



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

February 27, 2023

Re: Animal Welfare Assurance  
A3679-01 [OLAW Case E]

Ms. Amber Hood  
Director of Regulatory Compliance  
And Research Facilities  
Oklahoma State University Center -  
Health Sciences  
1111 West 17<sup>th</sup> Street  
Tulsa, OK 74107

Dear Ms. Hood,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 16, 2023 letter reporting the suspension of an animal activity at Oklahoma State University for Health Sciences, following up on an initial report on March 22, 2022. According to the information provided, OLAW understands that the Institutional Animal Care and Use Committee (IACUC) took this action after determining that regarding a Principal Investigator's (PI) mouse breeding colony there was inadequate recordkeeping and lack of an animal census. Furthermore, the protocol was not being followed and unweaned pups/neonates were being euthanized outside of the approved timeframe and being subjected to unauthorized tail snips. The suspension was reported to the NIH funding component as required and the grant was not charged for any unauthorized animal activities.

The corrective actions consisted of the IACUC requiring the PI to obtain a letter of support from the Department Chair and Dean and to outline the actions taken to address the concerns, requiring the PI and staff to undertake retraining, having the Institutional Official counsel the laboratory staff, and amending the protocol to remove mouse breeding and only allow mouse purchases from a vendor. The PI must provide a rationale for the protocol deviations and must explain the timing of the genotyping procedures. The PI started to provide the requested information but then resigned from the institution and the IACUC terminated the protocol.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. Please note that for cases which exceed three months for a resolution, an interim report should be submitted to OLAW. 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



OKLAHOMA STATE UNIVERSITY  
**CENTER FOR HEALTH SCIENCES**

1111 West 17<sup>th</sup> Street  
Tulsa, OK 74107  
918-582-1972  
[medicine.okstate.edu](http://medicine.okstate.edu)

16 February 2023

Brent Morse, DVM  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360  
6705 Rockledge Drive  
Bethesda, MD 20892

Dr. Morse,

Oklahoma State University Center for Health Sciences (OSU-CHS) in accordance with Assurance A3679-01 and PHS Policy IV.F.3., provides this report of noncompliance regarding serious deviation from a protocol reviewed and approved by the OSU-CHS IACUC related to one Principal Investigator (PI).

On March 21, 2022, the OSU-CHS IACUC reported suspension of an NIH-supported animal protocol. The IACUC promptly notified the Institutional Official, and the Institutional Official reported the suspension to the Office of Laboratory Animal Welfare on March 22, 2022. The funding agency - National Heart, Lung, and Blood Institute - was also notified about the protocol suspension. Animal facility access was deactivated to all personnel listed on the study.

Concerns regarding lack of animal census and breeding recordkeeping in a mouse colony were initially raised by post-approval monitoring staff to the OSU-CHS IACUC. The IACUC, animal care staff, research compliance staff, and veterinarian all attempted to obtain relevant records from the study team. However, communications with the PI were difficult in multiple interactions. The Institutional Official requested that the PI hand over relevant records and initiated an investigation on March 2, 2022. During the investigation, multiple issues were found supporting a failure to adhere to the IACUC-approved protocol by the PI. A summary of findings included:

- Protocol deviation: Census and breeding colony records were not accurately maintained according to the protocol.
- Protocol deviation: Unweaned pups/neonates were euthanized outside of the approved timeframe.
- Protocol deviation: Evidence showed tail snips from unweaned pups, however the protocol did not indicate sample collection of unweaned mice in the protocol.



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The IACUC determined that this was serious noncompliance to adhere to the IACUC-approved protocol. The PI, their Department Chair, Dean, and Provost were informed of the findings and corrective measures to address prior to IACUC's consideration of lifting the protocol suspension. Corrective measures included:

- PI must request from Department Chair and Dean a letter of support/recommendation addressed to the IACUC and submit to the IACUC. These letters should address actions taken to address the IACUC's concerns regarding communications, transparency, and attitude relating to animal welfare concerns. These letters would provide a high level of confidence that issues would not reoccur.
- PI and all study personnel must complete required refresher trainings.
- All study personnel must attend a scheduled face-to-face meeting with the Institutional Official to review the protocol and be educated on IACUC and animal facility management procedures.
- The protocol must be amended to remove mouse breeding, as no on-site breeding may occur. All new mouse acquisitions will need to be purchased from a commercial vendor.
- Provide specific and detailed written rationale to findings of protocol deviations (euthanasia of unweaned pups, sample collection & tail snips from euthanized pups)
- Provide specific and detailed written clarification regarding timing of genotyping (i.e., pre- or post- weaning)

Upon addressing the above conditions, the OSU-CHS IACUC was poised to consider actions taken to remediate concerns at a convened IACUC meeting. The PI did complete some of the required refresher training. However, ultimately, the Principal Investigator resigned from the institution. Upon notification of resignation, the IACUC formally terminated the suspended protocol.

Given the animal welfare concerns, OSU-CHS did not charge direct costs associated with the procurement, care, and use of the mice during June 2021 – March 2022 to NIH Award Number 7R00HL133590-04. These costs were paid from a nonfederal source.

The noncompliance was not found to impact other PHS-supported activities at OSU-CHS. OSU-CHS is committed to protecting the welfare of animals used in research and appreciates the guidance provided by OLAW in this regard. Should you have any questions regarding this report, please contact me. Thank you for your consideration of this matter.

Respectfully submitted,

(b) (6)

Amber N. Hood, MS, CPIA, CIP  
Institutional Official  
Director, Regulatory Compliance & Research Facilities  
Office of Research and Sponsored Programs

## McCoy, Devora (NIH/OD) [E]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Thursday, February 23, 2023 7:53 AM  
**To:** Hood, Amber  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: OLAW Case A3679-E

Good morning Amber,

Thank you for sending us this final report for case A3679-E and we will send an official response soon.

Best,  
Devora

Devora McCoy, BS, MBA ([pronunciation](#))  
Program Analyst  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

Phone: 301-435-2390  
Email: [devora.mccoy@nih.gov](mailto:devora.mccoy@nih.gov)

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**From:** Hood, Amber <[amber.hood@okstate.edu](mailto:amber.hood@okstate.edu)>  
**Sent:** Wednesday, February 22, 2023 4:29 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <[olawdco@od.nih.gov](mailto:olawdco@od.nih.gov)>  
**Subject:** [EXTERNAL] RE: OLAW Case A3679-E

Good afternoon,

Please accept this final report on the protocol suspension reported to you on 3/22/2022.

### Amber N. Hood, MS, CPIA, CIP

*Director, Regulatory Compliance & Research Facilities  
Office of Research and Sponsored Programs  
Oklahoma State University - Center for Health Sciences  
1111 West 17th Street, Tulsa, OK 74107*

(b) (6)



OFFICE OF  
**RESEARCH**  
OSU Center for Health Sciences

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**From:** McCoy, Devora (NIH/OD) [E] <[devora.mccoy@nih.gov](mailto:devora.mccoy@nih.gov)>  
**Sent:** Friday, February 10, 2023 9:41 AM  
**To:** Hood, Amber <[amber.hood@okstate.edu](mailto:amber.hood@okstate.edu)>

## McCoy, Devora (NIH/OD) [E]

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**From:** McCoy, Devora (NIH/OD) [E]  
**Sent:** Friday, February 10, 2023 10:41 AM  
**To:** amber.hood@okstate.edu  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** OLAW Case A3679-E

Good morning Amber,

I'm contacting you about a report that was emailed to our office on 3/22/22 regarding an NIH-supported protocol suspension. At your earliest convenience, can you please send us an interim or final report for this case?

Thanks,  
Devora

Devora McCoy, BS, MBA ([pronunciation](#))  
Program Analyst  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

Phone: 301-435-2390  
Email: [devora.mccoy@nih.gov](mailto:devora.mccoy@nih.gov)

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, March 23, 2022 7:22 AM  
**To:** Hood, Amber  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: A3679-01 Preliminary Report of Noncompliance

Thank you for this preliminary report, Ms. Hood. We will open a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation.

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

**From:** Hood, Amber <amber.hood@okstate.edu>  
**Sent:** Tuesday, March 22, 2022 10:54 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** [EXTERNAL] A3679-01 Preliminary Report of Noncompliance

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Assurance Number: A3679-01  
Institution: Oklahoma State University Center for Health Sciences  
1111 W 17th St, Tulsa, OK 74107

To Whom It May Concern:

I am promptly reporting suspension of an NIH-supported animal protocol by the OSU CHS IACUC on March 21, 2022. Concerns were raised during post-approval monitoring by the animal care staff. Lack of animal census/breeding recordkeeping and protocol deviations by the Principal Investigator seem evident. The IACUC has delineated conditions that must be met in order for the suspension to be lifted, including re-training of Principal Investigator and study personnel.

We will be contacting the funding agency - National Heart, Lung, And Blood Institute. A full report will be sent to OLAW after a full assessment and corrective measures are implemented.

Sincerely,

**Amber N. Hood, MS, CPIA, CIP**  
**Institutional Official, Animal Research Program**  
*Director, Regulatory Compliance & Research Facilities*  
*Office of Research and Sponsored Programs*  
*Oklahoma State University - Center for Health Sciences*  
*1111 West 17th Street, Tulsa, OK 74107*

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