

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 <u>Telephone</u>: (301) 496-7163 Facsimile: (301) 480-3387

November 12, 2020

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

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 November 3, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the City of Hope National Medical Center - Beckman Research Institute ("City of Hope"). This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the City of Hope Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: inappropriate euthanasia of mice. The final report states on July 16, 2020 the Center for Comparative Medicine (CCM) staff discovered a cage containing 20-30 mouse carcasses with the CO₂ still active from a euthanasia procedure conducted the previous evening. Upon a review of records, the principal investigator (PI) was identified and contacted about the incident by the CCM Associate Director. It is stated all lab members were required to print, review and sign the "IACUC Guidelines on Euthanasia of Rodents."

The IACUC Executive Committee (EC) discussed the incident and determined further investigation was warranted to identify the responsible individual. The PI was informed of the investigative results on August 31, 2020 and the IACUC EC met with the PI's laboratory staff to discuss the matter. The PI took responsibility for the incident and developed a corrective action plan. On October 6, 2020 the IACUC full committee reviewed the case and PI's corrective action plan and requested revisions. The finalized corrective action includes:

- Retraining of laboratory staff. The individual involved in the incident was required to retake the CCM/IACUC Training on Mouse Handling/Restraint & Biomethodology, as well as the CITI Training and this training was completed as of October 18, 2020.
- The lab will utilize CCM Services for euthanasia if they plan to euthanize more than a few cages.
- The PI emphasized the importance of communication between the PI and CCM staff so the PI and CCM may be notified of any questions or concerns.

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The IACUC is reviewing the City of Hope IACUC Guidelines on Euthanasia of Rodents to
ensure all procedures and expectations are clearly stated. Also, a communication will be sent to
all City of Hope animal users to emphasize the importance of ensuring quick and painless
euthanasia.

It is noted that this research is supported by PHS funds. Based on its assessment of this explanation, OLAW understands that the City of Hope National Medical Center - Beckman Research Institute has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

Jacquelyn T. Digitally signed by Jacquelyn T. Tubbs -S

Tubbs -S

Date: 2020.11.12 09:06:52

Jacquelyn T. Tubbs, DVM Animal Welfare Program Specialist Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC Contact



1500 East Duarte Road Duarte, CA 91010-3000 Phone 626-256-4673 www.cityofhope.org

November 3, 2020

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,

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 report of noncompliance regarding improper euthanasia of mice under animal use protocol entitled "The dynamics of adipogenesis in different fat depots throughout different occasions and locations in vivo" (the "Protocol"). The project involved federal funds from NIH Grant R01AG063854 for salary support for a postdoctoral fellow.

Incident Description:

In the morning on July 16, 2020, the Center for Comparative Medicine (CCM) staff found a cage overcrowded with mouse carcasses (approximately 20-30 mice) with the CO2 left on from a euthanasia procedure that was performed the previous evening. Upon a review of records, the CCM determine that the mice came from the Protocol noted above. The CCM Associate Director emailed the Principal Investigator (PI) of the Protocol on July 16, 2020 to inform her of the incident and require all lab members to print, review and sign the *IACUC Guidelines on Euthanasia of Rodents*. CCM notified the IACUC Executive Committee (EC) on July 17, 2020 of the incident.

On July 27, 2020, the IACUC Executive Committee (EC) met to discuss the issue and determined further investigation was needed to identify the individual responsible for this incident. The investigation included a review of CCM database and room access records to identify the individual who had culled a large number of mice and had accessed the room where the cage was found.

On August 31, 2020, the PI was informed of the results of the investigation. On September 8, 2020, the IACUC EC met with the PI's laboratory staff to discuss the incident. During this meeting, the PI took full responsibility for the incident and committed to developing a corrective action plan to prevent recurrence.

On October 6, 2020, the IACUC Full Committee reviewed the case and voted to classify this as a serious noncompliance as it resulted in pain and/or distress to animals. The IACUC reviewed the PI's corrective action plan and requested further revisions, including mandatory retraining of the individual who performed the euthanasia procedure in this instance. The finalized plan is described below.

Corrective Action Plan:

Page 1 of 2

Retraining of Laboratory Staff:

 On July 17, 2020, the PI met with all lab members to review the City of Hope IACUC Guidelines on Euthanasia of Rodents. The laboratory had active discussions while going through the proper procedures for euthanasia using carbon dioxide to ensure future compliance.

 The individual involved in the incident was required to retake the CCM/IACUC Training on Mouse Handling/Restraint & Biomethodology, as well as the CITI Training titled "Reducing Pain and Distress in Laboratory Mice and Rats". Training was completed as of

October 18, 2020.

Moving forward, the laboratory will utilize CCM Services for euthanasia if they plan to euthanize more than a few cages.

Since the incident, the PI has emphasized with all lab members the importance of open lines of
communication with the PI and with the CCM staff so that the PI and CCM are notified
immediately of any questions or concerns. The PI will routinely discuss animal experiments
during weekly lab meetings.

From an institutional perspective, the IACUC is reviewing the City of Hope IACUC Guidelines on Euthanasia of Rodents to ensure all procedures and expectations are clearly stated. Additionally, a communication will be sent to all City of Hope animal users to emphasize the

importance of ensuring quick and painless euthanasia.

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) if you have any questions or require additional information.

(b) (6)

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., DACLAM, Attending Veterinarian Alyse DiStefano, Director, Laboratory Research Protections Amanda Hammond, Senior Director, Research Protections

(b) (6)

Jaclyn Lucas, Director, Office of Sponsored Research

Wolff, Axel (NIH/OD) [E]

From:

OLAW Division of Compliance Oversight (NIH/OD)

Sent:

Friday, November 6, 2020 7:32 AM

To:

Alyse DiStefano

Cc:

OLAW Division of Compliance Oversight (NIH/OD)

Subject:

RE: Report of Noncompliance

Thank you for this report, Ms. DiStefano. We will send a response soon.

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

From: Alyse DiStefano <adistefano@coh.org> Sent: Wednesday, November 4, 2020 8:29 PM

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

Cc: Nadia Carlesso <ncarlesso@coh.org>: Richard Ermel <RErmel@coh.org>; Amanda Hammond

<ahammond@coh.org>;

(b) (6) Jaclyn Lucas < jalucas@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, Alyse

Alyse DiStefano

Director | Laboratory Research Protections City of Hope | 1500 E Duarte Rd, Duarte, CA 91010

Tol.

(b) (6) Email: adistefano@coh.org

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