



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
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Bethesda, Maryland 20892-7982
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) 402-2803

DATE: September 6, 2018

TO: Michael M. Gottesman, M.D.
Deputy Director for Intramural Research, NIH

FROM: Director
Division of Compliance Oversight, OLAW

SUBJECT: Animal Welfare Investigation (#009-18) - Animal Welfare Assurance
A4149-01 [Case 12K]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 14, 2018 memo regarding an incident of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the National Cancer Institute (NCI). According to the information provided, OLAW understands that on July 6, 2018 the NCI IACUC became aware that three individuals who had performed survival surgery procedures on mice used unacceptable surgical techniques, failed to adhere to the ACUC-approved protocol, and failed to use appropriate analgesics post-surgery. The PI was contacted and was asked to immediately stop all additional surgeries.

Corrective and preventive actions included having the individuals retake the OACU Animal User's Course and receive re-training from LASP veterinary staff on correct and appropriate surgical procedures and post-operative care. The individuals must also prove that they have read the ASP and perform the first surgery in the presence of an LASP veterinarian.

The actions taken to resolve the issue and prevent recurrence were appropriate and accepted by OLAW. 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: Dr. Stephen Denny
Dr. Richard Wyatt, OAI/OD
James B. Mitchell, Ph.D., Chair, NCI ACUC



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

August 14, 2018

TO: Brent C. Morse, D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare

FROM: Deputy Director for Intramural Research, NIH

SUBJECT: Animal Welfare Investigations - Assurance A4149-01 (#009-18)

This correspondence conveys the results of an investigation by the National Cancer Institute (NCI) Animal Care and Use Committee (ACUC) conducted in accordance with Assurance A4149-01 and PHS Policy IV.F.3. The adverse event involved a failure to adhere to the applicable ACUC approved protocol and utilize acceptable rodent surgery techniques.

The event was first reported to the NCI ACUC Chair on July 6, 2018 as noted in the attached NCI ACUC memorandum. The details of the ACUC investigation and the corrective actions taken by the animal care program are outlined in the attached memorandum.

Please contact me or Dr. Stephen Denny, Acting Director, Office of Animal Care and Use, if additional information or clarifications are required.

(b) (6)

Michael M. Gottesman, M.D.

Attachment

cc: Dr. Wyatt
Dr. Mitchell
Dr. Denny



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Radiation Biology Branch
Bldg. 10, Room B3-B69
Bethesda, Maryland 20892
Phone: 240-858-3101
Fax: 240-541-4528
E-Mail: jbm@helix.nih.gov

Date August 14, 2018

To Dr. Michael M. Gottesman, M.D.

From James B. Mitchell, Ph.D.
ACUC Chair, NCI

Subject Reportable Animal Incident: Improper Surgery Techniques (009-18)

On July 6, 2018, I as Chair of the NCI ACUC, was apprised of an incident in an NCI animal facility involving three individuals who had performed survival surgery procedures (mice) using unacceptable surgical techniques, failed to adhere to the ACUC approved protocol, and failed to use appropriate analgesics post-surgery. There were no animal deaths as a result of the surgery. On July 6, 2018, the PI of the ASP was notified of the incident and the individuals were asked to immediately stop all additional surgeries. This incident was reported to OACU the same day. Upon further investigation into the incident, the NCI ACUC decided that the incident should be reported to OLAW. OACU was contacted and subsequently reported the incident to OLAW. The NCI ACUC developed a list of corrective measures that is shown below. The PI and the individuals who performed the surgery apologized for the incident and were willing to comply with the corrective measures.

In order to prevent further recurrence, the individuals conducting the surgery were instructed to perform the following corrective actions:

- Immediately stopped from conducting surgical procedures on mice
- Have the individuals retake the OACU Animal User's Course
- Have the individuals receive re-training from LASP veterinary staff on correct and appropriate surgical procedures and post-operative care
- Individuals provide evidence to LASP veterinarians that the ASP had been read and followed
- After these measures, the individuals must demonstrate proficiency by performing the first surgery in the presence of an LASP veterinarian

This information was presented at the NCI ACUC meetings (July and August, 2018), where the ACUC approved the corrective measures. I feel with these measures in place this type of event is unlikely to reoccur in the future.

Please feel free to contact me if you have any questions.

(b) (6)

James B. Mitchell, Ph.D.
Chair, NCI ACUC

Cc: Tom Misteli, Ph.D.
Robert Hoyt, D.V.M., M.S.

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, September 05, 2018 7:34 AM
To: Denny, Stephen (NIH/OD) [E]; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: A4149-01 NIH IRP Reportable Event - (NCI ACUC; 009-18)

Thank you for this report Dr. Denny. 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: Denny, Stephen (NIH/OD) [E]
Sent: Wednesday, September 05, 2018 6:33 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: A4149-01 NIH IRP Reportable Event - (NCI ACUC; 009-18)

Dear OLAW/DCO,

Final reports from the NIH Institutional Official and the NIH National Cancer Institute ACUC addressing the animal incident referenced below are attached. If you have any questions please contact me via email or the phone number listed below. Thanks, Steve

STEPHEN L DENNY, DVM, MS, DACLAM | Acting Director, NIH Office of Animal Care and Use | Phone: (301) 496-5424

From: Denny, Stephen (NIH/OD) [E]
Sent: Thursday, August 02, 2018 12:35 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: A4149-01 Reportable Event - (NCI ACUC; 009-18)

Dear OLAW/DCO – I was recently informed by the NIH National Cancer Institute ACUC Chairman that one of their facility veterinarians reported an event where ACUC-approved survival surgery techniques were not followed as outlined in the Animal Study Proposal.

Their ACUC will perform a full investigation, propose corrective actions, and render a report in the near future. Sincerely, Steve

STEPHEN L DENNY, DVM, MS, DACLAM | Acting Director, NIH Office of Animal Care and Use | Phone: (301) 496-5424

A 4149-12 K

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, August 02, 2018 12:48 PM
To: Denny, Stephen (NIH/OD) [E]; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: A4149-01 Reportable Event - (NCI ACUC; 009-18)

Thank you for this preliminary report Dr. Denny. 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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To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
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Their ACUC will perform a full investigation, propose corrective actions, and render a report in the near future. Sincerely, Steve

STEPHEN L DENNY, DVM, MS, DACLAM | Acting Director, NIH Office of Animal Care and Use | Phone: (301) 496-5424