



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

September 11, 2019

Re: Animal Welfare Assurance  
A3153 [OLAW Case 2L]

Randall S. Mason  
Vice President, Research Operations  
Beth Israel Deaconess Medical Center  
330 Brookline Ave., GRZ 6  
Boston, Massachusetts 02215

Dear Mr. Mason,


The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 9, 2019 letter reporting a noncompliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (Policy) within the animal care and use program at the Beth Israel Deaconess Medical Center (BIDMC). Your letter supplements information in the initial prompt telephone report on August 7, 2019. According to the information provided, OLAW understands that between July 26<sup>th</sup> and August 1, 2019 two whistleblowers informed your IACUC of animal welfare infractions. These infractions included: unapproved retro-orbital bleeding on animals by an unapproved researcher; eye gel not used during surgery as required resulting in eyes becoming opaque; purposeful insufficient and inappropriate anesthetic use resulting in animal movement during surgery; falsification of surgery cards regarding the administration of analgesia; an undocumented researcher was provided access to the animal research barrier facility by the PI and directed to perform survival surgeries on mice; researchers told that only ethanol was required to sterilize instruments between surgeries, and; unapproved substances and non-surgical procedures were performed by the PI on mice. This activity was PHS funded.

Corrective and preventive actions included the IACUC, on August 13, 2019, voting unanimously that the PI and all those in his lab listed on the protocol be immediately and indefinitely prohibited from any animal work at your institution. It is further understood that the IACUC contacted the Chief of Neurology and that a faculty member in that Department will assume the role of PI of the protocol in question and the new PI will meet with the IACUC Chair and will oversee all trainees that would perform animal work under this protocol. Animals will be returned to the protocol from the Holding protocol and Post-Approval Monitoring will be conducted with the new PI.

OLAW appreciates the prompt consideration of this unfortunate matter by Beth Israel Deaconess Medical Center, which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident, to take corrective actions, and prevent recurrence. We commend the IACUC and the two whistleblowers for their actions to protect animal welfare and the integrity of animal research. **Please note** that charges can't be made to the grants during the period of noncompliance and that this issue must be reported to the Chief Grants Management Officer for the affected grants. OLAW concurs that the issues warranted reporting. We appreciate being informed of this matter 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 contact

Tijuanna DeCoster, Chief Grants Management Officer, NINDS



# Beth Israel Deaconess Medical Center



A teaching hospital of  
Harvard Medical School

Randall S. Mason  
Vice President, Research  
Operations  
Research & Academic Affairs  
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Axel V. Wolff, M.S., D.V.M.  
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

Re: Non-compliance on Beth Israel Deaconess Medical Center (BIDMC) protocol #083-2016 titled "Subarachnoid Hemorrhage in the Mouse Model". This study uses mice and is funded by NIH grant #1R01NS190174-01 under the title "Modulation of the TLR4-Lyn interaction in SAH" and #5R21NS099606-2A1 titled "The role of TLR4-dependent sterile inflammation in mediating adverse outcomes after SAH".

September 9, 2019,

Dear Dr. Wolff:

The Institutional Animal Care and Use Committee (IACUC) was informed by two whistleblowers over the period spanning July 26<sup>th</sup> and August 1<sup>st</sup>, 2019, of the following animal welfare infractions by the Principal Investigator (PI) of the above protocol:

- Unapproved retro-orbital bleeding on an anesthetized animal, by an unapproved researcher.
- Eye gel not used during a surgery as written in the protocol resulting in eyes becoming opaque.
- Insufficient Ketamine anesthesia used and noted by researchers. The PI stated that it was acceptable that it be used at 80% strength, to prevent animal death. Animal movement during surgery was described by researchers, but the PI restated that this was preferred, and disregarded the fact that the animal was not properly anesthetized.
- Falsification of surgical cards that analgesia (Buprenorphine) was administered to animals when in fact it was not.
- An undocumented researcher was provided access to the animal research barrier facility by the PI and directed to perform survival surgeries on mice.
- Researchers told that sterilization of instruments between surgeries only required ethanol.
- Unapproved substances and non-surgical procedures were performed by the PI on mice.

On August 13<sup>th</sup>, 2019 the IACUC met to discuss the PI's response to their letter dated August 2<sup>nd</sup> 2019. The Committee felt that there was serious and repeated lack of concern for animal welfare and policies. Additionally, that there was clear lack of remorse for numerous animals that likely suffered unnecessarily and a failure to address all concerns that were raised in their letter sent on August 2<sup>nd</sup> detailing the numerous issues of noncompliance.

After much discussion, and based on the information provided to them, the Committee voted unanimously that the PI and all those in his laboratory listed on the protocol be immediately and indefinitely prohibited from performing any animal work at Beth Israel Deaconess Medical Center. All animals currently in the facility were placed on the Attending Veterinarian's holding protocol. His card access to the animal facility as well as all individuals listed on the protocol was rescinded on August 14<sup>th</sup>, 2019. Further, the Department of Neurology Chair was notified and tasked with identifying a senior investigator in the Department that could assume the role of PI for the protocol and agree to oversee all trainees that would perform animal work under this protocol.

On September 5<sup>th</sup>, 2019, the IACUC discussed the Chairman's response to their letter. The Chief of Neurology provided a clear and concise response acknowledging the noncompliance and the decisions reached by the IACUC and designated a faculty member in his Department to assume the role of PI of

protocol #083-2016 and allow mice to be returned from the holding protocol. This response letter was discussed at the September 5<sup>th</sup> IACUC meeting and the committee unanimously agreed with the proposed plan and added that Post-approval Monitoring would be conducted with the new PI to assist in ensuring compliance with the protocol, animal welfare regulations, and policies. Before the new PI can begin animal work, the IACUC Chair will meet with him to ensure that he understands the responsibilities required of him.

Sincerely,

(b) (6)

Randall S. Mason  
Institutional Official, Vice President, Research Operations

Cc: Chief, Department of Neurology  
Principal Investigator  
IACUC Chair  
IACUC Administrator  
AAALAC, International

**Morse, Brent (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, September 09, 2019 2:34 PM  
**To:** (b) (6) OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** (b) (6)  
**Subject:** RE: please see 2 attached letters

Thank you for providing these two reports (b) (6) 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:** (b) (6)  
**Sent:** Monday, September 09, 2019 10:42 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6)  
**Subject:** please see 2 attached letters

Hello,

Please see the 2 attached letters.

Sincerely,

(b) (6)



Beth Israel Lahey Health   
Beth Israel Deaconess Medical Center



## Initial Report of Noncompliance

By: *sgm*Date: *8/7/19*Time: *Voicemail*Name of Person reporting: (b) (6)Telephone #: (b) (6)Fax #: (b) (6)Email: (b) (6)Name of Institution: *Beth Israel Deaconess Med. Cen.*  
Assurance number: *A3153*Did incident involve PHS funded activity? *Yes*

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened? *Unapproved person doing unapproved retro-orbital bleed.*Species involved: *Mouse*Personnel involved: *Researcher*

Dates and times: \_\_\_\_\_

Animal deaths: \_\_\_\_\_

Projected plan and schedule for correction/prevention (if known): \_\_\_\_\_

Projected submission to OLAW of final report from Institutional Official:

*Probably in September.*

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Case # \_\_\_\_\_