



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

November 23, 2021

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

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 letter received on November 17, 2021 via email reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Rhode Island Hospital. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the Rhode Island Hospital Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure to adhere to the IACUC-approved protocol. The final report states on October 26, 2021, it was noted that post-operative monitoring for a mouse was not conducted as described in the protocol for the animal that underwent an intracranial surgery. This incident was discovered during semiannual facility inspections. Investigative results from a subcommittee determined the animal was monitored appropriately on the day of surgery and day one post-surgery. However, only one of the two required monitoring checks was completed on days 2 and 3. The Principal Investigator accepted responsibility for the incident and the matter was reviewed by the full IACUC on November 17, 2021. The IACUC voted to accept the following corrective action plan:

- Refresher training was provided to the research group regarding post-operative monitoring and documentation.
- An updated monitoring form was developed specifically for the procedure and will be put into use by the research team.
- Veterinary Service Technicians were reminded to verify the performance and documentation of post-operative monitoring during daily rounds.

It is noted that this research is not supported by PHS funding. Based on its assessment of this explanation, OLAW understands that the Rhode Island Hospital 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.
Tubbs -S

Digitally signed by Jacquelyn T.
Tubbs -S
Date: 2021.11.23 14:10:51 -05'00'

Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



Lifespan

Office of Research

Administrative Office for the Animal Welfare Committee
167 Point St, Suite 1A Providence, RI 02903
Phone: 401-444-2093 Fax: 401-444-7960
August 2, 2021

**Rhode Island Hospital
The Miriam Hospital**

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 inform you of an incident of non-compliance with PHS Policy on the Humane Care and Use of Laboratory Animals at our institution. The work is not supported with federal funding,

On October 26, 2021, during the semiannual facility inspections, it was noted that the post-op monitoring for a single mouse that underwent intracranial surgery on 10/17/21 was not performed as specified in the IACUC approved protocol. In accordance with institutional policy, an investigative sub-committee was formed to review the matter. The sub-committee found that the mouse was monitored appropriately on the day of surgery and day one post-surgery, but only one of the two required monitoring checks were completed on days 2 and 3. The Principal Investigator accepted responsibility for the lapse and cooperated fully with the sub-committee.

The incident was reviewed at the 11/17/2021 regularly scheduled meeting of the full IACUC, at which time the IACUC voted to accept the following corrective action plan.

- Refresher training was provided to the research group regarding post-operative monitoring and documentation.
- An updated monitoring form was developed specifically for the procedure and will be put into use by the research team.
- Veterinary Services Technicians were reminded to verify the performance and documentation of post-op monitoring during daily rounds.

Sincerely,

(b) (6)

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

cc:

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, November 19, 2021 7:00 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Non-compliance 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: Wednesday, November 17, 2021 3:32 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Non-compliance Incident Report- A3922-01

Good afternoon,
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)

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