DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
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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

October 23, 2019

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

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

Dear Dr. Flotte,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 30, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Massachusetts Medical School. According to the information provided, OLAW understands that two pigs were pre-surgically fasted for a longer time period than described in the protocol. No adverse effects were noted with the pigs.

The corrective actions consisted of the veterinary staff counseling the research staff to follow the protocol and to give fruits or vegetable supplement if surgery is delayed. The laboratory staff was counseled on protocol adherence and the laboratory was subjected to post-approval monitoring. The Institutional Animal Care and Use Committee (IACUC) is developing a guidance document addressing fasting periods.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy.

Sincerely,

(b) (6)

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

cc: IACUC Chair
    Robert Gibbens, D.V.M., USDA-APHIS-AC

University of Massachusetts
UMASS Medical School

September 30, 2019

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 writing to inform you of an incident related to IACUC protocol A-2532-18.

On 8/14/2019, pre-surgical fasting signs were placed on the pen of pigs # 584 and # 585 at 3:45 pm after the pigs consumed a standard amount of daily feed. At 9:30 am on 8/15/2019, pig 584 was sedated for surgery and post-operatively received the standard amount of daily feed. At 1:30 pm on 8/15/2019 pig 585 was sedated for surgery and received the standard amount feed once returned to the pen.

During routine medical records review on 8/22/2019 by a husbandry staff member, it was brought to the attention of the PI and IACUC that pre-surgical fasting times for two pigs undergoing survival surgery may have exceeded the approved fasting period in the IACUC protocol, which is 8-16 hours.

As an immediate corrective action, the researchers consulted the veterinary staff. The veterinary staff advised the PI to follow the fasting period described in the protocol and also advised on how and when to safely supplement with produce if there were delays in surgical start times to avoid exceeding approved fasting periods.

The IACUC discussed this incident by full committee on 9/23/2019. In consultation with the veterinary staff, the IACUC determined that fasting times exceeded the approved period in the protocol, however there was no adverse impact on health since pigs continued to receive the standard amount of daily feed. The IACUC also determined a programmatic need for a guidance document defining "fasting period" to educate other researchers and standardize IACUC/veterinary expectations to avoid similar situations in the future. This is currently being drafted.

In addition, the PI was advised to meet with his staff to discuss the importance of protocol adherence. This also prompted a post-approval monitoring evaluation of this laboratory by a subcommittee of the IACUC to review the protocol and medical records. This evaluation is ongoing, and results must be submitted to the IACUC for review by November. If additional

findings requiring OLAWs consideration are identified during the investigation, they will be promptly reported.

Animal activities described in this report were supported by NIH R01 HL130376.

Sincerely,

(b) (6)

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

From:	OLAW Division of Compliance Oversight (NIH/OD)
Sent:	Friday, October 18, 2019 7:10 AM
To:	Moran, Casey
Cc:	OLAW Division of Compliance Oversight (NIH/OD)
Subject:	RE: Assurance D16-00196 (A3306-01) Report

Thank you for this report. We will send a response soon.

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

From: Moran, Casey <Casey.Moran@umassmed.edu>
Sent: Thursday, October 17, 2019 4:31 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Assurance D16-00196 (A3306-01) Report

Dear members of the Division of Compliance Oversight,

Re: Assurance # D16-00196 (A3306-01); A-2532-18

On behalf of the University of Massachusetts Medical School Institutional Official, Dean Flotte, I am submitting the attached report for your consideration.

Please contact me with questions or concerns regarding this report. Thank you for your consideration.

Best regards,
Casey

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