



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

February 6, 2020

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

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 January 27, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Rhode Island Hospital, following up on an initial report on December 8, 2021. According to the information provided, OLAW understands that a pig developed an infection at a surgical incision site and that the veterinary staff directed the laboratory staff to continue treatments over the weekend. Due to illness of the laboratory staffer, the treatment was not done. Also, post-operative monitoring was not appropriately documented by the laboratory staff.

The corrective actions consisted of retraining the laboratory staff on post-operative monitoring, adequate documentation, and the requirement for following veterinary directives. The weekend schedule will now be shared with the veterinarians, Principal Investigator, and laboratory staff. The monitoring form was updated and procedures will be performed earlier in the week to minimize weekend activities.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy. Unless informed to the contrary, OLAW assumes the pig involved recovered as expected. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair  
Robert Gibbens, D.V.M., USDA-APHIS-AC



**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**

January 27, 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 provide final follow-up to a report of non-compliance with PHS Policy on the Humane Care and Use of Laboratory Animals that was submitted by us on December 8, 2021. The work is supported in part with an NIH grant (1R01HL128831).

In brief, a single pig developed an infection along a surgical incision, which was being treated by veterinary staff. The lab staff was directed to continue treatment through the weekend of November 27-28, 2021, but treatment was not performed. In reviewing the animal care documents as part of this matter, the veterinarian discovered additional irregularities in the post-operative monitoring records. In accordance with institutional policy, an investigative sub-committee of the IACUC was formed to look into the matter.

**Findings**

- The veterinarian directed research staff to clean the surgical incision over the weekend, but this was not done due to illness of the assigned lab staff member.
- Research staff did not appropriately document post-operative monitoring.

**Corrective action**

- The veterinarian re-trained the research group on monitoring, documentation, and the expectations regarding compliance with veterinary directives.
- The lab and veterinarians developed a plan in which the weekend schedule will be sent to veterinary services, the PI, and the lab members each week, to ensure accountability and appropriate oversight.
- The protocol-specific post-op monitoring form was updated to facilitate accurate completion and promote adherence the IACUC-approved monitoring plan.

- Future errors in weekend monitoring compliance may result in a loss of animal care privileges for the responsible individuals, and/or a mandate that surgeries be done on earlier in the week to avoid weekend post-op monitoring requirements.

The incident was reviewed at the regularly scheduled January 26<sup>th</sup> 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), USDA/APHIS, NIH Grant  
Management Specialist

**Wolff, Axel (NIH/OD) [E]**

---

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, February 9, 2022 7:34 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Animal Welfare Incident Report Assurance A-3922-01

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:** Tuesday, February 8, 2022 11:48 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Paula Gladue - USDA (paula.s.gladue@usda.gov) <paula.s.gladue@usda.gov>; ace@aphis.usda.gov; Brasile Mejac, Ann Marie (NIH/NHLBI) [E] <brasilea@nhlbi.nih.gov>  
**Subject:** [EXTERNAL] Animal Welfare Incident Report Assurance A-3922-01

**CAUTION:** This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Good Morning,  
Enclosed please find a letter from our IO regarding an incident of non-compliance.  
The study is supported with NIH funds and the incident involved a USDA covered species.  
This is the conclusion to the preliminary report that was sent on 12/8/21.  
Please contact me if you have any questions about the report.  
Thank you

(b) (6)

**\*\*\*CONFIDENTIALITY NOTICE\*\*\***

*"This transmission is intended only for the addressee(s) listed above and may contain information that is confidential. If you are not the addressee, any use, disclosure, copying or communication of the contents of this message is prohibited. Please contact me if this message was transmitted in error."*

**Wolff, Axel (NIH/OD) [E]**

A3922-28

Rhode Island  
Hospital

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, December 10, 2021 7:43 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: preliminary report A3922-01

Thank you for this preliminary report, (b) (6). We will open a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation.

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

**From:** (b) (6)  
**Sent:** Wednesday, December 8, 2021 10:09 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** [EXTERNAL] preliminary report A3922-01

**CAUTION:** This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Good morning,

I would like to provide preliminary notification regarding an allegation of non-compliance within our institution. In brief, an animal developed an infection along a surgical incision. This was being treated by veterinary staff. The lab staff were directed to continue treatment through the weekend, but this was not done due to illness in the staff member assigned to come in to take care of the animal.

In reviewing the documents, the vet discovered other irregularities in the post op monitoring records.

An investigative sub-committee of the IACUC has been formed to look into the matter and the vet has a meeting with the lab staff next week.

We do not anticipate that the investigation will be complete in time for the December IACUC meeting, so we will not have a final report to you until the end of January.

Please contact me if you have any questions about our process or this item specifically.

(b) (6)

\*\*\*CONFIDENTIALITY NOTICE\*\*\*

*"This transmission is intended only for the addressee(s) listed above and may contain information that is confidential. If you are not the addressee, any use, disclosure, copying or communication of the contents of this message is prohibited. Please contact me if this message was transmitted in error."*