



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 2U]

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 preceded by a preliminary report to this Office on July 3, 2019.

According to the information provided, our Office understands that from September 2018 to March 20, 2019, retroorbital injections were performed as part of a procedure for 90 mice on a PHS funded activity, as discovered on a post-approval monitoring audit. The retroorbital injections were not part of the Institutional Animal Care and Use Committee (IACUC) approved protocol. The institution determined that the noncompliance was due to version control error by the laboratory staff.

The retroorbital injections were immediately discontinued, and the Principal Investigator (PI) submitted an amendment to include the procedure. In addition, the research compliance specialist counseled the laboratory, 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. 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. In addition, please ensure that no charges are made to the PHS grant for any unauthorized animal activities, and note that data resulting from activities that were not IACUC approved may encounter difficulties in terms of publication. 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

A3306-24



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 7, 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, I am submitting a final report of a recent incident of failure to adhere to IACUC protocol, A-1002-17.

On March 20, 2017, an amendment adding retroorbital injections in mice to protocol A-1002-17 was approved by the IACUC. In September 2018, a second amendment was approved by the IACUC on a previous version of the protocol which unintentionally did not include retroorbital injections. The protocol has since been absent of this procedure, however, the laboratory continued to perform retroorbital injections for adoptive transfer of CD8 T cells or spleen cells. Approximately 90 mice received retroorbital injections since September 2018.

This was a version control error by the laboratory. It was discovered during a post-approval monitoring audit and the laboratory immediately discontinued the procedure. The laboratory submitted an amendment to the IACUC to add retroorbital injections back into the protocol and will not conduct the procedure until approved by the IACUC. The research compliance specialist discussed protocol adherence with the laboratory. In addition, UMMS is in the process of developing and implementing an electronic application which will prevent 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.

This animal activity was supported by the following grants:

1. R01 AI114495
2. R01 AI129966

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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