



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

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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

October 29, 2019

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

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 October 24, 2019 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 5, 2019. According to the information provided, OLAW understands that 40 mice were subjected to a blood collection without approval from the Institutional Animal Care and Use Committee (IACUC). No adverse effects were noted in the mice.

The corrective actions consisted of amending the protocol, revising the technical services request form to ensure that all procedures have IACUC approval, retraining the laboratory staff, and ensuring that laboratory staff understand that only IACUC approved procedure may be performed. All institutional animal users have been informed about the requirement for following the protocol, the grant was not charged for any unauthorized animal activities, and the NIH funding component was notified.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to 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



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A3189-

October 24, 2019

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 #: U19AI135976  
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 blood collection procedures were performed on 40 mice without appropriate IACUC review and approval. No lab members performed the blood collection; it was requested by the study team and performed by SCRI's Office of Animal Care (OAC) staff.

No animals were harmed as a result of the incident. The incident occurred due to a misunderstanding that the blood collection procedure had been added to the IACUC protocol at the most recent triennial review. Immediately following the incident, the PI submitted an amendment to the protocol and obtained IACUC review and approval for the procedure.

The incident was discussed by an IACUC subcommittee and at a convened meeting. The IACUC required the following additional corrective actions:

1. OAC must revise their Technical Services Request (TSR) Form to inform study teams of their obligation to confirm the requested procedure is approved on the IACUC protocol before submitting;
2. OAC should consider revising the TSR Form to document which experiment in the IACUC protocol covers the requested procedure;
3. Lab members must re-take the online CITI module titled "Working with the IACUC"; and
4. The PI must document (via a sign off sheet) that lab members understand that only IACUC-approved procedures are permissible and are trained on how to use SCRI's electronic protocol management system.

All corrective actions have since been completed. In addition, the IACUC office and OAC have participated in several Research Institute-wide communications emphasizing the importance of conducting research per protocol. The IACUC accepted these corrective actions as being sufficient to prevent recurrence.

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

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

(b) (6)

IACUC Mailbox

**Morse, Brent (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, October 25, 2019 1:49 PM  
**To:** IACUC Mailbox; OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** Hendricks, James; Koszdin, Kari; Polek, Tara; (b) (6)  
**Subject:** RE: Final Report of Serious Non-Compliance with PHS Policy – Animal Welfare Assurance #D16-00119 (A3189-01)

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

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**From:** (b) (6) On Behalf Of IACUC Mailbox  
**Sent:** Friday, October 25, 2019 12:31 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>; (b) (6) IACUC Mailbox <IACUC@seattlechildrens.org>; (b) (6)  
**Subject:** Final Report of Serious Non-Compliance with PHS Policy – Animal Welfare Assurance #D16-00119 (A3189-01)

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](mailto:IACUC@seattlechildrens.org) with any questions.

Best Regards,

(b) (6)



**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Thursday, September 05, 2019 3:01 PM  
**To:** (b) (6) OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** Hendricks, James; Koszdin, Kari; Polek, Tara; IACUC Mailbox  
**Subject:** RE: Preliminary Notification of Serious Non-Compliance with PHS Policy – Animal Welfare Assurance #D16-00119 (A3189-01), Grant #U19AI135976

Thank you for providing this preliminary report. We will open a case file and await further information.

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)  
**Sent:** Thursday, September 05, 2019 1:58 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), Grant #U19AI135976

Dear OLAW,

This email serves as a preliminary report of serious non-compliance with PHS Policy at Seattle Children's Research Institute. Blood collection procedures were performed on 40 mice without appropriate IACUC review and approval. No animals were harmed.

An IACUC Subcommittee convened to discuss the incident on 9/3/19. 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](mailto:IACUC@seattlechildrens.org) with any questions.

Thank you,

(b) (6)