



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

March 24, 2020

Re: Animal Welfare Assurance
A3217-01 [OLAW Case 1D]

Ms. Tamara Deuser
Associate Vice President
Arizona State University
660 South Mill Avenue, (b) (4)
Tempe, AZ 85287-6111

Dear Ms. Deuser,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 20, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Arizona State University, following up on an initial report on January 21, 2020. According to the information provided, OLAW understands that two mice were not monitored every hour for the first sixteen hours following a bacterial injection, as was described in the approved protocol. The mice were not monitored at all during the first sixteen hours. Upon veterinary examination, one mouse had a rectal prolapse and both were lethargic.

The corrective action consisted of euthanizing the mice. The Institutional Animal Care and Use Committee Chair (IACUC) counseled the investigator to follow the protocol and to maintain a detailed log on findings from the hourly monitoring. The investigator was placed under enhanced IACUC oversight and will submit copies of the monitoring record and of analgesic administration to the committee.

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 IACUC to comply with the PHS Policy.

Sincerely,

(b) (6)

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

cc: IACUC Chair

March 20, 2020

Brent Morse, DVM
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

Re: Report of Noncompliance under Animal Welfare Assurance #DIG-00136

Research Facility: ISTB1
Species: *Mus musculus*
Principal Investigator: Tatiana Ugarova
Funding Source: National Institutes of Health
Incident: Failure to comply with full 16 hour monitoring post-procedure

On January 17, 2020 a DACT staff member notified the IACUC of a violation of protocol Ugarova 20-1748R. Specifically, the protocol states that after bacterial injection the mice will be monitored every hour for the first 16 hours. Two mice were injected at approximately 12pm on January 16, 2020 and the researcher left in the evening. The mice were not monitored for the full 16 hours. On the morning of January 17, 2020 DACT personnel alerted the veterinary team about the mice appearing lethargic and one of the two mice had a rectal prolapse. DACT staff could not state when the mice started acting abnormally. The researcher euthanized both mice promptly when notified.

The IACUC Chair met with Dr. Ugarova on February 7th, and discussed the non-compliance and ways to prevent it from happening in the future. The PI suggested a detailed log to be completed at each hourly monitoring. The researcher who did not stay the full 16 hours is now aware that she needs to monitor the mice for 16 hours as the protocol states even if the mice appear fine.

Corrective Action:

The IACUC Chair informed the committee of this non-compliance at the fully convened meeting on February 25, 2020. The committee requested that the researcher submit a copy of the record documenting the hourly monitoring and the administration of pain medications each time an experiment is conducted until such time the IACUC determines this action is no longer required.

The PI has stated she will strongly adhere to the request from the IACUC meeting of February 25, 2020 and will submit a copy of the record documenting the hourly monitoring as well as scheduled administration of pain medications for each future experiment.

The committee feels the PI will make the appropriate commitment to establishing sound practices that will benefit both animal welfare and compliant scientific study. The committee will monitor laboratory records to confirm this is the case.

Please let us know if you have any questions.

(b) (6)

Karen Kibler, PhD Chair, IACUC
Assistant Research Professor

(b) (6)
Karen.Kibler@asu.edu

(b) (6)

Tamara Deuser, MBA, PMP
Institutional Official, Associate Vice President

(b) (6)
Tamara.Deuser@asu.edu

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, March 24, 2020 6:38 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Adverse Event Report under Assurance D16-00136

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

From: (b) (6)
Sent: Monday, March 23, 2020 6:20 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Tamara Deuser <Tamara.Deuser@asu.edu>; Karen Kibler <Karen.Kibler@asu.edu>; iacuc@asu.edu; (b) (6)
(b) (6)
Subject: RE: Adverse Event Report under Assurance D16-00136
Importance: High

Good Afternoon,

On behalf of the ASU IACUC, I am submitting the final report for the adverse event reported below. If you have any questions or need further information please don't hesitate to contact me.

Best Regards,

(b) (6)

(b) (6)

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From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Tuesday, January 21, 2020 10:51 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: RE: Adverse Event Report under Assurance D16-00136

Thank you for this preliminary report, (b) (6) We will start a new case file 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

From: [REDACTED] (b) (6)

Sent: Tuesday, January 21, 2020 12:25 PM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: IACUC@asu.edu <IACUCasu.edu@mainex1.asu.edu>; Karen Kibler <Karen.Kibler@asu.edu>; Tamara Deuser <Tamara.Deuser@asu.edu>; [REDACTED] (b) (6)

Subject: Adverse Event Report under Assurance D16-00136

Importance: High

Good Morning,

On behalf of the ASU IACUC, I am submitting a preliminary report of a failure to adhere to an IACUC-approved protocol for mice monitoring. The IACUC is investigating this matter. A follow up message with a final report will be provided when the inquiry is complete.

If you have any questions please contact me.

Thank you,

[REDACTED] (b) (6)

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