



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

June 8, 2020

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

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 June 2, 2020 letter in response to the March 12, 2020 letter sent from the Office of Laboratory Animal Welfare (OLAW).

The update was requested based on the protocol suspension of a principal investigator (PI) based on several findings. Those findings included: a failure to monitor animals, a failure to euthanize animals when they had reached humane endpoints, an admission, by the PI, of conducting an unapproved pilot study, the failure of the PI to maintain accurate clinical observation records of infected animals and concern of a lack of honesty, on the part of the PI, during his discussions on the aforementioned concerns with the Attending Veterinarian and IACUC Vice Chair. As stated in the March 4, 2020 letter the corrective actions included:

- Completion of Restoring Professionalism and Integrity in Research (RePAIR) program at Washington University in St Louis by the PI.
- Completion of Working with the IACUC Refresher course and Post Procedure Care of Mice and Rats in Research: Minimizing Pain and Distress through the AALAS Learning Library by the PI and staff.
- Development of a score sheet containing a series of clinical parameters to determine humane endpoints by the PI in consultation with UTHSC veterinary staff.

The letter also states on April 24, 2020 the PI informed the IACUC office the in-person RePAIR course was cancelled due to the COVID 19 pandemic and requested the course be replaced with an online Research Integrity course offered by Epigeum. On April 28, 2020, the request was approved by the IACUC at its regularly scheduled meeting. On May 12, 2020 the PI informed the IACUC of completion of all tasks and upon verification, the protocol was reactivated on May 14, 2020 with the provision that there would be a 6-month probationary period, as previously stipulated by the IACUC. It is understood that the status of this protocol will be reassessed in 6 months.

Based on its assessment of this explanation, OLAW understands that the University of Tennessee Health Science Center has implemented appropriate measures to correct and prevent recurrences of these problems. We appreciate being informed of these matters and find no cause for further action by this Office.

Page 2 – Dr. Goodman
June 8, 2020
OLAW Case A3325-IN

Sincerely,
Jacquelyn T. Tubbs -S
Digitally signed by
Jacquelyn T. Tubbs -S
Date: 2020.06.08
11:47:29 -04'00'
Jacquelyn T. Tubbs, DVM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

June 2, 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. Morse or Dr. Wolff:

As requested in your response to a report of noncompliance (Assurance A3325-01, OLAW Case 1N) the University of Tennessee Health Science Center (UTHSC), is providing an update to the status of protocol # 19-016 entitled "*Role of interferons and inflammatory cell death in viral lung infections.*" The protocol associated with this report is PHS funded, USPHS Grant AG-060222.

As a reminder, Protocol 19-016 was suspended based on several factors including a failure to monitor animals, a failure to euthanize animals when they had reached humane endpoints, an admission, by the PI, of conducting an unapproved pilot study, the failure of the PI to maintain accurate clinical observation records of infected animals and concern of a lack of honesty, on the part of the PI, during his discussions on the aforementioned concerns with the Attending Veterinarian and IACUC Vice Chair.

The IACUC determined that the protocol suspension would be lifted upon completion of the following tasks:

- PI to complete the Restoring Professionalism and Integrity in Research (RePAIR) program at Washington University in St Louis
- PI and staff complete the Working with the IACUC Refresher course and Post Procedure Care of Mice and Rats in Research: Minimizing Pain and Distress (2020) through the AALAS Learning Library
- PI, in consultation with UTHSC veterinary staff, must develop a score sheet containing a series of clinical parameters to determine humane endpoints. These parameters must include frequency of monitoring and recording and animal identification. Final approval of these clinical endpoints requires signoff by UTHSC veterinary staff and IACUC approval via the protocol amendment process

On April 24, 2020 the PI informed the IACUC office that the in person RePAIR course scheduled for May 2020 had been cancelled due to the ongoing COVID 19 pandemic and

requested that this course be replaced with an online Research Integrity course offered by Epigeum. On April 28, 2020, at its regularly scheduled meeting, the IACUC approved this request.

The PI informed the IACUC of completion of all tasks described above on May 12, 2020 and upon verification, the protocol was reactivated on May 14, 2020 with the proviso that there would be a 6-month probationary period, as previously stipulated by the IACUC. During this time, for animals on study, records must be sent daily to a designated individual who will compare the recorded data to observational data collected by animal care staff.

The status of this protocol will be re-evaluated in 6 months.

Sincerely,

(b) (6)

Steven R. Goodman PhD
Vice Chancellor for Research

Copied:

(b) (6)

Jeffery Steketee, PhD	IACUC, Chair
(b) (6)	(b) (6)
David Hamilton, DVM AAALACi	Attending Veterinarian

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, June 5, 2020 7:14 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Incident Report A3325-01 - Case 1N

Thank you for this report, (b) (6) We will respond soon.

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

From: (b) (6)
Sent: Thursday, June 4, 2020 10:49 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Hamilton, David <dhamilt7@uthsc.edu>; Goodman, Steven R <sgoodma5@uthsc.edu>; Steketee, Jeffery D <jstekete@uthsc.edu>; (b) (6)
AAALAC International <accredit@AAALAC.org>
Subject: Re: Incident Report A3325-01 - Case 1N

Privileged and Confidential

Follow up report for OLAW Case 1N attached.

Please contact us if additional information is needed.

(b) (6)



(b) (6)

(b) (6)

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From: (b) (6)

Sent: Thursday, March 5, 2020 4:24 PM

To: olawdco@mail.nih.gov <olawdco@mail.nih.gov>

Cc: Goodman, Steven R <ssgoodma5@uthsc.edu>; Steketee, Jeffery D <istekete@uthsc.edu> (b) (6)

(b) (6) David Hamilton (dhamilt7@uthsc.edu) (b) (6)

(b) (6) AAALAC International <accredit@AAALAC.org>

Subject: Incident Report A3325-01

Privileged and Confidential

Report attached.

Please contact us if additional information is needed.

(b) (6)

(b) (6)

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Telephone: (301) 496-7163
Facsimile: (301) 480-3387

March 12, 2020

Re: Animal Welfare Assurance
#A3325-01 (OLAW Case 1N)

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 4, 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. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the UTHSC Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure of an investigator to ensure euthanasia of virally infected mice that had reached humane endpoints, as described in the approved protocol. A discussion with the PI about this concern, revealed additional findings. A quorum of the IACUC and its regularly scheduled meeting on February 25, 2020 examined and discussed the following findings:

- A failure to monitor animals twice daily based on weight and physical criteria (as per protocol).
- A failure to euthanize animals when they had reached humane endpoints.
- PI admission of conducting an unapproved pilot study to determine whether animals could recover from a weight loss larger than that in the approved protocol.
- Failure of the PI to maintain accurate clinical observation records of infected animals.

The committee discussed the PI's lack of honesty particularly his assertion that he had performed appropriate frequency of monitoring, prior to being confronted with room card access logs demonstrating the contrary. This led to a discussion of the potential falsification of weight records among the IACUC, given some animals could not be identified. Therefore, the IACUC unanimously voted on the following corrective actions:

- Suspension of the protocol.
- PI to complete the Restoring Professionalism and Integrity in Research (RePAIR) program at Washington University in St. Louis.

- PI and staff to complete the Working with the IACUC Refresher course and Post Procedure Care of Mice and Rats in Research: Minimizing Pain and Distress (2020) through AALAS Learning Library.
- PI, in consultation with the UTHSC veterinary staff, must develop a score sheet containing a series of clinical parameters to determine humane endpoints (including frequency of monitoring and recording of animal identification). Final approval of these clinical endpoints requires signoff by UTHSC veterinary staff and IACUC approval.
- Following successful completion of the above, and reinstatement of the protocol, there will be a 6mo probationary period. During this time, records must be sent daily to a designated individual who will compare the recorded data to observational records collected by animal care staff. Also, individual animal observation records must always be maintained in the animal housing rooms while animals are on study, and in the laboratory, to be available for IACUC inspection.

The PI was reminded that off protocol activities are not permitted and any failure to comply with the approved animal protocols, IACUC policies or LACU policies, could be grounds for immediate suspension of their animal research program and right to conduct animal research at UTHSC.

The final report indicates these activities were supported by PHS funds. Where applicable, please note that the PHS funding component must be notified directly of any suspension or termination of HHS (PHS) supported research. Based on the information provided, the Office of Laboratory Animal Welfare (OLAW) is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. **Please provide a status update after 3 months to this Office.**

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM
Veterinary Medical Officer
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

Tubbs, Jai (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, March 6, 2020 10:02 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Goodman, Steven R; Steketee, Jeffery D; (b) (6) Hamilton, David;
 (b) (6)
Subject: RE: Incident Report A3325-01

Hello,

Thank you for the final report. We will send an official response soon.

Kind Regards,

Jacquelyn Tubbs, DVM, DACLAM
 Veterinary Medical Officer
 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: Thursday, March 5, 2020 5:24 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Goodman, Steven R <sgoodma5@uthsc.edu>; Steketee, Jeffery D <jstekete@uthsc.edu>; (b) (6)
 (b) (6) Hamilton, David <dhamilt7@uthsc.edu>; (b) (6)
 AAALAC International <accredit@AAALAC.org>
Subject: Incident Report A3325-01

Privileged and Confidential

Report attached.

Please contact us if additional information is needed.

(b) (6)



March 4, 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. 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 findings of protocol non-compliance, as well as animal welfare concerns. The narrative below describes the findings and actions taken, regarding protocol # 19-016 entitled *"Role of interferons and inflammatory cell death in viral lung infections."* The protocol associated with this report is PHS funded, USPHS Grant AG-060222.

On February 19, 2020 the Institutional Animal Care and Use Committee (IACUC) was made aware of concerns related to a failure, on the part of the PI, to ensure euthanizing virally infected mice that had reached humane endpoints, as described in the approved protocol. Further, upon discussion with the PI about this concern, it became clear that animals were not receiving monitoring, as detailed in the protocol: namely, lapses in frequency of monitoring, as well as documented detail of clinical and physiologic findings were apparent.

A quorum of the IACUC examined these findings, during its regular meeting on February 25, 2020. During its deliberations of the incident, the committee discussed: (1) a failure to monitor animals twice daily based on weight and physical criteria, as described in the protocol; (2) a failure to euthanize animals when they had reached humane endpoints, as described in the protocol; (3) an admission, by the PI, of conducting an unapproved pilot study to determine whether animals could recover from a weight loss larger than that in the approved study; and (4) the failure of the PI to maintain accurate clinical observation records of infected animals.

The committee also discussed a lack of honesty, on the part of the PI, during his discussions with the Attending Veterinarian and IACUC Vice Chair about the issues described above. In particular, was the PI's assertion that he had performed the appropriate frequency of monitoring, prior to being confronted with room card access