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

November 26, 2018

Re: Animal Welfare Assurance
A3077-01 [OLAW Case 4R]

Ms. Robyn Diaz
Senior Vice President and Chief Legal Officer
St. Jude Children's Research Hospital
262 Danny Thomas Place, MS 400
Memphis, TN 38105-2794

Dear Ms. Diaz:

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 14, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at St. Jude Children's Research Hospital. According to the information provided, OLAW understands that on June 13, 2018 one mouse was found dead and the remaining two cage mates were provided supportive care as a result of food deprivation. It was determined that an imaging core technician transferred the three mice to a clean cage following the performance of an imagining procedure in a laboratory on June 11, 2018 but failed to provide food prior to returning the cage to the animal room. The missing feed went unnoticed for two days despite the performance of twice daily observations of the animals on June 12, 2018 by the imagining technician and daily observations by the assigned animal care technician.

The corrective actions consisted of improving communication by recommending that imaging core personnel identify all cages that have been returned to the animal room following imaging, which flags the Animal Resource Center (ARC) staff to perform comprehensive observations of all animals in marked cages; establishing a Standard Operating Procedure (SOP) to ensure adequate training of both ARC and imaging personnel regarding the care of animals that are transferred between the animal room and the laboratory; retraining the responsible ARC technician on the relevant SOP and advising the responsible imagining technician to either conduct daily observations of animals or assign the responsibility to an alternate laboratory technician.

The establishment and application of policies and practices that are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals at St. Jude Children's Research Hospital are commendable and avoid the perception of a double standard. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

Neera V. Gopee, DVM, PhD, DACLAM, DABT
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Chair

A3077-4R

St. Jude Children's Research Hospital

Robyn Diaz
Chief Legal Officer, Senior Vice President
Office of Legal Services

t 901.595.2288 f 901.595.5944
robyn.diaz@stjude.org

November 14, 2018

Axel Wolff, D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare/NIH
RKL1, Suite 360 MSC 7982
6705 Rockledge Dr.
Bethesda, MD 20892-7982

Subject: Report of Noncompliance/Animal Welfare Assurance D16-00043

Dear Dr. Wolff:

Please accept this written report, which documents an incident of noncompliance with Public Health Service (PHS) policy governing the care and use of laboratory animals. A description of the incident and the corrective actions taken to prevent the recurrence of a similar incident of noncompliance are provided below.

On June 13, 2018, an animal care technician reported one dead mouse and two live mice in a cage that did not have food or water. The Animal Resource Center (ARC) clinical veterinarian assigned to the area was called to provide supportive care to the two surviving mice and then notified the animal care and use committee (ACUC) about the dead mouse.

An investigation revealed the cage of mice was removed from the cage rack in an animal room on June 11, 2018 and taken to the imaging procedure lab down the corridor where the mice were imaged in accordance with an animal care and use protocol approved by the ACUC. Late in the afternoon following the imaging procedures, imaging core personnel placed the mice in a clean cage, returned the wire bar lid and cage top to the clean cage and returned the cage to the rack in the animal room. The following day (June 12, 2018), the ARC animal care technician regularly assigned to the room changed cages on the rack. Having observed the clean bedding in the cage, the technician assumed in error that the cage had been changed on the spot (spot change, which includes adding food and water at the same time the cage is changed) the day before, and continued changing the remaining cages on the rack. The technician from the research lab who conducts daily observations after imaging procedures also went to the facility to check the animals twice on June 12th.

The following corrective actions have been taken to prevent recurrence of the incident:

1) A contributing factor to this event was inadequate communication between the animal care staff and the imaging core personnel. To improve communication, the director of the ARC has advised the director of the imaging core to identify

all cages following the completion of imaging procedures at the time the cages are returned to the animal room. Identifying these cages will note to the animal care technicians that imaging procedures were performed and to conduct complete observation of the cage and the animals.

2) The ARC will develop a standard operating procedure in collaboration with the imaging core to ensure that all personnel from both departments are trained to manage the care of animals that transition between the animal room and the procedure lab.

3) The animal care technician will be retrained on the ARC SOP for conducting daily observations.

4) The research technician responsible for daily observations will be advised either to perform daily observations of animals or transfer custody for observations to other lab personnel.

The mouse involved in this report was not on a project supported by a PHS funded award to the Principal Investigator.

This incident was reported to the ACUC at the June 21, 2018 committee meeting and updates were provided at the meetings on July 19, 2018 and August 16, 2018.

If you require additional information about this matter, or if you believe that further action from the ACUC is warranted, please contact us.

Yours sincerely,

(b) (6)

Robyn Diaz, J.D.
Institutional Official

CC: Dr. James Downing, President and CEO
Dr. Jim Morgan, Scientific Director
(b) (6)
Dr. Christopher Calabrese, Administrative Director – Laboratory Operations
(b) (6)
Dr. Richard J. Rahija, Director, ARC
Dr. Stacey Schultz-Cherry, Chair, ACUC
(b) (6)

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, November 14, 2018 2:57 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Diaz, Robyn; Rahija, Richard J; Schultz-Cherry, Stacey; (b) (6)
Subject: RE: Report of Noncompliance/Animal Welfare Assurance D16-00043

Thank you for providing this report. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

From: (b) (6)
Sent: Wednesday, November 14, 2018 2:22 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Diaz, Robyn <Robyn.Diaz@STJUDE.ORG>; Downing, James <James.Downing@STJUDE.ORG>; Morgan, Jim <Jim.Morgan@STJUDE.ORG>; (b) (6) Calabrese, Christopher <Christopher.Calabrese@STJUDE.ORG>; (b) (6) Rahija, Richard J <Richard.Rahija@STJUDE.ORG>; Schultz-Cherry, Stacey <Stacey.Schultz-Cherry@STJUDE.ORG>; (b) (6) (b) (6)
Subject: Report of Noncompliance/Animal Welfare Assurance D16-00043

From
Robyn Diaz
Institutional Official

(b) (6)