



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

June 30, 2022

Re: Animal Welfare Assurance
#A3456-01 [OLAW Case 10E]
UMN IACUC #37029A

Dr. Michael J. Oakes
Interim Vice President for Research
University of Minnesota
(b) (4) Johnston Hall - 101 Pleasant St., SE
Minneapolis, MN 55455

Dear Dr. Oakes,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 2, 2022 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.

According to the information provided, this Office understands that the University of Minnesota Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to the conduct of animal activities prior to IACUC review and approval. The final report states one rat that previously underwent a left orthotopic kidney transplant with right native nephrectomy, underwent a second major survival surgery the following day to examine the status of the transplanted kidney. The second surgical procedure was not approved in the protocol. It is stated the veterinary staff observed the rat in poor health and euthanasia was performed by the research staff.

In response to the incident, the Principal Investigator (PI) halted second surgical procedures on rat kidney transplants until an amended protocol was approved by the IACUC, describing the second surgical procedures, including health monitoring and interventions related to the second surgery. Also, the PI has retrained the lab members to reinforce the need to review the approved protocol prior to performing procedures to ensure protocol compliance. Per the report, the IACUC will monitor ongoing compliance through semiannual surgical inspections and annual post-approval monitoring.

It is noted that this research is supported by NIH funding. 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.

Page 2 – Dr. Oakes
June 30, 2022
OLAW Case A3456-10E

Sincerely,

Jacquelyn

Digitally signed by Jacquelyn T.
Tubbs -S

T. Tubbs -S

Date: 2022.06.30 15:28:15 -0400

Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

McCoy, Devora (NIH/OD) [E]

From: McCoy, Devora (NIH/OD) [E]
Sent: Thursday, June 30, 2022 4:42 PM
To: oakes007@umn.edu
Cc: OLAW Division of Compliance Oversight (NIH/OD); impell@umn.edu; [REDACTED] (b) (6)
Subject: OLAW Case A3456-10F and A3456-10E
Attachments: SIGNED Compliance Case University of Minnesota 10F.pdf; SIGNED Compliance Case University of Minnesota 10E.pdf

Good afternoon Dr. Oakes,

Attached please find Dr. Tubbs' final responses to OLAW Cases A3456-10F and A3456-10E. If you have any questions, feel free to contact us by phone or by e-mail.

Best,
Devora

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

A3456-105

UNIVERSITY OF MINNESOTA

Twin Cities Campus

Institutional Animal Care and Use Committee (IACUC)

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Minneapolis, MN 55455
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June 2, 2022

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
UMN IACUC #37029A

Dear Dr. Wolff,

In keeping with the terms of our assurance, please be informed that we are making a report of non-compliance of an IACUC approved, NIH funded study involving rats. The basis of this report results from a self-reported incident. The report outlined that one rat that had undergone a left orthotopic kidney transplant with right native nephrectomy underwent a second major survival surgery the following day to examine the status of the transplanted kidney. This second surgical procedure to examine the kidney was not approved on the IACUC protocol. This deviation in protocol occurred on April 10, 2022 and involved one rat. The rat was noted by veterinary staff to be in poor health and was euthanized by lab staff on April 11, 2022 as requested by the veterinarian.

We want to inform you that we consider this matter closed. The PI ceased second surgical procedures on rat kidney transplants until an amended protocol was approved by the IACUC that described second surgical procedures as well as health monitoring and interventions relevant to the second surgery. In addition, the PI has retrained lab staff to reinforce the need to review the approved IACUC protocol before performing procedures to ensure that the protocol is adhered to. The IACUC will monitor ongoing compliance in this lab through semi-annual surgical inspections and annual post approval monitoring.

Sincerely,

(b) (6)

J. Michael Oakes, Ph.D.
Interim Vice President for Research
Institutional Official, University of Minnesota
101 Pleasant Street, S.E.
Minneapolis, MN 55455

CC: Richard Bianco, Chair, IACUC
Lynn Collura Impelluso, Institutional Veterinarian

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, June 3, 2022 7:52 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: [EXTERNAL] Two Reports

Thank you for this report. We will reply shortly.

Best,

Devora McCoy, BS, MBA
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
301-435-2390

From: (b) (6)
Sent: Thursday, June 2, 2022 2:06 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) Lynn Impelluso <impell@umn.edu>; Richard Bianco <bianc001@umn.edu>;
(b) (6)
Subject: [EXTERNAL] Two Reports

Dear Dr. Wolff,

Attached please find two reports-one of non-compliance and one of an adverse event. Please let me know if you have any questions.
Thank you,

(b) (6)