



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

May 5, 2025

Re: Animal Welfare Assurance  
A3012-01 [OLAW Case 1M]

Kenneth J. Fridley, Ph.D.  
Vice President for Research & Economic Development  
Eastern Virginia Medical School  
735 Fairfax Avenue  
(b) (4)  
Norfolk, VA 23507

Dear Dr. Fridley,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 1, 2025, letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Eastern Virginia Medical School. This letter had not been preceded by a preliminary report to OLAW. It is noted the research project is not supported by PHS funding.

According to the information provided, this office understands that the Eastern Virginia Medical School Institutional Animal Care and Use Committee (IACUC) determined that instances of noncompliance occurred with respect to failure to monitor animals under anesthesia, failure to adhere to the IACUC-approved protocol and institutional policies/procedures. The final report states on December 20, 2024, a mouse was not continuously monitored during an anesthetic procedure by a lab member for adverse effects, which is a protocol requirement. The animal died due to extended exposure to isoflurane while the Principal Investigator (PI) required medical attention from a self-injection incident. It is stated the animal death was not properly reported to the IACUC office in real-time via a dedicated Outlook mailbox by the PI. Per the report, the anesthetic protocol used by the PI was not a protocol-approved anesthetic procedure.

In response to these incidents, the following corrective measures were implemented (in summary):

- The IACUC Chair and the research compliance director reminded the PI that the PI is only allowed to perform procedures approved by the IACUC as outlined in the currently approved protocol. Additionally, the PI was reminded that protocols may be amended.
- The IACUC reiterated to the PI that the PI is solely responsible for maintaining compliance with institutional, regulatory, and funding agency requirements.
- The PI has submitted an amendment request to add the open-drop ISO anesthesia method to the protocol as an approved alternative.
- Another real-time reporting process will replace the dedicated Outlook mailbox reporting procedure. Once finalized and implemented, all relevant staff will receive appropriate training. A reminder to all relevant staff of current reporting requirements will be distributed.
- A project manager (PM) has been assigned to the research project to provide advice and oversight of all aspects of the IACUC-approved protocol and is expected to meet with the PI

and laboratory personnel, at least weekly, to discuss implementation of the approved protocol as it relates to the methodology and progress of the research being conducted. The PM is to provide input regarding proposed amendments to the currently approved protocol. The PM will submit verbal and/or written reports to the IACUC upon request.

- The IACUC approved Guidelines for Handling Noncompliance. This guidance document is a systematic framework for the review of and response to instances of confirmed noncompliance, whether intentional or unintentional. It applies to all faculty, staff, students, and volunteers who use live animal research models at VHS.

Based on its assessment of this explanation, OLAW understands that the Eastern Virginia Medical School has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

JACQUELYN T.  
TUBBS -S

Digitally signed by JACQUELYN T.  
TUBBS -S  
Date: 2025.05.05 13:51:58 -04'00'

Jacquelyn Tubbs, DVM, DACLAM  
Acting Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact



May 1, 2025

Jacquelyn T. Tubbs, D.V.M., DACLAM  
Acting Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare (OLAW)  
National Institutes of Health (NIH)  
6700B Rockledge Drive  
Suite 2500, MSC 6910  
Bethesda, MD 20892

Dear Dr. Tubbs:

**RE: Reportable Incident**  
**Macon & Joan Brock Virginia Health Sciences at Old Dominion University (VHS), Norfolk, Virginia**  
**Animal Welfare Assurance Number D16-00007**

We are writing to inform OLAW that the VHS Institutional Animal Care and Use Committee (IACUC) identified and resolved a deviation from standard practices which was determined to be reportable to your office.

**DoD FUNDING:** The following Department of Defense (DoD) funds provided support for this project: DoD-BCRP. DoD was provided a preliminary report on April 2, 2025, and a final report on April 14, 2025.

In accordance with federal expectation, the IACUC forwarded information regarding this incident to the appropriate sponsored research office for the review of direct costs associated with the procurement, care, and use of the animal(s) related to this deviation, as needed. Relevant costs will be paid from a nonfederal source, as appropriate.

**INCIDENT:** In a protocol investigating the role that EGFR/HER2/RAS/RAF/MEK/MAPK/SHC pathway activation plays in promoting tumor progression and metastasis in an animal model, the following protocol deviations were identified: (1) on December 20, 2024 a mouse was not under constant observation during an anesthetic procedure by a member of the research team for adverse effects, as required by protocol, and died due to prolonged exposure to isoflurane while the PI was attending to an accidental self-injection requiring immediate medical attention in compliance with the Occupational Health protocol with respect to the accidental self-injection; (2) the animal death was properly reported by the PI in the required annual progress report, but it was not properly reported to the IACUC Office in real-time via a dedicated Outlook mailbox by the PI as required; (3) the anesthetic protocol used by the PI during this tumor cell injection procedure, and for 25 other mice on and prior to December 20, 2024, was not a protocol-approved anesthetic procedure. The procedure used, an ambient procedure with an ISO-on cotton ball in a conical tube (open-drop method), is a valid anesthetic procedure for mice, but was not identified in the approved study protocol, which called for anesthetic induction in an induction chamber and maintenance using a nose cone (vaporizer method) for the duration of the injection procedure with a specific rate of ISO mixture.

**PRELIMINARY REPORT:** A preliminary report was provided to DoD on April 2, 2025, but no preliminary report was made to OLAW regarding this incident. The PI has been reminded of that expectation.

**RESOLUTION:** The IACUC approved the following actions to resolve this incident:





1. The IACUC Chair and the research compliance director reminded the PI that the PI is only allowed to perform procedures approved by the IACUC as outlined in the currently approved protocol. Additionally, the PI was reminded that protocols may be amended; however, all amendments must be approved by the IACUC prior to implementation.
2. The IACUC has reiterated to the PI that the PI is solely responsible for maintaining compliance with institutional, regulatory, and funding agency requirements.
3. The PI has submitted an amendment request to add the open-drop ISO anesthesia method to the protocol as an approved alternative.
4. Another real-time reporting process will replace the dedicated Outlook mailbox reporting procedure. Once finalized and implemented, all relevant staff will receive appropriate training. A reminder to all relevant staff of current reporting requirements will be distributed.
5. A project manager (PM) has been assigned to the research project to provide advice and oversight of all aspects of the IACUC-approved protocol and is expected to meet with the PI and laboratory personnel, at least weekly, to discuss implementation of the approved protocol as it relates to the methodology and progress of the research being conducted. Additional meetings may be scheduled at the request of the PM to ensure compliance. Moreover, the PM is to provide input regarding proposed amendments to the currently approved protocol. The PM will submit verbal and/or written reports to the IACUC upon request.
6. The IACUC will consider additional educational and/or corrective actions for the PI if warranted.
7. On April 3, 2025, the IACUC approved Guidelines for Handling Noncompliance. This guidance document is a systematic framework for the review of and response to instances of confirmed noncompliance, whether intentional or unintentional. It applies to all faculty, staff, students, and volunteers who use live animal research models at VHS. The newly approved guidance document has been shared with all animal use PIs and will be used by the IACUC if the PI fails to report a noncompliant event in real-time as required by IACUC guidelines.

VHS is committed to ensuring the humane care and use of animals involved in its animal care and use program and to maintaining compliance with PHS Policy.

Please do not hesitate to follow up should you have questions and/or concerns regarding this matter.

Sincerely,

**Kenneth Fridley**

Digitally signed by Kenneth  
Fridley  
Date: 2025.05.02 08:27:38 -04'00'

Kenneth J. Fridley, Ph.D.  
Vice President for Research & Economic Development  
Institutional Official  
Old Dominion University  
[kfridley@odu.edu](mailto:kfridley@odu.edu)

(b) (6)



(b) (6)

cc: Principal Investigator, VHS  
Department Chair, VHS  
Sr. Associate Vice President for Research, VHS  
IACUC Chair, VHS

## Ware, Teagan (NIH/OD) [E]

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, May 5, 2025 6:49 AM  
**To:** (b) (6)  
**Cc:** Fridley, Kenneth J.; (b) (6); OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: VHS (EVMS) OLAW PHS Assurance Number D16-0007 - Noncompliance Report

Good morning,

Thank you for providing this report, which has been assigned as OLAW case **A3012-1M**. We will send an official response soon.

Best,  
Teagan

Teagan Ware, MS, PMP  
Animal Welfare Program Analyst  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
6700B Rockledge Drive, Room 2505

Phone: 301-435-2390  
Email: [teagan.ware@nih.gov](mailto:teagan.ware@nih.gov)

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**From:** (b) (6)  
**Sent:** Friday, May 2, 2025 3:03 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Fridley, Kenneth J. <kfridley@odu.edu>; (b) (6)  
(b) (6)  
**Subject:** [EXTERNAL] VHS (EVMS) OLAW PHS Assurance Number D16-0007 - Noncompliance Report

Dear Dr. Tubbs:

**RE: Noncompliance Report**  
**Macon & Joan Brock Virginia Health Sciences at Old Dominion University (VHS), Norfolk, Virginia**  
**Animal Welfare Assurance Number D16-0007**

The attached report is sent on behalf of Kenneth J. Fridley, Ph.D., Institutional Official (b) (6). The Principal Investigator will be provided a copy of the report under separate cover. Please do not hesitate to follow up if you have questions about or require additional information regarding this report.

(b) (6)