

### 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 22, 2022

Re: Animal Welfare Assurance A3306-01 [OLAW Case 3J]

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 June 1, 2022, letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at University of Massachusetts Chan Medical School. This report was preceded by a preliminary report made on April 6, 2022. According to the information provided, OLAW understands that one semiannual report to the Institutional Official (IO) submitted on October 27, 2021, omitted a departure from the Guide for the Care and Use of Laboratory Animals (The Guide) in reference to housing animals outside of temperature ranges appropriate for the species. All departures involving temperature ranges were scientifically justified and approved by the IACUC in each protocol. Prior and subsequent reports to the IO included this departure information. There were no resulting impacts to animal health or wellbeing. The studies impacted were PHS funded.

As a corrective measure, the UMass Chan IACUC reviewed updated materials found on the OLAW website regarding departures from The Guide and will ensure all future reports to the IO will contain descriptions of departures.

OLAW appreciates the prompt consideration of this matter at the University of Massachusetts Chan Medical School, which is consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate steps have been taken to investigate this incident and to attempt to prevent recurrence. We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely.

Nicole L. Lukovsky- Digitally signed by Nicole akhsanov -S

L. Lukovsky-akhsanov -S

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC contact





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

6/1/2022

Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health 6700B Rockledge Drive, Suite 2500 Bethesda, MD 20892

Dear Members of the Division of Compliance Oversight,

University of Massachusetts Chan Medical School, in accordance with Assurance D16-00196 (A3306-01), provides this final report of noncompliance with the PHS policy, section IV.B.3.c. A preliminary report was made by phone to Nicole Lukovsky in March 2022. Specifically, one semiannual report to the Institutional Official, submitted on October 27, 2021, did not include a departure from the Guide for the Care and Use of Laboratory Animals for housing animals outside of temperature ranges appropriate for the species. All departures from the Guide involving such temperature ranges were scientifically justified and reviewed and approved by the IACUC in each protocol. Prior and subsequent reports to the Institutional Official included this departure.

To address the situation, the UMass Chan IACUC closely reviewed the updated materials found the Office of Laboratory of Animal Welfare website regarding departures from the Guide and will ensure all reports to the Institutional Official contain descriptions of departures.

While there was no resulting impact on animal health or well-being, the following NIH grants supported research activities involving the departure from the Guide omitted from the report to the IO.

R01-DK094004, R01-DK115918, R01 DK089101, R01 DK123028, R01 DK116056

Please contact me with questions or concerns.

Sincerely,

(b) (6)

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

# McCoy, Devora (NIH/OD) [E]

From:

Sent:	Friday, June 3, 2022 7:38 AM
То:	(b) (6)
Cc:	OLAW Division of Compliance Oversight (NIH/OD)
Subject:	RE: OLAW Report-University of Massachusetts Chan Medical School D16-00196
	(A3306-01)
Thank you for this report. We wi	I send a response shortly.
Best,	
Devora McCoy, BS, MBA	
Program Analyst	
Division of Compliance Oversigh	t
Office of Laboratory Animal Welf	
National Institutes of Health	
301-435-2390	
From:	(b) (6)
Sent: Wednesday, June 1, 2022 4	:53 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov></olawdco@od.nih.gov>	
Subject: [EXTERNAL] OLAW Report-University of Massachusetts Chan Medical School D16-00196 (A3306-01)	
To the OLAW Division of Compliance Oversight,	
-	assachusetts Chan Medical School Institutional Official, Dean Flotte, I am submitting a
	your consideration. Please be aware that a preliminary report was made to Nicole
Lukovsky in March, 2022.	
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Please contact me with questions	s or concerns. We appreciate your guidance on these matters.
Thank you,	
mank you,	(b) (d)

OLAW Division of Compliance Oversight (NIH/OD)

## Wolff, Axel (NIH/OD) [E]

A3306-35

From:

OLAW Division of Compliance Oversight (NIH/OD)

Sent:

Friday, April 8, 2022 7:17 AM

To:

Lukovsky-Akhsanov, Nicole (NIH/OD) [E]

Cc:

OLAW Division of Compliance Oversight (NIH/OD)

Subject:

RE: Preliminary Report: UMass Chan Medical School D16-00196

Thank you for this preliminary report, Nicole. DCO will start a new case file.

Axel Wolff

From: Lukovsky-Akhsanov, Nicole (NIH/OD) [E] <nicole.lukovsky@nih.gov>

Sent: Thursday, April 7, 2022 12:14 PM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Subject: Preliminary Report: UMass Chan Medical School D16-00196

Good day DCO,

unconfirmed at this time.

Please see below preliminary report from UMass Chan Medical School D16-00196, reported by 4/6/2022

(p) (g) Ot

The organization has an IACUC approved departure for acute and prolonged cold exposure studies. The most Semi-Annual Report to the IO included this departure however the Semi-Annual Report to the IO prior to the most recent report did not include this departure (even though it was IACUC approved) formally stated in the report due to the IACUC interpretation of the term departure. The studies with the departure were also likely PHS funded however

Given that reporting departures on the semi-annual report is a must and explicated stated in PHS policy, the organization was directed to complete a self-report of the non-compliance and plans on filing a final report shortly.

Please let me know if you have any additional questions.

Thank you

### -Nicole

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM Senior Animal Welfare Program Specialist Division of Assurances
Office of Laboratory Animal Welfare, NIH
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Bethesda, Maryland 20892-6910
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