



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) 480-3387

February 2, 2022

Re: Animal Welfare Assurance  
A3377-01 [OLAW Case 8X]

Dr. David P. Norton  
Vice President for Research  
University of Florida  
(b) (4) Grinter Hall  
Gainesville, FL 32611-5500

Dear Dr. Norton,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 25, 2022 letter reporting an adverse event involving research mice at the University of Florida. According to the information provided, OLAW understands that following an approved intracranial injection of tumor cells, 22 mice died and 6 required euthanasia. All procedures had been followed as approved.

Although no cause of death was evident, the Institutional Animal Care and Use Committee directed the Principal Investigator to test all substances for contamination, to ensure that all equipment is correctly calibrated and functioning correctly, and to initially use a small cohort of mice upon continuation of the procedure.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to reduce the likelihood of a recurrence of this problem. Although we are closing this case, please provide an update, either positive or negative, regarding the results of the next iteration of this study.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.  
Deputy Director  
Office of Laboratory Animal Welfare

cc: IACUC Chair



A3377-8X

Office of the Vice President for Research

223 Grinter Hall  
PO Box 115500  
Gainesville, FL 32611-5500  
352-392-1582

January 25, 2022

Axel Wolff, DVM  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360  
6705 Rockledge Drive  
Bethesda, MD 20892

Dear Dr. Wolff:

The University of Florida, in accordance with Assurance D16-00244 and PHS Policy IV.F.3., provides this report of an adverse event regarding mice found dead/euthanized following intracranial injection of tumor cells. A preliminary report was not sent to OLAW regarding this adverse event.

Thirty-one mice received intracranial injection of tumor cells on 12/13/21 per the IACUC protocol. One day later, 22 of the mice were found dead during the Animal Care Services morning well-being check, and six were euthanized due to reaching humane endpoint (lethargic, abnormal respirations). The remaining three mice were healthy and active.

The lab performs this procedure routinely. The surgeon involved in the incident has been successfully performing intracranial injections for the past 5 years.

The tumor cells were cultured in the lab in an aseptic situation. Cells were collected in PBS and methylcellulose with a 1:1 ratio.

The IACUC full committee voted on January 18, 2022 that this incident was an adverse event and was reportable through the IO to regulatory agencies. The following corrective actions have been required:

1. All substances used during the procedure must be tested by the PI for potential contamination and results reported to the IACUC.
2. Before repeating this procedure, the PI must provide to the IACUC evidence that the equipment used to conduct the intracranial injections is properly calibrated and functioning correctly.
3. The next time the procedure is performed, it will be limited initially to a small cohort of mice.

*The Foundation for The Gator Nation*

An Equal Opportunity Institution

The animals involved in this adverse event were not funded by PHS.

The University of Florida is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard.

Should you have any questions regarding this report, please contact Daniel R. Brown, Ph.D., IACUC Chair.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

David Norton, Ph.D.  
Vice President for Research  
Institutional Official

(b) (6)

**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, January 28, 2022 7:35 AM  
**To:** Research - IACUC  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: [EXTERNAL] Reportable Adverse Event (2021Dec02) [ ref:\_00D412ElGo.\_5001K15b9sf:ref ]

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

Axel Wolff, M.S., D.V.M.  
Deputy Director, OLAW

**From:** Research - IACUC <iacuc-crm@research.ufl.edu>  
**Sent:** Thursday, January 27, 2022 4:49 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6) drbrown@ufl.edu  
**Subject:** [EXTERNAL] Reportable Adverse Event (2021Dec02) [ ref:\_00D412ElGo.\_5001K15b9sf:ref ]

**CAUTION:** This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

To All Concerned,

I am sending the attached report of an adverse event from the University of Florida (D16-00244). UF did not send a preliminary report for this event.

The protocol involved in this noncompliance is not funded by PHS.

Please acknowledge receipt and let me know if you have any questions.

Best,

(b) (6)

