



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

May 29, 2019

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

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 May 17, 2019 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at Temple University. According to the information provided, OLAW understands that a clear bag of biohazardous animal waste and bedding was found on the dirty side of the cage wash. The bag had not yet been autoclaved for disposal. One specific laboratory was responsible for placing biohazard mouse waste into clear bags rather than red ones.

The corrective action consisted of autoclaving and discarding the bag and contents. All biohazardous waste will be collected in red or orange bags and processed according to institutional policies, the standard operating procedure was amended to state that infectious biohazardous waste will immediately be processed and discarded upon receipt by University Laboratory Animal Resources, laboratory personnel will be trained on appropriate handling and disposal of biohazardous animal waste, and staff was retrained on institutional safety procedures.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Sincerely,

(b) (6)

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

cc: IACUC Contact

A3594-U



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

May 17, 2019

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. Wolff:

In accordance with Assurance D16-00359 (A3594-01) and PHS Policy IV.F.3., please accept this report of noncompliance which involved the improper disposal of biological waste storage and handling in the pre-wash (the so-called "dirty side") of Temple's University Laboratory Animal Resource (ULAR) cage wash area. This incident was initially reported to OLAW, on April 4, 2019 via a telephone call by (b) (6). A recitation of the underlying facts and the corrective action plan are enclosed herein for your review.

#### Background

On the morning of March 27th, 2019, Environmental Health and Radiation Safety (EHRS) and the IACUC Office received an anonymous report of improper biological waste storage and handling in the pre-wash side of the ULAR cage wash area. EHRS visited this location the same morning to investigate these claims. EHRS interviewed the Operations Supervisor of Temple University ULAR. Upon investigation, EHRS discovered a transparent (not red) waste bag dated: "March 1, 2019," which contained biohazardous animal waste and bedding. The Operations Supervisor reported that the biohazardous animal waste bag was transported by a ULAR employee from a Principal investigator's (PI) lab, to the ULAR cage wash area, and had not yet been properly autoclaved or disposed. The Operations Supervisor further stated that ULAR had been using clear bags for transport and handling of biohazardous waste collected from cages of mice from this particular Investigator's lab.

On March 28, 2019 the Supervisor informed EHRS that "All Bio-waste observed yesterday has since been autoclaved and is currently in the process of being sorted and properly disposed of."

#### The Corrective Action Plan

The March 27, 2019 incident of non-compliance was discussed at the convened IACUC meeting that took place April 5, 2019. A corrective action plan was presented to the committee for review and discussion. The committee unanimously approved the plan and a letter detailing the proposed actions and it was forwarded to the PI and ULAR staff immediately after the



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conclusion of the IACUC meeting. The corrective action plan covered the following actions to be taken by the PI in question, the PI's lab and the ULAR staff:

1. All potentially infectious biohazardous waste in ULAR facilities shall be collected, processed and disposed of in accordance with Temple University's management of infectious or biological waste policies in red or orange biohazardous waste bags.
2. An SOP for waste disposal for ULAR facilities shall be updated to include the immediate processing and disposal of infectious biohazardous waste when received by ULAR.
3. Training for lab specific proper handling and disposal of biohazardous waste collected from infected animals has to be completed.
4. All ULAR staff and the Principal Investigator's lab shall complete Temple's online Biohazardous Waste Safety Training refresher. In addition, the Operations Supervisor of Temple University ULAR shall complete online Temple's Bloodborne Pathogens Safety Training refresher

The goal of the corrective action plan is to ensure safety in the use of animals and biohazards in research. Temple is pleased to report that all 4 specified elements of the corrective action plan 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,

DocuSigned by:  
(b) (6)

F3DC1C341459407...  
Michele Masucci, PhD  
Institutional Official  
Vice President for Research  
Temple University  
(b) (6)

masucci@temple.edu

## Morse, Brent (NIH/OD) [E]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Tuesday, May 21, 2019 2:18 PM  
**To:** (b) (6) OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Final Report - Temple University (D16-00359 /#A3594-01) Compliance Issue

Thank you for providing this report (b) (6) 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

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)  
**Sent:** Monday, May 20, 2019 11:29 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** Final Report - Temple University (D16-00359 /#A3594-01) Compliance Issue

Good Morning,

Please find attached the final report for a non-compliance issue that was first reported to OLAW on 04/05/2019. Please feel free to contact us with any questions, concerns, or if further clarification is needed.

Thank you in advance for your time and understanding,

(b) (6)



(b) (6)

