DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive - MSC 7982
Bethesda, Maryland 20892-7982
Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

DATE: February 22, 2017

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

FROM: Animal Welfare Program Specialist
Division of Compliance Oversight, OLAW

SUBJECT: Animal Welfare Investigation - Animal Welfare Assurance A4149-01 [Case 11L]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 21, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the National Cancer Institute, NIH, following up on an initial report on December 15, 2016. According to the information provided, OLAW understands that mice were subjected to a survival surgical procedure using unacceptable technique due to inadequate training and experience of the surgeon. The surgical site had not been appropriately prepared, the animals failed to receive analgesics, and wound clips subsequently fell off.

The immediate action taken upon discovery consisted of providing analgesics to the mice and stopping additional surgeries. The corrective actions consisted of notifying the Principal Investigator, having the responsible individuals undertake retraining and certify understanding of the protocol, and having a veterinarian oversee the next surgery.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

(b) (6)

Axel Wolff, M.S., D.V.M.

cc: Dr. Terri Clark
Dr. Richard Wyatt
Dr. James Mitchell

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

February 21, 2016

TO: Axel Wolff, 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 (#025-16)

This correspondence conveys the results of an investigation by the National Cancer Institute (NCI) Animal Care and Use Committee (ACUC) regarding an incident reported to your office on December 15, 2016. The incident involved an investigator performing surgical procedures without proper training and experience and which resulted in both inadequate surgical technique and inadequate post-surgical care.

As noted in the NCI ACUC memorandum, the incident was promptly reported to their ACUC Chair and a subcommittee was formed to investigate the issue. The details of the investigations and the corrective actions taken, which their ACUC concluded were adequate to prevent reoccurrence of this problem, are detailed in the attached memorandum.

It is my opinion that the NCI ACUC took appropriate actions investigating this incident, and I agree that these corrective actions should preclude such an incident from occurring in the future.

Please contact me or Dr. Terri R. Clark, Director, Office of Animal Care and Use, if additional information or clarifications are required.

(b) (6)

Michael M. Gottesman, M.D.

Attachment

cc: Dr. Mitchell
Dr. Clark
Dr. Wyatt

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: 301-496-7511
Fax: 301-480-2238
E-Mail: jbm@helix.nih.gov

Date February 20, 2017

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

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

Subject Reportable Animal Incident: Improper Surgery Technique A4149-01 (NCI; 025-16)

On December 15, 2016, I as Chair of the NCI ACUC, was apprised of an incident in an NCI animal facility involving two individuals who had performed survival surgery procedures (mice) using unacceptable surgical techniques. The surgical site was not adequately prepared for surgery and appropriate analgesics were not provided to those animals receiving surgery. All animals that had surgery on December 15, 2016 were given analgesics by the facility veterinarian once this problem was recognized. Further, multiple animals had wound clips fall out after the animals were returned to their cages. On December 15, 2016, the PI of the ASP was notified of the incident and the individuals were asked to immediately stop all additional surgeries. This violation was reported to OACU (reported on December 15, 2016), which was reported to OLAW. Following further investigation of the incident a list of corrective measures was developed 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 (January and February, 2017), where the ACUC confirmed 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.

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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, February 22, 2017 9:12 AM
To: Clark, Terri (NIH/OD) [E]
Subject: RE: Reportable Event - A4149-01 (NCI; 025-16)

Thank you for this final report, Terri. I will send a response soon.
Axel

From: Clark, Terri (NIH/OD) [E]
Sent: Wednesday, February 22, 2017 8:47 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: FW: Reportable Event - A4149-01 (NCI; 025-16)

Good morning – please find attached the final memo for addressing this reported events. Kind regards – Dr. Clark

Rear Admiral Terri R. Clark, DVM // Director, Office of Animal Care & Use, NIH
Assistant Surgeon General, USPHS Commissioned Corps // clarkte@od.nih.gov // 301-496-5425

From: Clark, Terri (NIH/OD) [E]
Sent: Thursday, December 15, 2016 12:25 PM
To: Wolff, Axel (NIH/OD) [E] <WolffA@OD.NIH.GOV>
Cc: Gottesman, Michael (NIH/OD) [E] <GottesmM@mail.nih.gov>; Wyatt, Richard G (NIH/OD) [E] <WyattRG@OD.NIH.GOV>
Subject: Reportable Event - A4149-01 (NCI; 025-16)

Hi Axel – I was informed today that the National Cancer Institute (NCI) had an incident that involved improper surgical technique.

The NCI ACUC will perform a full investigation, propose appropriate corrective actions, and render a report in the near future.

Kind regards - Terri

Rear Admiral Terri R. Clark, DVM, DACLAM // Director, Office of Animal Care and Use, OIR // Assistant Surgeon General
USPHS Commissioned Corps // 301-496-5424 // Clarkte@od.nih.gov // http://oacu.od.nih.gov

A4149-11L

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Friday, December 16, 2016 8:21 AM
To: Clark, Terri (NIH/OD) [E]
Subject: RE: Reportable Event - A4149-01 (NCI; 025-16)

Thanks Terri. I'll start a new case.
Axel

From: Clark, Terri (NIH/OD) [E]
Sent: Thursday, December 15, 2016 12:25 PM
To: Wolff, Axel (NIH/OD) [E] <WolffA@OD.NIH.GOV>
Cc: Gottesman, Michael (NIH/OD) [E] <GottesmM@mail.nih.gov>; Wyatt, Richard G (NIH/OD) [E] <WyattRG@OD.NIH.GOV>
Subject: Reportable Event - A4149-01 (NCI; 025-16)

Hi Axel – I was informed today that the National Cancer Institute (NCI) had an incident that involved improper surgical technique.

The NCI ACUC will perform a full investigation, propose appropriate corrective actions, and render a report in the near future.

Kind regards - Terri

Rear Admiral Terri R. Clark, DVM, DACLAM // Director, Office of Animal Care and Use, OIR // Assistant Surgeon General
USPHS Commissioned Corps // 301-496-5424 // Clarkte@od.nih.gov // http://oacu.od.nih.gov