenetic distance from MERS-CoV, we believe it is *highly unlikely* that these bat spike proteins attach to DPP4, and if so, that they would have any pathogenic potential. Finally, should any of these recombinants show evidence of enhanced virus growth >1 log in cells expressing the human, bat, mouse or other DPP4 receptor over wildtype parental backbone MERS-CoV strain or grow more efficiently in human airway epithelial cells, we will immediately: i) stop all experiments with the mutant, ii) inform our NIAID Program Officer and the Wuhan Institute of Virology IBC of these results and iii) participate in decision making trees to decide appropriate paths forward.

In addition, your progress report makes reference to two chimeric bat SARS-like CoVs constructed on a WIV-1 backbone.
NIAID requests additional information on these strains of SARS-like CoVs, including: the dates the strains were created; whether the chimeric viruses exhibit enhanced pathogenicity and/or transmissibility in

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mammals via the respiratory route compared to wild type SARS-CoV; and what research plans you have for these chimeric viruses.

These two chimeric bat-like CoVs were constructed on September 24, 2015. They use the backbone of a group 2b SARS-like bat CoV WIV1 and the spike proteins of two newly discovered bat SL-CoVs (Rs7327 and RsSHC014). The construction of these chimeric viruses aims to understand the receptor usage and infectivity of bat SL-CoVs that may be progenitors of SARS-CoV. We have not yet tested the pathogenicity of these viruses in animals.

We believe that this work would not be considered GoF because the pause specifically targeted experiments that altered the pathogenicity or transmissibility of SARS-CoV, MERS-CoV and any influenza virus. Our molecular clone is WIV1, which is a group 2b SARS-like bat coronavirus that has never been demonstrated to infect humans or cause human disease. It is about 10% different from SARS-CoV. Thus, we feel that introducing other group 2b SARS-like bat coronavirus spike glycoproteins into WIV1 is not subject to the pause. Moreover, we are introducing progressively more distant S glycoproteins into WIV1 (The RBD of Rs7327 differs from WIV1 in several amino acid residues while RsSHC014 is even more distantly related phylogenetically), so it seems progressively less likely that any of these viruses would be more pathogenic or transmissible than the SARS-CoV. This is further supported by the fact that Prof. Ralph Baric's group (Menacherya *et al*., 2015, Nature Medicine, 21 (12):1508-1512; Menacherya *et al*., 2016, PNAS, 113 (11): 3048-3053) took WIV1 spike and inserted it onto a SARS-CoV backbone and showed reduced pathogenicity in mice with human ACE-2 relative to SARS-CoV (mortality rates were much lower, therefore this is *loss-of-function*). This strongly suggests that the chimeric bat spike/bat backbone viruses should not have enhanced pathogenicity in animals.

Finally, as proposed above for the MERS-like viruses, should any of these recombinants show evidence of enhanced virus growth >1 log in cells expressing the human, bat, mouse or civet receptor over wildtype parental backbone SARS-CoV strain or grow more efficiently in human airway epithelial cells, we will immediately: i) stop all experiments with the mutant, ii) inform our NIAID Program Officer and the Wuhan Institute of Virology IBC of these results and iii) participate in decision making trees to decide appropriate paths forward.

If it is determined that the above research DOES include GoF work subject to the funding pause, provide detailed information on what research will remain viable with the removal of the GoF work and appropriate budget adjustments. Options include:

- For the specific aims that propose GoF work, provide a detailed description of changes that can be made to remove the GoF work but maintain the specific aim(s); or
- Remove the specific aims and experiments that are subject to the pause from the Research Plan and request to have the award budget renegotiated.

If these proposed activities within Specific Aim #3 are considered gain of function, we would propose changing them as follows:

1) Instead of the proposed work on MERS-like chimeric CoVs, we would
    a. model the 3-D structure of bat MERS-like CoV spike to assess its potential to bond to DPP4; and
    b. build pseudoviruses with MERS-like CoV spike to conduct experiments for DPP4 binding.

2) Instead of the proposed work on SARS-like chimeric bat CoVs, we would build pseudoviruses with the spike proteins from these viruses and assess receptor binding *in vitro*.

We look forward to your response to our letter and will not conduct any of this proposed work until we hear back from you.

Yours sincerely,

(b)(6)

Dr. Peter Daszak

PI
President and Chief Scientist
EcoHealth Alliance

Tel: (b)(6)
e-mail: (b)(6)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

May 28, 2016

Mr. Aleksei Chmura
Senior Coordinator of Operations
EcoHealth Alliance
460 West 34th Street – 17th Floor
New York, NY 10001

RE: 5R01AI110964-03

Dear Mr. Chmura:

Based upon information in the most recent progress report, NIAID has determined that the above referenced grant may include Gain of Function (GoF) research that is subject to the U.S. Government funding pause (http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf), issued on October 17, 2014. The following specific aims appear to involve research covered under the pause:

Aim 3: Testing predictions of CoV inter-species transmission

As per the funding pause announcement, new USG funding will not be released for GoF research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route. Therefore, the next non-competing segment of the award that starts June 1, 2016 cannot be released until a determination is reached based on the receipt and review of the information requested below. The research funding pause would not apply to characterization or testing of naturally occurring influenza, MERS, or SARS viruses, unless the tests are reasonably anticipated to increase transmissibility and/or pathogenicity.

NIAID requests that you provide the following information within 15 days of the date of this letter:

- **Determination as to whether the above research does or does not include GoF work subject to the funding pause.** Please provide a detailed explanation for this determination, including, but not limited to, descriptions of the MERS and MERS-like chimeric CoVs that you propose to create, and detailed descriptions of the experiments you plan to conduct. Your determination should also include whether each chimeric virus is reasonably anticipated to exhibit enhanced pathogenicity and/or transmissibility in mammals via the respiratory route compared to wild type MERS-CoV.

- **In addition, your progress report makes reference to two chimeric bat SARS-like CoVs constructed on a WIV-1 backbone.** NIAID requests additional information on these strains of SARS-like CoVs, including: the dates the strains were created; whether the chimeric viruses exhibit enhanced pathogenicity and/or transmissibility in mammals via the respiratory route compared to wild type SARS-CoV; and what research plans you have for these chimeric viruses.
- **If it is determined that the above research <u>DOES</u> include GoF work subject to the funding pause, provide detailed information on what research will remain viable with the removal of the GoF work and appropriate budget adjustments. Options include:**
    - For the specific aims that propose GoF work, provide a detailed description of changes that can be made to remove the GoF work but maintain the specific aim(s); or
    - Remove the specific aims and experiments that are subject to the pause from the Research Plan and request to have the award budget renegotiated.

If you have any questions about this matter please do not hesitate to contact the NIAID Program Officer.

Sincerely,

(b)(6)

Jenny Greer
Grants Management Specialist
NIAID/NIH/DHHS

(b)(6)

Erik J. Stemmy, Ph.D.
Program Officer
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

CC: Dr. Peter Daszak
Ms. Mary Kirker
Dr. Irene Glowinski
Dr. Andrew Ford

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Allergy
and Infectious Diseases
Bethesda, Maryland 20892

July 7, 2016

Mr. Aleksei Chmura
Senior Coordinator of Operations
EcoHealth Alliance
460 W. 34th Street – 17th Floor
New York, NY 10001

RE: 5 R01AI110964-03

Dear Mr. Chmura:

Thank you for your correspondence of June 28th, 2016, regarding the October 17, 2014 White House announcement of a U.S. Government-wide pause on certain gain-of-function (GoF) experiments and its potential impact on your research (http://www.whitehouse.gov/blog/2014/10/17/doing-diligence-assess-risks-and-benefits-life-sciences-gain-function-research). The research funding pause pertains to GoF research projects that may be reasonably anticipated to confer attributes to influenza, MERS, or SARS viruses such that the resulting virus would have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.

NIAID reviewed the original grant application, and the additional information provided by you, and made the following assessments regarding Aim 3 of the above-referenced grant:

- NIAID is in agreement that the work proposed under Aim 3 to generate MERS-like or SARS-like chimeric coronaviruses (CoVs) is not subject to the GoF research funding pause. This determination is based on the following: (1) the chimeras will contain only S glycoprotein genes from phylogenetically distant bat CoVs; and (2) recently published work demonstrating that similar chimeric viruses exhibited reduced pathogenicity. Therefore it is not reasonably anticipated that these chimeric viruses will have enhanced pathogenicity and/or transmissibility in mammals via the respiratory route.
- NIAID acknowledges that if any of the MERS-like or SARS-like chimeras generated under this grant show evidence of enhanced virus growth greater than 1 log over the parental backbone strain, Dr. Daszak will immediately stop all experiments with these viruses and provide the NIAID Program Officer and Grants Management Specialist, and Wuhan Institute of Virology Institutional Biosafety Committee, with the relevant data and information related to these unanticipated outcomes.

Please remember that the institution must comply in full with all terms and conditions placed on this grant. As indicated above, NIAID determinations are based on information from multiple sources, but primarily on our communication with you about the details of your proposed experiments and your research results. Should NIAID's determination change based on information obtained through the U.S. Government GoF deliberative process, described here http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf, you will be notified; however, until such time, or until the GoF research funding pause is lifted, NIAID's determination, indicated above, is final.

Please let us know if you have any questions, or if you require additional information.

Sincerely,

(b)(6)

Jenny Greer
Grants Management Specialist
NIAID/NIH/DHHS

(b)(6)

Erik J. Stemmy, Ph.D.
Program Officer
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

CC: Dr. Peter Daszak
Ms. Mary Kirker
Dr. Irene Glowinski
Dr. Andrew Ford