



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 2L]

Ms. Peggy McGill
Sr. Vice President of Research Administration
Rhode Island Hospital
1 Hoppin St., (b) (4)
Providence, RI 02903

Dear Ms. McGill,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 24, 2020 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 October 29, 2019. According to the information provided, OLAW understands that post-operative monitoring had not been performed in accordance with the protocol on 20 mice that had undergone surgery, post-operative monitoring records were inaccurate, two mice were noted in poor condition and subsequently died but the veterinarian had not been contacted, and two laboratory members monitoring the mice had not completed required training and did not have facility access.

The corrective actions consisted of the Institutional Animal Care and Use Committee (IACUC) suspending the animal use privileges for the Principal Investigator (PI) and staff to allow for retraining. Both on-line and in-person training was taken covering responsible conduct of research, ethics, post-operative care and monitoring, record keeping, and institutional procedures for entering the animal facility. The IACUC reinstated the animal use privileges for the PI and staff, the veterinary staff will oversee the surgeries and post-operative monitoring, the IACUC will monitor records, and another laboratory member has been trained to perform the surgery and competency will be assessed by the IACUC through post-approval monitoring.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

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

cc: IACUC Chair

Lifespan

Office of Research Administration

Administrative Office for the Animal Welfare Committee
1 Hoppin St, Suite 1.300 Providence, RI 02903
Phone: 401-444-2093 Fax: 401-444-7960

Rhode Island Hospital
The Miriam Hospital

January 24, 2020

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 the resolution to an incident of non-compliance with PHS Policy on the Humane Care and Use of Laboratory Animals which was reported to you on 10/29/2019. The work is supported in part with federal funds (NIDDK, 1 R01 DK113256-01A1).

Briefly, the IACUC received a report that post-operative monitoring was not performed appropriately for 20 mice that underwent surgery on 9/6/2019. In accordance with institutional policy, the matter was investigated by a subcommittee of IACUC members who met with the Principal Investigator and his staff. The subcommittee's findings were as follows:

- Post-op monitoring was not performed in accordance with the approved protocol.
- Post-op monitoring records were not completed accurately.
- The laboratory failed to notify the veterinary staff about an unanticipated poor outcome in two mice that eventually died untreated.
- Two members of the laboratory, who did not have appropriate training or facility access, entered the facility and were engaged with post-operative monitoring of the mice.

The subcommittee report was reviewed by the full IACUC at the regularly convened meeting on 10/23/19 at which time the IACUC voted to suspend animal use privileges for the PI and the involved staff to allow for retraining. The PI and the involved staff were required to complete extensive in-person and on-line training regarding responsible conduct of research, ethics in animal research, post-operative care, post-op monitoring, record keeping, and procedures for entering the animal facility.

As of 1/6/2020, the required training was verified as being complete.

The full IACUC was convened on 1/22/2020 and voted to lift the suspension and reinstate animal use privileges for the PI and his staff with the following stipulations:

- The researchers are required to notify Veterinary Services before scheduling any surgery to ensure protocol compliance at the time of the surgery and through-out the post-operative period. This increased monitoring will cease only when the IACUC is satisfied that the team is following the approved protocol faithfully.
- The IACUC Manager will perform an audit of surgical records, controlled substance records, and post-op care and monitoring documents after the first two rounds of surgery have been completed.
- The PI plans to train an additional staff member to perform the surgical procedure. The IACUC, in conjunction with Veterinary Services, will perform a Post Approval Monitoring (PAM) Assessment once this new surgeon is approved to perform the procedure independently.

Sincerely,

(b) (6)

Peggy McGill, MA, CRA
Vice President, Research Administration

cc:

(b) (6)

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, January 27, 2020 7:37 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Animal Welfare Incident- Resolution A3922-01

Good morning,

Thank you for the update. The formal letter will be added to the case file, and we have no additional comments or questions at this time.

Kind Regards,

From: (b) (6)
Sent: Friday, January 24, 2020 12:41 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Animal Welfare Incident- Resolution A3922-01

Good afternoon,

On 10/29/2019 we reported the suspension of animal use privileges for a research team at our institution. The matter has now been resolved and the suspension was lifted by the IACUC at the most recent meeting.

A formal letter from our IO describing the corrective actions taken is attached.

Please contact me if you have any questions about this matter.

Thank you

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For more information, please visit our website at www.Lifespan.org/research

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Office of Research Administration

Administrative Office for the Animal Welfare Committee
1 Hoppin St, Suite 1.300 Providence, RI 02903
Phone: 401-444-2093 Fax: 401-444-7960

Rhode Island Hospital
The Miriam Hospital

October 29, 2019

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 a recent incident of non-compliance with PHS Policy on the Humane Care and Use of Laboratory Animals that occurred at our institution. The work is supported in part with federal funds (NIDDK, 1 R01 DK113256-01A1).

The IACUC received a report that post-operative monitoring was not performed appropriately for 20 mice that underwent surgery on 9/6/2019. In accordance with institutional policy, the matter was investigated by a subcommittee of IACUC members who met with the Principal Investigator and his staff. The subcommittee's findings were as follows:

- Post-op monitoring was not performed in accordance with the approved protocol.
- Post-op monitoring records were not completed accurately.
- Two mice were observed by research staff as doing poorly on post-op day 4. However, there is no record that these animals received any further monitoring. The condition of these animals should have been reported to the veterinary staff directly, so that supportive care could be given or an earlier humane endpoint could be identified. The mice were found dead by veterinary services three days later during rounds.
- Two members of the laboratory, who did not have appropriate training or facility access, entered the facility and were engaged with post-operative monitoring of the mice.

The subcommittee report was reviewed by the full IACUC at the regularly convened meeting on 10/23/19. The following corrective actions were required:

- Animal use privileges for the PI and the involved staff are suspended for 30 days to allow for retraining. During this time the researchers will not be allowed to work with live animals in any capacity.

- The PI and involved staff must be retrained on post-operative care, post-operative monitoring, recordkeeping, and policies on facility access. This refresher training will be provided by Veterinary Services.
- The PI and the involved staff must complete extensive on-line training through CITI Program and the AALAS Learning Library.
- Once the researchers are permitted to resume working with animals, the lab will be under increased monitoring by the IACUC. They will be required to notify Veterinary Services before scheduling any surgery, to facilitate post-approval monitoring to ensure compliance with the protocol at the time of surgery and throughout the post-operative period. Increased monitoring will cease only when the IACUC is satisfied that the team is following the IACUC-approved protocol faithfully

We will provide a follow-up report to you after the suspension is lifted by the IACUC.

Sincerely,

(b) (6)

Peggy McGill, MA, CRA
Vice President, Research Administration

cc:

(b) (6)

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, October 29, 2019 3:03 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Animal Welfare Incident- Assurance A3922-01

Thank you for providing this preliminary report. We will open a case file and await further information.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: (b) (6)
Sent: Tuesday, October 29, 2019 2:56 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Animal Welfare Incident- Assurance A3922-01

Good afternoon, enclosed please find a preliminary report from our IO regarding the suspension of animal use privileges.

A follow-up report will be sent after the matter has been resolved.

Please call me if you have any questions about this issue.

Thank you

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(b) (6)

For more information, please visit our website at www.Lifespan.org/research

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