



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
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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

February 28, 2022

Re: Animal Welfare Assurance  
A3594-01 [OLAW Case 1B]

Dr. Michele M. Masucci  
Vice President for Research  
Temple University – Philadelphia  
1801 North Broad Street  
Philadelphia, Pennsylvania 19122

Dear Dr. Masucci,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 7, 2022 letter reporting four instances of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Temple University, following up on an initial telephone report on October 15, 2021. According to the information provided, OLAW understands the following about the incidents and the corresponding corrective actions:

- 1) Expired analgesic was used on five mice. Other drugs in the laboratory had also expired.

Corrective action: The Principal Investigator (PI) was notified and stopped further animal activities that used the drugs. The PI will track expiration dates and retrained staff to ensure that only in-date agents are used. Expired drugs will be separated and labeled for disposal.

- 2) Expired ketamine was used for some animal procedures.

Corrective action: Laboratory staff was counseled and retrained on the handling of controlled substances and on not using expired agents.

- 3) Four mice were subjected to an unapproved surgical procedure. Eight additional mice had undergone the procedure a day earlier and had been provided with post-operative care and monitoring.

Corrective action: The procedure was immediately stopped, the mice were given analgesics, and they were monitored for pain. The protocol was amended, laboratory staff was counseled to only perform approved procedures, and the PI and staff were retrained.

- 4) Eight animals were housed under an expired protocol for eight days.

Corrective action: The mice were transferred to a holding protocol, the study protocol was renewed, and the PI will closely track protocol expiration dates and improve communication with the Institutional Animal Care and Use Committee (IACUC).

Based on its assessment of these explanations, OLAW understands that measures have been implemented in each situation to correct and prevent recurrence of these problems. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy. Please remember to identify all species involved in noncompliant incidents when submitting the final report and ensure that no animal research activities were charged to the NIH grant during the time of lapsed approval for incident #4. Thank you for keeping OLAW apprised on these matters.

Sincerely,

(b) (6)

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

cc: IACUC Contact



Office of the Vice President  
for Research

Research Compliance  
Student Faculty Center  
3340 N. Broad Street, Suite 427  
Philadelphia PA 19140

A3594  
Institutional Animal Care  
and Use Committee  
Phone: (215) 707-7263  
Email: IACUC@temple.edu

February 7, 2022

Axel Wolff, MS, DVM  
Deputy Director  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360  
6705 Rockledge Drive  
Bethesda, MD 20892

Dear Dr. Wolff:

In accordance with Assurance D16-00359 (A3594-01) and PHS Policy IV.F.3., please accept this letter as our official report of various protocol deviations events that took place on five separate protocols at Temple University. The IACUC was made aware of these deviations between August 2021 and October 2021. These incidents were initially reported to you via a phone conversation with Ellen Walker, PhD, IACUC Chair, on October 15, 2021. A recitation of the underlying facts of each event along with the corrective action plans are enclosed herein for your review.

**Incident #1:** During inspections in 2019 the PI was informed verbally that their buprenorphine had expired. This drug is only used in one approved single surgical procedure and, although packaging materials were acquired to dispose of this drug, it was not done. The procedure was performed on a set of 5 mice in early 2021. In the intervening time, two other drugs used in the lab, pentobarbital sodium and xylazine also expired (the former in 2019, the latter only in late 2020). The PI was verbally informed of the expired substances but due to miscommunication and with additional later confusion caused by impact of Covid-19 restrictions, the PI thought that he was simply being reminded of the expired buprenorphine. As soon as the PI was aware that routinely used drugs were expired, all experiments using these drugs were halted and the PI self-reported the issue to the IACUC.

**Corrective Action:** The PI will explicitly note the expiration dates of all drugs used during surgeries and will be responsible for ensuring that new stocks are acquired prior to expiration. Any expired drugs will be separated from current stocks, marked expired and the lids will be covered with tape, prior to shipping for disposal. Disposal will be prioritized and will occur in a timely manner. Lab staff were retrained that no expired drugs can be used in surgeries and informed of the Corrective Action Plan during a devoted lab meeting.

**Funding:** This protocol was closed in December 2021 but was associated with NIH Funding (5R01NS094402-04)

**Incident #2:** During semiannual inspections an expired vial of Ketamine was found in the same safe as non-expired vials currently in use by the lab. While reviewing controlled substance usage logs and surgical records it was discovered that approximately 3 ml of the expired Ketamine was mistakenly used until April 8, 2021.

**Corrective Action:** During the inspection the lab was re-educated on the proper storage and reverse distribution of expired controlled substances. The PI held another meeting with the lab to go over proper procedure. All lab members including the PI retook the AALAS Learning Library courses on use of anesthetics and analgesics in small animals.

**Funding:** This protocol is associated with NIH Funding (5R01HL145177-03)



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**Incident #3:** On 08/25/2021 veterinary staff discovered lab personnel conducting an unapproved surgical procedure on a small cohort of 4 mice. The procedure was immediately stopped, and the animals were provided analgesics and monitored for signs of pain or distress. Upon further investigation it was discovered that the same procedure was performed a day earlier on another 8 mice and the lab was providing post-operative care and monitoring.

**Corrective Action:** The PI submitted the required IACUC amendment to add the procedure to the protocol which was approved after a thorough review. All lab personnel were retrained on the fact that no animal work can be performed that is not approved on the protocol and how it is a severe non-compliance issue. The following AALAS Learning Library Courses, "Common Compliance Issues" and "Working with the IACUC", were also taken by all lab personnel including the PI.

**Funding:** This protocol is associated with NIH Funding (5R01HL126933-04)

**Incident #4:** Due to an elongated review process for the triennial renewal, animals in house were on an expired protocol for eight days while the lab initiated a transfer of animals to a holding protocol. Animals stayed on the holding protocol until final approval of the triennial review was granted two days later.

**Corrective Action:** PI will be more diligent on tracking expiration dates and be more communicative with the IACUC during the review process.

**Funding:** This protocol is not supported by NIH funding.

All of these incidents were discussed at one of the convened IACUC meetings that took place between September and December 2021. Corrective action plans from each individual PI were presented to the Committee for review and discussion. The committee unanimously approved the various corrective action plans for each individual incident.

The goal of the corrective action plans explained above are to ensure that all work being performed is done so according to what is approved on each protocol. Temple is pleased to report that all elements of the corrective action plans have been completed prior to this report being submitted to OLAW.

On behalf of Temple University, we would like to thank OLAW for its commitment to supporting animal welfare. Your guidance and assistance were very helpful to us in this regard. Should you have any questions regarding this report, please contact Ellen Walker, PhD, IACUC Chair or (b) (6)

Thank you for your assistance.

Sincerely,

(b) (6)

Michele Masucci, PhD  
Institutional Official  
Vice President for Research  
Temple University

(b) (6)

masucci@temple.edu

**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, February 25, 2022 8:36 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Final Report - Temple University (#D16-00359) Compliance Issues

Thank you for this report, (b) (6) We will send a response soon.

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

**From:** (b) (6)  
**Sent:** Friday, February 25, 2022 8:28 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** [EXTERNAL] Final Report - Temple University (#D16-00359) Compliance Issues

**CAUTION:** This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Good Morning,

Please find attached the finalized report regarding several compliance concerns that were initially reported on 10/15/2021. Please feel free to contact us with any questions, concerns, or clarifications that may be needed.

Thank you in advance for your time, patience, and assistance.

(b) (6)





## Initial Report of Noncompliance

By: (b) (6)

Date: 10/15/21

Time: 9:15

Name of Person reporting: Ellen Walker  
 Telephone #: (b) (6)  
 Fax #:   
 Email:

Name of Institution: Temple U  
 Assurance number: A3594

Did incident involve PHS funded activity? Yes

Funding component:

Was funding component contacted (if necessary):

## What happened?

- 1) Expired drug buprenorphine, euth sol, xylazine given to 50 mice. No problems.
- 2) Expired Betanin given to mice
- 3) Work done without was not on protocol, heart ex on mice not approved

Species involved: mice, dog

Personnel involved:

Dates and times:

Animal deaths:

- 4) 2 dogs had sham ex, got antibiotics on different schedule due to unclear records, Dogs are ok
- 5) Preceding protocol applied, didn't get approved, put on holding protocol for 1 day, move all cage cards

→ Made separate report due to USDA queries

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

- 1) Retrain on record keeping, discard drugs, clearly label expired drugs.
- 2) Retrain staff
- 3) Excl mice, amend protocol, retrain
- 4) Clarify protocol
- 5) approve protocol next day, counsel investigators

Projected submission to OLAW of final report from Institutional Official:

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Case #