



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

August 16, 2021

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

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 July 29, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Rhode Island Hospital following up on an initial June 28, 2021 notification by email.

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 institutional policies/procedures and protocol suspension. The final report states on June 8, 2021, the IACUC received a report that mice used on an approved protocol may not have been handled appropriately. An investigative subcommittee was formed and the IACUC voted to suspend the protocol due to preliminary findings from the subcommittee.

The subcommittee's review revealed examples of noncompliance involving 10 mice. Those examples included: deviations from required animal husbandry procedures; failure to provide adequate notification to animal facility staff regarding hazardous substance use; inadequate post-procedure monitoring and recordkeeping, and failure to provide adequate post-operative analgesia. The report states the lapses occurred after the departure of an experienced lab member and insufficient onboarding of a new staff member.

Recommendations from the investigative subcommittee included the following:

- Extensive, across-the-board online and in-person retraining of the principal investigator (PI) and all lab staff by the Attending Veterinarian (AV).
- Retraining on the handling, transport, and documentation of chemical hazards by the Chair of the Institutional Biosafety Committee.
- When the lab resumes work it should be immediately included in the Institution's Post Approval Monitoring Program, with direct oversight as work is reinitiated, and the lab should be placed on probation for 6 months, with additional instances of noncompliance triggering additional consequences, which may include revocation of animal use privileges.

The incident and recommendations of the subcommittee were reviewed and approved by the IACUC on July 28, 2021. The committee also voted to lift suspension of the project with the following stipulations: the PI and staff can order animals, maintain the breeding colony, and continue training in study procedures under the direct supervision of the AV. However, the PI and staff are not authorized to independently perform procedures on animals until the AV signs off on their proficiency.

Page 2 – Mr. Henderson
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It is noted that this project is supported by PHS funds. 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: 2021.08.16 09:44:44
-04'00'

Jacquelyn Tubbs, DVM, DACLAM
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 1.A Providence, RI 02903
Phone: 401-444-2093 Fax: 401-444-7960

**Rhode Island Hospital
The Miriam Hospital**

July 29, 2021

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

Dear Dr. Morse,

I am writing to provide a final report regarding a recent incident of serious non-compliance with PHS Policy on the Humane Care and Use of Laboratory Animals that occurred at our institution. We filed a preliminary report on this matter on 6/24/2021. The work is supported with federal funds (1 R01 HL136347-01 and 3R01 HL136347-04S1).

In brief, on June 8, 2021, the IACUC received a report from a member of our veterinary services staff that mice used on an approved protocol may not have been handled appropriately. Work was immediately halted on the protocol and, in accordance with institutional policy, an investigative sub-committee was formed (6/9/2021) to investigate the matter. On June 23, 2021, the IACUC formally voted to suspend the protocol, based upon preliminary findings from the sub-committee. This suspension remained in place until July 28, 2021 (see below).

After a thorough review, the Subcommittee found several serious examples of noncompliance involving 10 mice, including: deviations from required animal husbandry procedures including transport, acclimation, identification, and co-housing of animals; failure to provide adequate notification to animal facility staff regarding hazardous substance use; inadequate post-procedure monitoring and recordkeeping, and failure to provide adequate post-operative analgesia (4 mice). The lapses occurred after an experienced lab member departed the lab and a new staff member was inadequately onboarded.

The Investigative Subcommittee recommended extensive, across-the-board online (6 CITI Program and 10 AAALAS training modules) and in-person retraining of the PI and all lab staff by the Attending Veterinarian (AV), including: rodent husbandry, handling, and identification; rodent transportation and acclimation; surgery and documentation, post-operative care and analgesia. They also recommended retraining on the handling, transport and documentation of chemical hazards by the Chair of the Institutional Biosafety Committee. The recommended training was initiated immediately.

The Subcommittee also recommended that when the labs resumed work it should be immediately included in the Institution's Post Approval Monitoring Program, with direct oversight as work is reinitiated, and that the Lab be placed on probation for 6 months, with additional instances of

noncompliance triggering additional consequences, which may include revocation of animal use privileges.

The incident and Subcommittee recommendations were discussed and approved at the regularly scheduled meeting of the full IACUC on July 28, 2021. At that meeting the IACUC also voted to lift the suspension of the project with the following stipulations: The PI and staff are allowed to order animals, maintain the breeding colony, and continue training in study procedures under the direct supervision of the Attending Veterinarian. However, the PI and staff are not authorized to independently perform procedures on animals until the AV signs off on their proficiency.

Once all training has been completed to the satisfaction of the AV and the researchers are authorized to work independently, the initial animal experiments will be subject to Post Approval Monitoring Assessment (PAMs) oversight, and all privileges to work independently will be probationary, with additional consequences for continued or repeated noncompliance.

Sincerely,

(b) (6)

Michael B. Henderson, JD, LL.M, MS
Vice President for Research

cc:

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, August 6, 2021 7:45 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Compliance Issue Follow-Up- 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: Thursday, August 5, 2021 9:16 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Fleg, Jerome L (NIH/NHLBI) [E] <flegj@nhlbi.nih.gov>
Subject: Compliance Issue Follow-Up- Assurance A3922-01

Good Morning,
I am pleased to report that the matter has been resolved and the IACUC voted to lift the suspension which was previously reported to you on 6/28/21.
The letter from our IO with the complete details is attached.
Please reach out to me if you have any question about this matter.

(b) (6)

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From: (b) (6)
Sent: Monday, June 28, 2021 9:36 AM
To: olawdco@mail.nih.gov
Cc: flegj@nhlbi.nih.gov
Subject: Compliance Issue- Assurance A3922-01

Good morning, enclosed please find a preliminary report from our IO regarding an IACUC imposed suspension of a federally funded project.
The IACUC is still investigating the matter and will send a final report once this matter has been resolved.
Please contact me if you have any questions.

Thank you

(b) (6)



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Lifespan

Office of Research

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

**Rhode Island Hospital
The Miriam Hospital**

June 24, 2021

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: Potential 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 potential non-compliance with PHS Policy on the Humane Care and Use of Laboratory Animals that occurred at our institution. The work is supported with federal funds (1 R01 HL136347-01 and 3R01 HL136347-04S1).

In brief, on June 8, 2021 the IACUC received a report that mice used on an approved protocol may not have been handled appropriately. Work was immediately halted on the protocol and, in accordance with institutional policy, an investigative sub-committee has been formed to investigate the matter. The sub-committee inquiry is not complete at this time, but a number of findings regarding animal welfare have been substantiated.

The incident was discussed at the regularly scheduled meeting of the full IACUC on June 23, 2021, at which time the members voted to formally suspend all animal work covered by the protocol until they received a final report from the investigative sub-committee and a plan for remediation.

We will provide a comprehensive follow-up report to OLAW after the remediation plan has been reviewed and approved by the IACUC.

Sincerely,

(b) (6)

Michael B. Henderson, JD, LL.M, MS
Vice President for Research

cc:

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, June 28, 2021 10:45 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Compliance Issue- Assurance A3922-01

Thank you for this preliminary report, (b) (6). We will open a new case file and look forward to receiving the final or interim reports from the IO after the IACUC has completed its investigation. Please also report the suspension to the NIH funding component.

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

From: (b) (6)
Sent: Monday, June 28, 2021 9:36 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Fleg, Jerome L (NIH/NHLBI) [E] <flegj@nhlbi.nih.gov>
Subject: Compliance Issue- Assurance A3922-01

Good morning, enclosed please find a preliminary report from our IO regarding an IACUC imposed suspension of a federally funded project.

The IACUC is still investigating the matter and will send a final report once this matter has been resolved.

Please contact me if you have any questions.

Thank you

(b) (6)

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