



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

February 7, 2022

Re: Animal Welfare Assurance  
#A3456-01 [OLAW Case 10A]  
UMN IACUC #38012A

Dr. Michael J. Oakes  
Interim Vice President for Research  
Institutional Official  
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 December 3, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at the University of Minnesota. According to the information provided, OLAW understands that 9 newborn mice were toe-clipped for identification purposes by a researcher. Although the procedure was performed as described in an existing University of Minnesota policy, this method of identification was not in the approved protocol. The incident was discovered during a routine post-approval monitoring inspection and no welfare concerns were reported. The mice involved in this incident were supported by NIH funding.

Corrective and preventive measures included retraining of the principal investigator and laboratory staff, who have confirmed that they will ensure all procedures are approved on the protocol prior to initiating them in the laboratory. Additionally, an amendment to add the toe-clipping procedure was submitted to the IACUC and has been approved.

OLAW appreciates the consideration of this matter by the University of Minnesota which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident and prevent recurrence. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Robyn M. Engel -S

Digitally signed by Robyn M.  
Engel -S  
Date: 2022.02.07 07:43:56 -05'00'

Robyn M. Engel, DVM  
Animal Welfare Program Specialist  
Office of Laboratory Animal Welfare

CC: IACUC contact

A3456-10A

# UNIVERSITY OF MINNESOTA

*Twin Cities Campus*

*Institutional Animal Care and Use Committee (IACUC)*

Mayo Mail Code 79  
D-528 Mayo Memorial Building  
420 Delaware St. SE  
Minneapolis, MN 55455  
Phone: 612-626-2126  
Fax: 612-626-6061  
[iacuc@umn.edu](mailto:iacuc@umn.edu)  
[www.research.umn.edu/iacuc](http://www.research.umn.edu/iacuc)

December 3, 2021

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: K01DK119634  
UMN IACUC #38012A

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 mice. The basis of this report results from a routine post approval monitoring inspection. During the inspection, it was discovered that 9 newborn mice were toe-clipped for identification purposes prior to IACUC approval for the procedure. The unapproved procedure was performed on 9 pups on September 14, 2021 and October 5, 2021.

We want to inform you that we consider this matter closed. Lab staff immediately ceased toe-clipping procedures and submitted an amendment to the protocol, which has now been approved by the UMN IACUC. The PI and lab staff have been re-trained and confirm that they will ensure all procedures are approved on the protocol prior to initiating them in the lab. Additionally, we would like to inform you that all toe-clipping procedures were performed according to the University of Minnesota IACUC Policy on Animal Identification by Toe Clipping and no welfare concerns were reported.

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

**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, December 6, 2021 7:22 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Reports of Non-Compliance UMN IACUC #38606A, UMN IACUC #38012A

Thank you for these reports, (b) (6) We will send responses soon.

Axel Wolff

**From:** (b) (6)  
**Sent:** Friday, December 3, 2021 4:04 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Lynn Impelluso <impell@umn.edu>; Richard Bianco <bianc001@umn.edu>; (b) (6)  
(b) (6)  
**Subject:** Reports of Non-Compliance UMN IACUC #38606A, UMN IACUC #38012A

Dear Dr. Wolff,

On behalf of Vice President Michael Oakes, attached please find two reports of non-compliance. Please let me know if you have any questions.  
Thank you,

(b) (6)