From: Spiro, David (NIH/NIAID) [E]
Sent: Fri, 1 Apr 2016 11:11:07 -0400
To: Lambert, Linda (NIH/NIAID) [E]; Hauguel, Teresa (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; Post, Diane (NIH/NIAID) [E]
Subject: RE: First draft - Informal assessment info and talking points draft 31Mar2016
Attachments: Informal assessment dmid draft 31Mar2016 (003)-DS.docx

Hi,
Looks great!
Just a few minor edits.

David

From: Lambert, Linda (NIH/NIAID) [E]
Sent: Thursday, March 31, 2016 5:30 PM
To: Hauguel, Teresa (NIH/NIAID) [E] (b) (6) Stemmy, Erik (NIH/NIAID) [E] (b) (6) Spiro, David (NIH/NIAID) [E] (b) (6) Post, Diane (NIH/NIAID) [E] (b) (6)
Cc: Glowinski, Irene (NIH/NIAID) [E] (b) (6)
Subject: First draft - Informal assessment info and talking points draft 31Mar2016

Feel free to weigh in – please!

Also – Teresa is prepping 3 bullet points to Dennis.

I'll need to get this or a pared down version to Dennis as well sometime before 1pm tomorrow.

Linda

FYI – approximately 935 *respiratory* projects in DMID in FY15.

INFORMAL ASSESSMENT OF THE SCOPE AND TYPES OF PROJECTS THAT WOULD BE CAPTURED BY THE 3 ATTRIBUTES
31 March 2016

Assessment:

1. Looked at **extramural program only** (did not look at intramural projects)
2. Limited to **Respiratory Pathogens**, **viruses and bacteria**. Excluded other routes of transmission (food/water, blood borne, sexually transmitted, etc.).
3. **Excluded non-human respiratory pathogens** (the pathogen doesn't infect humans but it is a model for a human respiratory infection).
4. Largely looked only at the **FY15 grant portfolio**, although some **large contract efforts** were included.
5. Looked primarily only at the **original specific aims** of the proposed work. No renewals. This is contrast to what is routinely done for assessing GoF for flu/SARS/MERS, in which we look at all progress reports, publications, etc.

If the "starting" pathogen proposed for the work is already highly transmissible or highly virulent in humans, such that any work directly with that virus already meets attribute 1 and 2 respectively.

Attribute 1: Likely highly transmissible in a relevant mammalian model.
Attribute 2: Likely highly virulent in a relevant mammalian model.
Attribute 3: Likely capable of wide and uncontrollable spread in human a relevant animal model or highly virulent in a relevant (because it was that way naturally or it was generated by genetic manipulation):

*Meets any **1** attribute	Meets any **2** attributes	Meets all **3** attributes
(Estimate: Thousands – the Respiratory portfolio alone is more than 900 projects) **Volume of projects captured: "Significant"**	(Estimate: Hundreds) **Volume of projects captured: "Significant"**	(Estimate: Several dozen) **Volume of projects captured:** **"Notable – a few dozen, but clearly much less if all 3 attributes are required."**
If **not limited** to respiratory pathogens (extrapolating): **Volume of projects captured:** Increases to "the vast majority of DMID's portfolio." "And we have several thousand projects."	If **not limited** to respiratory pathogens (extrapolating):. **Volume of projects captured:** Still significant but less than for "Meets any 1 attribute".	If **not limited** to respiratory pathogens (extrapolating):. **Volume of projects captured:** Still notable impact.

*Example: A bacterial or viral pathogen that is already either highly transmissible, highly virulent, or drug resistant could meet 2 if not all 3 criteria.
We support a lot of work to characterize these types of pathogens in *in vitro* and *in vivo* models; including studying the host response, immunopathology, and using them in screens for identifying new candidate therapeutics.

*Example: RSV – already readily transmissible, can be highly virulent in specific populations.

Commented [LL([1]: Can use a few more examples

*Dennis mentioned a bacterial example that he said he could give verbally.

If a "GAIN" in ~~a~~ transmissibility or virulence is needed to meet attribute 1, 2:

Attribute 1: Likely highly transmissible in a relevant mammalian model.
Attribute 2: Likely highly virulent in a relevant mammalian model.
Attribute 3: Likely capable of wide and uncontrollable spread in human a relevant animal model or highly virulent in a relevant (because it was that way naturally or it was generated by genetic manipulation):

Meets any **1** attribute	Meets **any 2** attributes	Meets all **3** attributers
(Estimate: Hundreds) Volume of projects captured: **"Significant"**	(Estimate: Dozens) Volume of projects captured: **"Significant"**	(Estimate: A few handfuls) Volume of projects captured: **"Notable, but clearly much less."**
If **not limited** to respiratory pathogens (extrapolating): Volume of projects captured: **"Significant"**	If **not limited** to respiratory pathogens (extrapolating): Volume of projects captured: **"Significant"**	If **not limited** to respiratory pathogens (extrapolating):. Volume of projects captured: **"Notable: Still expected to be in the "dozens" range.**

Commented [DJS2]: ??? Under a dozen?

OSP: It would also be useful, if not to NSABB to OSP, to hear whether in your professional judgment the attributes are capturing the truly concerning studies or missing a significant portion of concerning ones.

Commented [LL([3]: Feel free to edit/add/weigh in. especially with specifics

DMID: If all 3 attributes are required – especially #3, it is anticipated that this would capture the truly concerning studies.

If any of the 3 attributes are required, especially if the phenotype of the starting pathogen as being transmissible or highly virulent automatically meets the definition of GOFROC, this would encompass a significant portion of routine studies that are not concerning.

From: Dixon, Dennis M. (NIH/NIAID) [E]
Sent: Fri, 1 Apr 2016 13:48:53 -0400
To: Lambert, Linda (NIH/NIAID) [E]; Hauguel, Teresa (NIH/NIAID) [E]
Cc: Spiro, David (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; Post, Diane (NIH/NIAID) [E]; Glowinski, Irene (NIH/NIAID) [E]; NIAID BUGS; Dugan, Vivien (NIH/NIAID) [E]; Dixon, Dennis M. (NIH/NIAID) [E]
Subject: Re: IMPT - Talking points for Dennis and Teresa for today's WG call
Importance: High

Thanks very much Linda. Agree. Looks good. Three two things:

1. A small point. We did assess respiratory fungi too, since those are quite relevant.
2. From the current definition of GOF of concern (thanks to Teresa, below), it is clear that ALL THREE are required for the recommended process. Note the insertion of AND at the end of the second criterion (highlighted in yellow below).
3. Where is the flu team gathering to take the call? I may join you there.

Our combined presentation can reinforce the need for "all 3." The current definition does, however introduce new things not in the current "pause" or the HPAI Framework such as introduction of resistance.

Dennis

Current Definition in the Draft Report
Short Version
i. The pathogen generated is highly transmissible in a relevant mammalian model;
ii. The pathogen generated is highly virulent in a relevant mammalian model;
AND
iii. The pathogen generated is likely resistant to control measures or more capable of being spread among human populations than currently circulating strains of the pathogen

Long Version
Research proposals that can be reasonably anticipated to involve a GOF study of concern, as defined as a study that could generate a pathogen with all of the following attributes, should be reviewed carefully prior to determining whether it is appropriate to be funded:
i. The pathogen generated is highly transmissible in a relevant mammalian model.
Laboratory pathogens of greatest concern are those that would be expected to have the ability to transmit efficiently among mammalian hosts that serve as a proxy for human infections, particularly by the respiratory route. To be considered a GOF study of concern, the resulting pathogen would need to be anticipated (based on scientific evidence and/or expert judgment) to have the potential for sustained secondary transmission among humans.
ii. The pathogen generated is highly virulent in a relevant mammalian model.
Laboratory pathogens of greatest concern are those that would be expected to be highly virulent, causing significant morbidity or mortality in mammalian hosts that serve as a proxy for human infections. To be considered a GOF study of concern, the resulting pathogen would need to be

anticipated (based on scientific evidence and/or expert judgment) to have the potential for causing significant consequences in humans, such as severe disease symptoms or a high case fatality rate.
iii. The pathogen generated is likely resistant to control measures or more capable of being spread among human populations than currently circulating strains of the pathogen.
This characteristic could be conferred to a laboratory pathogen in a number of ways such as: incorporating resistance to medical countermeasures; altering its host range to include mammals for a pathogen that humans would lack population immunity; significantly altering the pathogen to evade host immunity; modifying the pathogen in such a way that it could be anticipated to suppress an immune response in humans. To be considered a GOF study of concern, the resulting pathogen would need to be anticipated (based on scientific evidence and/or expert judgment) to spread efficiently through human populations with no options for controlling its spread other than isolation or quarantine. Vaccines and countermeasures would be unavailable (or in quantities such that their widespread use would be impossible) or have minimal effectiveness.

From: Linda Lambert (b) (6)
Date: Friday, April 1, 2016 at 12:25 PM
To: "Dixon, Dennis M. (NIH/NIAID) [E]" (b) (6) Teresa Hauguel (b) (6)
Cc: David Spiro (b) (6) "Stemmy, Erik (NIH/NIAID) [E]" (b) (6) "Post, Diane (NIH/NIAID) [E]" (b) (6) 'Glowinski, Irene (NIH/NIAID) [E]" (b) (6) BUGS <bugs@niaid.nih.gov>, "Dugan, Vivien (NIH/NIAID) [E]" (b) (6)
Subject: IMPT - Talking points for Dennis and Teresa for today's WG call

Dear Dennis,

Pasted below are the bullets that you requested.

We laid this out so that Dennis - you give the intro to what we did, what the take home messages are, and then turn it over to Teresa for the details. Teresa will go through page 2.

After Teresa, the DMID part could end it there – but we've built in a couple more bullets after Teresa is done in case Dennis wants to say anything else, emphasize specific points, give a specific bacterial example, etc. "The Dennis page."

Take a look at the second take home message in red – I feel like we need to state our opinion on the attributes (OSP asked us for comment on it). Teresa – please make sure that you look at it – even though Dennis would be the one saying it to make sure it's consistent with what we agreed on. Please let everyone know.

I'll share the list of bugs with OSP and a summary of what we expect to convey message wise.

THANK YOU EVERYONE FOR WORKING ON THIS.

Linda

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Dennis – to start: THE DENNIS PAGE

- DMID has **not** undertaken a formal portfolio analysis, but we wanted to start looking at the likely impact of the different options proposed for defining GOFROC on the DMID's portfolio.
  - What we looked at:
    - **viruses and bacteria** that cause respiratory diseases
    - we **excluded** food/water borne, blood borne, vector borne, fungal diseases, etc.
    - we looked at our **grant portfolio primarily** and included some of our larger contract efforts
    - **extramural projects only** - we did not look at intramural projects

- The 2 bottom lines upfront (Dennis)

  a. Depending on the working group consensus on the options for the 3 attributes of GOFROC and how they are applied, the scope of the projects that will be pulled in will range from "**very limited**" to "**a very substantial**" portion of the research portfolio. Teresa will get into some of the details on this "range."

  b. Also – we do think that meeting all 3 attributes, and in particular the 3rd attribute will allow us to capture those studies that are the most concerning.

So now I turn this over to my Teresa Haugel to give a short summary of some of the details on what we've found so far in the DMID Portfolio.

Teresa……..(Teresa a go through the info on page 2)….

DENNIS:

After Teresa…. More Dennis bullets ….Dennis if you are comfortable with these – and if you'd like to giver your bacterial example…. Your call on the below based on how the Q/A/discussion is going):

- We would anticipate that depending on how GOFROC is defined (for example any one attribute) – a lot of routine infectious disease research COULD meet that definition
  - For example studies to look at virulence mechanisms of viruses or bacteria in *in vivo* models; e.g. studies of RSV immunopathology;
  - tuberculosis transmission studies in animal models;
  - work with **naturally occurring** highly virulent, highly transmissible resistant seasonal influenza viruses and AMR-bacterial strains may be captured.
  - Targeted or random mutagenesis studies of pathogens to identify and/or validate potential new therapeutic targets

==========

THE TERESA PAGE– SUMMARY:

- If all 3 attributes are required to constitute GOFROC, it is anticipated that this would capture the truly concerning studies (e.g., generating a highly transmissible, high pathogenic avian influenza virus). We estimate that this would encompass less than a few dozen projects within DMID.

- If GOFROC was defined as only attributes 1 and 2 (high transmissibility and high virulence) and the presence of the property in the starting virus fulfilled the attribute, this would encompass significantly more DMID projects (hundreds), some of which may not be those most concerning to the working group.
    - Examples: all work with seasonal flu viruses, RSV, and [insert bacterial pathogen] – any others????

- If any of the 3 attributes alone are considered GOFROC, this would encompass a significant portion of DMID's portfolio and number hundreds to thousands of projects depending of if the property had to be "gained" (hundreds) or presence of the property in the starting virus fulfilled the GOFROC attribute (thousands).

Teresa – you can go back to Dennis and say …anything else to add?

From: Slay, Raymond (NIH/NIAID) [E]
Sent: Wed, 6 Apr 2016 10:27:25 -0400
To: Adams, Miranda (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]
Subject: Re: NCE for A57

Thanks for the confirmation.

Ray

From: Adams, Miranda (NIH/NIAID) [E]
Sent: Wednesday, April 06, 2016 10:25 AM Eastern Standard Time
To: Stemmy, Erik (NIH/NIAID) [E]; Slay, Raymond (NIH/NIAID) [E]
Subject: RE: NCE for A57

Hi Ray,

Yes to your questions.

Best regards,

Miranda L. Adams, M.S., M.B.A.
Contract Specialist
Microbiology and Infectious Diseases
Research Contracts Branch-A (MIDRCBA)
Office of Acquisitions, DEA, NIAID, NIH-HHS
5601 Fishers Lane, Room 3D45, MSC 9821
Rockville, MD 20852-9821
Phone (b) (6)
Email: (b) (6)

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Wednesday, April 06, 2016 10:24 AM
To: Slay, Raymond (NIH/NIAID) [E] (b) (6) Adams, Miranda (NIH/NIAID) [E] (b) (6)
Subject: RE: NCE for A57

Hi Ray,

Yes, that should be right. 1st NCE was from the GoF pause, then we had a second ending this month. This one will extend the period to May 31st of this year. We shouldn't need any more mods for this option, but may exercise option 2. Haven't assessed the need just yet, though.

Erik

From: Slay, Raymond (NIH/NIAID) [E]
Sent: Wednesday, April 6, 2016 9:54 AM

To: Adams, Miranda (NIH/NIAID) [E] [redacted] Stemmy, Erik (NIH/NIAID) [E]
[redacted]
Subject: Re: NCE for A57

Hi Miranda,

A quick question. I'm looking at the MIS and it looks like there was a modification for a NCE start date of 09/15 end date 07/14/15, NCE due to funding pause, was this ever done? The next one starts 11/15/15 and ends 04/15/16, is this the one that should actually end 04/14/16? Was this MOD done as well? Then the last MOD shown start date of 04/15/16 end date of 05/13/16 is the one we need to do now? Just orienting myself a bit.

Thanks.

Ray Slay

From: Adams, Miranda (NIH/NIAID) [E]
Sent: Wednesday, April 06, 2016 09:10 AM Eastern Standard Time
To: Stemmy, Erik (NIH/NIAID) [E]; Slay, Raymond (NIH/NIAID) [E]
Subject: RE: NCE for A57

Hi Erik,

This will be mod 4 and the end date is April 14th not the 15th. That was the only things I saw that needed to be changed.

Best regards,

Miranda L. Adams, M.S., M.B.A.
Contract Specialist
Microbiology and Infectious Diseases
Research Contracts Branch-A (MIDRCBA)
Office of Acquisitions, DEA, NIAID, NIH-HHS
5601 Fishers Lane, Room 3D45, MSC 9821
Rockville, MD 20852-9821
Phone [redacted]
Email: [redacted]

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Wednesday, April 06, 2016 8:41 AM
To: Adams, Miranda (NIH/NIAID) [E] [redacted] Slay, Raymond (NIH/NIAID) [E]
[redacted]
Subject: NCE for A57

Hi Miranda and Ray,

I've prepared the RMAC for MSSM's NCE request. Can you please have a quick look and make sure I haven't missed anything, or made any mistakes? Particularly the Mod number… Is this 5 since we exercised one of the options?

Thanks!
Erik

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Wed, 6 Apr 2016 19:25:10 +0000
To: Slay, Raymond (NIH/NIAID) [E]
Subject: RE: NCE for A57

Thanks Ray!

From: Slay, Raymond (NIH/NIAID) [E]
Sent: Wednesday, April 6, 2016 1:56 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Subject: RE: NCE for A57

Hi Erik,

I have approved the MOD for A57.

Ray Slay

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Wednesday, April 06, 2016 10:24 AM
To: Slay, Raymond (NIH/NIAID) [E] (b) (6) Adams, Miranda (NIH/NIAID) [E] (b) (6)
Subject: RE: NCE for A57

Hi Ray,
Yes, that should be right. 1st NCE was from the GoF pause, then we had a second ending this month. This one will extend the period to May 31st of this year. We shouldn't need any more mods for this option, but may exercise option 2. Haven't assessed the need just yet, though.

Erik

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Sent: Wednesday, April 6, 2016 9:54 AM
To: Adams, Miranda (NIH/NIAID) [E] (b) (6) Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Subject: Re: NCE for A57

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Thanks.

Ray Slay

From: Adams, Miranda (NIH/NIAID) [E]
Sent: Wednesday, April 06, 2016 09:10 AM Eastern Standard Time
To: Stemmy, Erik (NIH/NIAID) [E]; Slay, Raymond (NIH/NIAID) [E]
Subject: RE: NCE for A57

Hi Erik,

This will be mod 4 and the end date is April 14th not the 15th. That was the only things I saw that needed to be changed.

Best regards,

Miranda L. Adams, M.S., M.B.A.
Contract Specialist
Microbiology and Infectious Diseases
Research Contracts Branch-A (MIDRCBA)
Office of Acquisitions, DEA, NIAID, NIH-HHS
5601 Fishers Lane, Room 3D45, MSC 9821
Rockville, MD 20852-9821
Phone (b) (6)
Email: (b) (6)

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Wednesday, April 06, 2016 8:41 AM
To: Adams, Miranda (NIH/NIAID) [E] (b) (6) Slay, Raymond (NIH/NIAID) [E] (b) (6)
Subject: NCE for A57

Hi Miranda and Ray,
I've prepared the RMAC for MSSM's NCE request. Can you please have a quick look and make sure I haven't missed anything, or made any mistakes? Particularly the Mod number... Is this 5 since we exercised one of the options?

Thanks!
Erik

From: Dugan, Vivien (NIH/NIAID) [E]
Sent: Thu, 7 Apr 2016 14:58:43 -0400
To: Stemmy, Erik (NIH/NIAID) [E]
Cc: Yao, Alison (NIH/NIAID) [E]
Subject: RE: Baric Gof

Thanks, again. I'll be sure to review before tomorrow's meeting – most appreciated.
Vivien

Vivien G. Dugan, Ph.D.
Program Officer in Systems Biology
Office of Genomics and Advanced Technologies (OGAT)
Division of Microbiology and Infectious Diseases/NIAID/NIH/DHHS
5601 Fishers Lane Room 7A29 MSC 9826
North Bethesda, MD 20892-9826
(b) (6) phone)
(b) (6)

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Thursday, April 07, 2016 2:58 PM
To: Dugan, Vivien (NIH/NIAID) [E] (b) (6)
Cc: Yao, Alison (NIH/NIAID) [E] (b) (6)
Subject: RE: Baric Gof

Attached was Maureen's first review of the request. I'd suggested that she send his original request to the committee (Teresa attached it to the agenda) and then use this document as the basis for her discussion.

From: Dugan, Vivien (NIH/NIAID) [E]
Sent: Thursday, April 07, 2016 2:56 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Cc: Yao, Alison (NIH/NIAID) [E] (b) (6)
Subject: RE: Baric Gof

Thanks, Erik!

Vivien G. Dugan, Ph.D.
Program Officer in Systems Biology
Office of Genomics and Advanced Technologies (OGAT)
Division of Microbiology and Infectious Diseases/NIAID/NIH/DHHS

5601 Fishers Lane Room 7A29 MSC 9826
North Bethesda, MD 20892-9826
(b) (6) phone)
(b) (6)

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Thursday, April 07, 2016 2:45 PM
To: Dugan, Vivien (NIH/NIAID) [E] (b) (6)
Cc: Yao, Alison (NIH/NIAID) [E] (b) (6)
Subject: Baric Gof

Hi Vivien and Alison,
Maureen will be presenting this at the Gof meeting tomorrow. Teresa just included it on the agenda she sent today.

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: (b) (6)
Email: (b) (6)

From: Hauguel, Teresa (NIH/NIAID) [E]
Sent: Fri, 8 Apr 2016 11:27:33 -0400
To: Glowinski, Irene (NIH/NIAID) [E]; Dixon, Dennis M. (NIH/NIAID) [E]; Lambert, Linda (NIH/NIAID) [E]; Spiro, David (NIH/NIAID) [E]; Post, Diane (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; Dugan, Vivien (NIH/NIAID) [E]; Mulach, Barbara (NIH/NIAID) [E]; Ford, Andrew (NIH/NIAID) [E]; Strickler-Dinglasan, Patricia (NIH/NIAID) [E]; Hanson, Christopher (NIH/NIAID) [E]; Delarosa, Patricia (NIH/NIAID) [E]; Santora, Kenneth (NIH/NIAID) [E]
Cc: Beanan, Maureen (NIH/NIAID) [E]; Powell, Shunetta (NIH/NIAID) [E]
Subject: CANCELLED: 4/8 DURC/GoF Meeting Agenda

Hi All,

Due to a number of people being out of the office this afternoon, we are cancelling today's meeting. We will plan to discuss these agenda items at our next meeting which is scheduled for Friday, April 15th at 3pm.

Have a nice weekend!

Teresa

Teresa M. Hauguel, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS
5601 Fishers Lane, Room 8E19
Bethesda, MD 20892
Phone: (b) (6)
Email: (b) (6)

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.

Please consider the environment before printing this e-mail

From: Hauguel, Teresa (NIH/NIAID) [E]
Sent: Thursday, April 07, 2016 10:11 AM
To: Glowinski, Irene (NIH/NIAID) [E] (b) (6) Dixon, Dennis M. (NIH/NIAID) [E] (b) (6) Lambert, Linda (NIH/NIAID) [E] (b) (6) Spiro, David (NIH/NIAID) [E] (b) (6) Hauguel, Teresa (NIH/NIAID) [E] (b) (6) Post, Diane (NIH/NIAID) [E] (b) (6) Stemmy, Erik (NIH/NIAID) [E] (b) (6) Dugan, Vivien (NIH/NIAID) [E] (b) (6) Mulach, Barbara

(NIH/NIAID) [E] (b) (6) Ford, Andrew (NIH/NIAID) [E] (b) (6)
Strickler-Dinglasan, Patricia (NIH/NIAID) [E] (b) (6) Hanson, Christopher
(NIH/NIAID) [E] (b) (6) Delarosa, Patricia (NIH/NIAID) [E]
(b) (6) Santora, Kenneth (NIH/NIAID) [E] (b) (6)
Cc: Beanan, Maureen (NIH/NIAID) [E] (b) (6)
Subject: 4/8 DURC/GoF Meeting Agenda

Hello Everyone,

Below is the agenda for tomorrow's DURC/GoF meeting.

Attached are documents for agenda items 1-3.

Weekly DURC/GoF Meeting Agenda
Friday, April 8, 2016
2:00-3:30pm
5601/7G31
Call in number (b) (6)
Passcode: (b) (6)

1. Projects for GoF Review
    a. Baric (CETR) – MERS/SARS viruses – Maureen B.
    b. Kawaoka (CEIRS) – influenza polymerase mutants – Diane
2. NSABB WG Updates – Dennis/Diane/Teresa
    a. Revised GOFROC attributes (attachment 1 from NSABB WG email)
3. GOFROC Strawman – Teresa
    a. Experiments that should/should not be covered
    b. Experiments that should be excepted
4. Other Updates
    a. Erasmus RMP – Ken/Tricia
5. Round Robin/Other Items

Teresa M. Hauguel, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases
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5601 Fishers Lane, Room 8E19
Bethesda, MD 20892
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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.

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Tue, 12 Apr 2016 15:45:16 +0000
To: Stemmy, Erik (NIH/NIAID) [E]
Subject: NSABB Meeting
Attachments: FW: National Science Advisory Board for Biosecurity (NSABB) Meeting, May 24, 2016 - 8:30am to 4:00pm http://1.usa.gov/1N0XHIK

From: Hauguel, Teresa (NIH/NIAID) [E]
Sent: Tue, 12 Apr 2016 10:09:07 -0400
To: Glowinski, Irene (NIH/NIAID) [E]; Dixon, Dennis M. (NIH/NIAID) [E]; Lambert, Linda (NIH/NIAID) [E]; Spiro, David (NIH/NIAID) [E]; Post, Diane (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; Mulach, Barbara (NIH/NIAID) [E]; Ford, Andrew (NIH/NIAID) [E]; Strickler-Dinglasan, Patricia (NIH/NIAID) [E]; Dugan, Vivien (NIH/NIAID) [E]; Hanson, Christopher (NIH/NIAID) [E]; Delarosa, Patricia (NIH/NIAID) [E]; Santora, Kenneth (NIH/NIAID) [E]
Subject: FW: National Science Advisory Board for Biosecurity (NSABB) Meeting, May 24, 2016 - 8:30am to 4:00pm http://1.usa.gov/1N0XHIK

FYI – see below for NSABB meeting information and registration.

At this meeting, the full NSABB will vote on the NSABB WG's GOFROC recommendations.

The meeting will be webcast.

Teresa M. Hauguel, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS
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From: Folkers, Greg (NIH/NIAID) [E]
Sent: Saturday, April 09, 2016 11:19 AM
Subject: National Science Advisory Board for Biosecurity (NSABB) Meeting, May 24, 2016 - 8:30am to 4:00pm http://1.usa.gov/1N0XHIK

Biosecurity
National Science Advisory Board for Biosecurity (NSABB) Meeting
May 24, 2016 - 8:30am to 4:00pm
National Institutes of Health

Wilson Hall, 3rd Floor, Bldg. 1
9000 Rockville Pike
Bethesda, MD 20892
The meeting agenda and links to the online registration and webcast will be available on this page. NSABB findings and draft recommendations will be posted prior to the meeting. Please check this website for updates.

Agenda
Agenda items include: (1) Finalization of NSABB findings and recommendations on a conceptual approach to evaluating proposed gain-of-function (GOF) studies; (2) discussion of next steps for U.S. government policy development regarding GOF studies; and (3) other business of the Board.

Meeting Pre-registration
This meeting is open to the public. There is no registration fee. Attendees and online viewers may pre-register online at https://palladianpartners.cvent.com/NSABBmay2016, or by calling Palladian Partners, Inc. (Contact: Ida Donner or Carly Sullivan at (b) (6) Online and telephone registration will close at 12:00 p.m. Eastern on May 18, 2016. After that time, attendees may register onsite on the day of the meeting. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should indicate these requirements upon registration on or prior to May 18.

Webcast
This meeting will be webcast. Click here to access the webcast when the meeting is live.

Public Comment
Time will be allotted on the agenda for the presentation of public comments. Members of the public interested in presenting prepared comments relevant to the mission of the NSABB should indicate so upon registration. Sign-up for delivering prepared oral comments will be limited to one per person or organization representative per open comment period. Individual presentations will be time-limited to facilitate broad participation from multiple speakers. Participants viewing the meeting by webcast may submit questions and comments during the meeting via email sent to nsabb@od.nih.gov. While time constraints and the volume of questions may not allow for all questions and comments submitted via email to be aired during the meeting, all relevant correspondence received will be relayed to the Board. Emailed correspondence should include the name, contact information, and when applicable, professional affiliation of the sender.

Directions to the NIH
Please visit theNIH Visitor Information page for directions to the NIH and a printable map of the NIH Bethesda campus.

Security Information
In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxis, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their

visit. Please visit the NIH Visitor Security page for important security and campus access information.

Additional questions, please contact:

Christopher Viggiani, Ph.D.
Executive Director, NSABB
NIH Office of Science Policy
6705 Rockledge Drive, Suite 750
Bethesda, Maryland 20892
(b) (6)

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Fri, 15 Apr 2016 18:52:12 +0000
To: Bumbray-Quarles, Devon (NIH/NIAID) [E]
Subject: RE: Grant Number: 2 R01 AI 089728 - 06, Li (PI)

Hi Devon,
Just wanted to check in, any word from the PI or institution yet?

Erik

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Thursday, April 07, 2016 10:14 AM
To: Bumbray-Quarles, Devon (NIH/NIAID) [E] (b) (6)
Subject: RE: Grant Number: 2 R01 AI 089728 - 06, Li (PI)

Thanks Devon. For other letters like this we've sent out the institution will often acknowledge receipt, or possibly reach out with clarifying questions. I just wanted to be sure I hadn't missed any correspondence.

Thanks again,
Erik

From: Bumbray-Quarles, Devon (NIH/NIAID) [E]
Sent: Thursday, April 07, 2016 10:11 AM
To: Stemmy, Erik (NIH/NIAID) [E (b) (6)
Subject: RE: Grant Number: 2 R01 AI 089728 - 06, Li (PI)

Hi Erik,

The letter gave them 15 days from the date the letter was sent, so they still have time to submit a response.

Thanks.

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Thursday, April 07, 2016 10:08 AM
To: Bumbray-Quarles, Devon (NIH/NIAID) [E] (b) (6)
Subject: RE: Grant Number: 2 R01 AI 089728 - 06, Li (PI)

Hi Devon,
Just wanted to check in to see if you'd had any communication from the institution or PI on this. Please let me know.

Thanks!
Erik

From: Bumbray-Quarles, Devon (NIH/NIAID) [E]
Sent: Thursday, March 31, 2016 11:51 AM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Subject: FW: Grant Number: 2 R01 AI 089728 - 06, Li (PI)

FYI. This was sent to the wrong person.

Devon B. Quarles
Ms. Devon Bumbray-Quarles
Grants Management Program

From: Bumbray-Quarles, Devon (NIH/NIAID) [E]
Sent: Thursday, March 31, 2016 11:42 AM
To: 'Kevin McKoskey' (b) (6)
Cc: (b) (6) awards@umn.edu; Kirker, Mary (NIH/NIAID) [E] (b) (6) Glowinski, Irene (NIH/NIAID) [E] (b) (6) Ford, Andrew (NIH/NIAID) [E] (b) (6) Stempinski, Erin (NIH/NHLBI) [C] (b) (6) Bumbray-Quarles, Devon (NIH/NIAID) [E] (b) (6)
Subject: Grant Number: 2 R01 AI 089728 - 06, Li (PI)

Dear Mr. McKoskey,

NIAID has determined that the above subject grant may include Gain of Function (GoF) research that is subject to the recently announced U.S. Government (USG) funding pause (http://www.phe.gov/s3/dualuse/Documents/gain-of-function.pdf), issued on October 17, 2014.

Please see the attached letter for more detailed information.

If you have any questions or concerns, please do not hesitate to ask.

Thank you.

Sincerely,
Ms. Devon Bumbray-Quarles
Grants Management Specialist
Grants Management Program
DHHS, NIH, NIAID, GMP
5601 Fishers Lane, Room 4E28, MSC 9824
Bethesda, MD 20892-9824
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F: 301.493.0597
(b) (6)

NIH National Institute of Allergy and Infectious Diseases

"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: Hauguel, Teresa (NIH/NIAID) [E]
Sent: Tue, 19 Apr 2016 09:45:53 -0400
To: Stemmy, Erik (NIH/NIAID) [E]
Subject: RE: GoF meeting this Friday?

Sure will do.

Teresa M. Hauguel, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS
5601 Fishers Lane, Room 8E19
Bethesda, MD 20892
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From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Tuesday, April 19, 2016 8:51 AM
To: Hauguel, Teresa (NIH/NIAID) [E] (b) (6)
Subject: RE: GoF meeting this Friday?

Hi Teresa,
I don't have a pressing need for a meeting this week, but I did want to report back on the institutional GoF response from the Fang Li award the next time we get together. Can you please add the attached response to the agenda for the next meeting?

Thanks!
Erik

From: Hauguel, Teresa (NIH/NIAID) [E]
Sent: Monday, April 18, 2016 12:59 PM
To: Post, Diane (NIH/NIAID) [E] (b) (6) Stemmy, Erik (NIH/NIAID) [E] (b) (6) Dugan, Vivien (NIH/NIAID) [E] (b) (6) Hanson, Christopher (NIH/NIAID) [E] (b) (6) Ford, Andrew (NIH/NIAID) [E] (b) (6)
Subject: GoF meeting this Friday?

Hi All,

We do not have a GoF meeting on the calendar for this Friday. However, if you have something pressing that needs to be discussed this week (our next meeting is 4/29) please let me know by COB tomorrow so that I can schedule a meeting for this Friday.

Best,
Teresa

Teresa M. Hauguel, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS
5601 Fishers Lane, Room 8E19
Bethesda, MD 20892
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Please consider the environment before printing this e-mail

From: Bumbray-Quarles, Devon (NIH/NIAID) [E]
Sent: Wed, 20 Apr 2016 12:12:21 -0400
To: Stemmy, Erik (NIH/NIAID) [E]
Subject: RE: Grant Number: 2R01AI089728 - 06 PI Name: Li, Fang

Great, thanks. I'll request the information.

Devon B. Quarles
Ms. Devon Bumbray-Quarles
Grants Management Program

From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Wednesday, April 20, 2016 12:07 PM
To: Bumbray-Quarles, Devon (NIH/NIAID) [E] (b) (6)
Subject: RE: Grant Number: 2R01AI089728 - 06 PI Name: Li, Fang

Hi Devon,
No, I haven't reached out to the PI about the concerns. We have been reviewing the Gain-of-Function response, and will discuss in the GoF committee meeting next Friday (4/29). We'll make our final GoF determination then.

Thanks!
Erik

From: Bumbray-Quarles, Devon (NIH/NIAID) [E]
Sent: Wednesday, April 20, 2016 12:05 PM
To: Stemmy, Erik (NIH/NIAID) [E] (b) (6)
Cc: Bumbray-Quarles, Devon (NIH/NIAID) [E] (b) (6)
Subject: Grant Number: 2R01AI089728 - 06 PI Name: Li, Fang

Hi Erik,

Have you reached out to the Grantee to receive a response for the following Summary Statement concerns? I didn't want to send a duplicate request and there wasn't anything submitted in the JIT.

BIOHAZARD COMMENT: There are concerns that recombinant coronaviruses altered to enhance proteolytic cleavage or binding of the human angiotensin converting enzyme 2 (ACE 2) receptor may have novel and unexpected virulence phenotypes. Therefore, biosafety level-3 (BSL-3) protections, training, and monitoring procedures should be considered unless otherwise indicated.

BUDGETARY OVERLAP: There is potential for budgetary overlap with the project R01AI110700 titled, "Mechanisms of MERS-CoV Entry, Cross-species Transmission and Pathogenesis" awarded to PI Ralph Baric (co-investigator on this proposal).

Thanks.

Sincerely,
Ms. Devon Bumbray-Quarles
Grants Management Specialist
Grants Management Program
DHHS, NIH, NIAID, GMP
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National Institute of Allergy and Infectious Diseases

"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: Ford, Andrew (NIH/NIAID) [E]
Sent: Thu, 21 Apr 2016 12:08:56 -0400
To: Hauguel, Teresa (NIH/NIAID) [E]; Glowinski, Irene (NIH/NIAID) [E]; Dixon, Dennis M. (NIH/NIAID) [E]; Lambert, Linda (NIH/NIAID) [E]; Spiro, David (NIH/NIAID) [E]; Post, Diane (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; Dugan, Vivien (NIH/NIAID) [E]; Mulach, Barbara (NIH/NIAID) [E]; Strickler-Dinglasan, Patricia (NIH/NIAID) [E]; Hanson, Christopher (NIH/NIAID) [E]; Delarosa, Patricia (NIH/NIAID) [E]; Santora, Kenneth (NIH/NIAID) [E]
Cc: Ford, Andrew (NIH/NIAID) [E]
Subject: RE: Reminder - no DURC/GoF meeting this week
Attachments: Review of Non-Fed-funded-DURC-SOPs 41816.docx, DURC and GOF, for thought

Dear All,

As mentioned at the April 15 DURC/GoF meeting, Trish, Barbara and I discussed with Chris V. and his group, the review of institutional DURC assessments about non-federally funded research received in accordance with the iDURC policy. The objective, from our perspective, was to discuss lessons learned and to get an idea as to how OSP was using the feedback they receive when responding to institutions. Thus far, 19 institutional assessments have been received; of these, additional information was requested for 3, while the other 16 should not have been sent (e.g. they did not include one of the 7 effects). Considering the topic of discussion, prior to the call OSP shared the attached draft SOP regarding review of non-federally funded research subject to the iDURC policy. Based on the draft SOP the agency/IC assigned to review the institutional assessment would assume the responsibility of corresponding with the institution, including sending the final disposition about the assessment. In addition, in instances of DURC the assigned agency/IC is to work with the institution to finalize the risk mitigation plan. We reiterated our recommendation that the activities associated with reviewing and finalizing the risk mitigation plans (RMP) be assigned to CDC/USDA due to their expertise in biosafety and biosecurity. He did provide some push back, but by the end of the call he seemed to understand that we view the science/research and biosecurity/biosafety to be separate issues resulting in our involvement in reviewing assessments and our recommendation regarding RMP review. There was also discussion that most likely no agency/IC would want to take, what would be perceived to be, ownership of the review of non-federally funded research and RMPs.

After the call, Chris V. followed-up with the attached email in which he discusses an idea explored in 2012 about creating a group – Federal Experts Panel on Dual Use Research (FEPDUR) – and the possibility of having such a group play a role in reviewing non-federally funded DURC research, proposed GOFROC research, and DURC/GoF manuscripts. He does mention a few pros and cons regarding the group.

Please note, Chris V. shared the draft SOP and FEPDUR idea for internal discussion by our DURC/GoF group; therefore, please do not distribute these items any further.

Should you have any questions please let us know.

Thanks
Andrew

Andrew Q. Ford, Ph.D.
Office of Scientific Coordination and Program Operations
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS
5601 Fishers Lane Room 7G64
Rockville, MD 20892
(b) (6)

From: Hauguel, Teresa (NIH/NIAID) [E]
Sent: Wednesday, April 20, 2016 10:51 AM
To: Glowinski, Irene (NIH/NIAID) [E] (b) (6) Dixon, Dennis M. (NIH/NIAID) [E] (b) (6) Lambert, Linda (NIH/NIAID) [E] (b) (6) Spiro, David (NIH/NIAID) [E] (b) (6) Hauguel, Teresa (NIH/NIAID) [E] (b) (6) Post, Diane (NIH/NIAID) [E] (b) (6) Stemmy, Erik (NIH/NIAID) [E] (b) (6) Dugan, Vivien (NIH/NIAID) [E] (b) (6) Mulach, Barbara (NIH/NIAID) [E] (b) (6) Ford, Andrew (NIH/NIAID) [E] (b) (6) Strickler-Dinglasan, Patricia (NIH/NIAID) [E] (b) (6) Hanson, Christopher (NIH/NIAID) [E] (b) (6) Delarosa, Patricia (NIH/NIAID) [E] (b) (6) Santora, Kenneth (NIH/NIAID) [E] (b) (6)
Subject: Reminder - no DURC/GoF meeting this week

Hi Everyone,

Just a quick reminder that there is no DURC/GoF meeting this week. Our next meeting is scheduled for Friday, April 29th at 3pm.

Hope you all get a chance to get outside and enjoy this beautiful weather today!

Best,
Teresa

Teresa M. Hauguel, Ph.D.
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Respiratory Diseases Branch
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NIH Office of Science Policy Process for Referring Non-Federally Funded Research Meeting the Scope of the USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern for Review by other Agencies or NIH Institutes and Centers

Overview

As stated in Section 7.2.B.iv of the *USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern,* if an institution that receives Federal funds for life sciences research identifies a non-Federally funded research project that involves one or more of the 15 listed agents and one or more of the seven listed experimental effects (Section 6.2), the institution must notify the National Institutes of Health (NIH) Office of Science Policy (OSP) within 30 days of the institutional review. NIH is responsible for referring this research to the most appropriate USG agency or NIH Institute or Center (I/C) who will then assume responsibility for this review and oversight of the research, as described in Section 7.3 of the Policy. The overall process is outlined as follows:

NIH OSP receives notification from an Institution of non-Federally funded research that meets the scope of the Policy.

↓

NIH OSP identifies the most appropriate USG agency or NIH I/C to review the research.

↓

NIH OSP contacts the selected USG agency or NIH I/C regarding review and oversight of the research.

↓

Selected USG agency or NIH I/C reviews all relevant information, and notifies the institution of its findings within 30 days of initial receipt of notification.

Standard Operating Procedures:

1. **NIH OSP receives notification of non-Federally funded research that meets the scope of the Policy.**

   - Within 30 days of the institutional review, the institution notifies the NIH OSP of any non-Federally funded research that involves one or more of the 15 listed agents and one or more of the seven listed experimental effects. The institution may use the reporting template included in the *Companion Guide*, or use its own reporting format provided the report contains the following information and supplemental materials:
     i. Contact information, including the Principal Investigator (PI), Institutional Review Entity (IRE), and Institutional Contact for Dual Use Research (ICDUR);
     ii. Project information, including a project identifier, a detailed description of the research, and the PI's assessment of whether the research meets any of the seven listed experimental effects;

iii. Findings from the institutional review, including dates of review and whether the research meets the definition of DURC; and
iv. Other documents relevant to the research (when applicable), including abstracts, manuscripts, and progress reports.

- NIH OSP will respond to the institution within 7 days to acknowledge receipt of this notification, explaining that the research is being referred for review to an appropriate USG agency or NIH I/C. OSP will inform the institution once the agency or NIH I/C has been identified (see steps 2 and 3 below). For cases in which the IRE determines that the research meets the definition of DURC, as per the Policy, institutions are to be advised to begin drafting a risk mitigation plan, which will be submitted to the relevant USG agency or NIH I/C, once identified.

- NIH OSP will maintain records of submissions from institutions.

2. NIH OSP identifies the most appropriate USG funding agency for reviewing the research.

- NIH OSP reviews all information reported by the institution to verify that the research meets the scope of the Policy, and to determine the most appropriate USG agency or NIH I/C to which the research should be referred. In cases where NIH is the most appropriate USG funding agency, NIH OSP determines which I/C within NIH would be most appropriate.

- NIH OSP will consider the following questions during its review process:
  i. Does the research indeed fall under the scope of the Policy?
  ii. Which USG funding agencies (or NIH I/Cs) fund similar research with the agent or toxin in question?
  iii. Does the PI receive Federal funding for similar or related projects? If so, how similar are these projects and who is the funding entity?
  iv. Is the Federal government funding similar or related projects conducted by other PIs or at other institutions? If so, what are these projects and which agencies are funding them?

3. NIH OSP contacts the relevant USG agency or NIH I/C regarding review of the research.

- Once NIH OSP has identified the most appropriate USG agency or NIH I/C for reviewing the research, NIH OSP will send to that agency or I/C the information reported by the institution along with a request that the agency or I/C fulfill the review and oversight requirements, as described in the Policy, for that particular non-Federally funded research.

  NOTE: *NIH OSP would like to assemble a formal list of agency representative who should be contacted in the event that a relevant project needs to be referred to that agency. Can D/As please send Kathryn Harris* (b) (6) *the name(s) of individuals who should be contacted regarding relevant reports of non-Federally funded projects subject to the institutional DURC policy?*

- If the identified USG agency or NIH I/C believes that it is not the most appropriate agency or I/C to conduct the review, it can decline and make a recommendation as to which USG agency or NIH I/C might be more appropriate. In these cases, NIH OSP again reviews the research

information, considers any recommendations provided by the first USG agency or NIH I/C, and determines a more appropriate USG funding agency or NIH I/C to review the research.

- In the event that no USG funding agency deems itself appropriate to receive the report of the research, NIH OSP will consult with OSTP for guidance.

- Once the most appropriate USG agency or NIH I/C agrees to fulfill review responsibilities under the Policy for the non-Federally funded research, NIH OSP notifies the institution and provides the relevant contact information. From this point on, all correspondence regarding the DURC review and oversight of this research, including subsequent institutional review notifications and requests for consultation, should occur directly between the selected USG agency or NIH I/C and the institution. At this stage the USG funding agency or NIH I/C proceeds with its oversight responsibilities in the same manner it would for a project conducted with Federal funds.

- In instances where institutions erroneously report a non-Federally funded project (e.g., the project does not involve a listed agent; the project involves a listed agent but does not involve any of the 7 categories), NIH OSP will educate the institution on the requirements of the policy.

4. **USG funding agency or NIH I/C reviews all relevant information, and notifies the institution of its findings.**

   - The selected USG agency or NIH I/C may request additional information (e.g., risk-benefit assessment, draft risk mitigation plan) from the institution, if necessary.

   - The selected USG agency reviews all relevant information to determine whether it agrees with the outcomes of the institutional review process, including whether the research meets the definition of DURC, as per the Policy.

   - Within 30 days, the selected USG agency or NIH I/C notifies the institution of the outcomes of its review process, including any decisions or recommendations. For research that has been determined to be DURC, the selected USG agency or NIH I/C works with the institution to finalize a risk mitigation plan within 90 days of the IRE's original DURC determination.

   - The USG agency or NIH I/C notifies NIH OSP of their final determination after the review.

From: Viggiani, Christopher (NIH/OD) [E]
Sent: Wed, 20 Apr 2016 11:08:46 -0400
To: Ford, Andrew (NIH/NIAID) [E]; Strickler-Dinglasan, Patricia (NIH/NIAID) [E]; Mulach, Barbara (NIH/NIAID) [E]
Cc: Harris, Kathryn (NIH/OD) [C]; Ramkissoon, Kevin (NIH/OD) [C]
Subject: DURC and GOF, for thought

Hi all,

Interesting call this morning, thanks. After the call we started talking internally and came back to an idea that was kicked around years ago. This potential solution has its pros and cons, which we can discuss sometime. It also has the potential to solve the GOF issue, and potentially other related issues. There are pros and cons.

In 2012 you might remember there was an idea to have a group called the FEPDUR—the Federal Experts Panel on Dual Use Research. This would be an interagency group of Federal Experts, kind of like FESAP. Originally, it was envisioned to be the USG group that would review any DURC manuscripts that came in (this was just in the wake of the H5 manuscripts and there was a feeling that an internal Federal group could be quicker and have more expertise than a FACA committee). Do you remember when the group reviewed the Arnon bot tox paper? That was kind of an ad hoc FEPDUR. For whatever reason, the FEPDUR died. But it could be a useful here.

What would you think about establishing an interagency group that could, for instance:

- Review non-Federally funded reports of DURC and advise on risk mitigation
- Review proposed GOF research of concern, as described by NSABB, and advise the funding agency
- Review DURC manuscripts that come in from journal editors or funding agencies

We would want to think carefully about this, there are real pros and cons. Some pros are that it would provide broad expertise and gives individual agencies some cover/assurance in their actions. Cons would be mission creep (e.g., what if this group wanted to review ALL DURC, even if that DURC is federally funded? Would we be OK with that?) and overly-zealous DAs (e.g., think of the recent ISATTAC debacle where security has overridden science). It would be important that it is clear that any new group provides recommendations only and that funding agencies retain authority over final decisions.

Just wanted to float this with you internally before we develop it further. We should talk more. Despite some of the concerns I have, I think this idea could have promise if we did it right.

cv

Christopher Viggiani, Ph.D.
Office of Science Policy
Office of the Director
National Institutes of Health
Office (b) (6) | | Mobile: (b) (6)

(b) (6)

OSP Blog: Under the Poliscope
Twitter: @CWolinetzNIH

From: Hauguel, Teresa (NIH/NIAID) [E]
Sent: Thu, 21 Apr 2016 18:55:33 -0400
To: Glowinski, Irene (NIH/NIAID) [E]; Ford, Andrew (NIH/NIAID) [E]; Dixon, Dennis M. (NIH/NIAID) [E]; Lambert, Linda (NIH/NIAID) [E]; Spiro, David (NIH/NIAID) [E]; Post, Diane (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; Dugan, Vivien (NIH/NIAID) [E]; Mulach, Barbara (NIH/NIAID) [E]; Strickler-Dinglasan, Patricia (NIH/NIAID) [E]; Hanson, Christopher (NIH/NIAID) [E]; Delarosa, Patricia (NIH/NIAID) [E]; Santora, Kenneth (NIH/NIAID) [E]
Subject: RE: Reminder - no DURC/GoF meeting this week

Yes, I will add it to the agenda for our 4/29 meeting.

Teresa M. Hauguel, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS
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Bethesda, MD 20892
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Email (b) (6)

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Please consider the environment before printing this e-mail

From: Glowinski, Irene (NIH/NIAID) [E]
Sent: Thursday, April 21, 2016 4:54 PM
To: Ford, Andrew (NIH/NIAID) [E] (b) (6) Hauguel, Teresa (NIH/NIAID) [E] (b) (6) Dixon, Dennis M. (NIH/NIAID) [E] (b) (6) Lambert, Linda (NIH/NIAID) [E] (b) (6) Spiro, David (NIH/NIAID) [E] (b) (6) Post, Diane (NIH/NIAID) [E] (b) (6) Stemmy, Erik (NIH/NIAID) [E] (b) (6) Dugan, Vivien (NIH/NIAID) [E] (b) (6) Mulach, Barbara (NIH/NIAID) [E] (b) (6) Strickler-Dinglasan, Patricia (NIH/NIAID) [E] (b) (6) Hanson, Christopher (NIH/NIAID) [E] (b) (6) Delarosa, Patricia (NIH/NIAID) [E] (b) (6) Santora, Kenneth (NIH/NIAID) [E] (b) (6)
Subject: RE: Reminder - no DURC/GoF meeting this week

Can we make sure this is on the agenda for discussion at our next meeting? Need to make sure Dennis is there as he has a lot of experience with the group referred to in one of the emails as similar (FESAP).

Thanks.

From: Ford, Andrew (NIH/NIAID) [E]
Sent: Thursday, April 21, 2016 12:09 PM
To: Hauguel, Teresa (NIH/NIAID) [E] (b) (6) Glowinski, Irene (NIH/NIAID) [E] (b) (6) Dixon, Dennis M. (NIH/NIAID) [E] (b) (6) Lambert, Linda (NIH/NIAID) [E] (b) (6) Spiro, David (NIH/NIAID) [E] (b) (6) Post, Diane (NIH/NIAID) [E] (b) (6) Stemmy, Erik (NIH/NIAID) [E] (b) (6) Dugan, Vivien (NIH/NIAID) [E] (b) (6) Mulach, Barbara (NIH/NIAID) [E] (b) (6) Strickler-Dinglasan, Patricia (NIH/NIAID) [E] (b) (6) Hanson, Christopher (NIH/NIAID) [E] (b) (6) Delarosa, Patricia (NIH/NIAID) [E] (b) (6) Santora, Kenneth (NIH/NIAID) [E] (b) (6)
Cc: Ford, Andrew (NIH/NIAID) [E] (b) (6)
Subject: RE: Reminder - no DURC/GoF meeting this week

Dear All,

As mentioned at the April 15 DURC/GoF meeting, Trish, Barbara and I discussed with Chris V. and his group, the review of institutional DURC assessments about non-federally funded research received in accordance with the iDURC policy. The objective, from our perspective, was to discuss lessons learned and to get an idea as to how OSP was using the feedback they receive when responding to institutions. Thus far, 19 institutional assessments have been received; of these, additional information was requested for 3, while the other 16 should not have been sent (e.g. they did not include one of the 7 effects). Considering the topic of discussion, prior to the call OSP shared the attached draft SOP regarding review of non-federally funded research subject to the iDURC policy. Based on the draft SOP the agency/IC assigned to review the institutional assessment would assume the responsibility of corresponding with the institution, including sending the final disposition about the assessment. In addition, in instances of DURC the assigned agency/IC is to work with the institution to finalize the risk mitigation plan. We reiterated our recommendation that the activities associated with reviewing and finalizing the risk mitigation plans (RMP) be assigned to CDC/USDA due to their expertise in biosafety and biosecurity. He did provide some push back, but by the end of the call he seemed to understand that we view the science/research and biosecurity/biosafety to be separate issues resulting in our involvement in reviewing assessments and our recommendation regarding RMP review. There was also discussion that most likely no agency/IC would want to take, what would be perceived to be, ownership of the review of non-federally funded research and RMPs.

After the call, Chris V. followed-up with the attached email in which he discusses an idea explored in 2012 about creating a group – Federal Experts Panel on Dual Use Research (FEPDUR) – and the possibility of having such a group play a role in reviewing non-federally funded DURC research, proposed GOFROC research, and DURC/GoF manuscripts. He does mention a few pros and cons regarding the group.

Please note, Chris V. shared the draft SOP and FEPDUR idea for internal discussion by our DURC/GoF group; therefore, please do not distribute these items any further.

Should you have any questions please let us know.

Thanks
Andrew

Andrew Q. Ford, Ph.D.
Office of Scientific Coordination and Program Operations
Division of Microbiology and Infectious Diseases
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5601 Fishers Lane Room 7G64
Rockville, MD 20892
(b) (6)

From: Hauguel, Teresa (NIH/NIAID) [E]
Sent: Wednesday, April 20, 2016 10:51 AM
To: Glowinski, Irene (NIH/NIAID) [E] (b) (6) Dixon, Dennis M. (NIH/NIAID) [E] (b) (6) Lambert, Linda (NIH/NIAID) [E] (b) (6) Spiro, David (NIH/NIAID) [E] (b) (6) Hauguel, Teresa (NIH/NIAID) [E] (b) (6) Post, Diane (NIH/NIAID) [E] (b) (6) Stemmy, Erik (NIH/NIAID) [E] (b) (6) Dugan, Vivien (NIH/NIAID) [E] (b) (6) Mulach, Barbara (NIH/NIAID) [E] (b) (6) Ford, Andrew (NIH/NIAID) [E] (b) (6) Strickler-Dinglasan, Patricia (NIH/NIAID) [E] (b) (6) Hanson, Christopher (NIH/NIAID) [E] (b) (6) Delarosa, Patricia (NIH/NIAID) [E] (b) (6) Santora, Kenneth (NIH/NIAID) [E] (b) (6)
Subject: Reminder - no DURC/GoF meeting this week

Hi Everyone,

Just a quick reminder that there is no DURC/GoF meeting this week. Our next meeting is scheduled for Friday, April 29th at 3pm.

Hope you all get a chance to get outside and enjoy this beautiful weather today!

Best,
Teresa

Teresa M. Hauguel, Ph.D.
Program Officer
Respiratory Diseases Branch
Division of Microbiology and Infectious Diseases
NIAID/NIH/DHHS

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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.

Please consider the environment before printing this e-mail 

From: Hauguel, Teresa (NIH/NIAID) [E]
Sent: Tue, 26 Apr 2016 14:27:20 -0400
To: Stemmy, Erik (NIH/NIAID) [E]
Subject: RE: Call for agenda items - 4/29 DURC/GoF Meeting

Thanks

Teresa M. Hauguel, Ph.D.
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From: Stemmy, Erik (NIH/NIAID) [E]
Sent: Tuesday, April 26, 2016 2:08 PM
To: Hauguel, Teresa (NIH/NIAID) [E] (b) (6)
Subject: RE: Call for agenda items - 4/29 DURC/GoF Meeting

Nothing else from me!

From: Hauguel, Teresa (NIH/NIAID) [E]
Sent: Monday, April 25, 2016 10:49 AM
To: Post, Diane (NIH/NIAID) [E] (b) (6) Stemmy, Erik (NIH/NIAID) [E] (b) (6) Dugan, Vivien (NIH/NIAID) [E] (b) (6) Ford, Andrew (NIH/NIAID) [E] (b) (6) Hanson, Christopher (NIH/NIAID) [E] (b) (6)
Subject: Call for agenda items - 4/29 DURC/GoF Meeting

Hi All,

Below is the draft agenda for this Friday's DURC/GoF meeting. Please let me know if you have any additional agenda items by COB Wednesday.

Thanks,
Teresa

Weekly DURC/GoF Meeting Agenda
Friday, April 29, 2016
3:00-4:00pm
5601/7G31
Call in number: (b) (6)
Passcode: (b) (6)

1. Projects for GoF Review
    a. Li (R01) – May Council – Erik
    b. Mehle (R01) – May Council – Teresa (tentative)
2. DURC Reach-Through Provision – Andrew
3. Updates
    a. NSABB WG – Dennis/Diane/Teresa
    b. GOFROC Strawman – Linda
    c. Erasmus RMP – Ken/Tricia/Diane
4. Round Robin/Other Items

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Please consider the environment before printing this e-mail

From: Spiro, David (NIH/NIAID) [E]
Sent: Wed, 27 Apr 2016 12:43:23 -0400
To: Kraigsley, Alison (NIH/NIAID) [E]; Roberts, Chris (NIH/NIAID) [E]; Post, Diane (NIH/NIAID) [E]; Hauguel, Teresa (NIH/NIAID) [E]; Stemmy, Erik (NIH/NIAID) [E]; Krafft, Amy (NIH/NIAID) [E]; Salomon, Rachelle (NIH/NIAID) [E]; Degrace, Marciela (NIH/NIAID) [E]; Ghenbot, Ghiorghis (NIH/NIAID) [C]
Subject: RE: ACTION: OD seeking activities w/ White House's National Science and Technology Council.

Hi,
The only interaction I am aware of that might involve the White House's National Science and Technology Council involved the GoF moratorium.
Has anyone had interactions with NSTC since Oct 2015?
Please let me know.

David

From: Lambert, Linda (NIH/NIAID) [E]
Sent: Wednesday, April 27, 2016 10:26 AM
To: NIAID RDB <RDB@niaid.nih.gov>
Subject: ACTION: OD seeking activities w/ White House's National Science and Technology Council.

Please see request below.

David, Christine – you or another member of your section please coordinate and let me know about your group – one way or the other.
Xin-Xing, Chris, Kristina – one of you please let me know too.

If you have something, please complete the spreadsheet.
Please get back to me if you do or do not have any activities on/before COB Tuesday May 3rd.

Thank you,
Linda

From: Coomes, Stephanie (NIH/OD) [E]
Sent: Wednesday, April 27, 2016 9:54 AM
To: DMID Chiefs-Principals <DMIDChiefs-Principals@mail.nih.gov>
Cc: NIAID BUGS <BUGS@niaid.nih.gov>
Subject: INPUT by May 4th: Notable Updates on NIH Activities with the NSTC- Spring 2016

Dear Branch Chiefs,

We received a request from NIH OD to provide updates on NIAID activities with the White House's National Science and Technology Council (NSTC) from October 2015 – present.

Attached is a spreadsheet to fill in with details of the activities as well as the responses we submitted for the last round in October 2015.

Please send updates to BUGS by **Wednesday, May 4th**.

Thank you,

Stephanie

Stephanie M. Coomes, Ph.D.
AAAS Science and Technology Policy Fellow
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From: Caviston, Juliane (NIH/NIAID) [C]
Sent: Monday, April 25, 2016 1:45 PM
To: NIAID BUGS <BUGS@niaid.nih.gov>
Cc: Lockmuller, Jane (NIH/NIAID) [E] (b) (6) Goodrich-Doctor, Adrienne (NIH/NIAID) [E] (b) (6) Silver, Cheryl (NIH/NIAID) [E] (b) (6) Harper, Jill (NIH/NIAID) [E] (b) (6) Hudgings, Carole (NIH/NIAID) [E] (b) (6) NIAID SPEB Policy <niaidspebpolicy@niaid.nih.gov>
Subject: Notable Updates on NIH Activities with the NSTC- Spring 2016: Response requested by noon, May 9, 2016

Dear BUGS,

Big Picture: The NIH OD has requested updates on recent NIAID activities with the White House's National Science and Technology Council (NSTC).

Background: The NIH Office of Science Policy (OSP) seeks to enhance its role in coordinating the NIH's involvement in the White House's National Science and Technology Council (NSTC). The goal is to help keep NIH leadership abreast of important initiatives and developments under discussion at the NSTC. OSP will be the contact between NIH staff and leadership to convey information about the NSTC that could affect the NIH such as the following:

- Relevant highlights, recommendations, or concerns raised by the NSTC
- Draft NSTC documents expected to require OD review/clearance in the near future

- NSTC initiatives under discussion (e.g., possible Fast-Track Action Committees or federal-wide data calls)
- Initiation or completion of groups relevant to NIH business
- Invitation to participate in an NSTC activity

Action: Please provide brief updates on NSTC activities over the past 6 months. I have attached a spreadsheet provided by OSP that they would like us to populate with our response. I have also attached the responses that we provided in October 2015 for your reference.

Respond By: Please respond to me (cc Cheryl Silver) **by Noon, Friday, May 9, 2016**.

Previously, Dr. Mike Kurilla reviewed and provided feedback on this request.

Please contact me if you have any questions.

Sincerely,
Juliane Caviston

Juliane Caviston, Ph.D. [C]
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