



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

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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

December 14, 2022

Re: Animal Welfare Assurance
#A3125-01 [OLAW Case W]

Dr. Maria Zuber
Vice President for Research
Massachusetts Institute of Technology
77 Massachusetts Ave., 3-234
Cambridge, MA 02139

Dear Dr. Zuber,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 13, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Massachusetts Institute of Technology, following up on an initial telephone report on October 13, 2022. According to the information provided, OLAW understands that a rhesus macaque was inadvertently left in its restraint device overnight. The animal had been performing behavioral tasks but was not returned to the housing room by the postdoctoral student. The animal did have access to water and the matter was reported to USDA.

The immediate action taken upon discovery consisted of the animal facility supervisor directing the student to return the monkey to the animal facility. A veterinarian examined the animal and found it to be in good condition. No additional studies were conducted with the animal while the matter was investigated. The corrective actions consisted of the laboratory developing a shared platform to allow all staffers to monitor one another while working with the primates; while the student was allowed to resume animal work, it must be conducted during the week; the student must ensure that another laboratory member is available nearby and that communication is documented; the monkey is to be continually monitored and this must be documented; and during breaks the other laboratory member must conduct the monitoring. The Principal Investigator will determine whether weekend work may resume, as well as the type of oversight that will be applied. All macaque protocols must include information on the monitoring of the primates and monitoring records must be maintained. Protocols must also outline the safeguards employed when investigators work with primates alone.

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 institution to comply with the PHS Policy and we recommend that post-approval monitoring occurs with this study to ensure ongoing compliance. 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
Robert Gibbens, D.V.M., USDA-APHIS-AC



MASSACHUSETTS INSTITUTE OF TECHNOLOGY

Maria T. Zuber*Vice President for Research**E. A. Griswold Professor of Geophysics*77 Massachusetts Avenue, Building 3-234
Cambridge, Massachusetts 02139-4307

Phone (617) 253-3206

Email mtz@mit.edu

Dec. 13, 2022

Axel Wolff, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1 Ste 360
6705 Rockledge Dr
Bethesda MD 20892

via e-mail

Re: Reportable program deficiency under PHS Assurance A3125-01 in accordance
with PHS Policy IV.F.3

Dear Dr. Wolff,

We write to report a deviation from the provisions of the PHS Policy and Guide. Drs. Pate and Heller made a preliminary report by phone to you on 10/13/2022 concerning a protocol violation that occurred during CAC-approved research activities under protocol number 2203000084 titled "Neural Basis of Information Processing in Sensorimotor Function * NHP." The USDA was notified on 10/17/2022 by Drs. Pate and Heller per OLAW recommendation.

Explanation of incident:

On Sunday 9/18/2022 at 1:50pm a rhesus macaque (*Macaca mulatta*) was brought from the animal facility to a lab by a postdoctoral student for IACUC approved neurocognitive behavioral research, in which the macaque performs behavioral tasks on an iPad while eye movements are monitored and water is rewarded for correct responses. The macaque sat in a chair during the session in a behavioral rig that allowed for free head and limb movement. The postdoctoral student neglected to return the macaque to the animal facility when they left at approximately 6:00pm, and the macaque remained in the lab overnight. Recordings made overnight show that the macaque slept for part of the night, intermittently performed tasks on the iPad, and had access to water. The following morning 9/19/2022 at 7:57am the animal facility supervisor noted that the macaque was not in its enclosure and contacted the postdoctoral student, who returned to the lab and returned the macaque to the animal facility at 8:30am.

The postdoctoral student immediately notified the Principal Investigator who notified a veterinarian, and the postdoctoral student immediately and voluntarily ceased all work with research animals pending CAC investigation of the incident. The veterinarian evaluated the monkey the same day and determined that it did not appear distressed or injured; the lab agreed not to work with the macaque again pending CAC investigation.

The incident was self-reported to the Attending Veterinarian and the CAC Chair by the Principal Investigator on 9/21/2022; an official CAC investigation was initiated.

On 10/4/2022, a CAC subcommittee including the Attending Veterinarian, a DCM staff veterinarian, the CAC Program manager, a faculty researcher CAC member and CAC community member met with the postdoctoral student to review the incident. The postdoctoral student had worked with macaques at the same lab at MIT for the previous 2 years. Typically, he would monitor the macaque by video camera while the macaque was performing tasks. On the day of the incident, the postdoctoral student began doing data analysis and became distracted, resulting in the student neglecting to return the monkey to its enclosure. The incident occurred on a weekend when minimal other personnel were present in the lab.

On 10/6/2022 the Attending Veterinarian, the CAC Chair and the CAC Program manager met with the Principal Investigator. He felt that the postdoctoral student was very conscientious in general and reported errors promptly. The lab had previously had a process for ensuring that all animals were returned to the animal facility at the end of a session but that process was discontinued at some point because they never identified any lapses.

On 10/6/2022 the CAC discussed the incident and the ongoing investigation during its monthly meeting, and on 10/26/2022 the CAC convened a special meeting to review the information obtained from the investigation. Discussion was finalized during the 11/3/2022 monthly CAC meeting.

The CAC identified violations of the approved CAC protocol: 1) the macaque remained out of the animal facility for more than 8 hours; and 2) the macaque was not adequately monitored while working in the lab.

The CAC also identified programmatic deficiencies in ensuring that all labs are properly monitoring macaques while in labs; and ensuring that lab personnel are working safely with macaques in labs.

Corrective and preventative actions:

Corrective Actions Independently Adopted by Laboratory:

Within days of the incident the lab developed a process using an iPad and shared platform for all lab members to be aware of when any lab member was working with a monkey so that all lab members can monitor each other.

Plan: (Approved by CAC 10/26/2022)

The Committee voted to allow the postdoctoral student to resume his macaque work with the following provisions:

For three months:

- 1) The postdoctoral student will not perform any weekend work with macaques.
- 2) When the postdoctoral student is working with a macaque, a "buddy" should be available in a nearby office, lab or another related space. The postdoctoral student should check in with this person at least once every two hours, more frequently if feasible. Check in can be by phone, text, online messaging platform or another method that assures that they have communicated. The check ins should be documented by the postdoc on a spreadsheet or other method that can be reviewed.
- 3) When the postdoctoral student is working with macaques there should be continuous documentation of monitoring of the animal similar to the continuous monitoring done when animals are under anesthesia, i.e. frequent notations that the animal is observed, the animal's activities etc.
- 4) Regular scheduled breaks (bathroom, food/drink etc.) should be worked into the session and the "buddy" should be informed when the postdoctoral student is taking a break and take over monitoring of the animal until the student's return.

After three months (~1/26/2023):

- 1) The PI will conduct an assessment of whether it is safe for the postdoc to work on weekends and/or without an onsite "buddy". The PI will present his assessment to the CAC Chair and DCM Attending Veterinarian. The postdoctoral student may resume weekend macaque work or work without an onsite "buddy" only with approval of the CAC.
- 2) If the postdoctoral student is allowed to work without an onsite "buddy" on weekends, then the PI or their designee will be notified by phone or text when the postdoctoral student is going into the lab to work with a macaque, will have a periodic check-in throughout the work period, and will notify the PI or their designee when the animal is returned to the animal facility.

Programmatic deficiencies:

On 11/3/2022 the CAC approved the following corrective and preventative actions:

Plan #1: To ensure that all labs are properly monitoring animals while in labs.

- 1) The plan for monitoring animals will be clearly articulated in all new animal protocols.
- 2) All macaque labs will submit CAC amendments that articulate the monitoring plan within 6 months. All labs will articulate monitoring plans with the next 3 year renewal.

- 3) Once a plan has been adopted, monitoring records with regular notations of the state of the animals will be kept while nonhuman primates are in the lab.

Plan #2: To ensure that lab personnel are working safely with animals in labs.

Solution(s):

- 1) With the next 3-year protocol renewal, each lab proposing in-lab work with live animals will submit a policy for "working alone" appropriate for the species and the occupational health and safety risks to personnel inherent in the research. Options could include a buddy system, regular check-ins, etc.
- 2) For labs that work with macaques, each lab will submit an amendment that articulates a policy for "working alone" within 6 months.

Funding source and impact on PHS-supported activities:

Animal research activities for this lab are supported by the NIH/NINDS, NIH/NIMH, NIH CRCNS US-French, Brain & Behavior Foundation, Simons Foundation, MIT and private donor funds.

We trust that OLAW will find our response to this incident and our plan to address the noted programmatic deficiency adequate. Please inform me or Drs. Pate or Heller if you need further clarification.

Sincerely,

(b) (6)

Maria T. Zuber

cc: AAALAC International
Dr. Howard Heller, Chair of Committee on Animal Care (CAC)
Dr. Eilis Karr, Veterinary Medical Officer, USDA
Dr. Kelly Metcalf Pate, Associate Professor and Director of the Division of Comparative Medicine (DCM), Attending Veterinarian

(b) (6)

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, December 13, 2022 2:32 PM
To: mtz@mit.edu
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reportable program deficiency report

Good afternoon Maria,

Thank you for sending us this final report and we will send an official response soon.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

From: mtz@mit.edu <mtz@mit.edu>
Sent: Tuesday, December 13, 2022 1:24 PM
To: Wolff, Axel (NIH/OD) [E] <WolffA@OD.NIH.GOV>
Cc: accredit@aaalac.org; Howard M Heller <hheller@mit.edu>; eilis.karr@usda.gov; Kelly Metcalf Pate <kpate@mit.edu>; (b) (6) Maria T. Zuber <mtz@mit.edu>
Subject: [EXTERNAL] Reportable program deficiency report

Maria T. Zuber

Vice President for Research
E. A. Griswold Professor of Geophysics
Massachusetts Institute of Technology
77 Massachusetts Avenue (b) (4)
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<http://orgchart.mit.edu/vice-president-research>

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Initial Report of Noncompliance

By: (b) (6)

Date: 10/13/22

Time: 900

Name of Person reporting: HOWARD Heller, MD, IACUC chair; Dr Metcalf-Pate, DVM
Telephone #: (b) (6)
Fax #:
Email:

Name of Institution: MASSACHUSETTS Institute of Technology
Assurance number: A3125

Did incident involve PHS funded activity? Yes
Funding component: _____
Was funding component contacted (if necessary): _____

What happened?

Post doc put monkey in restraint box for neuro study
on weekend, forgot animal + left there overnight

Species involved: Rhesus

Personnel involved:

Dates and times:

Animal deaths:

Projected plan and schedule for correction/prevention (if known): _____

Monkey checked by vet + was ok.

IACUC to check lab procedures + policies.

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____