



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 11, 2018

Re: Animal Welfare Assurance
A3189-01 [OLAW Case 1L]

James B. Hendricks, Ph.D.
President
Seattle Children's Hospital Research Institute
4800 Sand Point Way, N.E.
Seattle, Washington 98105

Dear Dr. Hendricks,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 26, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Seattle Children's Research Institute, following up on an initial report on September 25, 2018. According to the information provided, OLAW understands that a mouse was given a drug by an unapproved route. Specifically, an approved drug was given subcutaneously although the protocol stated that it would be given by intraperitoneal injection. This change occurred due to a problem with the electronic protocol management software which resulted in the pending significant change appearing as having been approved. There were no adverse effects exhibited by the mouse.

The corrective actions consisted of the Institutional Animal Care and Use Committee (IACUC) informing the researchers that the subcutaneous route was not approved. The Principal Investigator counseled the staff not to implement changes to a protocol until approved. The software problem was brought to the attention of computer personnel and senior leadership and a temporary fix was made. All users of the software were notified about the problem and the solution and the IACUC will continue to monitor the matter until fully resolved. The PHS grant was not charged for any unauthorized animal activities.

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 IACUC to comply with the PHS Policy.

Sincerely,

(b) (6)

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

cc: IACUC Chair



Seattle Children's®
HOSPITAL • RESEARCH • FOUNDATION

Research Institute

November 26, 2018

Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892

Subject: **Notification of Serious Non-Compliance with PHS Policy**
Institution: Seattle Children's Research Institute (SCRI)
Grant #: R01HL126523
Animal Welfare Assurance #: D16-00119 (A3189-01)

Dear OLAW,

This letter is to provide you with a full explanation of the circumstances and actions taken following an incident at our institution as required by PHS Policy IV.F.3.a.

The Institutional Animal Care and Use Committee (IACUC) office received information that a research team performed subcutaneous (SubQ) infusion of dexmedetomidine on a mouse during an IACUC-approved non-survival surgery. At the time, the protocol was only approved for intraperitoneal injection of dexmedetomidine in mice. The animal was not harmed as a result of the incident.

The incident likely occurred as a result of a technical problem with SCRI's electronic protocol management software. At the time of the incident, there was a pending IACUC amendment in progress to add SubQ continuous infusion as a new route option for this agent; however, the changes appeared on the parent protocol in the system as if they had already been reviewed and approved by the IACUC.

The IACUC discussed the incident and requested corrective actions from the PI and the IACUC office.

The following corrective actions were implemented after the incident:

1. The IACUC office immediately notified the study team that the SubQ route was not currently approved;
2. The PI reminded the study team to confirm the current status of the protocol before performing procedures and to communicate across the entire team when amendments are in progress;
3. The IACUC office escalated the technical problem to the software vendor, SCRI's internal software support team, and senior leadership staff; and
4. The software vendor provided a temporary fix to the problem until a permanent solution is identified.

This technical problem also has the potential to affect other animal protocols at SCRI, regardless of whether they involve PHS-supported activities. Therefore, the IACUC office sent a targeted communication to all affected users of the software notifying them of the technical problem and advising them how to proceed.

USPS Mail
PO Box 5371, M/S
Seattle, WA 98145-5005

West 8th
2001 Eighth Avenue
Seattle, WA 98121

Jack R. MacDonald Building
1900 Ninth Avenue
Seattle, WA 98101

Olive Lab Building
1100 Olive Way, Suite 100
Seattle, WA 98101

In addition, the convened IACUC will receive an update at the next IACUC meeting and continued updates until the technical problem is fully resolved. The IACUC accepted these corrective actions as being sufficient to prevent recurrence.

Unallowable charges will be removed from the above-referenced NIH grant. This matter will be reported to the funding component.

If you have any questions regarding this report, please feel free to contact me. Thank you for your consideration of this matter.

Sincerely,
SEATTLE CHILDREN'S RESEARCH INSTITUTE

(b) (6)

James B. Hendricks, PhD
President

Copy: Kari Koszdin, DVM, DACLAM, CPIA, Attending Veterinarian
Tara Polek, PhD, IACUC Chair
Kelly Uckun, CRA, CRCP, Director, Office of Sponsored Research
IACUC Mailbox

Ward, Joan (NIH/OD) [E]

From: [REDACTED] (b) (6) on behalf of IACUC Mailbox
<IACUC@seattlechildrens.org>
Sent: Friday, December 7, 2018 2:06 PM
To: OLAW Division of Compliance Oversight (NIH/OD)
Cc: Hendricks, James; Koszdin, Kari; Polek, Tara; IACUC Mailbox; [REDACTED] (b) (6)
Subject: Final Report RE: Preliminary Notification of Serious Non-Compliance with PHS Policy – Animal Welfare Assurance #D16-00119 (A3189-01)
Attachments: Notification of Serious Non-Compliance with PHS Policy D16-00119 (A3189-01).pdf
Follow Up Flag: Follow up
Flag Status: Flagged

Dear OLAW,

Please find attached a final report from Dr. Jim Hendricks pertaining to Serious Non-Compliance with PHS Policy, Animal Welfare Assurance #D16-00119 (A3189-01).

Please contact the IACUC office at IACUC@seattlechildrens.org with any questions.

Thank you,

[REDACTED] (b) (6)

[REDACTED] (b) (6)

From: [REDACTED] (b) (6)
Sent: Tuesday, September 25, 2018 4:51 PM
To: 'olawdco@mail.nih.gov'
Cc: Hendricks, James; Koszdin, Kari; Polek, Tara; IACUC Mailbox
Subject: Preliminary Notification of Serious Non-Compliance with PHS Policy – Animal Welfare Assurance #D16-00119 (A3189-01)

Dear OLAW,

This email serves as a preliminary report of serious non-compliance with PHS Policy at Seattle Children's Research Institute (SCRI). A research team used an unapproved route of drug administration during an approved procedure. No animals (mice) were harmed. The incident likely occurred as a result of a technical problem with SCRI's electronic protocol management software.

An IACUC Subcommittee has convened to discuss the incident. A final, detailed report will follow once the incident has been reviewed by the full IACUC.

Please contact the IACUC office at IACUC@seattlechildrens.org with any questions.

Thank you,



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Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, December 10, 2018 8:32 AM
To: IACUC Mailbox; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Hendricks, James; Koszdin, Kari; Polek, Tara; (b) (6)
Subject: RE: Final Report RE: Preliminary Notification of Serious Non-Compliance with PHS Policy – Animal Welfare Assurance #D16-00119 (A3189-01)

Thank you for providing this report (b) (6) 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

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From: (b) (6) **On Behalf Of** IACUC Mailbox
Sent: Friday, December 07, 2018 2:06 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Hendricks, James <james.hendricks@seattlechildrens.org>; Koszdin, Kari <Kari.Koszdin@seattlechildrens.org>; Polek, Tara <tara.polek@seattlechildrens.org>; IACUC Mailbox <IACUC@seattlechildrens.org>; (b) (6)
Subject: Final Report RE: Preliminary Notification of Serious Non-Compliance with PHS Policy – Animal Welfare Assurance #D16-00119 (A3189-01)

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Please contact the IACUC office at IACUC@seattlechildrens.org with any questions.

Thank you,
(b) (6)

(b) (6)

A3189-12

Ward, Joan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, September 26, 2018 8:25 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Preliminary Notification of Serious Non-Compliance with PHS Policy – Animal Welfare Assurance #D16-00119 (A3189-01)

Thank you (b) (6) for this preliminary report. We will open a case file and wait for your final report soon.

Regards,
Joan

From: (b) (6)
Sent: Tuesday, September 25, 2018 7:51 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Hendricks, James <james.hendricks@seattlechildrens.org>; Koszdin, Kari <Kari.Koszdin@seattlechildrens.org>; Polek, Tara <tara.polek@seattlechildrens.org>; IACUC Mailbox <IACUC@seattlechildrens.org>
Subject: Preliminary Notification of Serious Non-Compliance with PHS Policy – Animal Welfare Assurance #D16-00119 (A3189-01)

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An IACUC Subcommittee has convened to discuss the incident. A final, detailed report will follow once the incident has been reviewed by the full IACUC.

Please contact the IACUC office at IACUC@seattlechildrens.org with any questions.

Thank you,

(b) (6)

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