



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 – 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

June 27, 2018

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

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 June 26, 2018 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at McLean Hospital, following up on an initial telephone report on June 19, 2018. According to the information provided, OLAW understands that sixteen rats on approved food restriction had not received their allotted food allowance for three consecutive weekends. Miscommunication between the research and husbandry staff as well as a problem with the format of the food log contributed to this failure. The rats lost weight and one was dehydrated.

The immediate action taken upon discovery consisted of treating the sick rat which subsequently died. The corrective actions consisted of maintaining separate food log sheets and keeping them close to the animals. All food restricted animals will now be given unrestricted feed on weekends and the Principal Investigator will feed them on holidays.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. 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



June 26, 2018

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,

Thank you for speaking with me by phone on June 19<sup>th</sup>, 2018 to file the preliminary report regarding an incident that was discovered at our institution on June 18<sup>th</sup>, 2018. Per your request, here is our formal report describing the incident formatted according to reporting guidelines in OLAW NOT-OD-05-034

**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 (Sundry Fund)**

- 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 June 18, 2018 it was discovered that 6 cages containing 16 Sprague-Dawley rats (2-3 animals per cage) on a daily food-restricted regimen had not received their allotted food allowance over three consecutive weekends (June 2-3, 9-10, 16-17); rats had been food restricted to 85-90% of free-feeding weight to maintain them on a consistent body mass index to accommodate behavioral testing consistent with details described in the IACUC protocol covering the use and care of these research animals. Standard protocol for monitoring animals on food restricted diets includes marking cages with highly-visible, special (green) cage cards and maintaining a food log to ensure that each day, including weekends, animals received their allotted amount of animal chow (17-19 g based on their body weight). During the work week (Mon-Fri) the research laboratory staff (technicians) provided the rats with their allotted food. However, due to a miscommunication between the research laboratory and animal care staff (technicians) - who are attending animals as part of their normal routine husbandry duties over the weekends and had agreed to provide food to food-restricted animals on study - these 6 cages of rats received no food for 48 hrs over the three consecutive weekends. A major source of this failure had to do with the format of the food log that was being maintained to ensure that food restricted animals were fed their daily allotment; checkboxes that were to be checked by staff indicating that animals were fed were included on a single husbandry sheet documenting husbandry for all animals cages in the vivarium, not just food restricted animals. As there was another group of animals also on a food restricted regimen, the food log had been checked when this second set of animals received food, but not these 6 cages of rats. As a result, animal care staff had believed that all food-restricted animals had been fed.

The failure in the monitoring system and impact of the situation became clear on June 18, 2018 (Monday) when staff observed overall weight loss in this group of rats and one rat presented as sick-looking (thin and dehydrated) and had paraphimosis. The Attending Veterinarian treated the rat with subcutaneous fluids and offered wet food, trail mix and hydrogel in the bottom of the cage. Unfortunately, the animal expired the next day.

- 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 situation was reported by the PI and Attending Veterinarian to the IACUC Chairman on June 18, 2018 and a meeting of all individuals involved was convened on June 20, 2018 to discuss the incident and corrective actions. The immediate and long-term corrective plan, implemented by the PI and animal care staff, now involves the maintenance of separate food log sheets in close proximity to each group of animals maintained on food restriction. Further, so as to completely avoid this situation in the future, animals will be provided with food *ad libitum* over the weekends and the PI will provide food himself on Holidays

that fall on weekdays. 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,

(b) (6)



Edward G. Meloni, Ph.D.  
IACUC Chairman

(b) (6)



Kerry Ressler, MD  
Institutional Official

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

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**From:** Wolff, Axel (NIH/OD) [E]  
**Sent:** Wednesday, June 27, 2018 8:01 AM  
**To:** 'Meloni, Edward'  
**Subject:** RE: OLAW report

Thank you for this report, Dr. Meloni. We will send a response soon.

Axel Wolff

**From:** Meloni, Edward [mailto:emeloni@mclean.harvard.edu]  
**Sent:** Tuesday, June 26, 2018 12:21 PM  
**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

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), and was reported to you in a Preliminary Report (via phone) on June 18, 2018 by myself (IACUC Chair).

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

Sincerely,

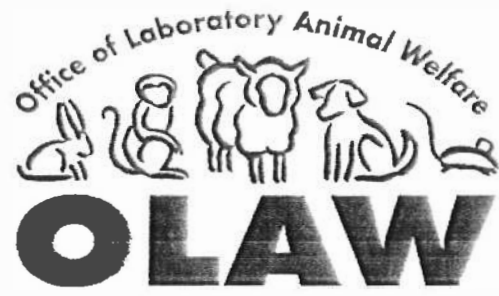
Ed Meloni

IACUC Chair

McLean Hospital

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

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# Initial Report of Noncompliance

By: Am

Date: 6/19/18

Time: 10:00

Name of Person reporting: E d Mahoney 2nd floor

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: Mc Clean Hospital

Assurance number: A3685

Did incident involve PHS funded activity? No

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

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

What happened?

On fast restricted diet. Not fed on weekend for 2 days.

Species involved: Rat

Personnel involved:

Dates and times:

Animal deaths: None

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

1 rat being treated. Will have test tubes filled up food.

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

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