



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) 402-7065

December 12, 2019

Re: Animal Welfare Assurance
A3295-01 [OLAW Case 4K]

Dr. Jane E. Strasser
Associate Vice President
University of Cincinnati
Office of Research Compliance and
Regulatory Affairs
P.O. Box 210567
Cincinnati, OH 45221-0567

Dear Dr. Strasser,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 19, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Cincinnati.

According to the information provided, OLAW understands that on August 28, 2019, a group of ten mice had received in-situ organ injection of tumor cells as part of an approved study and 31 days post injection one mouse was found dead and another mouse was euthanized for humane reasons. The veterinary staff determined the mice on study were past their approved experimental endpoint and the remaining mice were euthanized by the Attending Veterinarian. This study was supported by PHS funding.

As a corrective measure, the researcher and lab manager met for retraining on October 23, 2019 with the IACUC office and veterinarian. The principal investigator (PI) submitted an amendment to the IACUC to address experimental endpoint timelines and revised the monitoring frequency to ensure humane euthanasia.

OLAW appreciates the prompt consideration of this matter by the University of Cincinnati which is consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate steps have been taken to investigate this incident. We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely,

 (b) (6)

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact

A3295-4.K



Jane Strasser, Ph.D.
Associate Vice President for Research
Research Integrity Officer
University of Cincinnati
PO Box 210663
51 Goodman Drive
540 University Hall
Cincinnati, OH 45221-0663

Phone: (513) 558-5034
Fax: (513) 558-0549
Jane.Strasser@uc.edu

November 19, 2019

Brent Morse, D.V.M., DACLAM
Interim-Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500 MSC 6910
Bethesda, Maryland 20817

RE: PHS Assurance No. D16-00190 / (A3295-01)

In accordance with PHS Policy and the terms of our Assurance Statement, we are advising you of an issue of non-compliance discussed at the October 10, 2019 meeting of the University of Cincinnati Institutional Animal Care and Use Committee (IACUC).

Protocol Deficiency – Study Endpoint Oversight - Self-Reported by Responsible Researcher

On August 28, 2019 a group of ten mice had received an in-situ organ injection of tumor cells as part of an approved activity. Thirty-one days post-injection, one mouse was found dead and a second one was euthanized for humane reasons. It was determined by the LAMS veterinary staff that the mice on study were beyond the experimental endpoint as described in the IACUC protocol. The remaining mice were euthanized per the Attending Veterinarian. The IACUC deliberation was as follows

Corrective Actions:

- The PI submitted a protocol amendment to the IACUC to address the experimental endpoint timeline and revise the monitoring frequency accordingly to ensure humane euthanasia
- The IACUC Office and Veterinarian were requested to meet with the responsible researcher and lab manager to review the protocol for retraining which occurred on October 23, 2019.
- A letter was sent from the IO to the PI outlining the corrective actions that needed to be taken to restore regulatory compliance

Species: mouse
NIH Funding: R01 DK056029
 K08 GM131284
 R01 GM107625
 T32 GM008478
 R01 GM124156

Sincerely,

(b) (6)

Jane E. Strasser, Ph.D.
Associate Vice President for Research and Institutional Official

cc: George Babcock, Ph.D., Chair, Institutional Animal Care and Use Committee

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, November 20, 2019 8:03 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reports of Non-Compliance from University of Cincinnati D16-00190 (A3295-01)

Thank you for these reports, (b) (6) We will send replies soon.

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

From: (b) (6)
Sent: Tuesday, November 19, 2019 1:15 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Babcock, George (babcocgf) <babcocgf@ucmail.uc.edu>; Strasser, Jane (strassje) <strassje@ucmail.uc.edu>
Subject: Reports of Non-Compliance from University of Cincinnati D16-00190 (A3295-01)

Dear Dr. Morse, *et.al.*,

Please see the attached letters of non-compliance from the Institutional Official of the University of Cincinnati.

(b) (6)

