



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

September 20, 2023

Re: Animal Welfare Assurance
#A3352-01 [OLAW Case F]

Heather Bragg, MSL
Executive Director for Research Compliance
Carnegie Mellon University
5000 Forbes Avenue – (b) (4) Bldg.
Pittsburgh, PA 15213

Dear Ms. Bragg,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 14, 2023 letter reporting an adverse event involving a nonhuman primate at Carnegie Mellon University, following up on an initial report on April 3, 2023. According to the information provided, OLAW understands that a nonhuman primate with an external heart rate sensor sustained a burn when the device malfunctioned.

The corrective actions consisted of providing veterinary care to the animal, which subsequently recovered. The investigator redesigned the device and added additional safety features.

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 on Humane Care and Use of Laboratory Animals.

Sincerely,

(b) (6)

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

cc: IACUC Chair
Andrew Jones, D.V.M., Acting Director of Operations AC-APHIS-USDA

A3352-F



Confidential & Proprietary – FOIA Exempt

September 14, 2023

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

Dear Dr. Wolff:

Carnegie Mellon University, in accordance with Assurance D16-00229 (A3352-01) and PHS Policy IV.F.3., provides this follow-up incident report regarding an animal injury previously reported to you. The incident occurred in a Principal Investigator's (PI) animal study protocol, entitled "Normalizing Timing of Rhythms Across Internal Networks of Circadian Clocks (DARPA NTRAIN)." The research is funded by Air Force Research Laboratory (DARPA), PTE/Prime Award number FA8650-21-2-7199 via Northwestern University.

The initial report was submitted to you in April 2023. As a refresher, on March 29, 2023, the CMU IACUC office received information that an NHP in the above-referenced protocol had received an injury as a result of a malfunctioning external prototype sensor for measuring heart rate. When removing the sensor 2 days after being placed on the animal, it was noted that the skin under the sensor had hardened and turned white. There was also some bruising around the site. The sensor appeared to be damaged and it was determined that the sensor malfunctioned causing the device to overheat. The attending veterinarian examined the animal and agreed that the wound was consistent with a burn.

The research team and the attending veterinarian treated the animal for its injury and have reported that the wound has healed with no sequelae. The device has been re-designed to include additional safety features to prevent re-occurrence. No other incidents of this kind have occurred.

The CMU IACUC reviewed this follow-up information at their meeting in August 2023 and determined that no further action is needed.

Carnegie Mellon University is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Phil Campbell, IACUC

Chair at philc@andrew.cmu.edu.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)


Heather Bragg
Institutional Official
Office of Research Integrity & Compliance
Carnegie Mellon University

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, September 15, 2023 9:57 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: [EXTERNAL] Follow-up incident report - Carnegie Mellon University

Good morning (b) (6)

Thank you for sending us this final report for case A3352-F and we will send an official response soon.

Best,
Devora

Devora McCoy, BS, MBA ([pronunciation](#))
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: devora.mccoy@nih.gov

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From: (b) (6)
Sent: Thursday, September 14, 2023 11:12 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Heather Bragg <hbragg@andrew.cmu.edu>; (b) (6) Phil Campbell <philc@andrew.cmu.edu>
Subject: [EXTERNAL] Follow-up incident report - Carnegie Mellon University

Hello,

Attached, please find a follow-up incident report from Carnegie Mellon University - Assurance D16-00229 (A3352-01). The report is a follow-up to an incident originally reported in April 2023.

The report is being sent on behalf of the Institutional Official, Heather Bragg (copied here).

Please feel free to contact me with any questions.

(b) (6)

Carnegie Mellon University

April 3, 2023

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

Dear Dr. Wolff:

Carnegie Mellon University, in accordance with Assurance D16-00229 (A3352-01) and PHS Policy IV.F.3., provides this preliminary incident report regarding an animal injury in a Principal Investigator's (PI) animal study protocol, entitled "Normalizing Timing of Rhythms Across Internal Networks of Circadian Clocks (DARPA NTRAIN)." The research is funded by Air Force Research Laboratory (DARPA), PTE/Prime Award number FA8650-21-2-7199 via Northwestern University.

On March 29, 2023, the IACUC office received information that an NHP in the above-referenced protocol had received an injury as a result of a malfunctioning external prototype sensor for measuring heart rate. When removing the sensor 2 days after being placed on the animal, it was noted that the skin under the sensor had hardened and turned white. There was also some bruising around the site. The sensor appeared to be damaged and it was determined that the sensor malfunctioned causing the device to overheat. The attending veterinarian examined the animal and agreed that the wound was consistent with a burn. No other incidents of this kind have occurred.

To address the situation, veterinary treatment of the animal is occurring. The veterinarian prescribed NSAIDs and antibiotics for 14 days and additionally instructed topical application of a wound irrigation solution and burn cream twice daily until the wound is healed. The research team immediately implemented the treatments and as of the date of this letter report that the animal's wound is healing and he is acting normally.

In addition, the researchers have worked with their collaborators to discuss possible causes of the malfunction leading to overheating and ways to prevent recurrence. Design flaws of the device were identified and it will be re-designed along with adding safety features to prevent overheating of the device.

Carnegie Mellon University is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard.

Should you have any questions regarding this report, please contact Phil Campbell, IACUC Chair at philc@andrew.cmu.edu.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Heather Bragg
Institutional Official
Office of Research Integrity & Compliance
Carnegie Mellon University

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, April 4, 2023 10:47 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: [EXTERNAL] preliminary incident report - Carnegie Mellon University

Good morning (b) (6)

Thank you for sending us this preliminary report and we look forward to receiving the final report once completed. This report has been assigned OLAW case number **A3352-F**, so please reference this number when sending the final report.

Best,
Devora

Devora McCoy, BS, MBA ([pronunciation](#))
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: devora.mccoy@nih.gov

From: (b) (6)
Sent: Tuesday, April 4, 2023 9:45 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Phil Campbell <philc@andrew.cmu.edu>; Heather Bragg <hbragg@andrew.cmu.edu>; (b) (6)
(b) (6)
Subject: [EXTERNAL] preliminary incident report - Carnegie Mellon University

Hello,

Attached, please find a preliminary report of injury to an animal at Carnegie Mellon University - Assurance D16-00229 (A3352-01).

The report is being sent on behalf of the Institutional Official, Heather Bragg (copied here).

Please feel free to contact me with any questions.

(b) (6)