



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

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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) 402-7065

July 19, 2018

Re: Animal Welfare Assurance
A3217-01 [OLAW Case Z]

Ms. Tamara Deuser
Associate Vice President
Arizona State University
660 South Mill Avenue, [REDACTED]
Tempe, AZ 85287-6111

Dear Ms. Deuser,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your letter dated July 13, 2018 reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Arizona State University. Your letter supplements the information provided in an email report to this office on June 6, 2018. According to the information provided, OLAW understands that on March 5, 2018 your institution became aware that an experiment using methamphetamine was not identified in the IACUC-approved protocol but had been described in an annual review for that protocol. Upon further investigation it was determined that other protocol and program deficiencies existed including administrative deficiencies related to grant congruency. Lapses in the program review process also prevented this inconsistency from being discovered. It was determined that there were no animal welfare concerns. This animal activity was funded by the NIH.

Corrective actions to strengthen oversight within the lab included a plan for verification of congruency between requests for changes, protocols, grants and publications as well as general protocol management. The PI and veterinary staff will observe surgery, perfusion and injection procedures to help ensure appropriate practices are being used. Checklists are now available to enable personnel to perform self-checks in real time. Specific procedures will be discussed in biweekly meetings between the PI and individual personnel. The PI also documented some discrepancies between IACUC protocols and publications from the last four years. None of the discrepancies had resulted in an animal welfare consequence. In addition, the PI has provided an IACUC-required schedule of surgery dates to allow veterinary team members to observe the procedure unannounced. The IACUC Chair will also perform unannounced visits to the lab to talk with lab personnel. These corrective actions will be reviewed monthly by the IACUC.

Other programmatic corrective measures were instituted by the IACUC regarding handling of annual reviews and requests for Change relative to information in the referenced protocols.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident, provide corrective measures, and prevent recurrence. OLAW concurs that the incident warranted reporting. **Please be advised** that it is your institution's responsibility to report this incident, with the associated grant number(s), to the NIDA Chief Grants Management Officer copied below. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact
Pamela Fleming, Chief Grants Management Officer, NIDA

July 13, 2018

Brent C. Morse, DVM, DACLAM
Acting 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

Re: Report of Noncompliance under Animal Welfare Assurance #D16-00136

Research Facility: Interdisciplinary Science and Technology Building V
Species: *Mus musculus*, *Rattus rattus*
Principal Investigator: Janet Neisewander
Funding Source: National Institutes on Drug Abuse
Incident: Work performed without appropriate IACUC approval

The IACUC was notified on March 12, 2018 during the triannual AAALACi re-accreditation site visit, by one of the site visitors, that an experiment using methamphetamine was described on an annual review for protocol 16-1482R but not identified within the IACUC approved protocol.

An investigation by the IACUC Chair, with assistance from the Attending Veterinarian, and staff was initiated to determine what had happened. After review, it was concluded the use of methamphetamine in the experiment was performed without IACUC approval. During the review other protocol deficiencies were identified that are reported below and administrative deficiencies related to grant congruency were identified and corrected.

Corrective Actions

The deviations and internal investigation were reported to the IACUC at the convened meeting on April 26, 2018 IACUC. During this review the committee determined additionally that lapses had occurred in the program review process that could have provided an opportunity to discover and correct the discrepancy sooner. To meet the IACUC obligations, improve the oversight process and help prevent future instances, the IACUC Chair will be checking annual reviews more closely for consistency with the approved protocol. IACUC members were reminded of their responsibility to check and compare to the parent protocol all requests for changes that go through the Designated Member Review Process.

The results of the investigation were reported to the IACUC at the convened meeting on May 24, 2018, at which time the committee reviewed the findings of the investigation. Based on the information presented, the committee determined that there had been no animal welfare concerns, but there was a lab management issue. The committee required that the PI develop and submit a corrective action plan to the IACUC to address the deficiencies including lab management

issues and to strengthen oversight within the lab. Recommendations for improvement were suggested and the IACUC required the PI to:

- 1) Submit RFCs to reflect current funding on each protocol.
- 2) Review all protocols to verify that they correctly reflect the plan of the study; consider combining protocols where appropriate. Submit a report to the IACUC.
- 3) Devise a log for personnel to confirm they have checked the protocol to be sure any current procedure is covered.
- 4) Assign to one lab member the job of making sure that all RFCs/protocols and publications are congruent with the parent protocol. The PI will sign this reconciliation.
- 5) The PI will devise a plan for becoming more aware and involved in lab activities and develop a way to demonstrate this involvement (e.g., training session attendance).

The IACUC reviewed the plan submitted by the PI at the convened June 28, 2018, meeting, with the Principal Investigator in attendance. The plan confirmed that:

1. Requests for changes were submitted to add the appropriate funding sources to each protocol. The IACUC Coordinator and Chair are in the process of verifying grant congruency on these.
2. The Principal Investigator confirmed that all active protocols are current and accurate, and provide the appropriate instructions for future experiments. The Principal Investigator will work on merging all protocols that are relevant to a particular grant proposal.
3. At a mandatory lab meeting held on May 7, 2018, attended by lab personnel and the Attending Veterinarian and Chair, personnel were reminded of the requirement to read all protocols on which they work, including future protocols on which they will work. On June 21, a log was created and placed into a lab dropbox; all lab personnel will use the log to indicate completion of reading each protocol that applies to their work. The log will document and track who has read each of the protocols.
4. The PI has chosen to be the one (rather than a student or postdoc) to ensure that all requests for changes, protocols, and publications are congruent with the parent protocol.
5. The lab is coordinating with the veterinary staff to have them observe surgery, perfusion, and injection procedures to help ensure that appropriate practices are being used. The Principal Investigator is also stopping by the lab at least twice a week, unannounced, to ensure proper techniques are being used. Procedure checklists have been created to enable personnel to perform self-checks in real time as well. These checklists are available in each procedure room. The Principal Investigator meets with individual personnel biweekly, and during these meetings they will discuss specific procedures to help all personnel remain cognizant of the correct way to perform procedures, to identify potential issues of compliance, and to determine the need for a request for changes.
6. Additionally, the Principal Investigator self-audited publications from the past four years and identified discrepancies between the experimental details reported and the IACUC protocols covering those experiments: use of a related selective agonist not listed on the protocol; dosing inconsistent with the pertinent protocol, but that was within the range provided on other protocols; a slight variation in days of post-surgical recovery prior to the experiment; and substitution of a non-listed anesthesia for the one stated in the protocol (both were within accepted guidelines). None of the discrepancies had resulted in an animal welfare consequence.

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Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, July 17, 2018 9:13 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: IACUC@asu.edu
Subject: RE: Final Report - Assurance D16-00136

Thank you for this report. 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

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From: (b) (6)@asu.edu]
Sent: Monday, July 16, 2018 5:27 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Tamara Deuser <Tamara.Deuser@asu.edu>; (b) (6) Karen Kibler
<Karen.Kibler@asu.edu>; (b) (6) IACUC@asu.edu
Subject: Final Report - Assurance D16-00136

Dr. Morse,
On behalf of the IACUC,
I have attached the final report as a follow up to the preliminary report made on June 6, 2018.

Please let me know if you have any questions.

Thank you,

(b) (6)

Customer Service is our priority. Please click [here](#) to let me know how I am doing.

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, June 07, 2018 11:41 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of Noncompliance for D16-00136

Hello (b) (6)

Thank you very much. This helps.

Sincerely, Brent Morse

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

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From: (b) (6)@asu.edu]
Sent: Thursday, June 07, 2018 10:58 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: RE: Report of Noncompliance for D16-00136

Dr. Morse,
At this time, we believe it is conducting animal activities with rats without IACUC approval.

Thank you,
(b) (6)

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Thursday, June 07, 2018 4:42 AM
To: (b) (6)@asu.edu>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: RE: Report of Noncompliance for D16-00136

Thank you for contacting OLAW (b) (6) We will open a case file, but is there any other information available at this time? Helpful items would be approximate date that the issue occurred, species involved, approximate number of animals, general description of the apparent noncompliance such as protocol noncompliance, husbandry issue (food, water, cleaning, health checks), facility problem, etc. If you do not want to put this in writing at this time, I can take any additional information over the phone 301-594-2921. Thank you.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM

Acting 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)@asu.edu
Sent: Wednesday, June 06, 2018 7:02 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Report of Noncompliance for D16-00136

Dear OLAW,

On behalf of the ASU IACUC, I am making a preliminary report of an inconsistency that involves a noncompliance issue. The situation is being investigated and we will provide a full report as soon as the review by the IACUC is complete.

Please let me know if you have any questions.

Thank you,

(b) (6)

Customer Service is our priority. Please click [here](#) to let me know how I am doing.