



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) 480-3387

June 8, 2022

Re: Animal Welfare Assurance
A3922-01 [OLAW Case 2T]

Mr. Michael Henderson
Vice President of Research Administration
Rhode Island Hospital
1 Hoppin St., (b) (4)
Providence, RI 02903

Dear Mr. Henderson,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 4, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at Rhode Island Hospital. According to the information provided, OLAW understands that 17 mice were implanted with Alzet minipumps and recovered uneventfully from the approved surgical procedure. Ten minipumps emitted a chemotherapeutic drug, and approximately 3 weeks after the implantation several of the chemotherapeutic-treated animals developed wounds around the minipumps. This was unanticipated. The laboratory began treatment when they observed the wounds without consulting a veterinarian. The veterinarian discovered the affected animals during a routine inspection. Five of the most severely affected animals were euthanized and the veterinarian intervened with the laboratory to manage treatment of the remaining animals. Veterinary technicians and animal care staff did not detect the problem, and veterinary technician rounds were not conducted at the SOP-designated frequency. The mice involved in this incident were supported by NIH funding.

Corrective and preventive measures included the following: 1) The laboratory will cease experiments with the chemotherapeutic drug until the cause of the skin necrosis is determined. 2) The laboratory will develop pilot experiments to find methods to safely deliver the chemotherapeutic drug. 3) The laboratory staff will be retrained on monitoring animals and the requirement to report complications and unanticipated events to veterinary services. 4) Animal care and veterinary services staff will be retrained on health monitoring and reporting. 5) Staffing schedules will be revised to ensure veterinary service rounds are performed per SOP.

OLAW appreciates the consideration of this matter by Rhode Island Hospital which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Robyn M. Engel -S

Digitally signed by Robyn M.
Engel -S
Date: 2022.06.08 13:33:02 -04'00'

Robyn M. Engel, DVM
Animal Welfare Program Specialist
Office of Laboratory Animal Welfare

cc: IACUC contact



Lifespan

A3922-2T

Office of Research Administration

Administrative Office for the Animal Welfare Committee
167 Point St, Suite 1A Providence, RI 02903
Phone: 401-444-2093 Fax: 401-444-7960

**Rhode Island Hospital
The Miriam Hospital**

May 4, 2022

Brent Morse, DVM, DACLAM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW)
Rockledge 1, Suite 360, MSC 7982
Bethesda, Maryland 20892-7982

RE: Animal Welfare Incident at Rhode Island Hospital (Institutional Assurance No: A3922-01)

Dear Dr. Morse,

I am writing to report an instance of non-compliance with PHS Policy on the Humane Care and Use of Laboratory Animals at our institution. The work is supported in part with two NIH grants (R01CA218079-01A1 and a sub-award under P20GM119943).

In brief, on March 22, 2022, 17 mice were implanted with Alzet osmotic minipumps and all recovered from the procedure uneventfully. Ten of the minipumps emitted a chemotherapeutic drug. Approximately 3 weeks later, several of the chemotherapeutic-treated animals developed wounds around the minipumps. The development of wounds around the minipumps was unanticipated. Lab staff initiated treatment when they noticed the wounds on 4/11/22. The veterinarian discovered the affected animals on 4/12/22, during the semi-annual facilities inspection. She ordered immediate euthanasia of five of the most severely affected animals and intervened with the lab to manage treatment.

Findings

- The lab did not contact veterinary services when they noticed the development of wounds around the minipumps. Per policy, unanticipated outcomes must be referred to the veterinary staff for consultation.
- The lab treated mice without veterinary directive. No treatments of animals are allowed unless they are reflected in the ACUP and/or are ordered by the veterinarian.
- Veterinary technicians and animal care staff did not detect the declining health of the animals. Veterinary technician rounds were not conducted at the SOP-designated frequency.

Corrective actions for the Lab

- Cease experiments with the chemotherapeutic until the cause of the ulcerations/skin necrosis is determined.
- Perform pilot experiments to devise methods for safe delivery of the chemotherapeutic. Pilot experiments must be reviewed and approved by the IACUC.

- Retrain lab staff in on the monitoring of animals, and the requirement for reporting of complications and unanticipated events to veterinary services.

Corrective actions for Central Research Facility (CRF)

- Refresher training for veterinary services and CRF staff on health monitoring and reporting.
- Revise staffing/scheduling to ensure veterinary service rounds are performed per SOP.

The incident was reviewed at the 4/27/22 regularly scheduled meeting of the full IACUC, at which time the IACUC voted to accept the corrective action plan.

Sincerely,

(b) (6)

Michael B. Henderson, JD, LL.M, MS
Vice President, Office of Research
Lifespan Institutional IO

cc: (b) (6) NIH Grants
Management Specialists A. Wong and B. Iglesias

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, May 16, 2022 10:41 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Animal Welfare Incident report A3922-01

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: Monday, May 16, 2022 10:03 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: [EXTERNAL] Animal Welfare Incident report A3922-01

Good morning,
Enclosed please find a report from our IO regarding a recent incident of non-compliance at our institution.
Please contact me if you have any questions.
Thank you

(b) (6)