



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, Maryland 20892-6910  
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
Facsimile: (301) 480-3387

April 19, 2022

Re: Animal Welfare Assurance  
#A3312-01 (OLAW Case R)

Dr. Edward Burns  
Institutional Official  
Albert Einstein College of Medicine of Yeshiva University  
1300 Morris Park Avenue, (b) (4)  
Bronx, NY 10461

Dear Dr. Burns,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 22, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Albert Einstein College of Medicine (Einstein). This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the Albert Einstein College of Medicine Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: the conduct of animal activities at a foreign institution without prior approval from the IACUC or NIH. The final report states the Program Officer (PO) at the National Institute of Allergy & Infectious Diseases (NIAID) reviewed the annual progress report from a Principal Investigator (PI) from Albert Einstein College of Medicine. The PO identified a noncompliance regarding mouse studies conducted at (b) (4) a foreign institution. Specifically, the noncompliance involved the use of a foreign research organization to conduct a study of isofagaomine for treatment of *Clostridium difficile* infection in mice. An active protocol for the animal work at Einstein was previously reviewed and approved by the IACUC at Albert Einstein College of Medicine. However, the original protocol did not describe animal activities to be performed by a foreign institution.

The annual non-competing renewal of NIH research described ongoing and planned animal studies involving *C. difficile*. The continued animal studies were planned for a foreign contract research organization (CRO), in this instance (b) (4) because the organization specializes in animal models of *C. difficile* infection. The PO notified the investigator that foreign animal protocols required separate approval, apart from the original IACUC approval. In response, the PI self-reported that studies already underway were in noncompliance due to lack of prior approval of the foreign research organization. The report states the IACUC reviewed the proposal describing involvement of a foreign CRO on March 14, 2022, and it was approved by the committee. Also, a Memorandum of Understanding (MOU) was established between (b) (4) and Albert Einstein College of Medicine.

Direct costs associated with the (b) (4) mouse trial were paid from NIH research grant R01AI150971. When the noncompliance was discovered, all studies were halted, and no future studies will be initiated until approved by the Einstein IACUC and the NIH. It is stated the PI was unaware of the requirements and approvals necessary for CRO vendor research. The PI has provided assurance that any changes on the animal protocols associated with this grant will only be initiated after consultation with NIH and the Einstein IACUC and their approval. The IACUC states it had no prior knowledge of the PI engaging a foreign CRO. In response to this noncompliance, the follow corrective action plan was established:

- The PI submitted a new protocol to the IACUC for foreign involvement, "Clostridium difficile anti-toxin effects in mice (Virtual Mouse Protocol)" Protocol # 00001593 approved 03/14/2022 to 03/13/2025. This protocol contains all the animal work to be done by (b) (4)
- The PI assures the NIH OLAW and the Einstein IACUC that all future changes of animal protocol will only be initiated after consultation with them and upon their approval.
- The PI assures the IACUC that he will carefully review and adhere to approved study protocols.
- The PI has notified the NIH, (b) (4) (the CRO), and the Einstein IACUC of the requirements for institutional approvals at the level of both the IACUC and the NIH.
- An MOU has been established between the Albert Einstein College of Medicine and (b) (4) that all IACUC regulations will be complied with.
- Departmental administrative officials have been reminded of the existing Einstein IACUC policy that prior approval is required for CRO animal research.
- A request for NIH approval of foreign CRO involvement in the animal studies has been submitted.

Please note that since the animal work was not approved by the IACUC, any NIH funds used prior to March 14, 2022 should be returned to the grant. OLAW strongly suggests that Einstein review its policies and procedures for animal activities conducted at subgrantees and/or foreign institutions. Based on the information provided, the Office of Laboratory Animal Welfare (OLAW) is satisfied that appropriate actions have been taken to correct and prevent recurrence of the noncompliance.

We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

Jacquelyn T.  
Tubbs -S

Digitally signed by  
Jacquelyn T. Tubbs -S  
Date: 2022.04.19  
14:41:57 -04'00'

Jacquelyn Tubbs, DVM, DACLAM  
Senior Animal Welfare Program Specialist  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact  
Emily Linde, Grants Management Officer, NIAID  
Ryan Ranallo, Program Officer, NIAID

March 22, 2022

Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982  
Phone: 301-594-2061  
FAX: 301-402-2803  
Phone: 301-594-2061; 301-594-2921  
E-mail: [olawdco@mail.nih.gov](mailto:olawdco@mail.nih.gov)

**Animal Welfare Assurance number: D16-00200 (A3312-01)**

Dear OLAW Division of Compliance Oversight,

Dr. Vern Schramm notified the IACUC of a grant issue involving animal care that arose in the NIH review of his annual progress report on NIH grant R01AI150971-01A1 entitled "Targeting Clostridioides difficile with microbiome-sparing, resistant-proof anti-toxins". In an email of March 16, 2022 to Dr. Schramm, Dr. Ryan Ranallo of NIAID indicated that a non-compliance report needs to be filed regarding mouse studies at (b) (4). The email states "Importantly, it appears that work at (b) (4) has started without an approved Foreign Assurance which constitutes a non-compliance with PHS Policy. NIH OLAW oversees PHS-funded animal activities by the authority of the Health Research Extension Act of 1985 and the PHS Policy on Humane Care and Use of Laboratory Animals (Policy). The PHS Policy, section IV.A., requires that: "No activity involving animals may be conducted or supported by the PHS until the institution conducting the activity has provided a written Assurance acceptable to the PHS, setting forth compliance with the Policy." As such, NIH OLAW recommends that the primary awardee institution, Albert Einstein, submit a self-report of non-compliance to OLAW's Division of Compliance Oversight (DCO), detailing the non-compliance event and measures taken to ensure prevention from recurrence in the future. Details on reporting can be found on the DCO website: <https://olaw.nih.gov/guidance/reporting-noncompliance.htm>."

The Albert Einstein College of Medicine, in accordance with Assurance A0101-01 and PHS Policy IV.F.3., provides this report of noncompliance. The noncompliance regards the use a foreign research organization to conduct a study of isofagaomine for treatment of *Clostridium difficile* infection in mice. An active research protocol for this work at Einstein was previously reviewed and approved by the IACUC at the Albert Einstein College of Medicine, however, this original approval did not include the use of a foreign vendor to perform contract research. Dr. Vern L. Schramm's approved mouse study

protocol is currently entitled "Transition state analogs as antimicrobial agents", IACUC Protocol # 00001565, approval date 01/07/2022, expiration date 01/26/2025.

This incident was first reported to Dr. Ryan Ranallo on March 1, 2022 and clarified in subsequent communications. Ongoing and planned animal studies involving *Clostridium difficile* were described in the annual non-competing renewal of NIH research grant R01AI150971. Continued animal studies were planned for a foreign contract research organization (CROs), i.e. (b) (4) who specializes in animal models of *Clostridium difficile* infection. This incident was self-reported by the PI, when he was informed by Dr. Ranallo that foreign animal protocols needed separate approval, apart from the original IACUC approval to the research program PI, and that studies already underway were in non-compliance without prior approval of the foreign research organization.

The Albert Einstein College of Medicine IACUC reviewed the proposal for foreign CRO involvement on March 14, 2022 and it was approved for 3 years as a virtual mouse protocol with (b) (4) entitled "Clostridium difficile anti-toxin effects in mice (Virtual Protocol)" Protocol # 00001593 approved 03/14/2022 to 03/13/2025. These documents have been submitted to Dr. Ryan Ranallo and are in review. As part of this approval process, a Memoranda of Understanding (MOU) was executed between (b) (4) and the Albert Einstein College of Medicine.

Direct costs associated with the (b) (4) mouse trial during the -01 grant period (April 1 2021 – March 31, 2022) were paid from NIH research grant R01AI150971. Once the noncompliance was identified all studies were stopped and no future studies will be initiated until properly documented and approved by the Albert Einstein IACUC and the NIH.

Dr. Schramm was unaware of the specific and distinct requirements and approvals required for CRO vendor research and is responsible for this non-compliance. Dr. Schramm (the PI of the grant) assures the NIH OLAW and the Einstein IACUC that any changes on the animal protocols associated with this grant will only be initiated after consultation with them and upon their approval. The Albert Einstein College of Medicine IACUC had no prior knowledge of the PI engaging a foreign CRO.

**Based on the IACUC review we believe the following violation requires mandatory reporting by our institutional official to the Office of Laboratory Animal Welfare (OLAW):**

**Contract animal research at a foreign institution (CRO) without an approved protocol and assurance document.**

**The following corrective action plan was implemented after the incident:**

1. The PI submitted a new protocol to the IACUC for foreign involvement, "*Clostridium difficile* anti-toxin effects in mice (Virtual Mouse Protocol)" Protocol # 00001593 approved 03/14/2022 to 03/13/2025. This protocol contains all of the animal work to be done by (b) (4)
2. The PI assures the NIH OLAW and the Einstein IACUC that all future changes of animal protocol will only be initiated after consultation with them and upon their approval.



3. The PI assures the IACUC that he will carefully review and adhere to approved study protocols.
4. The PI has notified the NIH, (b) (4) (the CRO), and the Einstein IACUC of the requirements for institutional approvals at the level of both the IACUC and the NIH.
5. An MOU has been established between the Albert Einstein College of Medicine and Sporegen (the CRO) that all IACUC regulations will be complied with.
6. Departmental administrative officials have been reminded of the existing Einstein IACUC policy that prior approval is required for CRO animal research.
7. A request for NIH approval of foreign CRO involvement in the animal studies has been submitted.

The Albert Einstein College of Medicine is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Professor Louis M. Weiss, IACUC Chair [louis.weiss@einsteinmed.edu](mailto:louis.weiss@einsteinmed.edu)

This letter serves as the official notification from Dr. Edward Burns, the institutional official for our animal assurance, to the National Institutes of Health - Office of Laboratory Animal Welfare (OLAW) of this incident, our institutional actions to address the issues raised by this incident and the resolution of this problem.

Sincerely,

(b) (6)

Dr. Edward Burns  
Executive Dean, Einstein  
Institutional Official Einstein IACUC

(b) (6)

Dr. Louis M. Weiss  
Professor of Pathology and Medicine  
Chair, Einstein IACUC

Cc: Rvan Ranallo, Ph.D. [rvan.ranallo@nih.gov](mailto:rvan.ranallo@nih.gov)

(b) (6)

Vern L. Schramm, [vern.schramm@einsteinmed.edu](mailto:vern.schramm@einsteinmed.edu)

Science at the heart of medicine

**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, March 23, 2022 7:34 AM  
**To:** Edward Burns  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: D16-00200 (A3312-01)

Thank you for this report, Dr. Burns. We will send a response soon.

Axel Wolff, M.S., D.V.M.  
Deputy Director, OLAW

**From:** Edward Burns <ed.burns@einsteinmed.edu>  
**Sent:** Tuesday, March 22, 2022 4:17 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6) Louis Weiss <louis.weiss@einsteinmed.edu>;  
ryan.renallo@nih.gov; (b) (6) Vern Schramm  
<vern.schramm@einsteinmed.edu>  
**Subject:** [EXTERNAL] D16-00200 (A3312-01)

**CAUTION:** This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

To OLAW Division of Compliance Oversight, please see our institutional reply that is attached.  
Thank you for your consideration.

(b) (6)

Edward R. Burns, M.D.  
Executive Dean and Professor  
Albert Einstein College of Medicine  
1300 Morris Park Avenue

(b) (4)

Bronx, NY 10461

(b) (6)

**Note:** Newest email address

[ed.burns@einsteinmed.edu](mailto:ed.burns@einsteinmed.edu)

<https://einsteinmed.edu/leadership/executive-dean/>



Montefiore

**Morse, Brent (NIH/OD) [E]**

A3312

**From:** Lukovsky-Akhsanov, Nicole (NIH/OD) [E]  
**Sent:** Wednesday, March 16, 2022 3:56 PM  
**To:** Morse, Brent (NIH/OD) [E]  
**Subject:** Referral to DCO: R01AI150971-01A1  
**Attachments:** RE\_ RPPR for R01AI150971-01A1.pdf

Please assign to  
Dr. Tubbs

**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

Good day Brent,

Please see below regarding R01AI150971-01A1, prime awardee is Albert Einstein. It appears the work at one of the foreign collaborators, (b) (4) has already started however the organization does not hold an Assurance. The PO agreed to communicate the recommendation for self-reporting and also asked to be CC'd on OLAW's response once issued.

The attachment contains some other details that may be helpful but the primary information is in the email string below.

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

Regards,

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM  
Senior Animal Welfare Program Specialist  
Division of Assurances  
Office of Laboratory Animal Welfare, NIH  
6700B Rockledge Drive, Suite 2500, MSC-6910  
Bethesda, Maryland 20892-6910  
Office: 301-480-8196  
[Nicole.Lukovsky@NIH.gov](mailto:Nicole.Lukovsky@NIH.gov)



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**From:** Ranallo, Ryan (NIH/NIAID) [E] <[ryan.ranallo@nih.gov](mailto:ryan.ranallo@nih.gov)>  
**Sent:** Wednesday, March 16, 2022 3:49 PM  
**To:** Lukovsky-Akhsanov, Nicole (NIH/OD) [E] <[nicole.lukovsky@nih.gov](mailto:nicole.lukovsky@nih.gov)>  
**Subject:** Re: RPPR for R01AI150971-01A1

Thanks, Nicole. Yes, I think it would be helpful for me to have this documentation for the grant file.  
Really appreciate it.  
Best,

Ryan

---

**From:** "Lukovsky-Akhsanov, Nicole (NIH/OD) [E]" <[nicole.lukovsky@nih.gov](mailto:nicole.lukovsky@nih.gov)>  
**Date:** Wednesday, March 16, 2022 at 3:40 PM  
**To:** "Ranallo, Ryan (NIH/NIAID) [E]" <[ryan.ranallo@nih.gov](mailto:ryan.ranallo@nih.gov)>, "Tang, Sandy (NIH/OD) [E]" <[sandy.tang@nih.gov](mailto:sandy.tang@nih.gov)>, "OLAW Division of Assurances (NIH/OD)" <[olawdoa@od.nih.gov](mailto:olawdoa@od.nih.gov)>  
**Cc:** "Goffigan, Kalaya (NIH/NIAID) [E]" <[kalaya.goffigan@nih.gov](mailto:kalaya.goffigan@nih.gov)>  
**Subject:** RE: RPPR for R01AI150971-01A1

Ryan,

Thank you for the rapid response. There is no official format however it is likely that the chief GMO will be copied on our response to the organization's self-report. If you like, I can send a note along to DCO that you would like to be copied on OLAW's response as well. Please let me know.

Regards,

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM  
Senior Animal Welfare Program Specialist  
Division of Assurances  
Office of Laboratory Animal Welfare, NIH  
6700B Rockledge Drive, Suite 2500, MSC-6910  
Bethesda, Maryland 20892-6910  
Office: 301-480-8196  
[Nicole.Lukovsky@NIH.gov](mailto:Nicole.Lukovsky@NIH.gov)



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**From:** Ranallo, Ryan (NIH/NIAID) [E] <[ryan.ranallo@nih.gov](mailto:ryan.ranallo@nih.gov)>  
**Sent:** Wednesday, March 16, 2022 3:36 PM  
**To:** Lukovsky-Akhsanov, Nicole (NIH/OD) [E] <[nicole.lukovsky@nih.gov](mailto:nicole.lukovsky@nih.gov)>; Tang, Sandy (NIH/OD) [E] <[sandy.tang@nih.gov](mailto:sandy.tang@nih.gov)>; OLAW Division of Assurances (NIH/OD) <[olawdoa@od.nih.gov](mailto:olawdoa@od.nih.gov)>  
**Cc:** Goffigan, Kalaya (NIH/NIAID) [E] <[kalaya.goffigan@nih.gov](mailto:kalaya.goffigan@nih.gov)>  
**Subject:** Re: RPPR for R01AI150971-01A1

Thanks, Nicole. Yes, I will reach out to the PI/institution to request clarification on the VAS and to recommend they submit a self-report of non-compliance to DCO. Is there some type of feedback loop on our side to ensure this happens? Just wondering.

Thanks again.  
Best,  
Ryan



**From:** "Lukovsky-Akhsanov, Nicole (NIH/OD) [E]" <[nicole.lukovsky@nih.gov](mailto:nicole.lukovsky@nih.gov)>  
**Date:** Wednesday, March 16, 2022 at 2:24 PM  
**To:** "Ranallo, Ryan (NIH/NIAID) [E]" <[ryan.ranallo@nih.gov](mailto:ryan.ranallo@nih.gov)>, "Tang, Sandy (NIH/OD) [E]" <[sandy.tang@nih.gov](mailto:sandy.tang@nih.gov)>, "OLAW Division of Assurances (NIH/OD)" <[olawdoa@od.nih.gov](mailto:olawdoa@od.nih.gov)>  
**Cc:** "Goffigan, Kalaya (NIH/NIAID) [E]" <[kalaya.goffigan@nih.gov](mailto:kalaya.goffigan@nih.gov)>  
**Subject:** RE: RPPR for R01AI150971-01A1

Good day Dr. Ranallo,

I am the VAS reviewer for this project and wanted to briefly touch base. Attached is the VAS with comments for clarification based on the provided responses. Please ensure the responses are provided in tracked changes or different color font for ease of review.

Importantly, it appears that work at (b) (4) has started without an approved Foreign Assurance which constitutes a non-compliance with PHS Policy.

OLAW oversees PHS-funded animal activities by the authority of the Health Research Extension Act of 1985 and the PHS Policy on Humane Care and Use of Laboratory Animals (Policy). The PHS Policy, section IV.A., requires that:

*"No activity involving animals may be conducted or supported by the PHS until the institution conducting the activity has provided a written Assurance acceptable to the PHS, setting forth compliance with the Policy."*

As such, OLAW recommends that the primary awardee institution, Albert Einstein, submitted a self-report of non-compliance to OLAW's Division of Compliance Oversight (DCO), detailing the non-compliance event and measures taken to ensure prevention from recurrence in the future. Details on reporting can be found on the DCO website: <https://olaw.nih.gov/guidance/reporting-noncompliance.htm>. Will you be reaching out to them to provide this level of detail?

As always, please let me know if you have any questions or concerns and we look forward to hearing back from you.

Regards,

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM  
Senior Animal Welfare Program Specialist  
Division of Assurances  
Office of Laboratory Animal Welfare, NIH  
6700B Rockledge Drive, Suite 2500, MSC-6910  
Bethesda, Maryland 20892-6910  
Office: 301-480-8196  
[Nicole.Lukovsky@NIH.gov](mailto:Nicole.Lukovsky@NIH.gov)



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**From:** Ranallo, Ryan (NIH/NIAID) [E] <[ryan.ranallo@nih.gov](mailto:ryan.ranallo@nih.gov)>  
**Sent:** Wednesday, March 16, 2022 11:47 AM  
**To:** Tang, Sandy (NIH/OD) [E] <[sandy.tang@nih.gov](mailto:sandy.tang@nih.gov)>; OLAW Division of Assurances (NIH/OD) <[olawdoa@od.nih.gov](mailto:olawdoa@od.nih.gov)>  
**Cc:** Goffigan, Kalaya (NIH/NIAID) [E] <[kalaya.goffigan@nih.gov](mailto:kalaya.goffigan@nih.gov)>  
**Subject:** Re: RPPR for R01AI150971-01A1

Dear Sandy,

I received responses from the PI for this award and have pasted the information below (in red). Also, based on these responses, I can confirm that Program is requesting OLAW to review the VAS and negotiate Foreign Assurance(s) for any ongoing or anticipated work at (b) (4). Thank you very much for the swift initial response and for your ongoing support. Please let me know if you need anything else.

Best,  
Ryan

Ryan Ranallo, Ph.D.  
Program Officer  
Enteric and Sexually Transmitted Infections Branch  
National Institute of Allergy & Infectious Diseases  
National Institutes of Health  
5601 Fishers Lane, Room 8F46  
Rockville, MD 20852  
PH: 240-627-3351  
Email: [ryan.ranallo@nih.gov](mailto:ryan.ranallo@nih.gov)

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**From:** "Tang, Sandy (NIH/OD) [E]" <[sandy.tang@nih.gov](mailto:sandy.tang@nih.gov)>  
**Date:** Tuesday, March 15, 2022 at 10:39 AM  
**To:** "Ranallo, Ryan (NIH/NIAID) [E]" <[ryan.ranallo@nih.gov](mailto:ryan.ranallo@nih.gov)>, "OLAW Division of Assurances (NIH/OD)" <[olawdoa@od.nih.gov](mailto:olawdoa@od.nih.gov)>  
**Cc:** "Steele, Bianca (NIH/NIAID) [E]" <[bianca.steele@nih.gov](mailto:bianca.steele@nih.gov)>  
**Subject:** Re: RPPR for R01AI150971-01A1

Dear Ryan,

Thank you for the provided information. Can you please confirm the following:

1. OLAW understands that animal work at (b) (4) has already started. Can you please confirm if the animal work has already been completed or if it is in progress? If the work is in progress, what is the estimated completion date? The work at (b) (4) is still in progress. The estimated completion date is July 2024.
2. From the message below, it appears work at (b) (4) has not yet been started, is that correct? If work has already started, please advise if the work is still in progress along with estimated completion date if not already completed. The

proposed work at (b) (4) has not yet started. We estimate completion date to be July 2024.

3. A reference was made to collaborators in (b) (4) Is animal work anticipated or ongoing in (b) (4) (b) (4)? No animal work will be performed in (b) (4)

Please note there are no IIAs on file for this project. (b) (4) does not currently hold an OLAW Assurance and (b) (4) holds an Assurance under the (b) (4) OLAW believes that (b) (4) are the same organization however we request confirmation in the performance site to ensure accuracy. Confirmed. In addition, can you please confirm that program is requesting OLAW to review the VAS and negotiate Foreign Assurance(s) for any ongoing or anticipated work at (b) (4)? Confirmed. Note that OLAW does not issue Assurances retroactively therefore if work has been completed at either or both locations with no plans for ongoing work, no Assurance negotiation request will be initiated from OLAW.

Thank you,

Sandy Tang, B.A.  
Program Analyst, Division of Assurances  
Office of Laboratory Animal Welfare  
National Institutes of Health  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, Maryland 20892-6910  
(301) 496-8287  
[Sandy.Tang@nih.gov](mailto:Sandy.Tang@nih.gov)

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**From:** Ranallo, Ryan (NIH/NIAID) [E] <[ryan.ranallo@nih.gov](mailto:ryan.ranallo@nih.gov)>  
**Sent:** Monday, March 14, 2022 4:23 PM  
**To:** OLAW Division of Assurances (NIH/OD) <[olawdoa@od.nih.gov](mailto:olawdoa@od.nih.gov)>  
**Cc:** Steele, Bianca (NIH/NIAID) [E] <[bianca.steele@nih.gov](mailto:bianca.steele@nih.gov)>  
**Subject:** FW: [EXTERNAL] Re: RPPR for R01AI150971-01A1

Dear OLAW,

In reviewing the progress report for a noncompeting R01, Program identified ongoing and planned work (subcontract) involving vertebrate animals that had not been previously authorized through prior approval. Program requested prior approval for conducting this work along with the following:

- A full vertebrate animal section (VAS) for the work involving mice at the (b) (4) Additional information regarding the approval date from the institutional animal care and use committee (IACUC) and animal welfare assurance or foreign assurance.
- A formal request to use a new animal species (i.e., hamster model) for this project. To include a complete justification for the proposed changes and the potential impact on the project abstract, aims and project narrative. Include a full VAS for all proposed experiments involving hamsters. Additional information is needed regarding the approval date from the institutional animal care and use committee (IACUC) and animal welfare assurance or foreign assurance.

Program has reviewed the attached response and found it acceptable and would like to determine if the performance sites have the appropriate inter-institutional assurance on file. This information is needed to properly enter the Foreign Component Data (FACTS) so that the non-competing Notice of Award can be issued.

Please let me know if additional information is needed from the US-based institution or any other information.

Thanks in advance.  
Best,  
Ryan

Ryan Ranallo, Ph.D.  
Program Officer  
Enteric and Sexually Transmitted Infections Branch  
National Institute of Allergy & Infectious Diseases  
National Institutes of Health  
5601 Fishers Lane, Room 8F46  
Rockville, MD 20852  
PH: 240-627-3351  
Email: [ryan.ranallo@nih.gov](mailto:ryan.ranallo@nih.gov)

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**From:** (b) (6)  
**Date:** Monday, March 14, 2022 at 12:50 PM  
**To:** "Ranallo, Ryan (NIH/NIAID) [E]" <[ryan.ranallo@nih.gov](mailto:ryan.ranallo@nih.gov)>, "Steele, Bianca (NIH/NIAID) [E]" <[bianca.steele@nih.gov](mailto:bianca.steele@nih.gov)>  
**Cc:** (b) (6) Vern Schramm <[vern.schramm@einsteinmed.edu](mailto:vern.schramm@einsteinmed.edu)>  
**Subject:** Fw: [EXTERNAL] Re: RPPR for R01AI150971-01A1

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---

Attached, please find a prior approval request/vertebrate animal document

Thank you for your continued assistance and support. They are greatly appreciated.

Best Regards,

(b) (6)



From: [REDACTED] (b) (6)  
Sent: Monday, March 14, 2022 12:05 PM  
To: [REDACTED] (b) (6) Vern Schramm <vern.schramm@einsteinmed.edu>  
Subject: Fw: [EXTERNAL] Re: RPPR for R01AI150971-01A1

Dear [REDACTED] (b) (6)

Dr. Schramm has provided the attached response to the following request from Dr. Ranallo at the NIH regarding his NIH Progress Rpt. Please forward to Ranallo, Ryan (NIH/NIAID) [E] <ryan.ranallo@nihDe.gov> and Steele, Bianca (NIH/NIAID) [E] <bianca.steele@nih.gov> Please cc Dr. Schramm:

I will need the following:

1. A formal Prior Approval Request submitted from your institutional signing official that addresses the following:
  - The addition of all new and/or proposed foreign collaborations [REDACTED] (b) (4) To include the organization's full contact information (name, address, phone, and email) for the site and a detailed description all activities to be performed by the collaborator.
  - A full vertebrate animal section (VAS) for the work involving mice at the [REDACTED] (b) (4) The VAS should address the 4 points listed in the attached document. Additional information regarding the approval date from the institutional animal care and use committee (IACUC) and animal welfare assurance or foreign assurance.
  - A formal request to use a new animal species (i.e., hamster model) for this project. To include a complete justification for the proposed changes and the potential impact on the project abstract, aims and project narrative. Include a full VAS for all proposed experiments involving hamsters. The VAS should address the 4 points listed in the attached document. Additional information is needed regarding the approval date from the institutional animal care and use committee (IACUC) and animal welfare assurance or foreign assurance.

The links provided in my email below as well as this NIAID link on using vertebrate animals should contain all the details necessary to complete this request. Only after NIAID receives, reviews, and approves the prior approval request can a new (year two) Notice of Award be issued.

Thanks,

Ryan

Ryan Ranallo, Ph.D.

Program Officer



Enteric and Sexually Transmitted Infections Branch

National Institute of Allergy & Infectious Diseases

National Institutes of Health

5601 Fishers Lane, Room 8F46

Rockville, MD 20852

PH: 240-627-3351

Email: [ryan.ranallo@nih.gov](mailto:ryan.ranallo@nih.gov)

---

**From:** Vern Schramm <[vern.schramm@einsteinmed.edu](mailto:vern.schramm@einsteinmed.edu)>

**Sent:** Monday, March 14, 2022 11:40 AM

**To:** [REDACTED] (b) (6)

**Subject:** Fw: [EXTERNAL] Re: RPPR for R01AI150971-01A1

[REDACTED] (b) (6)

Prior to approval for R01AI150971, for the next year, the program officer requested an update justification for use of animals in CRO services.

All of the requested information is in the attached document. It needs to be signed by the institutional grants signing individual then submitted to the NIH personnel listed in the attached email.

I think it can be signed and sent to them with a cc to me, or signed and sent to me so I can send it.

Thanks [REDACTED] (b) (6)  
Vern

---

**From:** Ranallo, Ryan (NIH/NIAID) [E] <[ryan.ranallo@nih.gov](mailto:ryan.ranallo@nih.gov)>

**Sent:** Thursday, March 3, 2022 9:28 AM

**To:** Vern Schramm <[vern.schramm@einsteinmed.edu](mailto:vern.schramm@einsteinmed.edu)>

**Cc:** Steele, Bianca (NIH/NIAID) [E] <[bianca.steele@nih.gov](mailto:bianca.steele@nih.gov)>; [REDACTED] (b) (6)

**Subject:** Re: [EXTERNAL] Re: RPPR for R01AI150971-01A1

Good morning, Vern,

The draft looks good so far. However, the justification for requesting the change(s) in scope needs to be in narrative form and address all changes requested and why (i.e., scientific rationale or other rationale) the change is needed. For example, why did you decide to have the mouse work done at [REDACTED] (b) (4) as opposed to Albert Einstein as originally proposed in your application? Will all subsequent mouse work be done at this entity? Why does the hamster model need to be added and how will this advance the aims of your project? What, if any, alternatives were considered prior

to making the request? This narrative, along with the IACUC approvals and foreign assurances should be sufficient for NIAID to consider the request.

Thank you for your acute attention to this matter.

Best,  
Ryan

Ryan Ranallo, Ph.D.  
Program Officer  
Enteric and Sexually Transmitted Infections Branch  
National Institute of Allergy & Infectious Diseases  
National Institutes of Health  
5601 Fishers Lane, Room 8F46  
Rockville, MD 20852  
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**From:** Vern Schramm <[vern.schramm@einsteinmed.edu](mailto:vern.schramm@einsteinmed.edu)>  
**Date:** Wednesday, March 2, 2022 at 10:33 AM  
**To:** "Ranallo, Ryan (NIH/NIAID) [E]" <[ryan.ranallo@nih.gov](mailto:ryan.ranallo@nih.gov)>  
**Cc:** "Steele, Bianca (NIH/NIAID) [E]" <[bianca.steele@nih.gov](mailto:bianca.steele@nih.gov)>, (b) (6)  
(b) (6)  
**Subject:** Re: [EXTERNAL] Re: RPPR for R01AI150971-01A1

---

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---

Dear Ryan,

I am attaching a draft to be processed and signed by our institutional signing official.

Could you please have a look and see if I have covered everything correctly from your request?

I have requested the documented animal welfare assurances from the foreign vendors and will add that prior to submission.

Best Wishes,  
Vern

**From:** Ranallo, Ryan (NIH/NIAID) [E] <[ryan.ranallo@nih.gov](mailto:ryan.ranallo@nih.gov)>

**Sent:** Tuesday, March 1, 2022 2:34 PM

**To:** Vern Schramm <[vern.schramm@einsteinmed.edu](mailto:vern.schramm@einsteinmed.edu)>

**Cc:** Steele, Bianca (NIH/NIAID) [E] <[bianca.steele@nih.gov](mailto:bianca.steele@nih.gov)>; [REDACTED] (b) (6)

**Subject:** Re: [EXTERNAL] Re: RPPR for R01AI150971-01A1

Thanks, Vern.

I will need the following:

1. A formal Prior Approval Request submitted from your institutional signing official that addresses the following:
  - The addition of all new and/or proposed foreign collaborations [REDACTED] (b) (4) To include the organization's full contact information (name, address, phone, and email) for the site and a detailed description all activities to be performed by the collaborator.
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Thanks,  
Ryan

Ryan Ranallo, Ph.D.  
Program Officer  
Enteric and Sexually Transmitted Infections Branch  
National Institute of Allergy & Infectious Diseases  
National Institutes of Health  
5601 Fishers Lane, Room 8F46  
Rockville, MD 20852  
PH: 240-627-3351  
Email: [ryan.ranallo@nih.gov](mailto:ryan.ranallo@nih.gov)

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--

**From:** Vern Schramm <vern.schramm@einsteinmed.edu>  
**Date:** Tuesday, March 1, 2022 at 1:31 PM  
**To:** "Ranallo, Ryan (NIH/NIAID) [E]" <ryan.ranallo@nih.gov>  
**Subject:** [EXTERNAL] Re: RPPR for R01AI150971-01A1

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dear Ryan,

Mouse work in the first year was limited to fee for service, by purchase order. A company in the (b) (4) has one of the few mouse models of C. diff. toxin.

In consultation with our (b) (4) collaborators, we agreed that the highest priority in year one was the mouse work. The first-year allocation thus went for the fee for service mouse testing.

We are obtaining quotes for from a second vendor (b) (4) for testing in hamsters during year two. That is also fee for service by purchase order. That work has not begun. (b) (4) has offices in the US, but their animal testing is in (b) (4)

Please let me know if you need more information.

Best Wishes,  
Vern

**From:** Ranallo, Ryan (NIH/NIAID) [E] <ryan.ranallo@nih.gov>  
**Sent:** Tuesday, March 1, 2022 12:03 PM  
**To:** Vern Schramm <vern.schramm@einsteinmed.edu>  
**Cc:** Steele, Bianca (NIH/NIAID) [E] <bianca.steele@nih.gov> (b) (6)  
**Subject:** RPPR for R01AI150971-01A1

Dear Vern,

I hope you are doing well. In reviewing the RPPR for the aforementioned project it appears that you've started and/or will be starting a new collaboration with a non-US based organization to conduct some animal work. Please note that prior approval from NIAID is required to establish a subaward involving a new collaboration with a foreign organization and before any work can begin. Also, prior approval is required prior to changing any aspects of research involving vertebrate animals (e.g., new animal species). I'm sending you some NIAID links on subawards, seeking prior approval and type of activities that constitute a change in scope.

Using Subawards:

<https://www.niaid.nih.gov/grants-contracts/using-subawards>

When to seek prior approval:

<https://www.niaid.nih.gov/grants-contracts/prior-approval-establish-subaward>

Change in Scope:

<https://www.niaid.nih.gov/grants-contracts/ask-permission-change-scope>

Please review the information provided in these links and provide clarification on any new subawards with foreign institutions and any changes to your plans to use animal models (specifically the hamster model) to establish safety, PK, and efficacy against C. diff toxins. Also, based on information in the RPPR it appears that some of the year one budget has already been spent on work completed in the UK. Is this a new collaboration, what is the nature of the work, and did it involve animals or humans? Finally, have funds from this award been spent in (b) (4) as originally proposed.

Thanks for your attention to this request. I look forward to hearing from you.

Best,

Ryan

Ryan Ranallo, Ph.D.  
Program Officer  
Enteric and Sexually Transmitted Infections Branch  
National Institute of Allergy & Infectious Diseases  
National Institutes of Health  
5601 Fishers Lane, Room 8F46  
Rockville, MD 20852  
PH: 240-627-3351  
Email: [ryan.ranallo@nih.gov](mailto:ryan.ranallo@nih.gov)

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## Morse, Brent (NIH/OD) [E]

---

**To:** Morse, Brent (NIH/OD) [E]  
**Subject:** FW: Referral to DCO: R01AI150971-01A1  
**Attachments:** image003.png; image001.png; image002.png; RE\_ RPPR for R01AI150971-01A1.pdf

Brent C. Morse, DVM, DACLAM  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

**From:** Morse, Brent (NIH/OD) [E]  
**Sent:** Wednesday, March 16, 2022 4:02 PM  
**To:** Lukovsky-Akhsanov, Nicole (NIH/OD) [E] <[nicole.lukovsky@nih.gov](mailto:nicole.lukovsky@nih.gov)>  
**Subject:** Re: Referral to DCO: R01AI150971-01A1

Thank you, Nicole. We'll copy Ryan Ranallo on our final letter. Brent

Sent from my iPad

On Mar 16, 2022, at 3:56 PM, Lukovsky-Akhsanov, Nicole (NIH/OD) [E] <[nicole.lukovsky@nih.gov](mailto:nicole.lukovsky@nih.gov)> wrote:

Good day Brent,

Please see below regarding R01AI150971-01A1, prime awardee is Albert Einstein. It appears the work at one of the foreign collaborators, (b) (4) has already started however the organization does not hold an Assurance. The PO agreed to communicate the recommendation for self-reporting and also asked to be CC'd on OLAW's response once issued.

The attachment contains some other details that may be helpful but the primary information is in the email string below.

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

Regards,

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM  
Senior Animal Welfare Program Specialist  
Division of Assurances  
Office of Laboratory Animal Welfare, NIH  
6700B Rockledge Drive, Suite 2500, MSC-6910  
Bethesda, Maryland 20892-6910  
Office: 301-480-8196  
[Nicole.Lukovsky@NIH.gov](mailto:Nicole.Lukovsky@NIH.gov)

**From:** [Lukovsky-Akhsanov, Nicole \(NIH/OD\) \[E\]](#)  
**To:** [Tang, Sandy \(NIH/OD\) \[E\]](#)  
**Cc:** [OLAW Division of Assurances \(NIH/OD\)](#)  
**Subject:** RE: RPPR for R01AI150971-01A1  
**Date:** Tuesday, March 15, 2022 10:34:00 AM  
**Attachments:** [image001.png](#)  
**Importance:** High

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Good morning,

Thank you for the provided information. Can you please confirm the following:

1. OLAW understands that animal work at (b) (4) has already started. Can you please confirm if the animal work has already been completed or if it is in progress? If the work is in progress, what is the estimated completion date?
2. From the message below, it appears work at (b) (4) has not yet been started, is that correct? If work has already started, please advise if the work is still in progress along with estimated completion date if not already completed.
3. A reference was made to collaborators in (b) (4). Is animal work anticipated or ongoing in (b) (4) (b) (4)

Please note there are no IAs on file for this project. (b) (4) does not currently hold an OLAW Assurance and (b) (4) holds an Assurance under the (b) (4) OLAW believes that (b) (4) are the same organization however we request confirmation in the performance site to ensure accuracy. In addition, can you please confirm that program is requesting OLAW to review the VAS and negotiate Foreign Assurance(s) for any ongoing or anticipated work at (b) (4). Note that OLAW does not issue Assurances retroactively therefore if work has been completed at either or both locations with no plans for ongoing work, no Assurance negotiation request will be initiated from OLAW.

Thank you.

Regards,

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM  
Senior Animal Welfare Program Specialist  
Division of Assurances  
Office of Laboratory Animal Welfare, NIH  
6700B Rockledge Drive, Suite 2500, MSC-6910  
Bethesda, Maryland 20892-6910  
Office: 301-480-8196  
[Nicole.Lukovsky@NIH.gov](mailto:Nicole.Lukovsky@NIH.gov)



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**From:** Ranallo, Ryan (NIH/NIAID) [E] <[ryan.ranallo@nih.gov](mailto:ryan.ranallo@nih.gov)>  
**Sent:** Monday, March 14, 2022 4:23 PM  
**To:** OLAW Division of Assurances (NIH/OD) <[olawdoa@od.nih.gov](mailto:olawdoa@od.nih.gov)>  
**Cc:** Steele, Bianca (NIH/NIAID) [E] <[bianca.steele@nih.gov](mailto:bianca.steele@nih.gov)>  
**Subject:** FW: [EXTERNAL] Re: RPPR for R01AI150971-01A1

Dear OLAW,

In reviewing the progress report for a noncompeting R01, Program identified ongoing and planned work (subcontract) involving vertebrate animals that had not been previously authorized through prior approval. Program requested prior approval for conducting this work along with the following:

- A full vertebrate animal section (VAS) for the work involving mice at the [REDACTED] (b) (4). Additional information regarding the approval date from the institutional animal care and use committee (IACUC) and animal welfare assurance or foreign assurance.
- A formal request to use a new animal species (i.e., hamster model) for this project. To include a complete justification for the proposed changes and the potential impact on the project abstract, aims and project narrative. Include a full VAS for all proposed experiments involving hamsters. Additional information is needed regarding the approval date from the institutional animal care and use committee (IACUC) and animal welfare assurance or foreign assurance.

Program has reviewed the attached response and found it acceptable and would like to determine if the performance sites have the appropriate inter-institutional assurance on file. This is information is needed to properly enter the Foreign Component Data (FACTS) so that the non-competing Notice of Award can be issued.

Please let me know if additional information is needed from the US-based institution or any other information.

Thanks in advance.

Best,

Ryan

Ryan Ranallo, Ph.D.  
Program Officer  
Enteric and Sexually Transmitted Infections Branch  
National Institute of Allergy & Infectious Diseases  
National Institutes of Health  
5601 Fishers Lane, Room 8F46  
Rockville, MD 20852  
PH: 240-627-3351  
Email: [ryan.ranallo@nih.gov](mailto:ryan.ranallo@nih.gov)

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---

**From:** Regina Janicki <[regina.janicki@einsteinmed.edu](mailto:regina.janicki@einsteinmed.edu)>  
**Date:** Monday, March 14, 2022 at 12:50 PM  
**To:** "Ranallo, Ryan (NIH/NIAID) [E]" <[ryan.ranallo@nih.gov](mailto:ryan.ranallo@nih.gov)>, "Steele, Bianca (NIH/NIAID) [E]" <[bianca.steele@nih.gov](mailto:bianca.steele@nih.gov)>  
**Cc:** (b) (6) Vern Schramm <[vern.schramm@einsteinmed.edu](mailto:vern.schramm@einsteinmed.edu)>  
**Subject:** Fw: [EXTERNAL] Re: RPPR for R01AI150971-01A1

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Attached, please find a prior approval request/vertebrate animal document

Thank you for your continued assistance and support. They are greatly appreciated.

Best Regards,

(b) (6)

---

**From:** (b) (6)  
**Sent:** Monday, March 14, 2022 12:05 PM  
**To:** (b) (6) Vern Schramm <[vern.schramm@einsteinmed.edu](mailto:vern.schramm@einsteinmed.edu)>  
**Subject:** Fw: [EXTERNAL] Re: RPPR for R01AI150971-01A1

Dear (b) (6)

Dr. Schramm has provided the attached response to the following request from Dr. Ranallo at the NIH regarding his NIH Progress Rpt. Please forward to Ranallo, Ryan (NIH/NIAID) [E] <[ryan.ranallo@nih.gov](mailto:ryan.ranallo@nih.gov)> and Steele, Bianca (NIH/NIAID) [E] <[bianca.steele@nih.gov](mailto:bianca.steele@nih.gov)> Please cc Dr. Schramm:

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  - A full vertebrate animal section (VAS) for the work involving mice at the UK-based Sporegen. The VAS should address the 4 points listed in the attached document. Additional information regarding the approval date from the institutional animal care and use committee (IACUC) and animal welfare assurance or foreign assurance.
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The links provided in my email below as well as this NIAID link on using vertebrate animals should contain all the details necessary to complete this request. Only after NIAID receives, reviews, and approves the prior approval request can a new (year two) Notice of Award be issued.

Thanks,

Ryan

Ryan Ranallo, Ph.D.

Program Officer

Enteric and Sexually Transmitted Infections Branch

National Institute of Allergy & Infectious Diseases



National Institutes of Health  
5601 Fishers Lane, Room 8F46  
Rockville, MD 20852  
PH: 240-627-3351  
Email: [ryan.ranallo@nih.gov](mailto:ryan.ranallo@nih.gov)

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**From:** Vern Schramm <[vern.schramm@einsteinmed.edu](mailto:vern.schramm@einsteinmed.edu)>  
**Sent:** Monday, March 14, 2022 11:40 AM  
**To:** (b) (6)  
**Subject:** Fw: [EXTERNAL] Re: RPPR for R01AI150971-01A1

(b) (6)

Prior to approval for R01AI150971, for the next year, the program officer requested an update justification for use of animals in CRO services.

All of the requested information is in the attached document. It needs to be signed by the institutional grants signing individual then submitted to the NIH personnel listed in the attached email.

I think it can be signed and sent to them with a cc to me, or signed and sent to me so I can send it.

Thanks (b) (6)  
Vern

---

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**Sent:** Thursday, March 3, 2022 9:28 AM  
**To:** Vern Schramm <[vern.schramm@einsteinmed.edu](mailto:vern.schramm@einsteinmed.edu)>  
**Cc:** Steele, Bianca (NIH/NIAID) [E] <[bianca.steele@nih.gov](mailto:bianca.steele@nih.gov)>; (b) (6)  
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The draft looks good so far. However, the justification for requesting the change(s) in scope needs to be in narrative form and address all changes requested and why (i.e., scientific rationale or other rationale) the change is needed. For example, why did you decide to have the mouse work done at

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Thank you for your acute attention to this matter.

Best,

Ryan

Ryan Ranallo, Ph.D.  
Program Officer  
Enteric and Sexually Transmitted Infections Branch  
National Institute of Allergy & Infectious Diseases  
National Institutes of Health  
5601 Fishers Lane, Room 8F46  
Rockville, MD 20852  
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Email: [ryan.ranallo@nih.gov](mailto:ryan.ranallo@nih.gov)

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---

**From:** Vern Schramm <[vern.schramm@einsteinmed.edu](mailto:vern.schramm@einsteinmed.edu)>

**Date:** Wednesday, March 2, 2022 at 10:33 AM

**To:** "Ranallo, Ryan (NIH/NIAID) [E]" <[ryan.ranallo@nih.gov](mailto:ryan.ranallo@nih.gov)>

**Cc:** "Steele, Bianca (NIH/NIAID) [E]" <[bianca.steele@nih.gov](mailto:bianca.steele@nih.gov)>, (b) (6)

(b) (6)

**Subject:** Re: [EXTERNAL] Re: RPPR for R01AI150971-01A1

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Dear Ryan,

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Could you please have a look and see if I have covered everything correctly from your request?

I have requested the documented animal welfare assurances from the foreign vendors and will add that prior to submission.

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Vern

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**To:** Vern Schramm <[vern.schramm@einsteinmed.edu](mailto:vern.schramm@einsteinmed.edu)>

**Cc:** Steele, Bianca (NIH/NIAID) [E] <[bianca.steele@nih.gov](mailto:bianca.steele@nih.gov)>; (b) (6)  
(b) (6)

**Subject:** Re: [EXTERNAL] Re: RPPR for R01AI150971-01A1

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  - The addition of all new and/or proposed foreign collaborations (b) (4)  
To include the organization's full contact information (name, address, phone, and email) for the site and a detailed description all activities to be performed by the collaborator.
  - A full vertebrate animal section (VAS) for the work involving mice at the UK-based Sporegen. The VAS should address the 4 points listed in the attached document. Additional information regarding the approval date from the institutional animal care and use committee (IACUC) and animal welfare assurance or foreign assurance.
  - A formal request to use a new animal species (i.e., hamster model) for this project. To include a complete justification for the proposed changes and the potential impact on the project abstract, aims and project narrative. Include a full VAS for all proposed experiments involving hamsters. The VAS should address the 4 points listed in the attached document. Additional information is needed regarding the approval date from the institutional animal care and use committee (IACUC) and animal welfare assurance or foreign assurance.

The links provided in my email below as well as this NIAID link on using vertebrate animals should contain all the details necessary to complete this request. Only after NIAID receives, reviews, and approves the prior approval request can a new (year two) Notice of Award be issued.

Thanks,

Ryan

Ryan Ranallo, Ph.D.  
Program Officer  
Enteric and Sexually Transmitted Infections Branch  
National Institute of Allergy & Infectious Diseases  
National Institutes of Health  
5601 Fishers Lane, Room 8F46  
Rockville, MD 20852  
PH: 240-627-3351  
Email: [ryan.ranallo@nih.gov](mailto:ryan.ranallo@nih.gov)

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**From:** Vern Schramm <[vern.schramm@einsteinmed.edu](mailto:vern.schramm@einsteinmed.edu)>  
**Date:** Tuesday, March 1, 2022 at 1:31 PM  
**To:** "Ranallo, Ryan (NIH/NIAID) [E]" <[ryan.ranallo@nih.gov](mailto:ryan.ranallo@nih.gov)>  
**Subject:** [EXTERNAL] Re: RPPR for R01AI150971-01A1

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Dear Ryan,

Mouse work in the first year was limited to fee for service, by purchase order. A company in the UK called (b) (4) has one of the few mouse models of C. diff. toxin.

In consultation with our (b) (4) collaborators, we agreed that the highest priority in year one was the mouse work. The first-year allocation thus went for the fee for service mouse testing.

We are obtaining quotes for from a second vendor, (b) (4) for testing in hamsters during year two. That is also fee for service by purchase order. That work has not begun. (b) (4) has offices in the US, but I their animal testing is in (b) (4)

Please let me know if you need more information.

Best Wishes,  
Vern

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**From:** Ranallo, Ryan (NIH/NIAID) [E] <[ryan.ranallo@nih.gov](mailto:ryan.ranallo@nih.gov)>  
**Sent:** Tuesday, March 1, 2022 12:03 PM  
**To:** Vern Schramm <[vern.schramm@einsteinmed.edu](mailto:vern.schramm@einsteinmed.edu)>  
**Cc:** Steele, Bianca (NIH/NIAID) [E] <[bianca.steele@nih.gov](mailto:bianca.steele@nih.gov)> (b) (6)  
(b) (6)  
**Subject:** RPPR for R01AI150971-01A1

Dear Vern,

I hope you are doing well. In reviewing the RPPR for the aforementioned project it appears that you've started and/or will be starting a new collaboration with a non-US based organization to conduct some animal work. Please note that prior approval from NIAID is required to establish a subaward involving a new collaboration with a foreign organization and before any work can begin. Also, prior approval is required prior to changing any aspects of research involving vertebrate animals (e.g., new animal species). I'm sending you some NIAID links on subawards, seeking prior approval and type of activities that constitute a change in scope.

Using Subawards:

<https://www.niaid.nih.gov/grants-contracts/using-subawards>

When to seek prior approval:

<https://www.niaid.nih.gov/grants-contracts/prior-approval-establish-subaward>

Change in Scope:

<https://www.niaid.nih.gov/grants-contracts/ask-permission-change-scope>

Please review the information provided in these links and provide clarification on any new subawards with foreign institutions and any changes to your plans to use animal models (specifically the hamster model) to establish safety, PK, and efficacy against C. diff toxins. Also, based on information in the RPPR it appears that some of the year one budget has already been spent on work completed in the (b) (4). Is this a new collaboration, what is the nature of the work, and did it involve animals or humans? Finally, have funds from this award been spent in (b) (4) as originally proposed.



Thanks for your attention to this request. I look forward to hearing from you.

Best,

Ryan

Ryan Ranallo, Ph.D.

Program Officer

Enteric and Sexually Transmitted Infections Branch

National Institute of Allergy & Infectious Diseases

National Institutes of Health

5601 Fishers Lane, Room 8F46

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