DEPARTMENT OF HEALTH & HUMAN SERVICES

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FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500 – MSC 6910
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) 480-3387

DATE: May 19, 2022

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

FROM: Director
Division of Compliance Oversight, OLAW

SUBJECT: Animal Welfare Investigation (NCI #11-22) - Animal Welfare Assurance A4149-01 [Case 16P]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 11, 2022 memo regarding an incident of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the National Cancer Institute. According to the information provided, OLAW understands that on April 7, 2022, a group of 3 cages of mice assigned to an approved ACUC animal study protocol (ASP) were noted to have recently received tail biopsies, as subsequently confirmed by the principal investigator (PI) and investigator staff. The relevant ASP did not have tail biopsies as an approved procedure. The PI and staff indicated that they were unaware that tail biopsies were not on the protocol. Additional inquiries with the investigator staff determined that the tail biopsies were not performed according to ARAC guidelines or NCI ACUC approved procedures, in that the mice were older than 21 days of age when biopsied, > 2mm of tail was collected for the biopsy, inadequate analgesia was used (i.e. only topical lidocaine was used prior to the tail biopsies being performed), and it appears that inadequate hemostasis or post-biopsy collection monitoring had occurred. These deviations from the approved ACUC protocol meant that mice underwent the tail biopsy procedure without being on an approved analgesic regime and likely experienced unrelieved pain.

Corrective and preventive actions included the PI acknowledging these events, committing to amend the ASP to add tail biopsies, and to follow the ARAC and ACUC tail biopsy guidelines to ensure mice are not experiencing unnecessary pain or distress.

The actions taken to resolve the issue and prevent recurrence were appropriate and accepted by OLAW. OLAW suggests that enhanced oversight of this procedure by the ACUC may be warranted when once again performed. Also, it is strongly suggested that all members of the lab responsible for animal procedures have access to the approved ASP, ARAC and ACUC guidelines. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C. Morse -S
Date: 2022.05.19 15:46:02 -04'00'

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

cc: Dr. Stephen Denny
Dr. Richard Wyatt
Remy Bosselut, M.D., Ph.D., Chair, NCI ACUC

A4149 - 16P

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
Bethesda, Maryland 20892
www.nih.gov

May 11, 2022

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 D16-00602 (NCI 11-22)

This correspondence conveys the results of an animal incident investigation by the NIH National Cancer Institute (NCI) ACUC in accordance with Assurance D16-00602 and PHS Policy IV.F.3. The incident involved conducting tail biopsy procedures on mice that were not listed and authorized in the ACUC-approved animal study proposal. Three cages of mice were affected.

The event was first reported to the NIH Office of Animal Care and Use by the NCI Attending Veterinarian on April 22, 2022.

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

Michael M. Gottesman -S
Digitally signed by Michael M. Gottesman -S
Date: 2022.05.11 11:25:42 -04'00'

Michael M. Gottesman, M.D.

Attachment

cc: Dr. Wyatt
Dr. Bosselut
Dr. Denny

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Laboratory of Immune Cell Biology
Bldg. 37, Room 3016
Bethesda, Maryland 20892
Phone: 240 760-6866
Fax: 240 541-4483
E-Mail: bosselur@mail.nih.gov

Date: 5/9/2022

To: Dr. Michael M. Gottesman, M.D., Deputy Director for Intramural Research

From: Rémy Bosselut, M.D., Ph.D.
ACUC Chair, NCI

Subject: Reportable Animal Incident: Unapproved Animal Procedure

On April 7th, 2022, a group of 3 cages of mice assigned to an approved ACUC animal study protocol (ASP) were noted to have recently received tail biopsies, as subsequently confirmed by the principal investigator (PI) and investigator staff. The relevant ASP did not have tail biopsies as an approved procedure. The PI and staff indicated that they were unaware that tail biopsies were not on the protocol. Additional inquiries with the investigator staff determined that the tail biopsies were not performed according to ARAC guidelines or NCI ACUC approved procedures, in that the mice were older than 21 days of age when biopsied (born 3/9/22 or 3/14/22 and biopsied on 4/5/22), > 2mm of tail was collected for the biopsy, inadequate analgesia was used (i.e. only topical lidocaine was used prior to the tail biopsies being performed), and it appears that inadequate hemostasis or post biopsy collection monitoring had occurred. These deviations from the approved ACUC protocol meant that mice underwent the tail biopsy procedure without being on an approved analgesic regime and likely experienced unrelieved pain.

In addition to acknowledging these events, the PI committed to amend the ASP to add tail biopsies, and to follow the ARAC and ACUC tail biopsy guidelines to ensure mice are not experiencing unnecessary pain or distress.

These actions represent animal use that was not approved by the Animal Care and Use Committee necessitating the Attending Veterinarian to report this incident to the ACUC Chair and the Office of Animal Care and Use on April 22. This issue was discussed at the NCI ACUC Semiannual meeting on April 27, 2022; the committee approved the corrective measures and report of the incident to OLAW.

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

Sincerely,

(b) (6)

Rémy Bosselut, M.D., Ph.D.
Chair, NCI ACUC

Cc: Tom Misteli , Ph.D.
Glenn Merlino, Ph.D.
Joshua Kramer, D.V.M., M.S.

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, May 16, 2022 7:55 AM
To: Denny, Stephen (NIH/OD) [E]
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: D16-00602 NIH Animal Incident Report (NCI 11-22)

Thank you for this report. We will send a response soon.
Axel Wolff

From: Denny, Stephen (NIH/OD) [E] <stephen.denny@nih.gov>
Sent: Friday, May 13, 2022 1:25 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: D16-00602 NIH Animal Incident Report (NCI 11-22)

Dear OLAW/DCO,

The attached documents from the NIH Institutional Official and the NIH National Cancer Institute (NCI) address an animal incident involving the conduct of an animal procedure on mice which was not listed nor authorized in the pertinent ACUC-approved animal study proposal.
The incident was first reported to the NIH Office of Animal Care and Use by the NCI Attending Veterinarian on April 22, 2022.

If you have any questions please contact me via email or at the phone number listed below. Thank you, Steve

STEPHEN DENNY, DVM, MS, DACLAM, DACVPM | Director, Office of Animal Care and Use | NIH Bethesda Campus, Building 31/Room B1C37 | Phone: (301) 435-2188 | ***NIH . . . Turning Discovery Into Health*** |