

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) 402-7065

January 6, 2020

Re: Animal Welfare Assurance
A3001-01 [OLAW Case Q]

John A. Zaia, M.D.
Deputy Director for Clinical Research
City of Hope National Medical Center/Beckman Research Institute
1500 East Duarte Road
Duarte, CA 91010-3000

Dear Dr. Zaia,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 12, 2019 letter reporting two instances of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at City of Hope National Medical Center- Beckman Research Institute. According to the information provided, OLAW understands the following about the incidents and the corresponding corrective actions:

- 1) Six live mice were found in the carcass refrigerator due to a failure to confirm death following a euthanasia procedure. Miscommunication between the Principal Investigator (PI) and laboratory staffer contributed to the problem.

Corrective actions: The immediate action taken upon discovery consisted of appropriately euthanizing the mice. The PI will supervise staff closely when conducting animal procedures, a secondary physical method of euthanasia must be used to confirm death, the protocol was amended to state that cervical dislocation will be the secondary method, a standard operating procedure was developed covering euthanasia, the PI and staff were retrained on euthanasia and other procedures, and the laboratory will ensure adherence to the protocol.

- 2) Retro-orbital blood collection and intravenous injections had been performed although these activities had not been described in the approved protocol.

Corrective actions: The PI will supervise staff closely when conducting animal procedures, the PI and staff were retrained, and the laboratory will ensure adherence to the protocol. The NIH funding component was notified about both incidents and the grant was not charged for any unauthorized animal activities.

Based on its assessment of these explanations, OLAW understands that measures have been implemented in both situations to correct and prevent recurrence of the problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy. Please remember to always state the species involved in the noncompliance report (#2). Thank you for informing OLAW about this matter.

Page 2 – Dr. Zaia
January 6, 2020
OLAW Case A3001-Q

Sincerely,

 (b) (6)

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

cc: IACUC Contact

December 12, 2019

Division of Compliance Oversight
Office of Laboratory Animal Welfare
OLAW Division of Assurance
National Institutes of Health
Suite 360 MSC 7982
6705 Rockledge Dr.
Bethesda, MD 20817

To Whom It May Concern,

The City of Hope National Medical Center – Beckman Research Institute (“City of Hope”), in accordance with Assurance **A3001-01** and PHS Policy IV.F.3, provides this notification of reportable incidents that resulted in conditions that jeopardized the health or well-being of animals including actual harm or death to animals.

Funding: NIH Grant # R01HL141336

Description:

The first incident involved six live mice found in a carcass bag placed in the animal facility's carcass refrigerator. These animals were promptly euthanized by the Center for Comparative Medicine (CCM). The IACUC Executive Committee (EC) learned that the lab member performing the euthanasia procedure did not use a confirmatory method of euthanasia. The incident stemmed from a miscommunication regarding prioritized tasks between the Principal Investigator (PI) and the lab member.

The second incident involved Post-Approval Monitoring (PAM) observations of lab members performing methods of blood collection and injection. The IACUC EC learned that the retroorbital blood collection and IV injection route had been utilized without IACUC review and approval. This incident stemmed from a misunderstanding by lab members regarding what procedures were approved on the animal care and use protocol.

IACUC Determination:

The IACUC EC met on August 9, 2019 and September 16, 2019 to investigate these concerns and the corrective actions that had been taken. The IACUC EC recommended that these incidents be classified as serious noncompliance as it constituted a failure to adhere to the PHS “Policy on Humane Care and Use of Laboratory Animals” and resulted in actual harm or death to animals.

At its convened meetings on September 1, 2019 and November 4, 2019, the IACUC discussed this recommendation. A motion to accept these findings of serious noncompliance was made, seconded and approved. A letter from the IACUC Chair has been sent to the PI notifying him of this finding and reiterating the corrective actions.

Corrective Actions and Follow Up:

The lab reported that they had proactively:

- Outlined a detailed plan with the PI supervising animal procedures performed by lab members for new experiments in order to prevent any recurrence.
- Require the use of a secondary physical method of euthanasia to confirm death.

The IACUC requested that in addition to these corrective actions:

- An IACUC protocol amendment be submitted to state that all animals euthanized using CO2 is required to use cervical dislocation as a secondary confirmatory method of euthanasia.
- Provide a Standard Operating Procedure (SOP) outlining the euthanasia procedural steps in compliance with the IACUC Guidelines for the Euthanasia of Rodents.
- The PI and all lab members listed on the IACUC protocol complete a mandatory training session covering euthanasia, cervical dislocation, and refreshers for other procedures listed on the approved protocol.
- Implement a process for ensuring adherence by all lab members to the approved protocol.

Concluding Remarks:

In addition to the corrective action plan noted above, all expenses associated with these incidents have been transferred to a non-sponsored source and a notification regarding the situation has been sent to the NIH funding component. The IACUC has carefully reviewed these incidents with all parties involved and believes that an incident of this nature recurring is unlikely; all lab members received appropriate training, and the PI and lab members are committed to preventing a future occurrence.

Please be assured that City of Hope takes this matter very seriously and remains committed to full compliance with the federal and state regulations and requirements.

We believe this letter fulfills our reporting obligations; however, please contact me at (b) (6) (b) (6) if you have any questions or require additional information.

Sincerely,

(b) (6)

John A. Zaia, MD
Institutional Official

- cc: Nadia Carlesso, M.D., Chair, Institutional Animal Care and Use Committee
Richard W. Ermel, D.V.M., M.P.V.M., Ph.D., DAACLAM, Attending Veterinarian
Alyse DiStefano, Director, Laboratory Research Protections
Amanda Hammond, Senior Director, Research Protections
Ashley Baker Lee, Senior Vice President, Research Operations
(b) (6)
Jaclyn Lucas, Director, Office of Sponsored Research

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, December 18, 2019 6:53 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of Noncompliance

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

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

From: (b) (6)
Sent: Tuesday, December 17, 2019 5:09 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: John Zaia <JZaia@coh.org>; Nadia Carlesso <ncarlesso@coh.org>; Richard Ermel <RErmel@coh.org>; Amanda Hammond <ahammond@coh.org>; Ashley Lee <ashlee@coh.org>; (b) (6); Jaclyn Lucas <jalucas@coh.org>; Alyse DiStefano <adistefano@coh.org>
Subject: Report of Noncompliance

To Whom It May Concern,

Attached please find a report of noncompliance for your review.

Please let me know if you have any questions.

Thank you,

(b) (6)



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