



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

June 4, 2019

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

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 March 1 and May 29, 2019 letters reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Lifespan/Rhode Island Hospital. According to the information provided, OLAW understands that mice were being bred and produced offspring in numbers greater than what had been described in the approved protocol. The Principal Investigator (PI) failed to submit an amendment to increase animal numbers and did not indicate how the animals were being used.

The corrective action consisted of the Institutional Animal Care and Use Committee (IACUC) chair revoking the PI's access to the animals and directing separation of the breeding pairs. The IACUC suspended the study and required an explanation on the disposition of the mice. The PI attended an IACUC meeting, was retrained, provided a written explanation regarding disposition of the mice, and submitted a new protocol. The laboratory was placed on enhanced post-approval monitoring.

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 IACUC to comply with the PHS Policy.

Sincerely,

(b) (6)

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

cc: IACUC Contact



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**

May 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 provide a follow-up to the IACUC imposed suspension which we initially reported on March 1, 2019.

Briefly, the incident involved breeding of mice beyond numbers that were originally approved by the IACUC (272 approved, 462 used), and failure of the PI to communicate with the animal facility and IACUC administrative staff. The project was placed on hold by the IACUC Chair on February 19, 2019, and the protocol was formally suspended by a vote of the full board at its regularly scheduled meeting on February 27, 2019. At that meeting the IACUC requested from the PI an explanation for the disposition of all of the animals used on his protocol, and an amendment to revise the animal numbers for the project. The study was wholly supported with internal funds.

The Principal Investigator met with the IACUC Chair to review the incident and provide refresher training regarding the IACUC's expectations and requirements. The Principal Investigator subsequently provided a written explanation as to the disposition of the animals, and he appeared in person at the IACUC meeting on May 22, 2019. The investigator accepted full responsibility for poor management of the breeding colony and for failure to respond to requests from administrative staff.

The IACUC accepted the PI's response and voted to lift the suspension. However, IACUC approval for the initial study has since expired and a de novo application will be required to continue the work. As a stipulation for lifting the suspension the IACUC members agreed that more frequent oversight will be required for any new submissions from this investigator (mandatory, frequent PAMS) and there will be a low threshold for IACUC intervention for any future infractions.

Sincerely,

(b) (6)

Peggy McGilli, MA, CRA
Vice President, Research Administration

cc: (b) (6)

Ward, Joan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, May 30, 2019 9:05 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Animal Welfare Suspension Resolution- Assurance A3922-01

Thank you Jackie for this final report. Dr. Morse will respond soon.

Regards,
Joan

*Joan Ward
Program Specialist
Office of Laboratory Animal Welfare
National Institutes of Health
6705 Rockledge Dr., Suite 360
Bethesda, MD 20892
301-496-7163
wardjoa@od.nih.gov*

From: (b) (6)
Sent: Thursday, May 30, 2019 8:44 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Animal Welfare Suspension Resolution- Assurance A3922-01

Good Morning,
Enclosed please find a letter from our IO regarding a suspension, and eventual lifting of said suspension, by our IACUC.
This matter was initially reported to you on March 5th, 2019.
Please contact me if you have any questions about this matter.
Thank you

(b) (6)

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

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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**

March 1, 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 wholly supported with internal funds.

The incident involved breeding of mice beyond numbers that were originally approved by the IACUC. Despite repeated requests for clarification by animal facility and IACUC administrative staff, the Principal Investigator did not provide a clear description of how the animals were used and did not submit a request for additional animals. The IACUC Chair was advised of the situation and he immediately placed a hold on the work, which involved revoking access to the animals and separation of breeding pairs, until the matter could be reviewed at a convened meeting of the full IACUC.

The incident was discussed at the regularly scheduled meeting of the full IACUC on February 27, 2019, at which time the members voted to suspend the study until they received: 1) a suitable explanation for the disposition of the extra animals, and 2) an amendment to revise the animal numbers for the project. The PI has submitted a revision request for more animals, but it was not received until after the IACUC met on February 27. This request will be reviewed at the next IACUC meeting, which will be held on March 27, 2019.

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)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, March 6, 2019 6:43 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Animal Welfare Incident- Assurance 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: Tuesday, March 5, 2019 1:40 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 a research study. A follow-up report will be sent after the after has been resolved. Please call me if you have any questions about this matter. Thank you

(b) (6)

A large rectangular area of the document is completely redacted with a solid grey block.

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

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