



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) 480-3387

January 6, 2021

Re: Animal Welfare Assurance
A3240-01 [OLAW Case G]

Ms. Melany Dickens-Ray
Chief of Staff
University of Oklahoma
201 Stephenson Parkway, (b) (4)
Norman, OK 73019

Dear Ms. Dickens-Ray,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 22, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Oklahoma-Norman following up on an initial December 11, 2020 notification by telephone.

According to the information provided, this Office understands that the University of Oklahoma-Norman Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: the conduct of animal-related activities without appropriate IACUC review and approval. The final report states in June 2019, a graduate student captured fish from an Oklahoma lake and held them in aquaria for ~8wk to study chemical influences on invertebrate species. The procedures were repeated from another Oklahoma lake in May 2020. There were no reports of morbidity or mortality (per the report), and each fish was released back into its native environment following completion of the study.

On November 25, 2020, the student contacted the IACUC to request a copy of an approval letter for these activities. It was determined that no requests to review such activities had ever been received. The principal investigator (PI) reported working on a draft animal protocol for the proposed animal activities but failed to submit the protocol for IACUC review. The PI took responsibility for the noncompliance. During the committee meeting on December 2, 2020, the IACUC reviewed the matter and determined the incident reportable to OLAW. The following processes are already in place to prevent recurrence:

- The University's requirement that all research or teaching involving live vertebrate animals be reviewed and approved by the IACUC prior to initiation of those activities is prominently posted in the Graduate College Bulletin for students and faculty mentors.
- All faculty, students, and staff of the University working in research must complete required training on IACUC expectations and animal safety.
- All personnel planning to work with animals at the University are required to complete online training which describes both IACUC and investigator responsibilities when working with animals and important aspects of the protocol review process.
- Incoming graduate students are required to attend a departmental lecture each fall in which a member of the IACUC presents an overview of IACUC expectations and requirements for working with animals at the University.

The report further states the IACUC accepted the PI's commitment to seek IACUC approval. It is noted that this study is not supported by PHS funds. Based on its assessment of this explanation, OLAW understands that the University of Oklahoma-Norman has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. 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: 2021.01.06
13:33:16 -05'00'

Jacquelyn T. Tubbs, DVM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



The University of Oklahoma
OFFICE OF THE VICE PRESIDENT FOR RESEARCH AND PARTNERSHIPS

December 22, 2020

Brent Morse, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892
morseb@mail.nih.gov

Dear Dr. Morse:

The University of Oklahoma, in accordance with Assurance D16-00153 and PHS Policy IV.F.3., provides this report of noncompliance regarding an incident that my designee reported to you on December 11, 2020, involving a non-PHS funded study. The University's final report is as follows:

Beginning in June 2019, a graduate student captured fish from an Oklahoma lake and held them in aquaria for approximately eight weeks to study chemical influences on invertebrate species. The procedures were repeated with fish from another Oklahoma lake beginning in May 2020. None of the animals reportedly experienced morbidity or mortality, and each animal was released back into its native environment following the completion of the study period.

On November 25, 2020, the graduate student contacted the IACUC to request a copy of an approval letter for these activities. After an exhaustive search, the staff assistant for the IACUC confirmed that no requests to review such activities had ever been received. The Principal Investigator mentoring the graduate student reported working on a draft animal protocol in the spring of 2019 which captured the proposed animal activities, but ultimately failed to submit the protocol for IACUC review.

The Principal Investigator expressed to the IACUC Chair that this was an unfortunate incident, took responsibility for the noncompliance, and assured the IACUC that an incident of such nature would not occur again.

During its general Committee meeting on December 2, 2020, the IACUC reviewed a summary of the events and decided to report the incident to OLAW. The IACUC acknowledged that the following resources are already in place to prevent such an incident from occurring:

- 1) The University's requirement that all research or teaching involving live vertebrate animals be reviewed and approved by the IACUC prior to initiation of those activities is prominently posted in the Graduate College Bulletin for students and faculty mentors.
- 2) All faculty, students, and staff of the University working in research must complete required training on IACUC expectations and animal safety. This training is delivered by the Environmental Health and Safety Office and must be completed annually.
- 3) All personnel planning to work with animals at the University are required to complete online training which describes both IACUC and investigator responsibilities when working with animals and important aspects of the protocol review process. This training is hosted through the AALAS

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Learning Library and must be completed every three years.

- 4) Incoming graduate students are required to attend a departmental lecture each fall in which a member of the IACUC presents an overview of IACUC expectations and requirements for working with animals at the University.

The IACUC accepted the Principal Investigator's commitment to seek IACUC approval before working with vertebrate animals in the future. The Committee then determined that this was an isolated incident and not a programmatic failure. Because the study concluded in August 2020, the Investigator does not plan to submit a protocol for IACUC review that pertains to this incident.

The University is committed to protecting the welfare of animals used in research and appreciate the guidance and assistance provided by OLAW in this regard. If you have any questions regarding this report or the IACUC's actions, please contact me or Dr. Cameron Siler, IACUC Chair, at IACUC@ou.edu.

Sincerely,

(b) (6)

Melany Dickens-Ray, MS
Institutional Official
Associate Vice President for Research and Partnerships – Operations
University of Oklahoma

201 Stephenson Parkway, Suite 3100
Norman, Oklahoma 73019 • (405) 325-3806 • FAX (405) 325-6029

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Tuesday, December 22, 2020 12:28 PM
To: Budda, Madeline L (HSC)
Cc: Dickens Ray, Melany D.; (b) (6)
Subject: RE: Final Report D16-00153

Follow Up Flag: Follow up
Flag Status: Flagged

Thank you for providing this final report Dr. Budda. We will send an official response soon.

Best regards, Brent Morse

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

From: Budda, Madeline L (HSC) <Madeline-Budda@ouhsc.edu>
Sent: Tuesday, December 22, 2020 9:19 AM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Cc: Dickens Ray, Melany D. <mdickens@ou.edu>; (b) (6)
(b) (6)
Subject: Final Report D16-00153

Dear Dr. Morse,

Please see the attached report to follow up on our phone conversation earlier this month.

Happy Holidays and Warmest Regards,

Madeline

Madeline L Budda, DVM, MS, DACLAM
Director, Office of Animal Welfare Assurance
Vice Chair, Norman IACUC
University of Oklahoma
Madeline-Budda@ouhsc.edu
Main: (b) (6)
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Initial Report of Noncompliance

By: BCM

Date: 12/11/2020

Time: 4:30

Name of Person reporting: Madeline Budda, DVM

Telephone #: [REDACTED] (b) (6)

Fax #:

Email:

Name of Institution: Univ of OK Norman

Assurance number: A3240

Did incident involve PHS funded activity? No

Funding component:

Was funding component contacted (if necessary):

What happened? Masters Student captured 16 fish in OK between May 2019 and Summer 2020 and held them for several weeks. No IACUC approval.

Species involved: various

Personnel involved: Grad student

Dates and times: see above

Animal deaths:

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

Counseling of student and advisor. Program will increase outreach to Grad student programs re: protocol requirements.

Projected submission to OLAW of final report from Institutional Official:

< 60 days

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Case #