



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

January 6, 2020

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

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 December 4, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Seattle Children's Research Institute following up on an initial May 13, 2019 notification by email.

According to the information provided, this Office understands that Seattle Children's Research Institute Animal Care and Use Committee (ACUC) suspended three approved protocols in connection with a Division of Investigative Oversight (DIO) investigation. These protocols investigate the role of T-cells, inflammatory cytokines and enteric pathogens in the development and prevention of autoimmune diseases, such as experimental autoimmune encephalomyelitis and inflammatory bowel diseases, in mouse models. The final report states that the investigator is no longer at the institute and the protocols have been administratively closed. It has also been confirmed that these protocols were PHS-supported activities and the suspension of the protocols were not related to noncompliance with animal activities. We appreciate being informed of these matters and find no cause for action by this Office.

Sincerely,

(b) (6)

Jacquelyn T. Tubbs, DVM
Veterinary Medical Officer
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



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December 4, 2019

Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Subject: **Notification of Suspension of an Activity by the IACUC**
Institution: Seattle Children's Research Institute
Animal Welfare Assurance #: D16-00119 (A3189-01)

Dear OLAW,

This letter is to provide you with a final report following the suspension of an approved research activity by the IACUC, in accordance with PHS Policy IV.F.3.

On May 3, 2019, the convened IACUC suspended three approved protocols in connection with a Division of Investigative Oversight (DIO) investigation, case #6482. These protocols investigate the role of T-cells, inflammatory cytokines, and enteric pathogens in the development and prevention of autoimmune diseases, such as experimental autoimmune encephalomyelitis and inflammatory bowel diseases, in mouse models.

The investigator is no longer at Seattle Children's Research Institute; therefore, the protocols have been administratively closed.

If you have any questions regarding this report, please feel free to contact me.

Sincerely,
SEATTLE CHILDREN'S RESEARCH INSTITUTE

(b) (6)

James B. Hendricks, PhD
President

Copy: Kari Koszdin, DVM, DACLAM, Attending Veterinarian
Tara Polek, PhD, IACUC Chair
IACUC Mailbox

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

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, December 05, 2019 10:55 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Hendricks, James; Koszdin, Kari; Polek, Tara; IACUC Mailbox
Subject: RE: Notification of Suspension of an Activity by the IACUC – Animal Welfare Assurance #D16-00119 (A3189-01)

Thank you for providing this final 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)
Sent: Wednesday, December 04, 2019 6:47 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: RE: Notification of Suspension of an Activity by the IACUC – Animal Welfare Assurance #D16-00119 (A3189-01)

Dear OLAW,

Please find attached a final report from Dr. Jim Hendricks pertaining to suspension of an activity by the IACUC at Seattle Children's Research Institute. Please contact the IACUC office at IACUC@seattlechildrens.org with any questions.

Thank you,

(b) (6)

Connect with us online:



From: (b) (6)

Sent: Monday, May 13, 2019 12:20 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: Notification of Suspension of an Activity by the IACUC – Animal Welfare Assurance #D16-00119 (A3189-01)

Dear OLAW,

See attached a preliminary report of suspension of an activity by the IACUC at Seattle Children's Research Institute. Please contact the IACUC office at IACUC@seattlechildrens.org with any questions.

Thank you,

(b) (6)

Connect with us online:



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Research Institute

prelim.
A3189-1N

May 13, 2019

Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Subject: **Notification of Suspension of an Activity by the IACUC**
Institution: Seattle Children's Research Institute
Animal Welfare Assurance #: D16-00119 (A3189-01)

Dear OLAW,

This letter is to provide you with a preliminary report following the suspension of an approved research activity by the IACUC, in accordance with PHS Policy IV.F.3.

On May 3, 2019, the convened IACUC suspended three approved protocols in connection with a Division of Investigative Oversight (DIO) investigation, case #6482. These protocols investigate the role of T-cells, inflammatory cytokines, and enteric pathogens in the development and prevention of autoimmune diseases, such as experimental autoimmune encephalomyelitis and inflammatory bowel diseases, in mouse models.

The institution is cooperating with the ongoing DIO investigation and corrective actions will be taken. A final report will be forwarded to OLAW once the corrective action plan is finalized and a decision is made about the protocols. In the meantime, all affected animals have been transferred to the institutional emergency holding protocol to ensure immediate care and oversight.

If you have any questions regarding this report, please feel free to contact me.

Sincerely,
SEATTLE CHILDREN'S RESEARCH INSTITUTE

(b) (6)

James B. Hendricks, PhD
President

Copy: Kari Koszdin, DVM, DACLAM, Attending Veterinarian
Tara Polek, PhD, IACUC Chair
IACUC Mailbox

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

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, May 13, 2019 4:12 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Hendricks, James; Koszdin, Kari; Polek, Tara; IACUC Mailbox
Subject: RE: Notification of Suspension of an Activity by the IACUC – Animal Welfare Assurance #D16-00119 (A3189-01)

Thank you for providing this prompt, preliminary notification (b) (6). 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: Monday, May 13, 2019 3:20 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: Notification of Suspension of an Activity by the IACUC – Animal Welfare Assurance #D16-00119 (A3189-01)

Dear OLAW,

See attached a preliminary report of suspension of an activity by the IACUC at Seattle Children's Research Institute. Please contact the IACUC office at IACUC@seattlechildrens.org with any questions.

Thank you,

(b) (6)

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