DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive B 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
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

March 20, 2019

Re: Animal Welfare Assurance
#A3685-01 (OLAW Case G]

Dr. Kerry Ressler
Chief Scientific Officer
McLean Hospital
115 Mill Street
Belmont, MA 02478-9106

Dear Dr. Ressler,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 15, 2019 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at McLean Hospital. According to the information provided, OLAW understands that seven dead mice and one moribund one were found in an approved satellite facility. The dead mice were in a cage without food and water, one cage was flooded, other cages were dirty, and others were also without food. The animal care logs did not contain weekend daily health check information and security records showed that laboratory staff had not entered the room for many days to provide care.

The immediate action taken upon discovery consisted of the Attending Veterinarian euthanizing the moribund mouse and treating another mouse for dermatitis. The postdoctoral researcher responsible was retrained and was relieved of some animal oversight responsibilities. A log sheet was posted on the door of the housing room for laboratory staff to sign daily verifying the conduct of a health check, provision of food/water, and to check for dirty or flooded cages. The logs will document humidity, temperature, the primary contact, and will be checked by a secondary contact. On weekends the facility husbandry staff will provide animal care. No further problems have occurred since the corrective actions were implemented.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of these problems. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Sincerely,

(b) (6)

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

cc: IACUC Chair

A3685-G

McLean Hospital

115 Mill Street, Belmont, Massachusetts 02478-9106
Telephone 617 855-2000, FAX 617 855-3299

March 15, 2019

Dr. Axel V. Wolff
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
Phone: 301 594-2061

Dear Dr. Wolff,

Please find the following report formatted according to reporting guidelines in OLAW NOT-OD-05-034 documenting a non-compliance incident that occurred at our institution

Information to be included:

- Animal Welfare Assurance number
  (http://grants.nih.gov/grants/olaw/assurance/300index.htm)
  A3685-01

- Relevant grant or contract number(s) if the situation is related to an activity directly supported by PHS
  Not applicable. Animal work funded by internal support (non-PHS supported activity)

- A full description of any potential or actual affect on PHS-supported activities if the situation is not directly supported by the PHS but is in a functional, programmatic, or physical area that could affect PHS-supported activities (e.g., inadequate program of veterinary care, training of technical/husbandry staff, or occupational health; inadequate sanitation due to malfunctioning cage washer; room temperature extremes due to HVAC failures)
  No potential or actual impact on PHS-supported activities

- Full explanation of the situation, including what happened, when and where, the species of animal(s) involved, and the category of individuals involved (e.g., principal or co-principal investigator, technician, animal caretaker, student, veterinarian, etc.)

On December 28, 2018, upon her monthly animal census, the Animal Care Manager discovered 7 dead CD1 mice, and one moribund mouse, in an IACUC-approved satellite housing room. The Manager reported that cages in which the dead/moribund

animals were found were without food and water and one cage was flooded. Additionally, other cages of mice were dirty (had not been changed in two weeks) and were without food in the cage hoppers (23 out of 114) and were low on drinking water (supplied in bottles on the cage), although no deceased animals were found in these cages.

Immediately upon discovering the dead animals and neglected cages of animals, the Animal Care Manager contacted the Attending Veterinarian who evaluated the health of the remaining animals, euthanized the one moribund animal, and treated an additional animal for dermatitis. The specific individual (Postdoctoral researcher) responsible for care and husbandry of these animals was contacted and she arrived to change the bedding and provide food and water for all animal cages. The IACUC Chair was informed of the incident and then launched an investigation with the assistance of all parties involved including the PI of the laboratory using these animals for research.

Upon investigation, it was discovered that animal care maintenance logs were missing the required daily animal health checks/environment monitoring information on weekends (12/7 & 12/8; 12/10 & 12/11) as well as large gaps from 12/14 to 12/28 when the animals were discovered. Room security card access records were obtained from the Institution's Security Office and indicated that no staff/laboratory personnel had entered the satellite housing area from 12/14 to 12/21 and again from 12/21 to 12/28. The failure to provide and document daily checks on the animals, including week-long absences which led to animals not receiving food and water, was directly responsible for the animal deaths and unacceptable cage conditions.

- Description of actions taken by the institution to address the situation; and description of short- or long-term corrective plans and implementation schedule(s).

The laboratory staff-person responsible for care and use of these research animals has been relieved of some animal oversight duties and has received additional training from the laboratory manager about proper care and documentation of animal welfare. To ensure that an incident like this will not happen again, the laboratory has implemented a 'two check' system to guard against failures in animal care in this satellite housing room:

> The animal care sign-off log sheet is posted on the door of the housing room on which the primary contact (laboratory staff responsible for the research animals) will sign off daily (Mon-Fri) after checking the mice, for the availability of food/ water or if there are any flooded or overly dirty cages. Also humidity and temperature will be documented on that sheet as always. Additionally there is now a sheet showing exactly who the primary contact is for every day. In general the scientist directly using these animals for their research is in charge of these animals but (s)he is also responsible to make a monthly plan for a check by a second person to make sure at the end of the day that the primary contact was there. The primary contact will report back to the laboratory manager at the beginning of each month regarding this plan; the lab will have a calendar set up for

the second check which will be either staff involved in the experiment or the laboratory manager herself. Daily animal care and health check documentation will be provided by the Animal Care Facility (ACF) staff over the weekends to also be checked by the laboratory manager at the start of the week.

Since the incident and implementation of this corrective plan, the IACUC Chair and Attending Veterinarian have confirmed that all daily animal health checks have been documented and animals in this satellite housing room are healthy. With this corrective plan in place, it is reliably assured that such an incident will never happen again.

Thank you for your guidance on this incident and please contact me with any questions or if you need additional information.

Respectfully,

Edward G. Meloni, Ph.D.
IACUC Chairman

Kerry Ressler, MD, Ph.D.
Institutional Official

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Monday, March 18, 2019 11:35 AM
To: 'Meloni, Edward'
Subject: RE: OLAW report of non-compliance incident

Thank you for this report, Dr. Meloni. We will send a response soon. In future, please send all final reports to the Division of Compliance email address at olawdco@od.nih.gov
Axel Wolff

From: Meloni, Edward <emeloni@mclean.harvard.edu>
Sent: Monday, March 18, 2019 11:12 AM
To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Cc: (b) (6) Ressler, Kerry James <KRESSLER@MCLEAN.HARVARD.EDU>; (b) (6) (b) (6)
Subject: OLAW report of non-compliance incident

Dear Dr. Wolff,

Attached to this email please find the Formal Report for an animal welfare incident that occurred at our institution, McLean Hospital (Assurance #A3685-01) - the incident was initially reported to you via phone message in January 2019 by myself (IACUC Chair) and was followed by an internal investigation of circumstances surrounding the incident.

Please contact me by phone or email if you have any questions or we can provide any other information regarding this unfortunate incident.

Sincerely,

Ed Meloni

IACUC Chair

McLean Hospital

Edward G. Meloni, Ph.D.
Assistant Professor of Psychiatry
McLean Hospital
115 Mill St. Belmont, MA 02478
(b) (6)