



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

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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

April 23, 2019

Re: Animal Welfare Assurance
#A4752-01 (OLAW Case 1K)

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 27, 2019 letter reporting the results of your investigation into allegations against (b) (6) of Brigham and Women's Hospital (BWH) made by a whistleblower, (b) (3) (A).

(b) (3) (A) According to the information provided, OLAW understands that BWH Research Compliance, on behalf of the BWH IACUC, conducted interviews of individuals named by the whistleblower, along with additional laboratory members. No evidence was found that any noncompliance had taken place. For good measure, those interviewed were reminded that all work and personnel must be approved by the IACUC and lab members must be trained prior to beginning experiments with animals.

It is further understood that the whistleblower was provided a summary report informing him that you could not find evidence of the noncompliance he described.

OLAW appreciates the prompt consideration of these matters by Brigham and Women's Hospital in performing this investigation and providing our office with this report. We especially want to recognize your part as Institutional Official in providing transparency between your Office and OLAW. We appreciate your cooperation regarding this matter in particular and find no cause for further action by this office.

Sincerely,

(b) (6)

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Chair



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 27, 2019

FINAL REPORT

Non-Compliance Report: Assurance A4752-01
Brigham and Women's Hospital IACUC

Dear Dr. Morse,

This letter serves as a final report on the alleged noncompliance reported separately to both BWH IACUC and OLAW. A Whistleblower reported off-protocol experiments and untrained personnel in a laboratory (b) (3) (A). The individual provided names of past and current laboratory members to interview regarding these incidents.

BWH Research Compliance, on behalf of the BWH IACUC, conducted interviews of these individuals along with additional laboratory members; however, we could not find evidence that any noncompliance had taken place. For good measure, we reminded those interviewed that all work and personnel must be approved by the IACUC and lab members must be trained prior to beginning experiments with animals.

The IACUC discussed the reported concerns and were satisfied with the outcome of the investigation. The Whistleblower was provided a summary report informing him that we could not find evidence of the noncompliance he described.

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

Sincerely,

(b) (6)

Allison Moriarty

Vice President, Research Administration and Compliance
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

A Teaching Affiliate
of Harvard Medical School

A FOUNDING MEMBER OF



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

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

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.

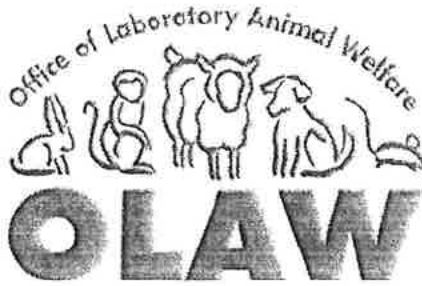
Kind regards,
Kathryn

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

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Division of Compliance Oversight

Record of Call for Case # A4752-1K

Date & Time	Message	Initials
2/6/19 2:00	Spoke w/ Kathryn Holthaus. She is conducting investigation + will send results to OLAW.	(b) (6)
3/19/19 1:00	Call from Ms. Holthaus. She will be sending OLAW a letter soon.	(b) (6)