



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 19, 2019

Re: Animal Welfare Assurance
A3632-01 [OLAW Case 1G]

Ellen Reinsch-Friese, M.H. and Adrian Corbett, Ph.D.
Wright State University
Office of Research and Sponsored Programs
3640 Colonel Glenn Hwy.
Dayton, OH 45435-0001

Dear Ms. Reinsch-Friese and Dr. Corbett,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 17, 2019 clarification letter regarding noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals at Wright State University.

Thank you very much for promptly providing additional information to clarify your programmatic corrections. Our office understands that the new euthanasia documentation policy applies to situations where research staff request that a laboratory animal resources staff euthanize animals. This policy complements the additional corrections describes in your original letter. OLAW concurs with the actions taken by your institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate having been informed of this matter and find no cause for further action by this office.

Sincerely;

(b) (6)

Nicolette Petervary, VMD, DACAW
Veterinary Medical Officer
Office of Laboratory Animal Welfare

cc: IACUC Chair

June 17, 2019

**WRIGHT STATE
UNIVERSITY**

Research and Sponsored Programs
3640 Colonel Glenn Hwy.
Dayton, OH 45435

Main (937) 775-2425
rsp@wright.edu

Nicolette Petervary, DVM, DACAW
Veterinary Medical Officer
Office of Laboratory Animal Welfare
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Dear Dr. Petervary:

Thank you for your response to our corrective action in OLAW Case 1G, from our Animal Welfare Assurance A3632-01.

You asked for further clarification about a policy change, which from our document, reads:

"The Laboratory Animal Resources department must institute a policy change by June 30, 2019 that requires animal care staff to provide investigators with written confirmation of euthanasia upon completion."

This policy change in no way restricts PIs or members of their staff on the animal protocol from performing their own euthanasia on their animals. This policy change only refers to the instance when a LAR staff member is requested to perform a euthanasia by either the PI of a protocol or documented staff from the PI's lab on the animal protocol. The written communication by the LAR staff member will indicate whether they were able to complete the euthanasia or if there was a problem which prevented them from being able to complete the euthanasia (e.g. unable to find the correct animal), which should prevent the miscommunication that occurred in this recent case. The proposed new policy says: *"LAR personnel that are requested to euthanize research animals by investigators or research staff are responsible for providing written confirmation to the individual who requested the service upon completion."*

I hope this clarifies our proposed actions for this reported incident.

Sincerely,

Ellen
Reinsch
Friese

Digitally signed
by Ellen Reinsch
Friese
Date: 2019.06.17
10:39:58 -04'00'

Ellen Reinsch-Friese, M.H.
Institutional Official
Interim Vice Provost for Research

(b) (6)

Adrian Corbett, Ph.D.
Chair, WSU-IACUC

cc: (b) (6)



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June 14, 2019

Re: Animal Welfare Assurance
A3632-01 [OLAW Case 1G]

Ellen Reinsch-Friese, M.H. and Adrian Corbett, Ph.D.
Wright State University
Office of Research and Sponsored Programs
3640 Colonel Glenn Hwy.
Dayton, OH 45435-0001

Dear Ms. Reinsch-Friese and Dr. Corbett,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 7, 2019 letter regarding noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals at Wright State University, which had been preceded by a preliminary report to OLAW on June 3, 2019. According to the information provided, our office understands that a transgenic mouse that had been identified by an animal care technician as having exceeded humane endpoints had not been euthanized in a timely manner. The post-doctoral associate tasked with euthanizing the animal after veterinary evaluation had placed the mouse in a transport cage without water in a non-animal location, where it was found three days later and euthanized at that time.

Corrective measures consisted of additional training for the principal investigator (P.I.) and laboratory members involved in the incident, P.I led training for all laboratory members emphasizing importance of timely euthanasia, and modified policies involving documentation for euthanasia, including voluntary additional documentation required by the P.I. from all lab members.

Based on its assessment of this explanation, OLAW understands that measures have been taken to prevent recurrence of this problem. OLAW concurs with the actions taken by your institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. However, one point requires additional clarification:

According to the corrective actions listed in your letter:

"The laboratory Animal Resources department must institute a policy by June 30, 2029 that requires animal care staff to provide investigators with written confirmation of euthanasia upon completion."

Does this mean that going forward, laboratory members will no longer be permitted to euthanize animals (i.e. only animal care staff will be performing euthanasia), or that care staff will be performing follow-up evaluations to ensure appropriate completion? Will this apply to all euthanasia's or only those situations where animal care staff identify a need to euthanize an animal? Thank you in advance for providing additional information to clarify your programmatic corrections.

Page 2 – Ms. Reinsch-Friese
June 14, 2019
OLAW Case A3632-1G

Sincerely:

(b) (6)

Nicolette Petervary, VMD, DACAW
Veterinary Medical Officer
Office of Laboratory Animal Welfare

cc: IACUC Chair



June 7th, 2019

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

Office of Research and
Sponsored Programs
3640 Colonel Glenn Hwy.
Dayton, Ohio 45435-0001

(937) 775-2425
fax: (937) 775-3781
rsp@wright.edu
www.wright.edu

Reference: Animal Welfare Assurance Number D16-00383 (A3632-01)
Wright State University

Dear Dr. Morse:

In compliance with *The PHS Policy on Humane Care and Use of Laboratory Animals* (Policy), "Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals" [NOT-OD-05-034, February 24, 2005, Office of Laboratory Animal Welfare (OLAW), Office of Extramural Research], and Wright State University's Animal Welfare Assurance (D16-00383/A3632-01), the purpose of this letter is to report an occurrence of noncompliance with the PHS Policy. A preliminary report of this noncompliance was made to Dr. Morse by phone on 6/3/19. The activities described in this report are not supported by an NIH grant.

On May 17, 2019, an animal care technician identified a transgenic mouse that had met the IACUC approved humane end-points. The principal investigator, post-doc, research associate, and veterinarian were notified. The veterinarian examined the mouse with the post-doc and it was agreed that the animal required euthanasia, and that the post-doc would perform the procedure at that time.

The mouse was not euthanized as planned, but instead was placed in an improperly labeled transportation cage without water. The cage was placed on the lower shelf of an animal housing rack not normally used for animals, where it was found by an animal care technician on May 20th, 2019. The veterinarian, principal investigator, post-doc, and research associate were immediately notified when the mouse was found. The veterinarian examined the mouse and euthanized it at that time.

A subcommittee of the IACUC was formed upon notification of the protocol violation and met on May 23, 2019. The following corrective actions were recommended and approved by the IACUC on June 6, 2019, and formally communicated to the investigator on June 7, 2019:

- The principal investigator, post-doc, and research associate must undergo additional training. The following training modules available through citiprogram.org must be completed by June 30, 2019:
 - Working with the IACUC: Investigators, staff and students (Basic Course)

- Working with genetically modified mice in research settings (Basic Course)
- The investigator must review with laboratory members the importance of following the IACUC approved Animal Use Protocol and ensuring timely euthanasia when humane endpoints have been reached by June 30, 2019.
- The investigator, post-doc, and research associate must meet with the animal vivarium staff by June 30, 2019 to review the requirements for proper housing of animals.
- The Laboratory Animal Resources department must institute a policy by June 30, 2019 that requires animal care staff to provide investigators with written confirmation of euthanasia upon completion. In addition, the investigator stated that she will require her laboratory members to provide written communication to animal care staff for animal health concerns.

Wright State University regrets this unfortunate deviation from the requirements of the PHS policy. If you have any additional questions or need clarification, please contact Dr. Emily S. Dudley, Director of Laboratory Animal Resources (b) (6) or Dr. Adrian Corbett, Chair of the Institutional Animal Care and Use Committee (b) (6) at Wright State University.

Sincerely,

(b) (6)

Ellen Reinsch-Friese, M.H.
Institutional Official
Interim Vice Provost for Research

(b) (6)

Adrian Corbett, Ph.D.
Chair, WSU-IACUC

cc: (b) (6)

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Monday, June 10, 2019 7:48 AM
To: (b) (6)
Subject: RE: Wright State University (D16-00383) Correspondence

Thank you for this final 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: Friday, June 07, 2019 5:44 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Cc: (b) (6)
Subject: Wright State University (D16-00383) Correspondence

Drs. Morse and (b) (6)

Please see the attached letter regarding an incident.

Best,

WRIGHT STATE
UNIVERSITY

(b) (6)



Initial Report of Noncompliance

By: *BDM*

Date: *6/3/19*

Time: *2:30*

Name of Person reporting: *Emily Dudley, DVM*
Telephone #: *(b) (6)*
Fax #: *(b) (6)*
Email: *(b) (6)*

Name of Institution: *Wright State U.*
Assurance number: *A3632*

Did incident involve PHS funded activity? *No*
Funding component: _____
Was funding component contacted (if necessary): _____

What happened? *Tg mouse on ASP w/endpoint on a Friday. Found w/o water on Monday. Euthanized by veterinarian. Was supposed to be euthanized by Post-doc on previous Friday.*
Species involved: *mouse*
Personnel involved: *Post-doc*
Dates and times: *5/17/19*
Animal deaths: _____

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

Projected submission to OLAW of final report from Institutional Official: _____

OFFICE USE ONLY
Case # _____