



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:  
Office of Laboratory Animal Welfare  
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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

July 5, 2018

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

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 June 27, 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, following up on an initial report on April 27, 2018. According to the information provided, OLAW understands that complications occurred during blood collection from the facial vein of mice and the site was changed to the retro-orbital sinus, although this site was not approved in the protocol. No adverse effects were noted in the animals due to this change.

The corrective actions consisted of counseling the laboratory staff to conduct procedures only as described in the approved protocol, amending the protocol to include other approved blood collection sites and methods, and retraining the technician responsible on following the protocol.

OLAW understands that the protocol involved was not PHS-supported, but concurs that the incident was serious and supports the actions taken by the institution. The establishment and application of policies and practices that are consistent with the provisions of the PHS Policy at St. Jude Children's Research Hospital are commendable and avoid the perception of a double standard. Thank you for keeping OLAW apprised on this matter.

Sincerely,

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

cc: IACUC Chair

June 27, 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 (A3077-01)

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.

The ACUC Chair assigned a subcommittee to investigate this self-reported event. The subcommittee of the ACUC met on Thursday April 26, 2018 and interviewed the PI and a member of her staff. The subcommittee learned that an Animal Resource Center (ARC) Technical Services Technician (TST) was collecting blood samples via the ACUC-approved blood collection method/site, the superficial temporal vein (facial vein); however, unexpected issues occurred with the approved technique and the PI laboratory staff member instructed the ARC TST to instead collect the samples by another method/site, the retro-orbital sinus (ROS). The subcommittee also learned that the ROS samples were collected without incident.

The subcommittee met on Monday April 30, 2018 and interviewed the ARC TST who collected the blood samples on April 24<sup>th</sup>. The subcommittee learned the following from this interview:

1. The issues that occurred during the facial vein collections were due to the blood spreading on the skin instead of "pooling", which made it difficult to capture the blood sample, leading to the change in method/site;
2. The PI laboratory staff member, who was present during the sample collections, instructed the ARC TST to switch to ROS collections at the time;
3. The ARC TST acknowledged that she knew that she should have reviewed the protocol prior to changing the collection site, however, she assumed the PI laboratory staff member knew if the ROS method was approved or not. Additionally, the ARC TST acknowledged that if this type of issue arises again, she will consult her supervisor.

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

1. The PI's laboratory staff have been instructed to comply with the approved protocol and the procedures listed therein;

Axel Wolff, D.V.M.

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June 27, 2018

2. The PI has amended the protocol to include other approved blood collection sites/methods; and,
3. The ARC TST has been retrained on the importance of reviewing the protocol to ensure the activity to be done has been approved by the ACUC.

This incident was reported to the ACUC at the May 17, 2018 meeting.

The mice involved in this report 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.

Sincerely,

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Robyn Diaz, J.D.  
Institutional Official

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

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

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Wolff, Axel (NIH/OD) [E]

A 3077 - #K

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, April 27, 2018 9:20 AM  
**To:** Schultz-Cherry, Stacey  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Report

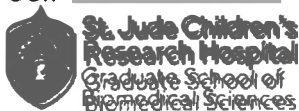
Thank you for this report, Dr. Schultz-Cherry. We will open a new case file.  
Axel Wolff

**From:** Schultz-Cherry, Stacey [mailto:Stacey.Schultz-Cherry@STJUDE.ORG]  
**Sent:** Friday, April 27, 2018 8:32 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6)@STJUDE.ORG>; (b) (6)@STJUDE.ORG>; Rahija,  
Richard J <Richard.Rahija@STJUDE.ORG>  
**Subject:** Report

Dear OLAW Division of Compliance Oversight,  
I am writing to let you know that the St Jude Children's Research Hospital ACUC investigated a noncompliance incident that occurred in April 2018 that was deemed reportable. A procedure was performed that was not on an investigators protocol. No animals were harmed. The report is forthcoming. Please feel free to contact me if you need additional information.

Thank you in advance for your attention.

Stacey Schultz-Cherry, PhD  
Member, Department of Infectious Diseases  
St. Jude Children's Research Hospital  
Memphis, TN 38105  
Phone: (b) (6)  
Fax: (b) (6)  
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