



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

January 15<sup>th</sup>, 2020

Re: Animal Welfare Assurance  
A3153-01 [OLAW Case 2M]

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

Dear Mr. Mason,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 6, 2019 letter regarding noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals at the Beth Israel Deaconess Medical Center. Your letter was preceded by a preliminary report to OLAW by telephone on September 23, 2019. According to the information supplied, OLAW understands that 25 lamprey larvae died on September 18, 2019 from the inadvertent addition of bleach to their tank. Earlier that day, during routine cleaning procedures, the facility supervisor failed to label a carboy that was filled with bleach in a room housing lamprey. Later, a researcher added the contents of the carboy to the tank of lamprey larvae unaware that it contained bleach and not water. The lamprey larvae died immediately, and the researcher reported the deaths to her supervisor who contacted the facility supervisor. After the facility supervisor went to the tank room, she determined what happened and self-reported the incident on September 19, 2019. The animal activity was reported to be PHS supported in the preliminary report, and your letter indicated that the per diems were covered by departmental funds.

Corrective actions included the Principal Investigator discussing the incident and indicating that use of cleaners was unnecessary and autoclaving on a regular schedule was sufficient. Additionally, the facility manager submitted an SOP for lamprey husbandry that described autoclaving all carboys at least once per month and discontinuing use of all cleaners and bleach. The SOP was reviewed and approved by the IACUC, and the animal care staff were trained on the SOP.

OLAW accepts the corrective actions to prevent recurrence of this noncompliance and concurs with the actions taken by the institution to comply with the PHS Policy. We appreciate being informed of these matters and find no cause for further action by this Office at this time.

Sincerely,

(b) (6)

Jane Na, DVM  
Veterinary Medical Officer, OLAW  
National Institutes of Health

cc: IACUC Chair  
IACUC Contact



# Beth Israel Deaconess Medical Center



A teaching hospital of  
Harvard Medical School

Randall S. Mason, MBA  
Vice President, Research  
Operations  
Institutional Official for Research  
Research Integrity Officer  
Research & Academic Affairs  
330 Brookline Ave, BR-264  
Boston, MA 02215

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

rmason@bidmc.harvard.edu

Re: Non-compliance on Beth Israel Deaconess Medical Center (BIDMC) protocol #063-2017 titled "Developing smart anti-glycan reagents (SAGRs) using the ancient immune system of the sea lamprey *petromyzan marinus*". This study uses lamprey and the per diems were covered by departmental funds.

November 6, 2019,

Dear Dr. Wolff:

On September 19<sup>th</sup>, 2019, the Research North Animal Facility Supervisor self-reported to the ARF Director, that she was responsible for the death of 25 lamprey larvae. The Supervisor was cleaning the frog/lamprey system on September 18<sup>th</sup>, 2019 and added bleach to a carboy in the room, but failed to label the carboy. Per SOP, bleach is added to the carboy and remains in the carboy for 24 hours. It is then disposed of and a detoxification solution is added and sits for an additional 24 hours. After those 24 hours the carboy is rinsed with RODI water and then is ready to use.

Later on September 18<sup>th</sup>, 2019, a Researcher used what she thought was pure water in the carboy to replenish the water in the lamprey tanks. The Researcher was unaware that there was bleach in the carboy when she added it to the tanks. The lamprey larvae immediately succumbed to the bleach solution and rose to the top of the tank dead. The Researcher reported this to her Supervisor. The Researcher's Supervisor then called the Research North Animal Facility Supervisor, who went into the tank room, and realized what had happened. No attempts were made to revive the lamprey larvae as they were clearly dead, indicated by complete lack of movement, and no reaction to physical stimulation. It is unclear where the miscommunication occurred.

On September 25<sup>th</sup>, 2019, a letter was sent from the IACUC to the Animal Facility Manager, and copied to the Research North Facility Supervisor, the Researcher, the Researcher's Supervisor and the Principal Investigator. This letter requested a response within 5 days of receipt with a plan going forward to prevent it from happening again.

On September 30<sup>th</sup>, 2019, the Principal Investigator responded with a letter stating that the incident was discussed and that using cleaners such as bleach to prevent pathogens from growing in the water was unnecessary and that utilizing a regular schedule of autoclaving would be sufficient.

On October 2<sup>nd</sup>, 2019, the Animal Facility Manager responded with a letter to the IACUC and submitted SOP C19-062: *Animal Husbandry Direct Care: Sea Lamprey Larvae* for discussion at the October 3<sup>rd</sup>, 2019 IACUC meeting and the SOP was found to require minor modifications. The Research North Animal Care Staff have been trained on the newly revised SOP and the Animal Facility has instituted the practice of autoclaving all carboys inside the facilities at least once per month and discontinuing the use of all cleaners and bleach. The minor edits to the newly revised SOP have been reviewed via IACUC designated member review and approved.

Sincerely,

(b) (6)

Randall S. Mason  
Vice President, Research Operations

Cc: Animal Facility Manager  
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:** Tuesday, January 14, 2020 7:42 AM  
**To:** (b) (6) OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: please see 1 attached letter

Thank you for reaching out to OLAW. We will send you an official response to your report very 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.

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**From:** (b) (6)  
**Sent:** Monday, January 13, 2020 12:51 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** RE: please see 1 attached letter

Hello,

I am writing to find out if there will be an official response letter from OLAW with regards to the attached report/letter.

We did receive the e-mail from you below. I just want to make sure we are not waiting for another response to close the loop.

Thank you, have a great day.

(b) (6)

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**From:** OLAW Division of Compliance Oversight (NIH/OD) [mailto:olawdco@od.nih.gov]  
**Sent:** Tuesday, November 12, 2019 7:40 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** [External] RE: please see 1 attached letter

Thank you for this report, (b) (6) We will send a reply soon.

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

**From:** [REDACTED] (b) (6)  
**Sent:** Friday, November 8, 2019 4:21 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** [REDACTED] (b) (6)  
**Subject:** please see 1 attached letter

Hello,

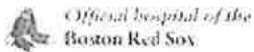
Please see the attached letter.

Sincerely,

[REDACTED] (b) (6)



Beth Israel Lahey Health   
Beth Israel Deaconess Medical Center



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This message is intended for the use of the person(s) to whom it may be addressed. It may contain information that is privileged, confidential, or otherwise protected from disclosure under applicable law. If you are not the intended recipient, any dissemination, distribution, copying, or use of this information is prohibited. If you have received this message in error, please permanently delete it and immediately notify the sender. Thank you.





# Beth Israel Deaconess Medical Center



A teaching hospital of  
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Randall S. Mason, MBA  
Vice President, Research  
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Sincerely,

(b) (6)

Randall S. Mason  
Vice President, Research Operations

Cc: Animal Facility Manager  
Principal Investigator  
IACUC Chair  
IACUC Administrator  
AAALAC, International

**Wolff, Axel (NIH/OD) [E]**

---

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Tuesday, November 12, 2019 7:40 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: please see 1 attached letter

Thank you for this report, (b) (6) We will send a reply soon.

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

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**From:** (b) (6)  
**Sent:** Friday, November 8, 2019 4:21 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6)  
**Subject:** please see 1 attached letter


Hello,

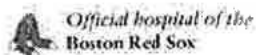
Please see the attached letter.

Sincerely,

(b) (6)



Beth Israel Lahey Health   
Beth Israel Deaconess Medical Center



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**Initial Report of Noncompliance**

By: JN

Date: 9/23/19

Time: 12:03 PM voicemail

Name of Person reporting: (b) (6)  
Telephone #: (b) (6)  
Fax #:  
Email:

Name of Institution: **Beth Israel Deaconess Medical Center, Inc.**  
Assurance number: **A3153-01**

Did incident involve PHS funded activity? **Yes**  
Funding component: \_\_\_\_\_  
Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

**Care staff cleaning frog system and poured bleach into a carboy which was not labeled. Later an investigator used the liquid in the carboy to replenish water in lamprey tanks resulting in some lamprey deaths.**

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

Projected submission to OLAW of final report from Institutional Official:

**Planning to review this incident this week**

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