



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

August 22, 2019

Re: Animal Welfare Assurance
#A3306-01 [OLAW Case 2T]

Dr. Terence Flotte
Dean, Provost and Executive Deputy Chancellor
University of Massachusetts Medical School
55 Lake Avenue North
Worcester, MA 01655

Dear Dr. Flotte,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your letter dated August 12, 2019 regarding a reportable noncompliance at your institution. This is a final report that was not preceded by a preliminary report to this Office.

According to the information provided, our Office understands that fasting from 7/16/19 to 7/18/19 was performed as part of a procedure for 20 mice on a non-PHS funded activity. The fasting was not part of the Institutional Animal Care and Use Committee (IACUC) approved protocol. The institution determined that the fasting had been part of a prior protocol but had been inadvertently left off the currently approved revision.

The 20 mice were immediately removed from the study and euthanized, and the Principal Investigator (PI) submitted an amendment to include the fasting of the animals. In addition, the IACUC counseled the PI, counseling and training were provided to the laboratory staff and a new electronic system is being developed to prevent recurrence. At a full committee meeting, the IACUC determined these corrective measures to be sufficient.

Based on its assessment of this explanation, OLAW understands that measures have been taken to prevent recurrence of this problem. Although this activity was not PHS funded, the establishment and application of policies and practices that are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals are commendable and avoid the perception of a double standard. OLAW concurs with the actions taken by your institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. However, because of a recently reported similar incident, please contact our Office if the corrective actions are not carried out as described. We appreciate having been informed of this matter and find no cause for further action by this Office at this time.

Sincerely,

(b) (6)

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

cc: IACUC Contact

A3306-2T



Institutional Animal Care and Use Committee (IACUC)
Office of Research
University of Massachusetts Medical School
55 Lake Avenue North
Worcester, MA 01655-0002 USA
508.856.5416 (office) 508.856.5004 (fax)

August 12, 2019

Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 260
6705 Rockledge Drive
Bethesda, MD 20892

Dear members of the Division of Compliance Oversight,

RE: Assurance # D16-00196 (A3306-01)

On behalf of the University of Massachusetts Medical School (UMMS), I am submitting a final report of a recent incident of failure to adhere to IACUC protocol, A-2548-19.

From 7/16/19 to 7/18/19, 20 mice were fasted as part of a procedure for preventing and treating enterotoxigenic E. coli. Fasting was previously described in the protocol, however the procedure was inadvertently omitted from a subsequent revision approved on 2/1/2019. The oversight was discovered on 7/18/19 when Department of Animal Medicine husbandry staff attempted to verify the proposed fasting period listed on a cage card with the description in the IACUC protocol. The PI was immediately notified that fasting was not approved in the protocol, and the mice were removed from the study and euthanized on 7/18. The PI submitted an amendment to the protocol to include fasting. The IACUC Office discussed the incident and protocol adherence with the PI. The PI also instructed all study personnel to rereview the protocol immediately as it was approved on 2/1/2019 and follow as written until the associated amendment has been approved.

In addition, UMMS is in the process of developing and implementing an electronic application which will assist in preventing version control errors such as this in the future, once all protocols have been migrated into the system. The IACUC discussed this incident by full committee and determined the corrective actions to be sufficient.

Animal activities described in this report were not covered by NIH funds.

Please let me know if you have additional questions.

Sincerely,

(b) (6)

Terence Flotte, M.D.
Institutional Official
Dean, Provost and Executive Deputy Chancellor
University of Massachusetts Medical School

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, August 21, 2019 4:15 PM
To: Moran, Casey; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Assurance D16-00196 (A3306-01)

Thank you for providing these reports. We will send official responses soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: Moran, Casey [mailto:Casey.Moran@umassmed.edu]
Sent: Wednesday, August 21, 2019 3:59 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Assurance D16-00196 (A3306-01)

Dear members of the Division of Compliance Oversight,

On behalf of the University of Massachusetts Medical School Institutional Official, Dean Flotte, I am submitting three reports for your consideration:

1. A final report related to IACUC protocol A-1633-19. A preliminary report was submitted on July 3rd, 2019.
2. A final report related to IACUC protocol A-1002-17. A preliminary report was submitted on July 3rd, 2019.
3. A report related to IACUC protocol A-2548-19.

Please contact me with questions or concerns regarding these report.

Thank you,
Casey

Casey Moran
Director, IACUC/IBC Office
Tel: (b) (6)
<http://inside.umassmed.edu/iacuc/>
<http://inside.umassmed.edu/IBC/>



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