



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

June 17, 2022

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

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 June 14, 2022 letter reporting two 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) An animal (dog?) failed to receive the complete post-operative antibiotic regimen outlined in the approved protocol.

Corrective action: The protocol was amended to clarify the length of time antibiotics are to be administered based on clinical signs.

- 2) An animal (dog?) was given three separate anesthetic administrations to conduct an approved urinary catheterization, although the protocol was only approved for one.

Corrective action: The protocol was amended to clarify the anesthetic regimen.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of both problems. OLAW concurs with the actions taken by the institution to comply with the PHS Policy. Please ensure that final noncompliance reports clearly state the species involved and either reiterate the information provided in the preliminary report or correct it. 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
Robert Gibbens, D.V.M., USDA-APHIS-AC



Office of the Vice President
for Research

Research Compliance
Student Faculty Center
3340 N. Broad Street, (b) (4)
Philadelphia PA 19140

A3594-1C
Institutional Animal Care
and Use Committee
Phone: (b) (6)
Email: IACUC@temple.edu

June 14, 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 two protocol deviations that took place under one approved protocol at Temple University. The IACUC was made aware of these deviations between September 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: Upon post operative record review by veterinary staff, it was noted that an animal did not receive the approved antibiotics past post-operative day one. The protocol states that the antibiotic will be administered "BID 1 day prior to surgery and continuing for 1-5 days post-surgery".

Corrective Action: The protocol was amended to clearly state that prophylactic antibiotics will be administered "BID 1 day prior to surgery and 1 day after surgery if there are no signs of post operative infection. Antibiotics will be given on the additional days only if signs of post-operative infection are evident.

The amendment was reviewed and approved by the IACUC on 09/16/2021

Funding: This protocol is associated with the NIH funding (5R01NS070267-12)

Incident #2: During the conduct of an approved urinary catheterization procedure the animal was given three separate injections of propofol. The approved protocol states that the frequency/duration for propofol use is a "single infusion to enable placement of endotracheal tube or urinary catheterization".

Corrective Action: The protocol was amended to clearly state that propofol will be given to effect using the minimally effective dose within 5-8 mg/kg dose range and supplemental injections will be administered as required to maintain anesthesia.

The amendment was reviewed and approved by the IACUC on 10/04/2021

Funding: This protocol is associated with the NIH funding (5R01NS070267-12)

These incidents were discussed at the convened IACUC meeting that took place on October 1st, 2021

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 Jennifer Ippolito, CPIA, IACUC Assistant Director.



**Office of the Vice President
for Research**

Research Compliance
Student Faculty Center
3340 N. Broad Street, (b) (4)
Philadelphia PA 19140

**Institutional Animal Care
and Use Committee**
Phone: (b) (6)
Email: IACUC@temple.edu

Thank you for your assistance.

Sincerely,

(b) (6)

MICHELE M. MASUCCI (Jun 15, 2022 11:05 EDT)

Michele Masucci, PhD
Institutional Official
Vice President for Research
Temple University
(b) (6)
masucci@temple.edu

McCoy, Devora (NIH/OD) [E]

From: (b) (6)
Sent: Wednesday, June 8, 2022 9:47 AM
To: OLAW Division of Compliance Oversight (NIH/OD)
Subject: Re: [External] RE: Final Report - Temple University (#D16-00359) Compliance Issues

Good Morning Devora,

I will investigate the status of this and get back to you as soon as possible. Apologies for the delay and oversight.

Thank you for your patience,

(b) (6)

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Wednesday, June 8, 2022 9:43 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [External] RE: Final Report - Temple University (#D16-00359) Compliance Issues

Good morning (b) (6)

I'm contacting you regarding another case (OLAW Case# A3594-1C) that was also reported on 10/15/2021 by Ellen Walker regarding two animals that received antibiotics and anesthetics on different schedules than described in the protocol. Can you please provide an update on this case?

Thanks,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

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?

2 dogs had sham surgery; got antibiotics and anesthetics at different schedule than described in the protocol. Records and protocol not precise. Dogs ok

Species involved: Dogs

Personnel involved:

Dates and times:

Animal deaths:

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

Clarify protocol

Projected submission to OLAW of final report from Institutional Official:

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Case #