



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Office of Laboratory Animal Welfare  
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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: April 22, 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 #04-22) - Animal Welfare Assurance  
A4149-01 [Case 16I]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 1, 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 January 31, 2022, a group of six mice was intravenously injected with a suspension of tumor cells in Matrigel. One animal died. It was determined that both the cell line and Matrigel batch had been approved for subcutaneous injection, but not for intravenous injection. In addition, it was found that a non-ACUC approved derivative of that cell line had been used by the same group for subcutaneous injection following an ACUC-approved procedure. The latter activity affected neither animal health nor welfare.

To correct and prevent the issue, the PI has: 1) ended the experiment in question, 2) reviewed the protocol and ensured that all new experiments were postponed until the protocol accurately reflected the planned work, and 3) committed to submit a modification to the protocol to update it for planned activities. The facility veterinarian also discussed this event and the corrective actions with laboratory staff over email.

The action taken to resolve the issue and prevent recurrence was appropriate and accepted by OLAW. OLAW suggests that, if the experiment is restarted, initial enhanced oversight by the ACUC may be warranted. 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: 2022.04.25 07:49:46 -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



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health  
Bethesda, Maryland 20892

[www.nih.gov](http://www.nih.gov)

April 1, 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 04-22)

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 the administration of a non-ACUC approved substance into experimental mice.

The event was first reported to the NIH Office of Animal Care and Use by the Attending Veterinarian on February 4, 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: 2022.04.01 16:51:33 -0400

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:** 03/24/2022

**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: Off-protocol animal activity

On January 31, 2022, a group of 6 mice assigned to an approved animal study proposal was intravenously injected with a suspension of tumor cells in Matrigel. One animal died. Upon investigation by the Facility Veterinarian it was found that both the cell line and Matrigel batch had been approved for subcutaneous injection, but not for intravenous injection. In addition, it was found that a non-ACUC approved derivative of that cell line had been used by the same group for subcutaneous injection following an ACUC-approved procedure. The latter activity affected neither animal health nor welfare. Nonetheless, both 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 February 4.

This was the first such instance for this group. The Principal Investigator expressed apologies for the mistake to the AV and ACUC Chairman; and the PI has: 1) ended the experiment in question and euthanized the remaining mice, 2) reviewed the protocol and ensured that all new experiments were postponed until the protocol accurately reflected the planned work, and 3) committed to submit a modification to the protocol to update it for planned activities. The facility veterinarian also discussed this event and the corrective actions with laboratory staff over email. This issue was discussed at the NCI ACUC meeting on March 9, 2022. The committee approved the corrective measures. The committee feels these measures will prevent similar events from occurring in the future.

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]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, April 6, 2022 7:29 AM  
**To:** Denny, Stephen (NIH/OD) [E]  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: D16-00602 NIH Animal Incident Report (NCI 04-22))

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

**From:** Denny, Stephen (NIH/OD) [E] <stephen.denny@nih.gov>  
**Sent:** Monday, April 4, 2022 8:39 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** D16-00602 NIH Animal Incident Report (NCI 04-22))

Dear OLAW/DCO,

The attached documents from the NIH Institutional Official and the NIH National Cancer Institute (NCI) address an animal incident involving the administration of a non-ACUC approved substance into experimental mice. The event was first reported to the NIH Office of Animal Care and Use by the NCI Attending Veterinarian on February 4, 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* |