



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

November 26, 2019

Re: Animal Welfare Assurance
#A3348-01 (OLAW Case 2E)

Dr. Thomas F. Murray
Provost and Institutional Official
Creighton University
2500 California Plaza
Omaha, NE 6817

Dear Dr. Murray,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 6, 2019 letter responding to OLAW concerns regarding an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Creighton University.

According to the information provided, OLAW understands that no animal welfare issues were noted as a result of the noncompliance and all animals were in apparent good health when examined by the Attending Veterinarian (AV). The AV retrained the principal investigator (PI) on the IACUC requirements via email and in-person meeting regarding protocol review procedures, requirements for amendments and modification, re-use of animals, and minimization of pain and distress in animals. Additionally, the PI discussed the non-compliance via conference call with the IACUC. The PI has departed the institution as previously scheduled, preventing the possibility for any future re-training.

OLAW appreciates the prompt consideration of this matter by Creighton University, which is consistent with the philosophy of institutional self-regulation. OLAW expects the IACUC to evaluate the impact of animal welfare as the primary concern when reviewing non-compliance incidents and to formalize all changes to the protocol including timeline extensions via protocol amendment mechanisms. Based on the information provided, OLAW is satisfied that appropriate steps have been taken to investigate this incident. Although this activity was not PHS funded, the application of the standards of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely,

(b) (6)

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact

Lukovsky-Akhsanov, Nicole (NIH/OD) [E]

From: (b) (6)
Sent: Wednesday, November 6, 2019 4:10 PM
To: Lukovsky-Akhsanov, Nicole (NIH/OD) [E]
Cc: Morse, Brent (NIH/OD) [E]
Subject: Creighton University - A3348-01 (OLAW Case 2E)
Attachments: Response Letter OLAW 9.2019.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Drs. Lukovsky-Akhsanov & Morse –

In the OLAW response Letter dated October 22, 2019 (Attached) for OLAW Case 2E states "OLAW requests more information regarding the reported non-compliance by November 13, 2019." Following a phone conversation with Dr. Morse on November 6, 2019, it was communicated that the required information was acceptable via email.

Below you will find the requested information, please let me know if any additional information is required:

1. Was a protocol amendment submitted and formal amendment review for the collection of the additional data point conducted as described in the Animal Welfare Assurance? *No amendment was submitted as the non-invasive data collection point was already described and approved on the protocol.*
2. Where there any animal welfare concerns that resulted in distress, pain or injury to animals due to the conduct of the unapproved activities and extended timepoint? *No animal welfare issues were noted as a result of this noncompliance, when examined by the AV all animals were in apparent good health.*
3. Was any re-training or counseling provided to the regarding IACUC requirements including protocol review procedures and minimization of pain and distress in animals? *Yes, the AV re-trained the PI on IACUC requirements via email and in a personal meeting regarding protocol review procedures, requirements for amendments/modifications, re-use of animals and minimization of pain and distress in animals. Furthermore, following this incident and termination of the study, the PI was previously scheduled to depart from the University preventing the possibility for any extended re-training. Additionally, during the course of the investigation the PI was offered the opportunity to discuss this non-compliance with the IACUC. As the PI was not on campus at the time, he discussed the incident via conference call.*
4. Please clarify if the protocol was active or expired at the time of this occurrence. *Protocol was active.*

Thank You,

(b) (6)

(b) (6)



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October 22, 2019

Re: Animal Welfare Assurance
#A3348-01 (OLAW Case 2E)

Dr. Thomas F. Murray
Provost and Institutional Official
Creighton University
2500 California Plaza
Omaha, NE 68178

Dear Dr. Murray,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 4th, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Creighton University as a follow-up to the preliminary telephone report on August 30th, 2019. According to the information provided, OLAW understands that the Attending Veterinarian (AV) found 18 mice were still in the facility past the approved study end-point. The AV contacted the principal investigator (PI) who confirmed that the mice were being "re-used" in a different experimental group without IACUC approval. The PI voluntarily halted the study until a fully convened IACUC meeting was conducted. The animals on this study were not supported by NIH funding.

OLAW understands that, the IACUC allowed the PI to collect one more non-invasive data point followed by humane euthanasia of animals. Additionally, the PI will not be publishing the data from this study.

OLAW appreciates the prompt consideration of this matter by Creighton University, which is consistent with the philosophy of institutional self-regulation. OLAW requests more information regarding the reported non-compliance by November 13th, 2019. Was a protocol amendment submitted and formal amendment review for the collection of the additional data point conducted as described in the Animal Welfare Assurance? Were there any animal welfare concerns that resulted in distress, pain or injury to animals due the conduct of the unapproved activities and extended timepoint? Was any re-training or counseling provided to the PI regarding IACUC requirements including protocol review procedures and minimization of pain and distress in animals? Please clarify if the protocol was active or expired at the time of this occurrence as the statement "...the PI confirmed he had extended the protocol's timeline while reusing..." is unclear.

We appreciate being informed of this matter and please feel free to contact us with any further questions or concerns.

Sincerely,

(b) (6)

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact

Creighton UNIVERSITY

Office of the Provost
Research Compliance

October 4, 2019

Dr. Brent Morse
Office of Laboratory Animal Welfare
National Institutes of Health
Division of Compliance Oversight
6705 Rockledge Drive
RKL1, Suite 1050, MSC 7982
Bethesda, Maryland 20892-7982

Re: Creighton's Institutional Animal Care and Use Committee (IACUC) Animal Incident Report,
Assurance Number **A3348-01/D16-00226**

Dear Dr. Morse:

Creighton University is submitting a finalized report regarding a protocol violation that was initially reported to you via phone on August 30, 2019 by the Research Compliance Auditor.

Background Information/Protocol Violation:

During rounds on 7/31/19, the Attending Veterinarian (AV) noticed 18 mice that were still in the ARF subsequent to the end point of the protocol. At this time, the AV contacted the PI who confirmed he had extended the protocol's timeline while re-using the mice in a different experimental group without submitting a modification to the IACUC for approval. The PI agreed to voluntarily halt the study until a fully convened IACUC meeting could be conducted to discuss and vote on a corrective action plan.

Corrective Action Plan Taken:

The following corrective action plan was formulated by the IACUC during a fully convened meeting and carried out by the PI:

- The IACUC decided to allow the investigator to collect one more noninvasive data point and humanly euthanize the animals.
- The IACUC also determined that the PI would not be allowed to publish data from this study.

Reporting:

The following agencies/organizations will be contacted regarding this noncompliance:

- The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC).
- No additional reporting is required as this is not a PHS funded project.

Please feel free to contact Dr. Thomas F. Murray, Provost and Institutional Official, at (b) (6) or Dr. Joseph A. Knezetic, Director of Research Compliance, at (b) (6) if you have any further questions.

Sincerely,

(b) (6)

Thomas F. Murray Ph.D.
Institutional Official and
Provost

(b) (6)

Joseph A. Knezetic, Ph.D.
Director of Research Compliance

CC: IACUC Chair
Animal Resource Facility Director
Research Compliance Office

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, October 15, 2019 1:00 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Murray, Thomas F; Knezetic, Joseph A; (b) (6)
Subject: RE: Creighton University -- 3 OLAW Reports

Thank you for these reports (b) (6) We will send official responses soon.

Best regards, Brent Morse

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

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: (b) (6)
Sent: Tuesday, October 15, 2019 11:43 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Murray, Thomas F <tfmurray@creighton.edu>; Knezetic, Joseph A <joe@creighton.edu>; (b) (6)
Subject: Creighton University -- 3 OLAW Reports

Please find attached 3 separate finalized written reports regarding incidents reported to you via phone August 30, 2019.

Thank You,
(b) (6)

(b) (6)





Initial Report of Noncompliance

By: BM

Date: 8/30/19

Time: 11:40
(b) (6)

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #: (b) (6)

Email: (b) (6)

Name of Institution: Creighton U.

Assurance number: A3348

Did incident involve PHS funded activity? No

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? Mice reused on protocol w/o IACUC approval.

Species involved: Mice

Personnel involved: PI

Dates and times: _____

Animal deaths: No

Projected plan and schedule for correction/prevention (if known): _____

Projected submission to OLAW of final report from Institutional Official: _____

OFFICE USE ONLY

Case # _____