



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

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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

July 16, 2025

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

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

Dear Dr. Fridley,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 20, 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 supported by NIH funding and the funding component will be notified of the incident.

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 adhere to the IACUC-approved protocol. The final report states on May 27, 2025, two male rats were provided oral ibuprofen in their drinking water prior to surgery. However, this analgesic was not included in the approved protocol. It is stated the protocol includes the use of isoflurane, meloxicam, and buprenorphine. In response to the finding, the animals were taken off oral ibuprofen and meloxicam was administered instead. Per the report, health records revealed the affected animals did not exhibit any adverse effects following the incident. It is understood the Principal Investigator (PI) accepted responsibility for the noncompliance.

The matter was reviewed by the IACUC at the meeting held on June 5, 2025, and the committee accepted the PI's corrective action plan. The plan involved the investigator's assurance that research personnel will be retrained on the protocol and will adhere to the approved protocol. Per the report, the laboratory has been performing cranial surgeries more than 20 years and has a history of compliance with regulatory requirements and institutional guidelines and best practices based on email correspondence.

OLAW appreciates being notified by Eastern Virginia Medical School of this issue. Your reporting of this incident is consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals for institutional self-monitoring, self-reporting, and self-correction. We find no cause for further action by this Office.

Sincerely,

JACQUELYN T.
TUBBS -S

Digitally signed by JACQUELYN T.
TUBBS -S
Date: 2025.07.16 07:57:51 -0400

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

cc: IACUC Contact

Ware, Teagan (NIH/OD) [E]

From: Tubbs, Jacquelyn (NIH/OD) [E]
Sent: Tuesday, July 1, 2025 6:45 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: Fridley, Kenneth J.; (b) (6); Brown, Milton L.; Hosseini, Ali; Robinson, Shannon M.
Subject: RE: REPORTABLE INCIDENT; PHS Assurance Number D16-00007; Macon & Joan Brock VHS @ ODU

Follow Up Flag: Follow up
Flag Status: Flagged

Hello,

Based on the final report, it appeared the corrective action plan may have involved more than the PI's assurance to perform retraining of their staff. Thank you for the clarification and I have no additional questions.

Kind Regards,

J. Tubbs

From: (b) (6)
Sent: Monday, June 30, 2025 4:41 PM
To: Tubbs, Jacquelyn (NIH/OD) [E] <jacquelyn.tubbs@nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Fridley, Kenneth J. <kfridley@odu.edu>; (b) (6)
Hosseini, Ali <hosseia@odu.edu>; Robinson, Shannon M. <s4robins@odu.edu>
Subject: [EXTERNAL] RE: REPORTABLE INCIDENT; PHS Assurance Number D16-00007; Macon & Joan Brock VHS @ ODU

Dear Dr. Tubbs:

The corrective action plan is the Principal Investigator's assurance that laboratory personnel will be retrained on the protocol to ensure adherence to the protocol as approved by the IACUC. This particular laboratory has an established history of compliance with regulatory requirements and institutional guidelines and best practices; therefore, the IACUC determined this event to be an isolated, accidental incident that is not indicative of serious or continuing noncompliance. The IACUC sees no need for a more extensive corrective action plan at this time.

Per the request of the IACUC Chair, I have attached the Principal Investigator's written report of the incident. The laboratory's swift attention to the matter, the PI's prompt reporting, and the laboratory's history of compliance informed the IACUC's decision.

Please do not hesitate to contact me if additional information is required.

Kindest regards,

(b) (6)

(b) (6)

From: Tubbs, Jacquelyn (NIH/OD) [E] <jacquelyn.tubbs@nih.gov>
Sent: Monday, June 30, 2025 6:51 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; (b) (6)
Cc: Fridley, Kenneth J. <kfridley@odu.edu>; (b) (6)
Hosseini, Ali <hosseia@odu.edu>; Robinson, Shannon M. <s4robins@odu.edu>
Subject: RE: REPORTABLE INCIDENT; PHS Assurance Number D16-00007; Macon & Joan Brock VHS @ ODU

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Good morning,

The final report states “In addition, the IACUC accepted the PI’s corrective action plan, which includes the assurance that laboratory personnel will be retrained on the protocol and will adhere to the IACUC-approved protocol.” Please describe the corrective action plan that was accepted by the IACUC regarding this matter.

Kind Regards,

J. Tubbs

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Tuesday, June 24, 2025 6:58 AM
To: (b) (6)
Cc: Fridley, Kenneth J. <kfridley@odu.edu>; (b) (6)
Hosseini, Ali <hosseia@odu.edu>; Robinson, Shannon M. <s4robins@odu.edu>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Tubbs, Jacquelyn (NIH/OD) [E] <jacquelyn.tubbs@nih.gov>
Subject: RE: REPORTABLE INCIDENT; PHS Assurance Number D16-00007; Macon & Joan Brock VHS @ ODU

Good morning,

This report has been assigned as OLAW case **A3012-1N**. We will send an official response soon.

Disclaimer: Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected, or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

Best,
Teagan

June 20, 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 of off-protocol activity related to the IACUC-approved protocol, entitled "Effects of Social Isolation and Loneliness during Early Life on Neurocognitive Development and Addiction," which is supported by NIH National Institute on Drug Abuse (NIDA) Grant 1R34DA061156-01. The incident was reported to the VHS Institutional Animal Care and Use Committee (IACUC) by the Principal Investigator (PI). The NIH funding agency and the institutional sponsored research office will be informed of the self-report. Relevant costs will be paid from a nonfederal source, as appropriate.

The research laboratory has performed cranial surgeries for more than 20 years and currently has three IACUC-approved surgical (craniotomy) protocols. The protocol referenced in this report is designed to develop methods to assess the effects of social isolation (SI) and enhanced social isolation (ESI) on brain development and addictive behaviors using a rodent model where cranial implants are surgically placed to record sleep and local field potentials. Approved pre-operative anesthetic and analgesic agents include isoflurane, meloxicam, and buprenorphine. On May 27, 2025, two male rats were administered oral ibuprofen in their drinking water prior to surgery, which is not included in the approved protocol as a pre-operative analgesic procedure although it is included in the laboratory's two other protocols. Immediately upon detection, the rats were taken off oral ibuprofen and given meloxicam as described in the approved protocol. One animal was administered meloxicam approximately 4.5 hours following surgery and the other approximately 3 hours post-surgery. Health check records document that both animals were bright, alert, and responsive the following morning and no adverse effects were noted in either animal thereafter. The PI accepted full responsibility for the incident.

The IACUC reviewed the noncompliance report at its June 5, 2025 meeting and determined that the incident was accidental and not indicative of serious or continuing noncompliance. In addition, the IACUC accepted the PI's corrective action plan, which includes the assurance that laboratory personnel will be retrained on the protocol and will adhere to the IACUC-approved protocol.

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,

(b) (6)

Kenneth J. Fridley, Ph.D.
Vice President for Research & Economic Development
Institutional Official
Old Dominion University
kfridlev@odu.edu

(b) (6)

KJF/(b) (6)

cc: Principal Investigator
IACUC Chair
Sponsored Programs and Research Development Office
NIH NIDA Grants Management Office

Ware, Teagan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, June 24, 2025 6:58 AM
To: (b) (6)
Cc: Fridley, Kenneth J.; Mu, David; Brown, Milton L.; Hosseini, Ali; Robinson, Shannon M.; OLAW Division of Compliance Oversight (NIH/OD); Tubbs, Jacquelyn (NIH/OD) [E]
Subject: RE: REPORTABLE INCIDENT; PHS Assurance Number D16-00007; Macon & Joan Brock VHS @ ODU

Good morning,

This report has been assigned as OLAW case **A3012-1N**. We will send an official response soon.

***Disclaimer:** Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected, or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.*

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

From: Tubbs, Jacquelyn (NIH/OD) [E] <jacquelyn.tubbs@nih.gov>
Sent: Tuesday, June 24, 2025 6:14 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) Fridley, Kenneth J. <kfridley@odu.edu>; (b) (6) Hosseini, Ali <hosseia@odu.edu>; (b) (6)
(b) (6)
Subject: RE: REPORTABLE INCIDENT; PHS Assurance Number D16-00007; Macon & Joan Brock VHS @ ODU

Good morning,

Thank you for the preliminary report. A case number will be assigned and we look forward to receiving the final report.

Kind Regards,

J. Tubbs

From: (b) (6)

Sent: Monday, June 23, 2025 4:07 PM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: Tubbs, Jacquelyn (NIH/OD) [E] <jacquelyn.tubbs@nih.gov>; Moore, Holly (NIH/NIDA) [E] <holly.moore@nih.gov>;
Fridley, Kenneth J. <kfridley@odu.edu>; (b) (6) Hosseini,
Ali <hosseia@odu.edu>; (b) (6)

Subject: [EXTERNAL] REPORTABLE INCIDENT; PHS Assurance Number D16-00007; Macon & Joan Brock VHS @ ODU

Dear Dr. Tubbs:

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

The attached report is sent on behalf of the Macon & Joan Brock Virginia Health Sciences at Old Dominion University (VHS), Kenneth J. Fridley, Ph.D., ODU Institutional Official, and (b) (6). The Principal Investigator is aware of the report and will be provided a copy of the fully executed document under separate cover.

Please feel free to contact me should you have questions and/or concerns regarding this matter.

Kindest regards

(b) (6)