



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

October 17, 2019

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

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 September 30<sup>th</sup>, 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 (SCRI). Your letter supplements the information emailed in a preliminary report on July 31<sup>st</sup>, 2019. According to the information provided, a research member injected an approved substance (Complete Freund's Adjuvant), via an unapproved route (intraperitoneal) and frequency (twice) to 62 mice and no ill effects were noted to the animals. As a corrective measure, all staff members must take online training and submit certificates to the IACUC office, schedule in-person training with clinical veterinary staff and be trained on SCRI's electronic protocol system or provide attestation via signature sheet confirming they had been trained in the electronic protocol system. The animals on this study were supported by NIH funding.

OLAW appreciates the prompt consideration of this matter by Seattle Children's Research Institute, which is consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. OLAW understands that data generated from this study was used for NIH-NIAID grant application and expects that the funding component will be contacted to report the data generated from the non-compliance. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact  
Emily Linde, NIAID



September 30, 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 #: R01AI112619  
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 member administered Freund's Complete Adjuvant (CFA) using an unapproved injection route (intraperitoneal) and frequency (twice) in 62 mice. CFA was approved on the protocol to be administered once via subcutaneous injection only. No animals were harmed as a result of the incident.

The unapproved procedure and data resulting from the procedure were included in a manuscript submission that incorrectly stated that all procedures were IACUC approved. The data were also included in a grant application submitted to NIAID (2R01AI112619-06).

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

1. All staff must re-take the online CITI module titled "Working with the IACUC" and submit completion certificates to the IACUC office;
2. All staff must schedule an in-person group training with the clinical veterinarian to discuss appropriate use of CFA as an adjuvant and compliance with an approved IACUC protocol; and
3. All staff must be trained on the use of SCRI's electronic protocol system. If staff were previously trained, a signature sheet signed by all laboratory members confirming they were trained can be submitted to the IACUC office.

The IACUC accepted these corrective actions as being sufficient to prevent recurrence. All corrective actions have since been completed by the PI.

Because OLAW requires a journal be notified when animal activities are incorrectly identified as having been conducted with IACUC approval and CFA injections are not approvable as performed due to the potential for significant pain and adverse effects in the animals, the IACUC also made a recommendation to me (as the Institutional Official) that further dissemination of these data not occur.

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

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, October 7, 2019 7:04 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Final Report of Serious Non-Compliance with PHS Policy – Animal Welfare Assurance #D16-00119 (A3189-01), Grant #RO1AI112619

Thank you for this report, (b) (6) We will send a response soon.

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

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**From:** (b) (6)  
**Sent:** Friday, October 4, 2019 6:10 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>; Uckun, Kelly <Kelly.Uckun@seattlechildrens.org>  
**Subject:** Final Report of Serious Non-Compliance with PHS Policy – Animal Welfare Assurance #D16-00119 (A3189-01), Grant #RO1AI112619

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)

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**From:** (b) (6)  
**Sent:** Wednesday, July 31, 2019 3:25 PM  
**To:** 'olawdco@mail.nih.gov' <olawdco@mail.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 #RO1AI112619

Dear OLAW,

This email serves as a preliminary report of serious non-compliance with PHS Policy at Seattle Children's Research Institute. A research team member used an unapproved route and frequency of adjuvant administration during an approved procedure. No animals (mice) were harmed.

An IACUC Subcommittee convened to discuss the incident on 7/29/19. 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)



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**Ward, Joan (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, August 5, 2019 9:29 AM  
**To:** (b) (6)  
**Subject:** RE: Preliminary Notification of Serious Non-Compliance with PHS Policy – Animal Welfare Assurance #D16-00119 (A3189-01), Grant #RO1AI112619

Thank you (b) (6) for this preliminary report. We will await your final report after the IACUC review.

Regards,  
Joan

**From:** (b) (6)  
**Sent:** Wednesday, July 31, 2019 6:25 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 #RO1AI112619

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Please contact the IACUC office at [IACUC@seattlechildrens.org](mailto:IACUC@seattlechildrens.org) with any questions.

Thank you,

(b) (6)

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