



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

December 16, 2019

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

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 December 10, 2019 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 telephone report on December 10, 2019. According to the information provided, OLAW understands that mice were given an experimental substance which was not described in the approved protocol. No adverse events were noted in the mice.

The corrective actions consisted of counseling the investigator and amending the protocol.

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. Please ensure that the PHS grant is not charged for any unauthorized animal activities. Thank you for keeping OLAW apprised on this matter.

Sincerely,

 (b) (6)

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

cc: IACUC Chair



13077-
Robyn Diaz
Chief Legal Officer, Senior Vice President
Office of Legal Services

t 901.595.2288 f 901.595.5944
robyn.diaz@stjude.org

December 10, 2019

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

Dear Dr. Wolff:

Subject: Report of Noncompliance/Animal Welfare Assurance D16-00043 (A3077-01)

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 to be taken to prevent the recurrence of a similar incident of noncompliance are provided below.

In late October of 2019, an Animal Resources Center (ARC) Husbandry Services Supervisor (HSS) and an ARC staff veterinarian (vet) met with an investigator and her laboratory as part of required annual meetings with investigators. During their discussion, it was found that a substance administered to the animals was not contained in the approved IACUC protocol, and there no animal welfare concerns. The investigator was notified, and a protocol amendment was submitted for IACUC review on Friday, November 1, 2019. The IACUC approved the protocol amendment on November 11, 2019.

The mice involved in this report were part of a PHS funded project.

This incident was reported to the IACUC at the monthly meeting on November 21, 2019.

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 these matters, or if you believe that further action from the ACUC is warranted, then please contact us.

Yours sincerely,

(b) (6)

Robyn Diaz, J.D.
Institutional Official

CC:

(b) (6)

Dr. Harshan Pisharath, Director, ARC
Dr. Stacey Schultz-Cherry, Chair, ACUC
(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, December 11, 2019 10:28 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of Noncompliance/Animal Assurance

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

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

From: (b) (6)
Sent: Wednesday, December 11, 2019 10:23 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
(b) (6) Pisharath, Harshan <Harshan.Pisharath@STJUDE.ORG>; Schultz-Cherry, Stacey <Stacey.Schultz-Cherry@STJUDE.ORG>; (b) (6) Diaz, Robyn <Robyn.Diaz@STJUDE.ORG>
Subject: Report of Noncompliance/Animal Assurance

From Robyn Diaz, Chief Legal Officer and Institutional Official.

CC: (b) (6)
Dr. Harshan Pisharath, Director, ARC
Dr. Stacey Schultz-Cherry, Chair, ACUC
(b) (6)

(b) (6)



Initial Report of Noncompliance

By: (b) (6)

Date: 12/9/19

Time: 11:40

Name of Person reporting:

Telephone #:

Fax #:

Email:

Stacy Schultzy - Cherry, Chair

Name of Institution:

Assurance number:

St. Jude Children's Hosp.
A3077Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

A substance given to ~15 mice that was not on the protocol.

Species involved:

Personnel involved:

Dates and times:

Animal deaths:

Mice
Researcher
IACUC notified late Oct. 2019

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

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____