



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) 480-3387

May 15, 2020

Re: Animal Welfare Assurance  
#A4107-01 (OLAW Case 2A)

Dr. Alison Preston,  
Interim Vice President for Research  
University of Texas at Austin  
P.O. Box 7996  
Austin, TX 78713

Dear Dr. Preston,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 11, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Texas at Austin (UT) following up on an initial March 12, 2020 notification by email.

According to the information provided, this Office understands that the UT Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure to adhere to the IACUC-approved protocol. The final report states that animal care staff found 14 dead mice during daily animal checks. The mice were recently inoculated with the *Bordetella pertussis*. The principal investigator (PI) was approved to perform health checks every 12h after inoculation to closely monitor animals in case symptoms developed that required humane euthanasia. A review of laboratory records, and discussion of the event revealed mice were monitored every 24h and were administered a dosage of *Bordetella pertussis* that was higher than that approved in the IACUC protocol.

The corrective actions included the following:

- The protocol was amended to adjust the dosage of *Bordetella* and include welfare checks at least twice per day (no more than 12h apart).
- The investigator performing the procedures met with veterinary staff to discuss a more thorough method to observe animals for euthanasia criteria.
- The PI conducted a meeting with all lab members to review the animal use protocol to ensure all members were familiar with procedures approved by the IACUC.

It is noted that this research is supported by PHS funds. Based on its assessment of this explanation, OLAW understands that the University of Texas at Austin has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. We appreciate being informed of these matters and find no cause for further action by this Office.

*Page 2 – Dr. Preston*  
*May 15, 2020*  
*OLAW Case A4107-2A*

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM  
Animal Welfare Program Specialist  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Chair



THE UNIVERSITY OF TEXAS AT AUSTIN  
Office of the Vice President for Research

P.O. Box 7996 • FAC 426, G1400 • Austin, Texas 78713-7996 • 512-471-2877 • FAX 512-471-2827

May 11, 2020

Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
RKL 1, Suite 360, MSC 7982  
6705 Rockledge Drive  
Bethesda, MD 20892-7982

Subject: Report of Non-Compliance with PHS Policy on Humane Care and Use of Laboratory Animals

To Whom It May Concern:

The University of Texas at Austin (UT), Animal Welfare Assurance #A4107-01, submits this report in compliance with section IV.F.3 of the PHS Policy on Humane Care and Use of Laboratory Animals and with the published guidance document NOT-OD-05-034 "Guidance on Prompt Reporting to OLAW under the PHS Policy on Humane Care and Use of Laboratory Animals." This letter is to report non-compliance in which the investigator failed to adhere to the IACUC-approved protocol. The initial report was made on March 12, 2020.

During daily animal checks, animal care staff discovered 14 deceased mice. The mice had recently undergone a procedure in which they were inoculated with the bacteria *Bordetella pertussis*. The investigator was approved to perform health checks on the animals every 12 hours after inoculation in order to closely monitor animals in case they showed symptoms that would necessitate humane euthanasia. After reviewing laboratory records and discussing the event with the investigators, it was found that the mice were only monitored every 24 hours and the mice had also been administered a dosage of *Bordetella pertussis* that was higher than that approved in the IACUC protocol.

The protocol was amended to adjust the dosage of *Bordetella pertus* and include welfare checks at least twice per day, no more than 12 hours apart in order to increase the observation times. The investigator performing these procedures met with veterinary staff to discuss a more thorough way to observe animals for euthanasia criteria. The PI conducted a meeting with all lab members to review the animal use protocol in order to ensure all lab members are familiar with what procedures have been approved by the IACUC.

The protocol this report pertains to is funded by NIH project number 5R01AI122753-05, entitled "Systematic Evaluation of B. Pertussis Act's Role as a Protective Antigen". The grant officer has been copied on this notification.

Director, Division of Compliance Oversight  
May 11, 2020  
Re: PHS Assurance Number A4107-01  
Page 2

Sincerely,

DocuSigned by:  
(b) (6)  
4D672C31237C4EC...

Alison R. Preston  
Interim Vice President for Research  
University of Texas at Austin

ARP:cim

cc: S. John Mihic, Chair, Institutional Animal Care and Use Committee  
(b) (6)  
Glen Otto, Attending Veterinarian, Institutional Animal Care and Use Committee  
Xin-Xing Gu, Program Official, NIH

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, May 11, 2020 10:58 AM  
**To:** IACUC  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Final report of non-compliance- University of Texas Austin (#A4107-01)

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

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

**From:** IACUC <IACUC@austin.utexas.edu>  
**Sent:** Friday, May 8, 2020 2:13 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** IACUC <IACUC@austin.utexas.edu>; Alison R. Preston (VPR) <preston@austin.utexas.edu>; Mihic, S J <mihic@austin.utexas.edu>; (b) (6) Otto, Glen <gotto@austin.utexas.edu>; (b) (6) Gu, Xin-Xing (NIH/NIAID) [E] <xin-xing.gu@nih.gov>  
**Subject:** Final report of non-compliance- University of Texas Austin (#A4107-01)

Dear OLAW,

On behalf of Dr. Alison Preston, Interim Vice President for Research at the University of Texas at Austin, please find attached the final report involving noncompliance on NIH grant award 5R01AI122753-05. The initial report was made on March 12, 2020. Please let me know if you have any questions.

Thank you,  
(b) (6)

(b) (6)

[The RSC office is physically closed. Staff are working remote and responding to emails and voicemails as usual.]

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, March 13, 2020 9:46 AM  
**To:** IACUC  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Report of protocol noncompliance- University of Texas at Austin

Thank you for this preliminary report, (b) (6). We will open a new case and look forward to receiving the final report from the IO after the IACUC has completed its investigation.

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

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**From:** IACUC <IACUC@austin.utexas.edu>  
**Sent:** Thursday, March 12, 2020 3:34 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6) Otto, Glen  
<gotto@austin.utexas.edu>; Mihic, S J <mihic@austin.utexas.edu>  
**Subject:** Report of protocol noncompliance- University of Texas at Austin

To Whom It May Concern,

On behalf of (b) (6) at the University of Texas at Austin, please accept this initial report of non-compliance for NIH project number 5R01AI122753-05, under Assurance A4107-01.

During daily animal checks, animal care staff discovered 14 deceased mice. The mice had recently undergone a procedure in which they were inoculated with the bacteria Bordetella pertussis. The investigator was approved to perform health checks on the animals every 12 hours after inoculation in order to closely monitor animals in case they showed symptoms that would necessitate humane euthanasia. After reviewing laboratory records and discussing the event with the investigators, it was found that the mice were only monitored every 24 hours and the mice had also been administered a dosage of Bordetella pertussis that was higher than that approved in the IACUC protocol.

As per NOT-OD-05-034, failure to adhere to IACUC-approved protocols is reportable.

The IACUC will continue to review the matter. After finishing the review, a final report of its conclusions and actions will be submitted to the Office of Laboratory Animal Welfare. In the meantime, please let me know if you have any questions.

Sincerely,

(b) (6)