



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) 402-7065

March 29, 2019

Re: Animal Welfare Assurance
#A4752-01 (OLAW Case 10)

Ms. Allison P. Moriarty
Vice President, Research Administration
and Compliance
Brigham and Women's Hospital
75 Francis Street
Boston, MA 02115

Dear Ms. Moriarty,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 18, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Brigham and Women's Hospital. According to the information provided, OLAW understands that mice were being singly housed without enrichment which was contrary to the approved protocol.

The corrective actions consisted of counseling and retraining the Principal Investigator and the postdoctoral fellow responsible. The protocol was amended for clarity and mice will be socially housed with enrichment.

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.

Sincerely,

(b) (6)

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

cc: IACUC Chair
Director of Research Subjects Protection and Laboratory Safety Compliance



BRIGHAM AND WOMEN'S HOSPITAL

Institutional Animal Care and Use Committee

Brent Morse, D.V.M., DACLAM
Acting Director, Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

March 18, 2019

FINAL REPORT (UPDATED)

Non-Compliance Report: Assurance **A4752-01**
Sponsors: **5R01NS088137-05**
Brigham and Women's Hospital IACUC

Dear Dr. Morse,

This letter serves as a final report of non-compliance that has been reviewed by the Brigham and Women's Hospital Institutional Animal Care and Use Committee.

During animal care rounds, an animal care technician found a few cages of mice housed alone and without enrichment. Upon discussion with the responsible postdoctoral fellow and review of the protocol, it was determined that there had been some drift in the protocol. The fellow had been singly housing animals at specific experimental timepoints and had also been removing the environmental enrichment. Due to some unclear language in the protocol, the fellow had thought that single housing was acceptable.

The veterinarian and IACUC staff met with the research fellow and Principal Investigator to discuss the protocol and provide retraining. The researchers now understand the IACUC policies on single housing mice and enrichment and have submitted an amendment to clarify the language in the protocol. Alternative solutions were determined and single housing and withholding enrichment will not be continued or requested for this project. Once the amendment to clarify the protocol is approved, the IACUC will consider this matter resolved.

Thank you for your review of these incidents. Please let us know if any further action is required at this time.

Sincerely,

(b) (6)

Allison Moriarty

Vice President, Research Operations
Institutional Official for the BWH IACUC

CC: **Amber Hoggatt, DVM, DACLAM**

Attending Veterinarian & Director, Center for Comparative Medicine, Brigham & Women's Hospital

Srinivasan Mukundan, Jr., Ph.D., M.D.

Chairman, Brigham & Women's Hospital Institutional Animal Care and Use Committee

(b) (6)

Kathryn Holthaus, MS, MA

Director of Research Subjects Protection and Laboratory Safety Compliance

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Wednesday, March 27, 2019 1:31 PM
To: 'Holthaus, Kathryn'; OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6) Moriarty, Allison P.; Mukundan, Srinivasan, Jr., M.D., Ph.D.; Hoggatt, Amber
Subject: RE: Noncompliance Reports A4752-01

Thank you for providing these letters providing both a correction and a final report, Ms. Holthaus. We will send official responses soon.

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: Holthaus, Kathryn [mailto:kholthaus@bwh.harvard.edu]
Sent: Wednesday, March 27, 2019 1:02 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: 'accredit@aaalac.org' <accredit@aaalac.org>; Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; (b) (6) (b) (6) Moriarty, Allison P. <AMORIARTY@BWH.HARVARD.EDU>; Mukundan, Srinivasan, Jr., M.D., Ph.D. <smukundan@bwh.harvard.edu>; Hoggatt, Amber <ahoggatt1@bwh.harvard.edu>
Subject: Noncompliance Reports A4752-01

Dear Dr. Morse,

Thank you for speaking with me last week regarding our need to provide an update to the list of sponsors on one final report of noncompliance previously reported to you on March 15, 2019. Please find this updated letter attached to this email. We also attach here a follow up to our investigation of noncompliance reported to both BWH Research Compliance and OLAW, which we discussed in the same conversation. Both concerns were discussed at recent IACUC meeting at Brigham and Woman's Hospital, AWA# # D16-00941 (A4752-01). Thank you in advance for your review of these incidents and please let us know if any further action or clarification is required at this time.

Kind regards,
Kathryn

Kathryn A. Holthaus, M.S., M.A.

*Director of Research Subjects Protection and Laboratory Safety Compliance
Research Administration and Compliance*

Office: (b) (6)
kholthaus@bwh.harvard.edu
brighamandwomens.org

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, March 15, 2019 12:40 PM
To: Holthaus, Kathryn
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Noncompliance Reports A4752-01

Thank you for these reports, Ms. Holthaus. We will send responses soon.

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

From: Holthaus, Kathryn <kholthaus@bwh.harvard.edu>
Sent: Friday, March 15, 2019 10:56 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: 'accredit@aaalac.org' <accredit@aaalac.org>; Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; (b) (6)
(b) (6) Moriarty, Allison P. <AMORIARTY@BWH.HARVARD.EDU>; Mukundan, Srinivasan, Jr., M.D., Ph.D. <smukundan@bwh.harvard.edu>; Hoggatt, Amber <ahoggatt1@bwh.harvard.edu>
Subject: Noncompliance Reports A4752-01

Dear Dr. Morse,

Please find two, final noncompliance reports attached to this email (in one PDF) that were reviewed and discussed at a recent IACUC meeting at Brigham and Woman's Hospital, AWA# # D16-00941 (A4752-01). Thank you in advance for your review of these incidents and please let us know if any further action is required at this time.

Best regards,
Kathryn

Kathryn A. Holthaus, M.S., M.A.

*Director of Research Subjects Protection and Laboratory Safety Compliance
Research Administration and Compliance*

Office: (b) (6)
kholthaus@bwh.harvard.edu
brighamandwomens.org



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