



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
#A3325-01 (OLAW Case 1M)

Dr. Steven Goodman
Vice Chancellor for Research
University of Tennessee Health Science Center
910 Madison Avenue – (b) (4)
Memphis, TN 38163

Dear Dr. Goodman,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 24, 2020 letter responding to my February 26, 2020 request for additional information regarding an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Tennessee Health Science Center. According to the information provided, OLAW understands the following:

- 1) The species of animal involved was mouse.
- 2) Five mice died- three were found dead and two were moribund and were euthanized.
- 3) To reduce noncompliance, the Principal Investigator (PI) counseled the laboratory staff that all animal studies must have prior approval from the Institutional Animal Care and Use Committee (IACUC), that studies cannot begin without written instructions from the PI, and staff was trained on carefully reading bottle labels of reagents.
- 4) The primary grantee was informed about the matter.
- 5) A memorandum of understanding was in place between the primary grantee and the sub-awardee.
- 6) IACUC approved guidelines and procedures are in place to reduce the likelihood of such an incident occurring in another laboratory. The topics of proper animal transfers and protocol amendments will be discussed in an IACUC newsletter and during the semiannual inspection.
- 7) The charges to the grant were negligible therefore no reconciliation of funds was necessary.
- 8) The laboratory was placed on enhanced post-approval monitoring.
- 9) The protocol was amended and the laboratory staff was retrained.

Based on its assessment of these explanations, OLAW has a better understanding of the facts involved in this case and of the measures taken to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy. 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 Chair



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March 24, 2020

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

Dr. Wolff:

In response to your letter dated February 26, 2020, OLAW Case 1M, regarding our report of non-compliance, where animal activities had been conducted without prior review and approval by the Institutional Animal Care and Use Committee. Specifically, animals had been donated to a laboratory but not transferred to the correct protocol, animals were treated with an experimental drug not listed on the protocol, and the vehicle for delivery of the drug was incorrect and led to the animal's death. Please see below the additional information requested.

- 1) What species of animal was involved? *mouse*
- 2) How many animals died? *A total of 5 mice were injected. 3 were dead and 2 found moribund the next day. The two moribund mice were euthanized upon being found.*
- 3) What specific measures were implemented by the Principal Investigator to reduce the risk of noncompliance? *The PI informed all staff of a summary of the errors. Staff was informed of the need to verify that new studies are included in an IACUC approved protocol and studies will not begin until staff has received written instructions from the PI. Training on reading of labels on the bottles was also provided.*
- 4) Was the primary grantee informed about the matter? *Yes. Primary grantee has been notified by UTHSC Office of Sponsored Projects.*
- 5) Was a Memorandum of Understanding in place between the prime grantee and the performance site (if necessary) as stated in the Guide for the Care and Use of Laboratory Animals on p. 15, Collaborations? *Yes*
- 6) Have any program wide measures been taken to prevent such an incident from occurring in another laboratory? *Program wide measures in the form of IACUC approved guidelines and procedures are in place. Additionally, a reminder of the need for proper transfer of animals and*

protocol amendment will be the primary topic in the Spring IACUC newsletter as well as a point of emphasis during the Spring inspection of laboratories.

7) Was the NIH grant charged for any unauthorized animal activities? *The grant would have been charged per diems for the single cage for the day that the animals were injected and the day following when they were found dead/moribund. A total of \$1.82 would be charged to the grant.*

8) Was the laboratory placed on enhanced post-approval monitoring? *The IACUC requested enhanced PAM.*

9) Provide any additional corrective/preventive measures and an assessment of the current status of the study. *The PI has amended his protocol to include metformin and has provided retraining of his staff.*

Please let us know if additional information is needed.

Sincerely,

(b) (6)

Steven R. Goodman PhD
Vice Chancellor for Research

Copied:

(b) (6)

Jeffery Steketee, PhD IACUC, Chair

(b) (6)

David Hamilton, DVM Attending Veterinarian

Wolff, Axel (NIH/OD) [E]

From: Walker, Keri (NIH/OD) [C]
Sent: Tuesday, March 24, 2020 10:57 AM
To: Wolff, Axel (NIH/OD) [E]
Subject: FW: [Ext] OLAW Case A3325-1M
Attachments: OLAW Case 1M follow up.pdf

From: UTHSC Institutional Animal Care and Use Committee <iacuc@uthsc.edu>
Sent: Tuesday, March 24, 2020 10:55 AM
To: Walker, Keri (NIH/OD) [C] <keri.walker@nih.gov>
Cc: Steketee, Jeffery D <jstekete@uthsc.edu>; (b) (6) Hamilton, David
<dhamilt7@uthsc.edu>; (b) (6)
Subject: Re: [Ext] OLAW Case A3325-1M

Privileged and Confidential

Keri, attached is Dr. Goodman's response to Dr. Wolff's letter dated 2/26/2020. If additional information is needed, please let us know.

Thanks,

(b) (6)

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From: Walker, Keri (NIH/OD) [C] <keri.walker@nih.gov>
Sent: Wednesday, February 26, 2020 12:42 PM
To: sgoodmana5@uthsc.edu <sgoodmana5@uthsc.edu>
Cc: UTHSC Institutional Animal Care and Use Committee <iacuc@uthsc.edu>
Subject: [Ext] OLAW Case A3325-1M

Dear Dr. Goodman,

Attached please find Dr. Wolff's interim response to OLAW Case A3325-1M.

If you have any questions, feel free to contact us by phone or by e-mail.

Best Regards,
Keri

Keri Walker
Program Specialist (Contractor)
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Dr., Suite 2500
Bethesda, MD 20892
301-435-2390
keri.walker@nih.gov



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February 26, 2020

Re: Animal Welfare Assurance
#A3325-01 (OLAW Case 1M]

Dr. Steven Goodman
Vice Chancellor for Research
University of Tennessee Health Science Center
910 Madison Avenue – (b) (4)
Memphis, TN 38163

Dear Dr. Goodman,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 24, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Tennessee Health Science Center. According to the information provided, OLAW understands that animal activities had been conducted without prior review and approval by the Institutional Animal Care and Use Committee. Specifically, animals had been donated to a laboratory but not transferred to the correct protocol, animals were treated with an experimental drug not listed on the protocol, and the vehicle for delivery of the drug was incorrect and led to the animal's death.

The corrective actions consisted of counseling the Principal Investigator on protocol compliance and retraining the laboratory staff.

In order for OLAW to have a complete understanding of the matter, please provide the following additional information:

- 1) What species of animal was involved?
- 2) How many animals died?
- 3) What specific measures were implemented by the Principal Investigator to reduce the risk of noncompliance?
- 4) Was the primary grantee informed about the matter?
- 5) Was a Memorandum of Understanding in place between the prime grantee and the performance site (if necessary) as stated in the *Guide for the Care and Use of Laboratory Animals* on p. 15, Collaborations?
- 6) Have any program wide measures been taken to prevent such an incident from occurring in another laboratory?
- 7) Was the NIH grant charged for any unauthorized animal activities?
- 8) Was the laboratory placed on enhanced post-approval monitoring?

- 9) Provide any additional corrective/preventive measures and an assessment of the current status of the study.

Please provide the requested information by **March 27, 2020**. Feel free to contact me should you have any questions.

Sincerely,

(b) (6)

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

cc: IACUC Chair

A3325-1M



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February 24, 2020

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Bethesda, MD 20892-7982

Dr. Morse or Dr. Wolff:

The University of Tennessee Health Science Center (UTHSC), in accordance with Assurance A3325-01 and PHS Policy IV.F.3, reports noncompliance for the conduct of animal-related activities without appropriate IACUC review and approval. The narrative below describes the findings and actions taken in this matter.

On January 23, 2020 the Institutional Animal Care and Use Committee (IACUC) was made aware of lab non-compliance that included 1) Animals donated to the lab but not transferred to the correct protocol prior to use, 2) animals treated with metformin before the protocol was amended to include this compound and 3) the wrong vehicle was used for metformin, which ultimately led to the animals' death.

A quorum of the IACUC examined these findings, during its regular meeting on February 11, 2020. During its deliberations of the incident, the IACUC considered the PI's proactive response to the protocol noncompliance, to reeducate the staff and put into place procedures to reduce the risk of further noncompliance.

Following discussion, the IACUC unanimously voted:

- Due to PI's proactive response, no sanctions were imposed

The PI was reminded that any future failure to comply with an approved animal protocol, IACUC procedures, or Lab Animal Care Unit procedures, no matter how minor, could be grounds for immediate suspension of their animal research program.

The protocol associated with the report of non-compliance was PHS funded, USPHS Grant U01 CA-189283, prime awardee institution Beckman Research Institute – City of Hope.

Sincerely,

(b) (6)

Steven R. Goodman PhD
Vice Chancellor for Research

Copied:

(b) (6)

Jeffery Steketee, PhD

IACUC, Chair

(b) (6)

David Hamilton, DVM
AAALACi

Attending Veterinarian

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, February 26, 2020 10:47 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Incident Report A-3325-01

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

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

From: (b) (6)
Sent: Wednesday, February 26, 2020 10:41 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Goodman, Steven R <sgoodma5@uthsc.edu>; (b) (6) Steketee, Jeffery D <jstekete@uthsc.edu>; (b) (6) Hamilton, David <dhamilt7@uthsc.edu>; AAALAC International <accredit@AAALAC.org>
Subject: Incident Report A-3325-01

Report attached.

Please contact us if additional information is needed.

(b) (6)

UTHSC

(b) (6)

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