



DEPARTMENT OF HEALTH & HUMAN SERVICES

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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

May 31, 2022

Re: Animal Welfare Assurance  
#A3456-01 [OLAW Case 10C]  
UMN IACUC #38606A

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 May 4, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the March 25, 2022 following up on an initial University of Minnesota (UMN) notification by email.

According to the information provided, this Office understands that the UMN Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: suspension of a researcher's privilege to work with animals. The Principal Investigator's (PI) research was formally suspended by the IACUC on March 22, 2022. The initial report indicated the IACUC planned to review the progress of the PI intermittently until an adequate plan for correction was identified, satisfactory progress verified, and the researcher demonstrated understanding of and ability to fulfill the requirements of the IACUC and the obligations inherent in the conduct of research using animal subjects.

The final report states on May 3, 2022, the committee discussed the PI's corrective action plan. The PI and laboratory worked closely with various groups to identify the causes of previous compliance issues and to implement the following actions:

- Retraining of all lab members on IACUC policies, protocol content, rat handling and anesthesia, recordkeeping, and chemical safety. This retraining included both online and hands-on components and is reflected in updated personnel training records that were submitted to the IACUC.
- Updates to recordkeeping forms and practices. A staff member will now be dedicated to animal monitoring and documentation for future anesthetic procedures, and record templates have been updated to prompt documentation of all required parameters. The updated templates were submitted to the IACUC.
- Reorganization of IACUC protocols, closing two protocols and updating the remaining one to include all animal procedures that will be conducted going forward.
- Addition of experienced staff to the lab's protocol to assist with procedures and provide ongoing procedural training.

It is understood the IACUC determined the corrective actions will allow the PI and research staff to adhere to compliance moving forward. As a result, the committee unanimously voted to reinstate the privileges of the PI to work with animals. It is also understood that future compliance will be monitored by monthly submission of procedural records, unannounced post-approval monitoring, and regularly scheduled surgical and post-approval monitoring inspections.

Page 2 – Dr. Oakes  
May 31, 2022  
OLAW Case A3456-10C

It is noted that this research is supported by PHS funding. Your prompt and thorough resolution of this matter is commendable and consistent with the PHS Policy philosophy of monitored self-regulation. We appreciate having been informed of these matters and find no cause for further action by this Office.

We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,  
Jacquelyn T.  
Tubbs -S

Digitally signed by Jacquelyn  
T. Tubbs -S  
Date: 2022.05.31 14:22:46  
+04'00'

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

cc: IACUC Contact

# 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)

May 4, 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 Numbers: 1R01MH127548-01, P41EB027061  
UMN IACUC #37521A, #38940A, #39251A

Dear Dr. Wolff,

The following is a final report regarding the suspension of a University of Minnesota PI that was originally reported to you on March 25<sup>th</sup>, 2022. We can confirm that the funding component has been informed of the suspension, that all animals were placed on the holding protocol during the suspension, that no animal activities were performed and that the grants were not charged.

The UMN IACUC reviewed and discussed the principal investigator's corrective action plan during a full committee meeting on May 3, 2022. The PI and laboratory have worked closely with representatives of the IACUC, animal care staff, and environmental health and safety staff to identify the causes of previous compliance issues and implement the following steps:

- Retraining of all lab members on IACUC policies, protocol content, rat handling and anesthesia, recordkeeping, and chemical safety. This retraining included both online and hands-on components and is reflected in updated personnel training records that were submitted to the IACUC.
- Updates to recordkeeping forms and practices. A staff member will now be dedicated to animal monitoring and documentation for future anesthetic procedures, and record templates have been updated to prompt documentation of all required parameters. The updated templates were submitted to the IACUC.
- Reorganization of IACUC protocols, closing two protocols and updating the remaining one (#38940A) to include all animal procedures that will be conducted going forward.
- Addition of experienced staff to the lab's protocol to assist with procedures and provide ongoing procedural training.

The committee feels that the corrective actions outlined above will allow the investigator and research group to conduct animal research in compliance moving forward. Therefore, the committee voted unanimously at this meeting to reinstate the investigator's privilege to work with animals. We consider the matter closed at this time.

Future compliance will be monitored by monthly submission of procedural records, unannounced post approval monitoring, and regularly scheduled surgical and post approval monitoring inspections.

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:** Friday, May 6, 2022 7:44 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: [EXTERNAL] Update on UMN IACUC #37521A, #38940A, #39251A

Thank you for this update, (b) (6) We will send a response soon.  
Axel Wolff

**From:** (b) (6)  
**Sent:** Wednesday, May 4, 2022 12:28 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Lynn Impelluso <impell@umn.edu>; Richard Bianco <bianc001@umn.edu>  
**Subject:** [EXTERNAL] Update on UMN IACUC #37521A, #38940A, #39251A

Dear Dr. Wolff,

Attached please find an update to reports #37521A, #38940A, and #39251A.  
Thank you,

(b) (6)

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(b) (6)

**CAUTION:** This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

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

AD to open case

A3456-10C

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, April 22, 2022 11:51 AM  
**To:** Bennett, Yvonne (NIH/NIMH) [E]  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** FW: Notice of IACUC Suspension - R01MH127548

**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-081.html>  
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-044.html>

Hello Dr. Bennett,

Attached are two Notices which address actions to be taken during a suspension. The grant is not to be charged for any research activities involving animals. Animal upkeep or per diem could be charged if an agreement is made with the funding component.  
We will copy you on the outcome of this case upon resolution.

Axel Wolff, M.S., D.V.M.  
Deputy Director, OLAW

**From:** Bennett, Yvonne (NIH/NIMH) [E] <[yvonne.bennett@nih.gov](mailto:yvonne.bennett@nih.gov)>  
**Sent:** Friday, April 22, 2022 11:26 AM  
**To:** Laboratory Animal Welfare, Office of (NIH/OD) <[OLAW@OD.NIH.GOV](mailto:OLAW@OD.NIH.GOV)>  
**Cc:** Chia, Jackie (NIH/NIMH) [E] <[jackie.chia@nih.gov](mailto:jackie.chia@nih.gov)>; Diggs, Julius (NIH/NIMH) [E] <[julius.diggs@nih.gov](mailto:julius.diggs@nih.gov)>; Farber, Greg (NIH/NIMH) [E] <[farberg@mail.nih.gov](mailto:farberg@mail.nih.gov)>  
**Subject:** FW: Notice of IACUC Suspension - R01MH127548

Dear OLAW, I am forwarding this notice. Please let us know how to proceed.

Yvonne

Yvonne M. Bennett, Ph.D.  
Program Officer, NIMH  
Office of Technology Development and Coordination

(b) (6)

**From:** (b) (6)  
**Sent:** Friday, April 8, 2022 8:50 AM  
**To:** Chia, Jackie (NIH/NIMH) [E] <[jackie.chia@nih.gov](mailto:jackie.chia@nih.gov)>; Bennett, Yvonne (NIH/NIMH) [E] <[yvonne.bennett@nih.gov](mailto:yvonne.bennett@nih.gov)>  
**Cc:** (b) (6)  
**Subject:** Notice of IACUC Suspension - R01MH127548

Good Morning,

I am writing to report that at its meeting held on March 22, 2022, the University's institutional Animal Care and Use Committee (IACUC) suspended the animal work being conducted at the University under the above referenced grant. During the suspension period, no costs related to the animal work will be incurred/charged to this project.

Please note that this suspension impacts the animal work conducted at the University of Minnesota only. The animal work being conducted at the University of Eastern Finland, our foreigner partner under this award, is not been affected by this suspension.

At this time, (b) (6) are working with the IACUC on a corrective action plan. They expect the required materials will be submitted to the IACUC by the end of the month so it reaches them in time for their meeting on May 3rd. During this period, they will also be continuing with the theoretical and development work on phantoms, so no long lasting impact on the project is expected.

Should you have any questions or require further information, please let me know. We will notify you as soon as the IACUC approval is reinstated.

Thank you,

(b) (6)





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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, May 6, 2022 7:41 AM  
**To:** Laboratory Animal Welfare, Office of (NIH/OD)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: [EXTERNAL] Re: Notice of IACUC Suspension - R01MH127548

Thank you Neera. DCO will continue with this case.  
Axel

**From:** Laboratory Animal Welfare, Office of (NIH/OD) <OLAW@OD.NIH.GOV>  
**Sent:** Wednesday, May 4, 2022 11:49 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>  
**Subject:** FW: [EXTERNAL] Re: Notice of IACUC Suspension - R01MH127548

Dear Brent and Axel,

Please see the report of an IACUC suspension below for DCO's acknowledgement and records.

Thanks.  
Neera

**From:** Bennett, Yvonne (NIH/NIMH) [E] <yvonne.bennett@nih.gov>  
**Sent:** Wednesday, May 04, 2022 11:23 AM  
**To:** Laboratory Animal Welfare, Office of (NIH/OD) <OLAW@OD.NIH.GOV>  
**Cc:** Chia, Jackie (NIH/NIMH) [E] <jackie.chia@nih.gov>  
**Subject:** FW: [EXTERNAL] Re: Notice of IACUC Suspension - R01MH127548

Dear OLAW, we are forwarding this update to you - please let us know if we need to do anything.  
Yvonne Bennett  
Program Officer  
NIMH  
Office of Technology Development and Coordination

**From:** (b) (6)  
**Sent:** Wednesday, May 4, 2022 7:26 AM  
**To:** Chia, Jackie (NIH/NIMH) [E] <jackie.chia@nih.gov>; Bennett, Yvonne (NIH/NIMH) [E] <yvonne.bennett@nih.gov>  
**Cc:** (b) (6)  
**Subject:** [EXTERNAL] Re: Notice of IACUC Suspension - R01MH127548

Good Morning,

In follow up to my April 8<sup>th</sup>, I am writing to advise you that the University's Institutional Animal Care and Use Committee (IACUC) has voted to reinstate the use of animals under the above referenced grant. A copy of their email notification is provided below.



----- Forwarded message -----

From: iacuc Inst Animal Care and Use Committee <[iacuc@umn.edu](mailto:iacuc@umn.edu)>

Date: Tue, May 3, 2022 at 4:54 PM

Subject: IACUC Suspension of Animal Work Lifted

To: [REDACTED] (b) (6)

Cc: [REDACTED]

Dear [REDACTED] (b) (6)

At the May 3, 2022 IACUC meeting the committee discussed the steps you have taken to improve research compliance in your lab. The committee appreciates the cooperation that you and your staff have demonstrated and the extensive retraining on animal handling, recordkeeping, and chemical safety that has been completed.

The committee has voted to reinstate your use of animals. Any animals on the RAR holding protocol may be transferred back to your protocol, effective immediately.

The committee requests that you delay resuming animal experiments until the amendment for protocol 2103-38940A is approved, so that the changes proposed in the amendment can be implemented.

In addition, the committee requests that you submit procedural (i.e. anesthetic, surgical) records on a monthly basis for committee review. These can be sent to [iacuc@umn.edu](mailto:iacuc@umn.edu).

Sincerely,

[REDACTED] (b) (6)

As previously noted, the suspension only applied to work conducted at the University of Minnesota.

Should you have any questions or require further information, please let me know.

Thank you,

[REDACTED] (b) (6)

## 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)

March 25, 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 Numbers: 1R01MH127548-01, P41EB027061  
UMN IACUC #37521A, #38940A, #39251A

Dear Dr. Wolff,

In keeping with the terms of our assurance, please be informed that we are making a report of a suspension of a researcher's privilege to work with animals. This researcher does receive NIH funding. Suspension of these activities occurred during a convened IACUC meeting held on March 22, 2022.

The committee formally suspended the PI's animal research program indefinitely and will review the progress of the PI intermittently until an adequate plan for correction can be identified, satisfactory progress is verified, and the researcher demonstrates understanding of and ability to fulfill the requirements of the IACUC and the obligations inherent in the conduct of research using animal subjects. We consider this a preliminary report and will submit an interim or final report with additional details by May 1, 2022.

The Institution takes these matters very seriously. If you have any questions, please feel free to contact the IACUC Chair, Richard Bianco at (b) (6) or our Institutional Veterinarian, Dr. Lynn Impelluso, at (b) (6)

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, March 28, 2022 7:09 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: [EXTERNAL] Suspension Letter

Thank you for this preliminary report, (b) (6). We will open a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation. Please also report the suspension to the NIH funding component.

Axel Wolff

**From:** (b) (6)  
**Sent:** Friday, March 25, 2022 2:16 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Richard Bianco <bianc001@umn.edu>; Lynn Impelluso <impell@umn.edu>  
**Subject:** [EXTERNAL] Suspension Letter

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Dear Dr. Wolff,

On behalf of interim Vice President Michael Oakes, attached please find a letter outlining the suspension of a researcher's privilege to work with animals.

Please let me know if you have any questions.

Thank you,

(b) (6)

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(b) (6)