



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR U.S. 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

April 13, 2020

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

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 the March 31st receipt of your letter dated March 4, 2020 reporting a protocol noncompliance at the University of Massachusetts Medical School. According to the information provided, OLAW understands that on February 6, 2020 it was determined that STZ had been injected into a cage of mice. The cage was not properly labeled and it was also determined that STZ was not allowed on the protocol. Work on the protocol was stopped while the pending protocol amendment to add the use of STZ was under review. The activity was not funded by the PHS.

Corrective and preventive actions included counseling of the PI and the lab staff. An amendment adding the use of STZ was approved by the IACUC. For-cause audits of the lab will be conducted by the PAM including unannounced observations.

The prompt consideration of this matter by the University of Massachusetts Medical School was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to resolve the issue and prevent recurrence were appropriate. Although this activity was not PHS funded, the application of the standards of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S Digitally signed by Brent C. Morse -S
Date: 2020.04.13 13:17:17 -04'00'

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Chair



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)

March 4, 2020

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 report of a recent incident of failure to adhere to IACUC protocol, A-2564-19.

On 02/06/20 a technician performing routine cage changes observed that a group of animals, associated with the above noted protocol, were injected with STZ to induce diabetes. The cages were not labeled appropriately and, in the process of following up with the PI, found that the injection of STZ to induce diabetes was not listed on the currently approved protocol. The IACUC Chair and Vice-Chair were immediately notified of the noncompliance, and the PI was informed that all work relating to the procedure must immediately be suspended. The PI had an amendment under review to add the STZ injection to the protocol; however, this amendment was not approved until the following day, 02/07/20.

The IACUC discussed this incident by full committee on 02/24/20. At this time, the IACUC elected to not suspend the PI and instead initiated a for-cause PAM audit with the lab that will include unannounced observations of the lab. These observations will be reported to the IACUC on a continuing basis. The PAM specialist will initiate the PAM audit with a required lab meeting to discuss the importance of protocol adherence and the consequences of non-compliance. The PI was informed in writing of the serious nature of performing a procedure not approved by IACUC and was warned that any further non-compliance or unanticipated events not reported promptly to the IACUC may result in suspension of their IACUC protocol as determined by the full committee.

Animal activities described in this report were covered by internal funds.

Thank you for your consideration. 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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, March 31, 2020 9:29 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Assurance D16-00196 (A3306-01) Final Report

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: Tuesday, March 31, 2020 9:09 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: RE: Assurance D16-00196 (A3306-01) Final Report

To whom it may concern,

Please find the attached final report for IACUC protocol A-2564-19. The initial incident was reported on 2/12/20. I am filing this on behalf of the University of Massachusetts Medical School Institutional Official, Dean Flotte, assurance #D16-00196 (A3306-01).

Please contact me with any questions.

Sincerely,

(b) (6)

(b) (6)

<http://inside.umassmed.edu/IBC/>

13306-24

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, February 12, 2020 1:18 PM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Assurance D16-00196 (A3306-01) Preliminary Report

Thank you for this preliminary report. We will open 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: (b) (6)
Sent: Wednesday, February 12, 2020 12:48 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: Assurance D16-00196 (A3306-01) Preliminary Report

To whom it may concern,

I am submitting a preliminary report on behalf of the University of Massachusetts Medical School Institutional Official, Dean Flotte, assurance #D16-00196 (A3306-01).

1. IACUC protocol A-2564-19: On 02/06/20 an animal medicine technician performing routine cage changes noted that a group of animals associated with the previously noted protocol were injected with STZ to induce diabetes. The technician noted that the cages were not labeled appropriately and, in the process of following up with the PI, found that the injection of STZ to induce diabetes was not listed on the currently approved protocol. The IACUC was immediately notified of the noncompliance and the PI was informed that all work relating to STZ could not be performed. The PI did have an amendment under review to add the STZ injection to induce diabetes, however this amendment was not approved until 02/07/20. This incident will be discussed by the IACUC at an upcoming meeting and a final report will be submitted thereafter.

Please contact me with any questions.

Sincerely,

(b) (6)

(b) (6)



Office of Research

55 Lake Avenue North, Suite S1-859
Worcester MA 01655-0002