



NATIONAL INSTITUTES OF HEALTH

PUBLIC HEALTH SERVICE

FOR US POSTAL SERVICE DELIVERY: Office of Laboratory Animal Welfare Rockledge One, Suite 360 6705 Rockledge Drive – MSC 7982 Bethesda, Maryland 20892-7982 Home Page: http://grants.nih.gov/grants/olaw/olaw.htm FOR EXPRESS MAIL: Office of Laboratory Animal Welfare Rockledge One, Suite 360 6705 Rockledge Drive Bethesda, Maryland 20817 <u>Telephone</u>: (301) 496-7163 <u>Facsimile</u>: (301) 402-7065

April 2, 2018

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

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 26, 2018 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 a rat protocol was missing monitoring documentation that animals had gone beyond the approved endpoint, rats were undergoing treatments and experiments on two different protocols, and two technicians performing animal activities were not listed on one protocol.

The corrective action consisted of the laboratory stopping the study while amending the protocol to clarify the experiments and add the technicians. The laboratory staff was retrained on monitoring, documentation, endpoints, and following protocols as approved by the Institutional Animal Care and Use Committee.

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.

Sincercly,	
	(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

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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 26, 2018

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 a resolved issue of non-compliance that has been reviewed at the last meeting of the Brigham and Women's Hospital Institutional Animal Care and Use Committee.

Species: Rats Grant: 5P01HL048743-22

During veterinary rounds, it was discovered that monitoring documentation was missing from experimental rat cages and experimental rats had gone beyond the endpoint described in the protocol. On further investigation, it was determined that the rats were undergoing treatments and experiments on two different IACUC-approved protocols and that the two research technicians performing these experiments were not listed on one of the protocols.

The laboratory responded immediately and this combined study was halted until an amendment was submitted and approved by the IACUC to clarify the experiments and add the research technicians to the second protocol. The lab members met with both the IACUC administrative staff and the veterinary staff and were retrained on monitoring, documentation and endpoints in addition to following their protocols as approved.

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 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

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A Teaching Affiliate of Harvard Medical School

A FOUNDI NO MEMBER OF



Morse, Brent (NIH/OD) [E]

From:	OLAW Division of Compliance Oversight (NIH/OD)
Sent:	Friday, March 30, 2018 7:26 AM
То:	(b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc:	(b) (6) Moriarty, Allison P.; Mukundan, Srinivasan, Jr., M.D., Ph.D.;
	Hoggatt, Amber
Subject:	RE: A4752-01 Reports of Noncompliance
Thank you for these reports	(b) (6) We will send official responses soon.
	Sincerely, Brent Morse
Brent C. Morse, DVM, DACLAM	
Acting Director	
Division of Compliance Oversight	t
Office of Laboratory Animal Well	fare
National Institutes of Health	
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From:	^{(b) (6)} @bwh.harvard.edu]
Sent: Thursday, March 29, 2018	5:05 PM
To: OLAW Division of Compliance	e Oversight (NIH/OD) <olawdco@od.nih.gov></olawdco@od.nih.gov>
Cc: Morse, Brent (NIH/OD) [E] <n< td=""><td>norseb@mail.nih.gov>;</td></n<>	norseb@mail.nih.gov>;
	@BWH.HARVARD.EDU>; Mukundan, 5rinivasan,Jr.,M.D.,Ph.D.
	>; Hoggatt, Amber <ahoggatt1@bwh.harvard.edu></ahoggatt1@bwh.harvard.edu>
Subject: A4752-01 Reports of No	ncompliance
Dear Dr. Morse,	

Please find two reports of non-compliance attached to this email which were reviewed and discussed at our recent IACUC meeting at Brigham and Women'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,

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