



January 26, 2026

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

Joanne Billings, MD, MPH
Interim Vice President for Research and Innovation
University of Minnesota – Main Campus
224 McNamara Alumni Center
200 Oak St. SE
Minneapolis, MN 55455

Dear Dr. Billings,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 20, 2026, letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals 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 instances of noncompliance occurred with respect to failure to adhere to IACUC-approved protocols and conditions that jeopardize the health and well-being of animals. The final report states that between February 2025 and November 2025, higher than expected mortality occurred in a study involving pigs. Per the report, an investigation was conducted, and several instances of protocol noncompliance were identified (i.e., inadequate intraoperative monitoring, failure to adhere to blood collection frequency and anesthetic administration as outlined in the protocol, and suspected thermal burns).

Per the final report, the IACUC discussed the incidents and requested that the Principal Investigator voluntarily pause the surgeries on this study to allow for a thorough assessment of factors contributing to the complications experienced. In summary, several recommendations were made regarding modifications to the protocol and refinements in surgical practices which are required to be incorporated into the protocol amendment. Once the amendment is approved, transplant surgery may resume in one animal with increased veterinary oversight and submission of all relevant records for IACUC review. The need for any further procedural changes and/or continued veterinary oversight of surgeries will be assessed based on outcomes. 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 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,

Angelina M. Williams -S Digitally signed by Angelina M. Williams -S
Date: 2026.01.26 10:09:30 -05'00'
Angelina Williams, DVM, MPH, DACLAM, DACVPM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact
Louis DiVincenti, Senior Veterinary Medical Officer - Research

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Institutional Animal Care and Use Committee (IACUC) Office

(b) (4)
Room 224 McNamara Ctr
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Minneapolis, MN 55455
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iacuc@umn.edu
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January 20, 2026

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: R01 DK117425
NSF Grant Number: 1941543
UMN IACUC #42583A

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 and associated protocol noncompliance on an IACUC approved, NIH and NSF funded study involving pigs. The basis of this report results from a self-reported incident. The report outlined that between February 2025 and November 2025, higher than expected mortality was observed in an IACUC-approved study in a model involving auto-transplant of cryopreserved kidneys in pigs. During investigation of these events by the IACUC, the following instances of noncompliance with the protocol were also identified: lack of blood pressure monitoring during surgery in three animals, blood collected from one animal at a higher frequency than approved, anesthetic agent dosing at a higher level than approved in one animal, and one animal in which body temperature was not maintained within the approved range.

Out of nine animals undergoing surgery during this period, five required euthanasia shortly after surgery due to complications, including poor kidney function and potential infection. One animal died under anesthesia during surgery due to cardiac arrest. Two additional animals were euthanized prior to transplant due to failure of the rewarming process for the cryopreserved kidney. Additionally, heat pad burns were suspected in one animal and cautery burns were suspected in another animal.

We want to inform you that we believe appropriate steps have been taken to prevent recurrence of these adverse events and noncompliances. 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 identified the noncompliances described above as well as several recommendations for modifications to the protocol and refinements in surgical practices. The IACUC is requiring that a protocol amendment be submitted to incorporate these changes and that the PI comply with all requirements of the amended protocol. Once the amendment is approved, transplant surgery may resume in one animal with increased veterinary oversight and submission of all relevant records to the IACUC for review. 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 compliance and success of this study closely through both direct observation and review of records.

Sincerely,

(b) (6)

Joanne Billings, MD, MPH
Interim Vice President for Research and Institutional Official

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

Ware, Teagan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, January 21, 2026 6:55 AM
To: (b) (6)
Cc: Erin Dickerson; Nate Koewler; OLAW Division of Compliance Oversight (NIH/OD); Ilana Cohen; Joanne Billings
Subject: RE: [EXTERNAL] OLAW non-compliance report for NIH Grant R01 DK117425 and NSF Grant 1941543

Good morning,

Thank you for providing this report, which has been assigned as OLAW case **A3456-11T**. 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: Tuesday, January 20, 2026 6:04 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Erin Dickerson <edickers@umn.edu>; Nate Koewler <koew0004@umn.edu>; Ilana Cohen <iecohen@umn.edu>; Joanne Billings <billi001@umn.edu>; accredit@aaalac.org
Subject: [EXTERNAL] OLAW non-compliance report for NIH Grant R01 DK117425 and NSF Grant 1941543

Dear Dr. Wolff,

Attached please find the report sent on behalf of VP Billings.

Kindly,
(b) (6)

