



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

August 29, 2018

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

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 August 28, 2018 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at St. Jude Children's Research Hospital, following up on an initial report on June 20, 2018. According to the information provided, OLAW understands that seven mice died of dehydration due to problems with the lixits. In one situation, the valve was not properly installed while in two other situations the lixit fell off. Misalignment of the rack frame and watering manifold can lead to dislodged valves. The missing valves were in the bedding and not visible to the animal care staff during daily health checks.

The corrective actions consisted of developing a new Standard Operating Procedure (SOP) addressing installation of the quick disconnect lixit valves including verifying that it is properly seated, and that water is flowing. Malfunctioning valves will be returned to the manufacturer, valves will also be sent out for refurbishing as part of routine maintenance, misaligned racks will be taken out of service, and annual maintenance is performed on the racks. All technical and husbandry staff has been trained on the new SOP.

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

cc: IACUC Chair



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

t 901.595.2288 f 901.595.5944  
robyn.diaz@stjude.org

August 28, 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 describes incidents of noncompliance with Public Health Service (PHS) policy governing the care and use of laboratory animals. A description of the incidents and the corrective actions taken to prevent the recurrence of similar incidents of noncompliance are provided below.

During the past six months, there were three isolated instances where a total of seven mice died from dehydration because a watering valve on our automatic watering system failed to perform. In each instance, the individual valve was installed in a quick disconnect fitting on the manifold of the rack. One of the three incidents occurred because the valve was not installed correctly. The second and third incidents occurred when the valve was found detached from the manifold in the bedding on the floor of the cage. According to the manufacturer of the equipment, misalignment of the rack frame and watering manifold is another reason the valve dislodges from the manifold. The dislodged valves were not visible to the animal care technician who performed the daily health check of the mice.

As a result of these incidents, the following corrective actions have been implemented:

1. The ARC has developed a standard operating procedure (SOP) that describes the procedure for installing quick disconnect valves on the manifold as they are sanitized or replaced. The procedure includes steps to ensure the valve is properly installed in the manifold. A valve grip test and water flow test are performed to ensure the valve is properly installed and that water flows from the valve before the cage is placed back in the rack. The procedures in the SOP will identify valves that fail to perform at the time that they are installed. Valves that do not perform are returned to the manufacturer for repairs. All ARC technical services and husbandry personnel have been trained on this SOP.

August 28, 2018

2. The ARC has begun returning the valves to the manufacturer to have them refurbished as part of a routine maintenance procedure.
3. Racks that are out of alignment will be taken out of service. The manufacturer of the cages and racks will be on site in October 2018 to perform annual maintenance of racks.

These three incidents were reported independently as they occurred to the ACUC at the April, May and June 2018 meetings.

The mice involved in these three-separate incidents were not on projects supported by a PHS funded award to the Principal Investigators.

We are committed to protecting the welfare of the animals used in research at St. Jude Children's Research Hospital. If you require additional information about this report, 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. Richard J. Rahija, Director, ARC  
Dr. Stacey Schultz-Cherry, Chair, ACUC

(b) (6)

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, August 29, 2018 7:27 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Report of Noncompliance/Animal Welfare Assurance D16-00043

Thank you for this report, (b) (6) I will send a response shortly.

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

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**From:** (b) (6)@STJUDE.ORG]  
**Sent:** Tuesday, August 28, 2018 5:36 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)@STJUDE.ORG>; (b) (6)  
(b) (6)@STJUDE.ORG>; (b) (6)@STJUDE.ORG>; Rahija, Richard J <Richard.Rahija@STJUDE.ORG>; Schultz-Cherry, Stacey <Stacey.Schultz-Cherry@STJUDE.ORG>; (b) (6)  
(b) (6)@STJUDE.ORG>  
**Subject:** Report of Noncompliance/Animal Welfare Assurance D16-00043

From Robyn Diaz, JD, Institutional Official

cc:

Dr. James Downing, President and CEO  
Dr. Jim Morgan, Scientific Director

(b) (6)

Dr. Richard J. Rahija, Director, ARC  
Dr. Stacey Schultz-Cherry, Chair, ACUC

(b) (6)

(b) (6)

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, June 20, 2018 1:26 PM  
**To:** Rahija, Richard J  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Preliminary report

Thank you for this report. We will send a response soon.  
Axel Wolff

**From:** Rahija, Richard J [mailto:Richard.Rahija@STJUDE.ORG]  
**Sent:** Wednesday, June 20, 2018 1:03 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6)@STJUDE.ORG>; Schultz-Cherry, Stacey <Stacey.Schultz-Cherry@STJUDE.ORG>;  
(b) (6)@STJUDE.ORG>  
**Subject:** Preliminary report

Dear Colleagues:

The St. Jude Children's Research Hospital ACUC received a report about the death of mice that was related to an animal care error. The incident was judged to be reportable and a report will be provided to OLAW by the IO. Please contact me if you have questions or need additional information.

Dr. Rahija  
Richard J. Rahija, D.V.M., Ph.D., D.A.C.L.A.M.  
Director, Animal Resources Center  
St. Jude Children's Research Hospital  
262 Danny Thomas Place  
Memphis, TN 38105  
(b) (6)

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