DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
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) 402-7065

August 7, 2018

Re: Animal Welfare Assurance
A3256-01 [OLAW Case E]

Mr. David Wood
Medical Center Director
Department of Veterans Affairs
Medical Center
500 West Fort Street
Boise, Idaho 83702

Dear Mr. Wood,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 27, 2018 letter responding to my April 19, 2018 request for additional information regarding an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Veterans Affairs Boise Medical Center. The matter involved the conduct of animal activities under an expired protocol and the conduct of some in vitro work during a lapse in approval by the Subcommittee on Research Safety.

According to the information provided, OLAW understands that the study in question was not supported by NIH or NSF, there are no plans to use the data collected during the lapse, the Principal Investigator has left the VA and the study will be closed, and the Institutional Animal Care and Use Committee (IACUC) does not have a holding protocol. A standard operating procedure was developed to address the efficient flow of research documents

Based on its assessment of this explanation and review of the supporting document, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy and recommends that the IACUC develop a holding protocol on which animals are placed during a protocol lapse and no research activities may be performed. Also, note that many institutions notify investigators one or more times in advance of an upcoming lapse in study approval to ensure timely renewal. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b)(6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair
(b)(6) D.V.M., Ph.D., VA Chief Veterinarian
(b)(6) Ph.D., ORO

DEPARTMENT OF VETERANS AFFAIRS
Medical Center
500 West Fort Street
Boise ID 83702-4598

July 27, 2018

In Reply Refer To: 531/151

Dr. Axel Wolff
Deputy Director
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, Maryland 20892-7982

RE: Animal Welfare Assurance
A3256-01 [OLAW Case E]

Dear Dr. Wolff,

Please accept my apology for not responding to A3256-01 (OLAW Case E) when initially requested. (b)(6) and this fell through the cracks.

As stated in your letter dated April 19, 2018, the Office of Animal Welfare (OLAW) acknowledged receipt of our April 10, 2018 reporting of an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Veterans Affairs Boise Medical Center. The noncompliance was animal activities conducted under an expired protocol. Specifically, mice were used on a bacterial study for three months without Institutional Animal Care and Use committee (IACUC) approval. There was also a three-month lapse in approval by the Subcommittee on Research Safety for the same protocol and some invitro work was conducted.

Corrective action of the development of a standard operating Procedure (SOP) to address the efficient flow of research documents has been written and is attached.

We are providing the following information so OLAW may have a complete understanding of this matter.

1. Was the study in question funded by PHS or NSF?
   Response: no

2. What plans does the Principal Investigator (PI) have for the data collected during the lapse?
   Response: The PI has no plans for the data used during the lapse. The PI left the VA May 30, 2018 and the study will most likely be closed.

3. Does the IACUC have a holding protocol in place for use when a research protocol expires?
   Response: no

4. Provide a synopsis of the proposed SOP to ensure that all required approvals are in place before animal work is conducted.
   Response: please see attached SOP

If you have any additional questions or require clarification please contact (b)(6)
Research Administrative Officer, (b)(6) @va.gov or (b)(6)
Thank you

Sincerely,

(b)(6)

David Wood, MHA, FACHE
Medical Center Director

Cc: (b)(6)

Process for Preventing and Handling Research Subcommittee Study Lapses
Standard Operating Procedure
Research Service
April 10, 2018

The primary objective is to prevent study lapses but considering the many people and steps involved, this SOP also provides guidance on handling a study lapse.

Preventing Study Lapses

- At the beginning of the fiscal year, Subcommittee facilitators will email all their PIs of their study(s) annual renewal months and the dates by which the renewals are needed to be placed on the subcommittee agenda.
- The email sent will be documented in the following folder: S:/Research Admin/COMMITTEES AND PROGRAMS/subcommittee name/PI Annual Renewal Reminders.

Documenting Study Lapses

- Study lapses will be documented in the appropriate subcommittee minutes for the month in which the lapse occurred. The minutes will say the number of months the lapse occurred and why the lapse occurred if known.
- The lapse will also be documented in the Research Operations System Application (ROSA) in the specific study folder.

Notifying PIs of Study Lapses

- Immediately after the subcommittee meeting, the subcommittee facilitator or the Research Administrative Officer (AO) will email the PI and tell them of the lapse and tell them they must stop all work on the study until their lapse is corrected.
- A memo from the subcommittee chair will also go out to the PI regarding their study lapse. The lapse will also be reported to the ACOS/R&D.
- The subcommittee facilitator or the subcommittee chair may contact the PI during this time and ask if there are any study activities being conducted and if possible, verify activity or no activity by reviewing lab notebooks for the study.
- The PI will submit the proper documents to the subcommittee facilitator before the next subcommittee meeting and include a statement that no study activities were conducted during the study lapse time.
- The subcommittee will review and vote on the lapsed study and document the decision and the vote in the meeting minutes.
- If the study renewal is approved, the PI will receive an approval memo from the subcommittee chair stating that they may commence their study activities again.

Gopee, Neera (NIH/OD) [E]

From: Gopee, Neera (NIH/OD) [E]
Sent: Wednesday, August 01, 2018 11:15 AM
To: (b)(6)
Cc: Wood, David (Boise); (b)(6)
Subject: RE: Response to OLAW Request for additional information regarding preliminary noncompliance report for A3256-E

Thank you for providing the requested information (b)(6) We will send an official response soon.

Best Regards,
Neera

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Veterinary Medical Officer
Office of Laboratory Animal Welfare
National Institutes of Health

From: (b)(6) @va.gov]
Sent: Wednesday, August 01, 2018 10:52 AM
To: Gopee, Neera (NIH/OD) [E] (b)(6)
Cc: Wood, David (Boise) (b)(6) @va.gov>; (b)(6)
(b)(6)
Subject: Response to OLAW Request for additional information regarding preliminary noncompliance report for A3256-E
Importance: High

Hello Dr. Gopee,

Attached please find a letter from our Medical Center Director regarding your request for additional information regarding the report of noncompliance for A3256-E.

If you need any clarification or additional information please feel free to contact me or Dr. (b)(6) IACUC Chair.

Sincerely,

(b)(6)
Research Service Admin Officer
Boise VAMC (531)
Mail stop 151
500 W. Fort St.
Boise, ID 83702
Phone: (b)(6)
Fax: (b)(6)
(b)(6) @va.gov

Gopee, Neera (NIH/OD) [E]

From: Gopee, Neera (NIH/OD) [E]
Sent: Friday, July 27, 2018 1:24 PM
To: (b)(6)
Cc: (b)(6)
Subject: RE: OLAW Request for additional information regarding preliminary noncompliance report for A3256-E

Thank you for your prompt response (b)(6) I look forward to receiving the additional information on Monday.

Best Regards,
Neera

From: (b)(6) @va.gov]
Sent: Friday, July 27, 2018 1:22 PM
To: Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>
Cc: (b)(6)
Subject: RE: OLAW Request for additional information regarding preliminary noncompliance report for A3256-E

Dear Dr. Gopee,

We sure are communicating a lot these past few weeks.

I hope Dr. Wolff and you will accept my sincere apology for not responding to your April 19 letter requesting additional information on our noncompliance report A3256-E. I was out having surgery at the time this noncompliance was identified and corrected and your communication got lost in the email.

I am preparing a response to your questions and concerns for our medical center director. He is out of the office today so you should receive it Monday July 30, 2018.

Sincerely

(b)(6)
Research Service Admin Officer
Boise VAMC (531)
Mail stop 151
500 W. Fort St.
Boise, ID 83702
Phone: (b)(6)
Fax: (b)(6)
(b)(6) @va.gov

From: Gopee, Neera (NIH/OD) [E] (b)(6)
Sent: Friday, July 27, 2018 8:44 AM

To: (b)(6) @va.gov>
Cc: (b)(6) @va.gov>
Subject: [EXTERNAL] OLAW Request for additional information regarding preliminary noncompliance report for A3256-E
Importance: High

Dear Dr. (b)(6)

I am writing with regards to the non-compliance case which was reported by Dr. Wood on April 10, 2018 involving two incidents of lapsed subcommittee approval on a single protocol at Boise VA Medical Center. To date we do not have a record of receiving the additional information that was requested by Dr. Wolff in a memo dated April 19, 2018 and which was due by May 15, 2018. OLAW requests that the requested information be submitted to the OLAW Division of Compliance Oversight (NIH/OD) olawdco@od.nih.gov no later than **August 10, 2018**.

If you have any questions or concerns regarding this matter, please do not hesitate to contact me.

Regards,
Neera

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

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Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

April 19, 2018

Re: Animal Welfare Assurance
A3256-01 [OLAW Case E]

Mr. Nathanael Stewart
Acting Medical Center Director
Department of Veterans Affairs
Medical Center
500 West Fort Street
Boise, Idaho 83702

Dear Mr. Stewart,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 10, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Veterans Affairs Boise Medical Center. According to the information provided, OLAW understands that animal activities were conducted under an expired protocol. Specifically, mice were used on a bacterial study for three months without Institutional Animal Care and Use Committee (IACUC) approval. Also, there was a three month lapse in approval by the Subcommittee on Research Safety for the same protocol and some in vitro work was conducted.

The corrective action consisted of developing a standard operating procedure (SOP) to address efficient flow of research documents.

In order for OLAW to have a complete understanding of this matter, please provide the following information:

1) Was the study in question funded by PHS or NSF? If so, please provide the grant number(s).

2) What plans does the Principal Investigator have for the data collected during the lapse? Note that most journal will not publish data collected without IACUC approval.

3) Does the IACUC have a "holding protocol" in place for use when a research protocol expires?

4) Provide a synopsis of the proposed SOP to ensure that all required approvals are in place before animal work is conducted.

Please provide the requested information by **May 15, 2018**.

Sincerely,

(b)(6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair
(b)(6) D.V.M., Ph.D., VA Chief Veterinarian
(b)(6)

A3256-E

DEPARTMENT OF VETERANS AFFAIRS
Medical Center
500 West Fort Street
Boise ID 83702-4598

April 10, 2018

In Reply Refer To: 531/00

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Veterinary Medical Officer
Office of Laboratory Animal Welfare
National Institutes of Health
6705 Rockledge Dr.
RKL 1, Suite 360, MSC 7982
Bethesda, MD 20892-7982

Dear Dr. Gopee,

This report is to inform you of a recent triennial animal and biosafety research compliance audit at the Boise VA Medical Center (A3256-01) where two incidents of lapsed subcommittee approval for research were discovered within a single protocol, ORO Case Number 531-0020-A.

One incident was a three-month lapse of Institutional Animal Care and Use Committee (IACUC) approval. The protocol expired on January 28, 2016; the continuing review was approved on April 27, 2016. Animal research was conducted during the lapse, which included the infection of mice with antibiotic resistant Streptococcus.

A second incident involved a three-month lapse of the Subcommittee on Research Safety (SRS) approval. The protocol expired on February 10, 2017 and a continuing review was approved on May 11, 2017. Although no animal research was conducted during the lapse, bench research continued intermittently.

Research Administration staff and the involved principal investigator have investigated the documents in question and the research document flow. They are working on a standard operating procedure to prevent any reoccurring incidents. The Director of Research Safety and Animal Welfare, VHA Office of Research Oversight requires an update by April 17, 2018.

Please acknowledge your receipt of this report so we may include it with our update to ORO.
If you have any questions or wish to discuss any aspect of this case, please contact our Research Administrative Officer, (b)(6) at (b)(6)@va.gov or (b)(6)

Sincerely,

(b)(6)

(b)(6)

Nathanael Stewart
Acting Medical Center Director

Cc: David Wood, MHA, FACHE, Medical Center Director
(b)(6)

VA HEALTH CARE | Defining EXCELLENCE in the 21st Century

Memorandum

Date: March 6, 2018

From: Director, Research Safety & Animal Welfare, VHA Office of Research Oversight (ORO), (101/10R), Washington, DC

Subj: ORO Case No. 531-0020-A

To: Director, Boise VA Medical Center (BVAMC), Boise, ID (531/00)

1. Thank you for your February 16, 2018, report of serious noncompliance due to two lapses of approval related to a single protocol.

2. From the information provided, we understand that:

   a. During a recent triennial animal and biosafety research compliance audit, two incidents of lapsed subcommittee approval for research were discovered within a single protocol.

   b. One incident was a three-month lapse of Institutional Animal Care and Use Committee (IACUC) approval. The protocol expired on January 28, 2016; the continuing review was approved on April 27, 2016. Animal research was conducted during the lapse, which included the infection of mice with antibiotic resistant *Streptococcus*.

   c. A second incident involved a three-month lapse of the Subcommittee on Research Safety (SRS) approval. The protocol expired on February 10, 2017 and a continuing review was approved on May 11, 2017. Although no animal research was conducted during the lapse, bench research continued intermittently.

3. We concur with actions taken and commend your institution's prompt investigation, response, and reporting to our Office. Please provide our Office with an update by **April 17, 2018,** to include: confirmation that the NIH, Office of Laboratory Animal Welfare and the Association for the Assessment and Accreditation of Laboratory Care, International have been notified of the lapse in IACUC approval, a brief description of the procedures now in place to prevent a recurrence, and procedures to stop research activity when project approvals expire.

4. If you have any questions or wish to discuss any aspect of this case, please contact our group by email at (b)(6) @va.gov.

(b)(6)

cc:
ACOS/R&D (531/151)
AO/R&D (531/151)
RCO (531/00)