



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

November 27, 2018

Re: Animal Welfare Assurance
A3194-01 [OLAW Case 1N]

Emily Holmes, Ph.D.
Vice President, Research Services
Scripps Research Institute
10550 North Torrey Pines Road
Mail TPC 8
La Jolla, CA 92037

Dear Dr. Holmes,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 14, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at The Scripps Research Institute. Your letter supplements the information contained in the prompt preliminary telephone report to OLAW on August 29, 2018. According to the information provided, OLAW understands that on August 27, 2018 three singly-housed mice were found in a refrigerated chamber. They had been there for five hours with food and a gel pack but no bedding. The animals were immediately moved to standard housing. They were not in clinical pain or distress. A post-doc had mistaken a completed preliminary review of a submitted amendment adding this experiment as the final IACUC approval. This activity was funded by the PHS.

Corrective and preventive action included counseling of the PI and post-doc regarding the need to obtain final IACUC approval prior to initiation of studies with research animals. The IACUC approved the amendment of October 1, 2018. No unallowable costs were charged to the grant.

OLAW appreciates the consideration of this matter by The Scripps Research Institute, which was 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 concurs that the incident warranted reporting. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Chair

CONFIDENTIAL

November 14, 2018

Brent Morse, D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive
Suite 2500, MSC 6910
Bethesda, MD 20817
olawdco@mail.nih.gov

RE: Animal Welfare Assurance D16-00122 (A3194-01)

Dear Dr. Morse:

We are writing to finalize the oral report to OLAW of August 29, 2018, regarding initiation of a study prior to IACUC review and approval. An overview of the event and the IACUC response is provided below.

- 1) On August 27, 2018, three singly housed mice were found by husbandry staff in a refrigerated chamber. There was no bedding in the cages but a gel pack, along with food pellets were found on the cage floor. The animals were not in clinical pain or distress but were immediately removed from this location and returned to standard housing.
- 2) Investigation by the IACUC determined the following:
 - a. The animals were placed in the refrigerated chamber earlier that day for the purpose of quickly manipulating each animal's energy balance and to measure if food intake is affected by the change in energy expenditure. The total time within the chamber was less than five hours.
 - b. An amendment to the lab's approved IACUC protocol was received in the IACUC office on August 21, 2018 and a preliminary review completed. The post-doc mistakenly understood this submission and review to be final IACUC review and approval.
 - c. The amendment was scheduled for IACUC review on September 19, 2018. After review at the IACUC meeting and response to IACUC-required modifications final amendment approval was granted on October 01, 2018.
- 3) Members of the Department of Animal Resources and the IACUC met with the PI and post-doc to remind them of the need to obtain IACUC approval prior to initiation of studies with research animals.

- 4) This study was supported in part by NIH grants K01DK114165 with no unallowable costs charged to this award.

The Scripps Research Institute remains committed to ensuring the proper care and treatment of animals used in research and teaching at the institution. If you require any further information, please contact us at iacuc@scripps.edu.

Sincerely,

(b) (6)

Emily Holmes, Ph.D.
Vice President, OPERA
Institutional Official

(b) (6)

Juan Carlos de la Torre, Ph.D.
Chair, Institutional Animal Care and Use Committee
Professor, Dept. of Immunology and Microbiology

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, November 21, 2018 7:53 AM
To: IACUC Department; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Emily Holmes; (b) (6)
Subject: RE: Noncompliance Report for D16-00122 (A3194-01)

Thank you for this report Dr. Holmes. 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

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: IACUC Department [mailto:iacuc@scripps.edu]
Sent: Tuesday, November 20, 2018 4:39 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Emily Holmes <eholmes@scripps.edu>; (b) (6)
Subject: Noncompliance Report for D16-00122 (A3194-01)

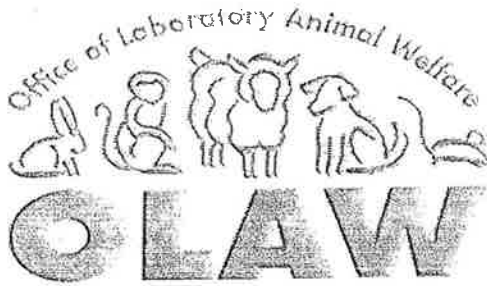
Dr. Morse,

Please see the attached written report for Animal Welfare Assurance D16-00122 (A3194-01) regarding noncompliance incidents and corrective actions.

If you have any questions or concerns, please write or call.

Respectfully,
Emily Holmes, Institutional Official

Emily Holmes, Ph.D.
Vice President, Research Services
The Scripps Research Institute
10550 N. Torrey Pines Road, TPC8
La Jolla, CA 92037
Tel: (b) (6)
Fax: (b) (6)



Initial Report of Noncompliance

By: *BM*Date: *8/31/18*Time: *Voicemail from 8/29/18*
(b) (6)

Name of Person reporting: [REDACTED]

Telephone #: [REDACTED]

Fax #: [REDACTED]

Email: [REDACTED]

Name of Institution: *Scripps Rsch. Inst.*
Assurance number: *A3194*

Did incident involve PHS funded activity? _____

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? *Mice placed in cold box (environ. chamber) before amendment was approved. Found & removed same day.*Species involved: *mice*Personnel involved: *Researcher*Dates and times: *8/27/18*Animal deaths: *No.*

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

Projected submission to OLAW of final report from Institutional Official: _____

OFFICE USE ONLY

Case # _____