



Office of Laboratory Animal Welfare
Bethesda, Maryland 20892

Telephone: (301) 496-7163
Home Page: <https://olaw.nih.gov>

December 4, 2025

Re: Animal Welfare Assurance
A3456-01 [OLAW Case 11R]

Joanne Billings, MD, MPH
Interim Vice President for Research and Innovation
University of Minnesota – Main Campus
(b) (4)

200 Oak St. SE
Minneapolis, MN 55455

Dear Dr. Billings,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 12, 2025, letter reporting an adverse event at the University of Minnesota. This letter had not been preceded by a preliminary report to OLAW. It is noted that this study is supported by PHS funding.

According to the information provided, this office understands that the University of Minnesota Institutional Animal Care and Use Committee (IACUC) determined that an incident occurred with respect to conditions that jeopardize the health or well-being of animals, resulting in the death of animals. The final report states that between August 2024 and April 2025, a total of 6 sheep were either euthanized, found dead post-operatively, or died during the procedure, which constituted a higher-than-expected mortality for an IACUC-approved study involving surgical implantation.

Per the final report, the Principal Investigator (PI) and study team worked with veterinary staff to adjust anticoagulant dosing and timing, as well as adding pre-operative assessment of adequate hematocrit and hemoglobin. The IACUC requested a voluntary pause on surgeries for this study to allow for a thorough assessment of factors that may have contributed to the complications experienced. After extensive review of records and discussion with the PI, the committee required the PI to identify a new surgeon for the procedure, adjust anesthetic monitoring parameters, and improve surgical recordkeeping. With these changes in place, the IACUC has now cleared implant surgery to resume with direct veterinary oversight throughout at least the first surgery. The need for any further procedural changes and/or continued veterinary oversight of surgeries will be assessed based on outcomes. The IACUC, in collaboration with veterinary staff, will continue to monitor the success of this study closely through both direct observation and review of records. With this, the IACUC determined the corrective action plan was adequate, and no further action was required.

Based on its assessment of this explanation, OLAW understands that the University of Minnesota has implemented appropriate measures to correct and prevent recurrence of these problems. We appreciate being informed of this matter and find no cause for further action by this Office.

Sincerely,

Angelina M. Williams -S Digitally signed by Angelina M. Williams -S
Date: 2025.12.04 17:26:05 -05'00'

Angelina Williams, DVM, MPH, DACLAM, DACVPM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

(b) (4)

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Institutional Animal Care and Use Committee (IACUC) Office

(b) (4)

200 Oak St SE (b) (4)
Minneapolis, MN 55455

Phone: (b) (6)

iacuc@umn.eduwww.research.umn.edu/units/iacuc

November 12, 2025

TO: Axel Wolff, DVM
Office of Laboratory Animal Welfare
National Institutes of Health
RKL1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

RE: University of Minnesota Animal Care Program D16-00288 (A-3456-01)
NIH Grant Number: 5R61HL161755-02
UMN IACUC #40700A

Dear Dr. Wolff,

In keeping with the terms of our assurance, please be informed that we are making a report of an unanticipated adverse event on an IACUC approved, NIH funded study involving sheep. The basis of this report results from a self-reported incident. The report outlined that between August 2024 and April 2025, higher than expected mortality was observed in an IACUC-approved study involving surgical implantation of a transcatheter vein valve.

Out of six animals undergoing surgery during this period, one animal was found dead during the post-operative period, potentially due to hemorrhage or stroke, and two required euthanasia shortly after surgery due to complications involving hemostasis at the surgical site. Two additional animals were euthanized due to the test article not functioning as desired.

We want to inform you that we believe appropriate steps have been taken to prevent recurrence. The PI and study team worked with veterinary staff to adjust anticoagulant dosing and timing, as well as adding pre-operative assessment of adequate hematocrit and hemoglobin. After notification of the issues on this study, the IACUC requested, and the PI agreed to, a voluntary pause on surgeries for this study to allow for a thorough assessment of factors that may have contributed to the complications experienced. After extensive review of records and discussion with the PI, the committee required the PI to identify a new surgeon for the procedure, adjust anesthetic monitoring parameters, and improve surgical recordkeeping. With these changes in place, the IACUC has now cleared implant surgery to resume with direct veterinary oversight throughout at least the first surgery. The need for any further procedural changes and/or continued veterinary oversight of surgeries will be assessed based on outcomes.

The IACUC, in collaboration with veterinary staff, will continue to monitor the success of this study closely through both direct observation and review of records.

Sincerely,

(b) (6)

Joanne Billings, MD, MPH
Associate Vice President for Research Integrity and Compliance
Deputy Institutional Official, University of Minnesota

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Institutional Animal Care and Use Committee (IACUC) Office

(b) (4)

200 Oak St SE (b) (4)
Minneapolis, MN 55455

Phone: (b) (6)

iacuc@umn.edu

www.research.umn.edu/units/iacuc

200 Oak Street, S.E.
Minneapolis, MN 55455

CC: Erin Dickerson, Chair, IACUC
Nate Koewler, Institutional Veterinarian
AAALAC

Ware, Teagan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, November 13, 2025 1:10 PM
To: (b) (6)
Cc: Joanne Billings; Erin Dickerson; Nate Koewler; OLAW Division of Compliance Oversight (NIH/OD); Tracey Mavetz
Subject: RE: [EXTERNAL] OLAW non-compliance report for UMN IACUC #40700A

Good afternoon,

Thank you for providing this report, which has been assigned as OLAW case **A3456-11R**. 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
6705 Rockledge Drive (RKL 1), MSC 7983

Phone: 301-435-2390
Email: teagan.ware@nih.gov

From: (b) (6)
Sent: Thursday, November 13, 2025 10:57 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Joanne Billings <billi001@umn.edu>; Erin Dickerson <edickers@umn.edu>; Nate Koewler <koew0004@umn.edu>; AAALAC International <accredit@aaalac.org>; (b) (6)
Subject: [EXTERNAL] OLAW non-compliance report for UMN IACUC #40700A

Dear Dr. Wolff,

Attached please find the non-compliance letter sent on behalf of Deputy IO Billings.

Thank you,

(b) (6)

