



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

December 12, 2018

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

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 December 6, 2018 letter reporting an instance 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 September 13, 2018. According to the information provided, OLAW understands that over 500 cages of mice were being held on three protocols that had expired. The investigator had been issued numerous reminders of the pending expiration but did not submit renewal applications in a timely manner. The Institutional Animal Care and Use Committee (IACUC) was also waiting for approval from the Institutional Biosafety Committee.

The corrective action consisted of the IACUC approving the triennial renewals. The IACUC requested a letter of explanation and correction from the Principal Investigator, the PI was counseled by animal care and use program officials and was required to submit future protocol renewals six months prior to expiration, a separate breeding protocol must be submitted to the IACUC for approval, and the PI must undertake online retraining.

OLAW understands that the protocols involved were not PHS-supported, but concurs that the incidents were serious and supports the actions taken by the IACUC. The establishment and application of policies and practices that are consistent with the provisions of the PHS Policy at Temple University are commendable and avoid the perception of a double standard. Thank you for keeping OLAW apprised on this matter.

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

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

December 6, 2018

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

Dear Dr. Brown:

Temple University, in accordance with Assurance A3594-01 and PHS Policy IV.F.3., provides this report of noncompliance regarding the expiration of three protocols prior to their triennial approvals resulting in over 500 cages of mice being left on non-compliant protocols. This incident was first reported to Dr. Brent Morse, OLAW, on September 13, 2018 via a telephone call by Ellen Walker, Ph.D., IACUC Chair.

Since June 2018 the IACUC had been working with the Principal Investigator to submit the triennial renewals of his three active protocols, all which expire in relative proximity of each other. The PI was sent notices from the University's protocol management system at 120 days, 90 days, 60 days and 30 days prior to the expiration of the protocols. Direct emails from the IACUC Office were also sent. Revisions of the protocols were finally submitted electronically on June 15th for review at the July 13th IACUC meeting. Each protocol went through no less than three rounds of reviewer comments. Approval of the new IACUC protocols were also contingent on the approval of the Institutional Biosafety Committee (IBC) for new hazards and strains of mice being used. Submission of all of the relevant IBC related materials for review were not sent until August 20th for review at the September 18th meeting. Final approval of the triennial renewals was finally obtained on September 21, 2018.

This incidence of non-compliance was discussed at the convened IACUC meeting that took place October 5, 2018 and a tentative corrective action plan, drafted by the IACUC Chair, the Attending Veterinarian, and the IACUC Assistant Director, was presented to the committee for review and discussion. After discussion, the committee unanimously approved the plan and a letter detailing the proposed actions was forwarded to the PI immediately after the conclusion of the meeting. The corrective action plan consisted of the following items:

1. The Principal Investigator will submit a letter to the IACUC, on departmental letterhead, describing, in appropriate detail, the noncompliance of three expired protocols on



**Office of the Vice President
for Research**

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

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

August 23rd, September 3rd, and September 9th. The letter is to include an accurate accounting of the number of animals the PI had in-house at the time, which includes the animals attributable to the three expired protocols. The letter must also detail a plan that the Principal Investigator (PI) will institute a plan to manage the compliance portions (those governed by the IACUC and the Institutional Biosafety Committee (IBC)) of their research program. This letter must be signed by the PI and their Departmental Chair.

2. The Principal Investigator must schedule a meeting with the IACUC Chair, the IACUC Assistant Director, a representative of ULAR, the Associate VP for Research Compliance, and their Departmental Chairman; at which all parties will discuss the noncompliance described in this letter and what procedures and practices will be implemented to prevent such noncompliance in the future
3. The Principal Investigator is required to submit all relevant documentation, whether to the IACUC or IBC, in a timely manner. The first drafts of any Protocol Renewals shall be submitted by the PI or their designee no later than 180 days prior to expiration. Failure to submit relevant documentation in a timely manner will be considered a violation of this Corrective Action Plan, and may result in further action.
4. The Principal Investigator shall submit a separate breeding protocol to the IACUC for approval after one year (i.e., start Summer 2019) to better manage the breeding colony and the number of mice from the other experimental protocols. After the approval of the breeding protocol by October 2019, within the following year, all your breeding mice should be transferred to the breeding protocol from the experimental protocols and the breeding removed from ACUPs 4807, 4808, 4810.
5. The Principal Investigator must complete or retake (if he has already completed it) all of the online training (IACUC/AALAS Learning Library, under "AALAS Courses") listed below. The courses to be completed are: (a) Common Compliance Issues, (b) Working with the IACUC, (c) Ethical Decision-Making in Animal Research Course, (d) Working with the Laboratory Mouse, (e) Essentials for IACUC Members (to understand the importance to the committee of timely submissions). (f) Colony Management: Breeding and Recordkeeping, (g) Colony Management: Daily Work Flow, and (h) Colony Management: Plans and Strategies.

The goal of the action plan is to help the PI develop more effective strategies to ensure compliance in their use of animals in research. Item # 1 of the corrective action plan was completed on October 15, 2018. Item #2 took place on November 8, 2018. Item #3 will take

(b) (6)

(b) (6)

(b) (6)

(b) (6)

(b) (6)

(b) (6)

(b) (6)

(b) (6)

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Monday, October 22, 2018 4:22 PM
To: 'ellen.walker@temple.edu'
Subject: OLAW extension

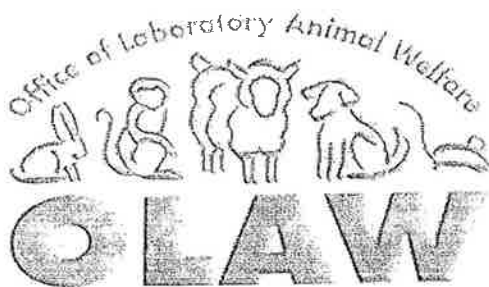
Hello Dr. Walker,

I received your request for an extension for your compliance case you reported on September 13, 2018. That is fine. I'll expect the final report before December 7th. If you require more time, please contact me. BTW – you have an out of office message on your voicemail from September. It wouldn't let me leave a message. Just FYI. It happens to me sometimes too.

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.



Initial Report of Noncompliance

By: EDM

Date: 9/13/18

Time: 3:20

Name of Person reporting: Ellen Walker, PhD, chair

Telephone #: (b) (6)

Fax #: (b) (6)

Email: (b) (6)

Name of Institution: Temple Univ.

Assurance number: A3594

Did incident involve PHS funded activity? Yes (NEI + NINDS)

Funding component: (b) (6)

Was funding component contacted (if necessary): (b) (6)

What happened? PI allowed 3 protocols to expire on * AUG 20th
Also awaiting IBC approval of new protocols. SEP 6th

Species involved: Mice

Personnel involved: PI

Dates and times: SEP 11th

Animal deaths: No

~ 550 (~ 1/2 breeding) cages

Projected plan and schedule for correction/prevention (if known): (b) (6)

Told to contact GMOs

Projected submission to OLAW of final report from Institutional Official: (b) (6)

OFFICE USE ONLY

Case #: (b) (6)