



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 14, 2021

Re: Animal Welfare Assurance
#A3125-01 (OLAW Case U]

Dr. Maria T. Zuber
Vice President for Research
Massachusetts Institute of Technology
77 Massachusetts Ave., (b) (4)
Cambridge, Massachusetts 02139

Dear Dr. Zuber,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 1, 2021 letter reporting the outcome of three allegations of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Massachusetts Institute of Technology, following up on a discussion with the Attending Veterinarian on March 12, 2021. According to the information provided, OLAW understands that a reporter had obtained information on possible animal welfare concerns in a Principal Investigator's laboratory and had reported them to institutional officials. An extensive investigation was conducted by the Division of Comparative Medicine Director, Institutional Animal Care and Use Committee, and Attending Veterinarian who could not substantiate any animal welfare concerns. The specific allegations that were either not true or unable to be confirmed included:

- a report of improper animal care
- a report of unauthorized transport of mice in a rented vehicle
- a report of housing of mice in an unauthorized satellite facility

To ensure that the laboratory maintains compliance, the staff was counseled on appropriate animal care, housing requirements, and the procedures for reporting animal welfare concerns. New faculty members will be apprised on the procedures that need to be performed prior to starting animal activities, including importing and housing animals. The policies and procedures for reporting animal welfare concerns will be updated and will include information on collecting such information when conducting exit interviews.

Based on the information provided, OLAW understands that the allegations could not be confirmed and that additional steps were taken to ensure that staff understand the policies and procedures for conducting animal activities and for reporting animal welfare concerns. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

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

cc: IACUC Chair



Date: 6/1/2021

To: Axel Wolff, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892

From: Dr. Maria T. Zuber, Institutional Official, Vice President for Research at MIT

cc: Dr. Kelly Ann Metcalf Pate, Director of the Division of Comparative Medicine
(DCM), Attending Veterinarian (starting May 1, 2021)

(b) (6)

Dr. James G Fox, Attending Veterinarian (ending April 30, 2021)
CAC Program Manager

(b) (6)

AAALAC, International

Re: Potential protocol noncompliance under PHS Assurance A3125-01

Dear Dr. Wolff,

Dr. Fox made a preliminary report concerning this potential protocol noncompliance to you on 3/12/2021. The incident was investigated by the DCM Director, Attending Veterinarian, the CAC Chair, and the CAC Program Manager. The CAC discussed this issue at convened meetings on 04/08/21 and 05/13/21. The experimental use of the potentially affected mice was supported by NIH funding under NINDS R0113-A0-00-005933, NIH BRAINS 1R01MH107680-01, and NINDS R00 R00NS078115.

On 3/4/2021 MIT General Counsel contacted the Attending Veterinarian and DCM Director to relay two concerns about the Halassa laboratory's work with animals that had been relayed to them by a BuzzFeed reporter who contacted the Vice President for Research soliciting comments for an article in preparation. These concerns dated back to 2017 and 2018 and stemmed from the reporter's interviews with several former Halassa lab members. No allegations or concerns of negative welfare for animals currently in the lab were made or found at any time throughout this investigation.

The DCM Director, CAC Chair, Attending Veterinarian, and CAC Program Manager met with Dr. Michael Halassa on 3/17/21, who denied all allegations.

Between 3/18/21 and 4/9/21 the DCM Director, CAC Chair, and CAC Program Manager met with 2 current and 5 former lab members, performed an unannounced inspection to the current lab space and animal housing space with an interview of the current lab manager, and spoke with a departmental administrative officer (AO) who was the human resources representative for the department at the time of the incident. Two separate concerns/allegations were identified throughout the course of the investigation. Each concern is outlined and addressed below:

1. Concern 1: Improper animal care

Basis for concern: This concern was based on a single 2018 email communication that had been provided to the reporter by a former lab member. The correspondence was from a DCM veterinary technician to a lab member wherein a veterinary technician notified a lab member that 4 mice that were on study required a temporary pause in the study, supportive care, and, for one mouse, further evaluation by veterinary staff. The email was provided to MIT leadership by the reporter to support their concern.

Investigation: The DCM Director, CAC Chair and CAC Program Manager reviewed the email in question. They confirmed that the procedures described were consistent with those approved in the CAC protocol. The DCM Director interviewed the DCM veterinary technician who sent the email to determine if they had concerns about the animals' welfare or the way in which the lab responded. The veterinary technician stated that they did not have concerns about these specific animals or the lab, and that the lab had always been responsive to their requests; they also reported that the lab had made notable efforts to further improve their surgical procedures and models to optimize post-surgical recovery in collaboration with DCM between 2018 and the present. Follow-up emails documented the lab's appropriate response to the veterinary technician's requests to care for the mice, and the lab's commitment and actions towards further refining their model in the years that followed.

Conclusion: This was found to not be a valid concern. All procedures were described in the approved CAC protocol, and the email is evidence of the veterinary technician appropriately recognizing the needs of the animals and advising the lab on the steps needed to properly care for them. The lab appears to have responded accordingly to the instructions of veterinary staff and were overall interested in and responsive to suggestions of how to improve animal welfare.

2. Concern 2: Unauthorized transport & housing of mice

Basis for concern: The reporter recounted verbal reports from former lab members that a subset of implanted mice were allegedly transported via personal vehicle / rented van or SUV driven by a lab member during the lab's move from NYU to MIT in November 2017. According to those lab members, this was done at the request of Dr. Halassa. These mice were then allegedly housed in drawers in the post-doc office so that they could continue with experiments without having to interrupt the research timeline while in quarantine. They were later allegedly moved directly into the DCM vivarium with the rest of the colony.

Investigation: Between 3/18/21 and 4/9/21 the DCM Director, CAC Chair, and CAC Program Manager met with 2 current and 5 former lab members, and reviewed CAC and DCM records in an attempt to determine the validity of these allegations.

CAC records indicated that the Halassa lab was first approved to procure and work with mice at MIT on 10/19/2017, and that CAC inspected the lab space and approved it for animal work on 11/17/2017 with EHS completing their inspection on 11/21/2017. Halassa lab members were first given access to animal facilities on 11/02/2017. DCM per diem records indicated that the Halassa lab first had mice in the animal facilities 11/14/2017; these mice had been received from Taconic through routine channels, and additional mice were transferred into the room on 11/15/2017 with notes (potentially written by the lab) indicating that these additional mice were from an MIT collaborator. DCM per diem and import records indicate that a subset of mice arrived from NYU on 11/21/2017 through approved channels via an approved courier. The census for the Halassa lab further increased on 11/22/2017; these mice could have originated from procurement of mice from a collaborator or by separating mice out from pre-existing cages.

Regarding allegations of unauthorized transport of mice from NYU to MIT in a rented vehicle, of those interviewed: 2 reported seeing a rented vehicle being loaded with mice for an aborted transport attempt in mid-November (one specified 11/16/2017) with both of these individuals claiming that the illegal transport actually occurred later in mid-November though neither had directly observed that second vehicle containing mice; 2 reported hearing about the alleged transport being arranged but had no direct knowledge of it actually happening; and 3 denied or were not aware of any transport of animals other than by way of official means. One of those who claimed to have been involved with loading the mice provided email and text messages recounting the rental of a van on 11/16/2017 and an SUV on 11/18/2017; mice were never identified in correspondence as being the cargo.

Regarding allegations of unapproved housing of mice in the lab or office space, of those interviewed: 3 reported mice being housed for periods of > 12 hours in lab and/or office spaces with 2 recounting them being housed in the lab and/or office space during the CAC and/or EHS inspections and all 3 indicating that housing mice outside the vivarium for > 12 hours was a routine occurrence throughout their tenure in the lab; 1 suspected mice had been housed in the office space (such housing would never be approved by DCM or CAC) but could not recall or confirm; and 3 denied or did not recall any mice being kept > 12 hours outside the vivarium. CAC reports of inspections of the Halassa laboratory space in 2017 and 2018 do not contain any evidence consistent with housing mice for > 12 hours in the lab space; office spaces are not routinely inspected.

On 3/25/21 the DCM Director, CAC Chair, and CAC Program Manager performed an unannounced visit to the Halassa lab space and interviewed the current lab manager (who was not a lab member at the time of the move). There were no findings of concern or deficiencies, including no evidence for illegal satellite housing of mice.

During the interviews of lab members, 2 lab members claimed to have reported their concerns about animal transport and housing to the department's Human Resources Manager and one claimed to have filed a formal complaint with the NYU IACUC. To determine if there were any existing prior reports of these allegations, the following queries were made:

On 3/23/21 the DCM Director, CAC Chair, and CAC Program Manager met with the former Human Resources manager for the department (now the current department AO) who had performed exit interviews with several formal lab members, including one of those who allegedly observed the mice loaded in the SUV; there was no record of illegal mouse transport or housing being recorded in that exit interview. This manager additionally interviewed 25 current and recently departed lab members in June 2020 about their experience in the lab. These interviews were not focused on animal care within the lab, but did contain the question, "Does [Dr. Halassa] model and practice scientifically ethical behavior? (ex. Treats animal and/ or human subjects with care and respect)" to which the responses were "yes" or "I don't know".

On 03/19/2021, the CAC Chair reached out to the Chair of the NYU IACUC and was referred to the Vice President, Internal Audit, Compliance & Enterprise Risk Management at NYU. On 3/30/2021 the DCM Director and CAC Chair met with this individual and inquired if there had been any reports to the IACUC or others at NYU regarding irregularities or policy violations when Dr. Halassa transferred animals from NYU to MIT in 2017. NYU stated that they would be unable to provide any information on the matter.

Conclusion: The investigation was inconclusive. Though former lab members claimed to have knowledge of unauthorized mouse transport and housing, no documentation or proof of off-policy transport or illegal housing within the laboratory could be obtained. Census records for this time period showed an increase in number of animals in the colony consistent with period of time in question, but no proof that the increase in numbers was a result of illicit movement of mice.

At the 4/8/21 monthly CAC meeting, a summary of concerns 1 and 2 were presented to the full committee. At the 5/13/21 convened CAC meeting, the investigations of concerns 1 and 2 were discussed and the following preemptive actions were endorsed:

1. To guarantee that all current Halassa lab member are aware of the proper procedures, CAC / DCM personnel will convene a mandatory group meeting with all Halassa lab members outlining the expectations for proper animal care, the need to not house animals > 12 hours outside the facility, and the procedures for reporting concerns about animal welfare.
2. To make sure that new faculty hoping to do animal work at MIT are aware of the proper procedures for importation of animals and housing animals, AOs will be instructed on the need to connect new incoming faculty with DCM and CAC leadership during the recruitment process at the interview and/or negotiations stage. These meetings will allow the DCM Director and CAC leadership to assess the needs of incoming faculty for their animal research, and make sure that the incoming faculty are aware of the proper steps that must be taken prior to initiating animal research. AOs will be reminded of this duty yearly during a meeting with the DCM Director.
3. To ensure that the channels for reporting animal welfare concerns are effective, the CAC will complete a review of their standard signage and outreach emails on anonymous reporting. Furthermore, AOs, human resource managers and other individuals tasked with completing exit interviews will receive training on how to report or advise personnel to report animal welfare concerns.

We trust that OLAW will find our response to these allegations adequate. Please inform me or (b) (6) Fox or (b) (6) if you need further clarification.

Regards,

(b) (6)

Maria T. Zuber

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, June 9, 2021 7:19 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of investigation of alleged noncompliance under PHS Policy, Assurance A3125-01

Thank you for this report, (b) (6) We will send a response soon.

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

From: Abigail Lynn Powell <ascherer@mit.edu>
Sent: Monday, June 7, 2021 12:16 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) James G Fox <jgfox@mit.edu>; (b) (6) cacpo <cacpo@mit.edu>; (b) (6) accredit@aaalac.org
Subject: Report of investigation of alleged noncompliance under PHS Policy, Assurance A3125-01

To Whom it May Concern,

Please find attached a memo signed by our IO, Dr. Maria T Zuber, regarding the investigation of an alleged noncompliance which occurred at MIT (PHS Assurance A3125-01, AAALAC unit 000191) in 2017 and 2018, as preliminarily reported to Dr. Axel Wolff by Dr. James Fox on 3/12/21.

Thanks,

(b) (6)