



DEPARTMENT OF HEALTH & HUMAN SERVICES  
HEALTH

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF

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

July 11, 2022

Re: Animal Welfare Assurance  
#A3456-01 [OLAW Case 9Y]  
UMN IACUC #37090A, #36898A

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 July 6, 2022 letter providing an update/final report on the actions taken in response to the suspension of an animal activity at the University of Minnesota reported on August 21, 2021. According to all of the information provided in reference to this case, OLAW understands the following:

- On August 26, 2021 the University of Minnesota notified OLAW that a cat on an NIH grant and approved institutional protocol was overdosed with a paralytic agent. Although a reversal drug was given, the veterinary staff directed euthanasia due to potential organ damage caused by hypovolemia and hypoxemia. Due to other issues of concern in this laboratory, the Institutional Animal Care and Use Committee (IACUC) formally suspended the study.
- On August 30, 2021, OLAW acknowledged the report of suspension and posed numerous questions regarding the corrective action plan, confirmation that the funding component was notified of the suspension, confirmation regarding use of a holding protocol and that the grant was not charged for animal activities during the suspension period, request for information on how depth of anesthesia is measured during application of a paralytic agent, details of the suspension, any post-approval monitoring (PAM) plans, and an explanation of other animal related problems identified in this laboratory.
- On September 19, 2021, the Principal Investigator (PI) on the suspended cat study informed the NIH Program Officer of the suspension and on personnel changes in the laboratory which impacted the project. The details leading to the suspension by the IACUC were outlined. As noted above, one cat was inadvertently administered 4.5X the approved dosage of a paralytic drug and the animal was euthanized at the direction of the veterinarian. This followed up on the euthanasia of three other cats due to respiratory complications. The PI presented a corrective action plan to the IACUC.
- On September 21, 2021 OLAW contacted the NIH/NIMH Program Officer and the Director, Office of Technology Development and Coordination to inform them of the serious nature of this case and the expectations under relevant NIH Guide Notices applicable to this type of situation.

July 11, 2022

OLAW Case A3456-9Y

- On September 30, 2021 you provided an interim report on the suspension confirming that the suspension had been reported to the funding component, that all animals on the study had been placed on a holding protocol, and that the grant was not charged for any animal activities during the suspension period. We note that the suspension applied not only to cats, but to rodent studies as well. No problems had occurred in the rodent portion of the protocol therefore the IACUC lifted the suspension covering this work.

Corrective actions were provided and stated that laboratory staff will review all relevant protocols and standard operating procedures prior to conducting animal activities; staff will check all drugs, supplies, and equipment prior to conducting animal activities; staff will pre-calculate all drug dosages and have them double checked by another individual; staff will be familiar with abnormal animal physiology, how to maintain appropriate physiology during the procedure, and when to seek veterinary assistance; staff will conduct planning meetings to discuss the studies and any improvements; staff is cognizant of how to conduct anesthesia, how to maintain normal physiology, and how to ensure animal welfare.

Although rodent activities were allowed to continue, the cat portion of the protocol remained suspended. The IACUC, veterinary staff, subject matter experts, and senior administration worked with the PI to instill a culture of compliance and to ensure animal welfare.

- On July 6, 2022 a final report was received and indicated that two PAM inspections were conducted on the rodent activities. Two minor deficiencies were identified and corrected. The IACUC cancelled the original cat protocol and required the PI to submit a new one. No cats remained on the cancelled protocol or on the holding protocol. A consulting veterinary anesthesiologist provided input on the anesthetic regimen, monitoring, refinements of procedures, and a limit on the number of anesthetic events for each animal. The IACUC approved the protocol for use of a limited number of cats and will continue to monitor this study carefully. The approval resulted in lifting of the suspension. The conduct of the anesthetic procedure will be under the direct supervision of veterinary staff. All requirements outlined in the corrective action plan will be followed and PAM will also continue. The enhanced supervision will only be discontinued upon verification of proficiency by the PI and staff.

Based on its assessment of these explanations, OLAW is satisfied that extensive, appropriate corrective actions have been implemented and we commend the involvement of the IACUC, veterinary staff, subject matter experts, senior administration, and the Institutional Official in ensuring animal welfare. As a matter of note, the concern about the appropriate use of paralytics was incorporated in bullet V of the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training in 1985. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals and we hereby close this investigation.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.  
Deputy Director  
Office of Laboratory Animal Welfare

cc: IACUC Chair

Robert Gibbens, D.V.M., USDA-APHIS-AC

Gregory Farber, Ph.D., NIMH Director, Office of Technology Development and Coordination

Yvonne Bennett, Ph.D., NIMH Program Officer

**McCoy, Devora (NIH/OD) [E]**

---

**From:** McCoy, Devora (NIH/OD) [E]  
**Sent:** Wednesday, July 13, 2022 8:39 AM  
**To:** oakes007@umn.edu  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD); Bennett, Yvonne (NIH/NIMH) [E]; Farber, Greg (NIH/NIMH) [E]; Robert.m.gibbens@usda.gov; iacuc@umn.edu  
**Subject:** OLAW Case A3456-9Y  
**Attachments:** A3456-9Y.pdf

Good morning Dr. Oakes,

Attached please find Dr. Wolff's final response to OLAW Case A3456-9Y. 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

# 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)

July 6, 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: R01MH111413, R01MH111447, and 1R01NS118330-01  
UMN IACUC #37090A, #36898A  
OLAW case# A3456-9Y

Dear Dr. Wolff,

The following is an update and final report regarding the suspension of a University of Minnesota PI that was originally reported to you on August 26, 2021.

Our previous interim report described the reinstatement of the rodent protocol (UMN IACUC #36898A) on September 7, 2021 as well as the planning, preparation, and monitoring procedures agreed upon by the investigator and the IACUC. The rodents were released from the holding protocol and work resumed on protocol #36898A. Two post-approval monitoring inspections have been conducted since reinstatement of this protocol. During these visits, minor deficiencies related to the rodent studies were identified and have been corrected.

Following extensive discussions with both the lab and expert consultants, the committee required the investigator to develop and submit a new protocol for the use of cats, in order to incorporate feedback from the committee on best practices. The previous cat protocol (UMN IACUC #37090A) was permanently closed. No cats remained on this protocol, nor on the holding protocol, at the time of closure.

A new protocol for the use of cats, UMN IACUC #39581A, was submitted by the investigator. This protocol underwent both veterinary pre-review, feedback from a consulting veterinary anesthesiologist, and full committee review. Specific aspects that were changed in relation to the previous protocol include anesthetic regimens and monitoring to reflect recommendations of the consulting anesthesiologist, removal of several procedures to focus only on non-invasive imaging, and limits on the number of anesthetic events per animal. The committee approved this protocol for a limited number of animals and will carefully assess any future requests for additional animals.

The committee voted to lift the suspension and reinstate the investigator's ability to use cats at a full committee meeting on June 28, 2022. The committee is requiring that all anesthetic procedures in cats be conducted under the direct supervision of RAR veterinary staff or Veterinary Medical Center anesthesiologists. Additionally, the lab will be required to follow the corrective action plan outlined in the previous interim report, which includes training of staff on SOPs, equipment, and monitoring; confirmatory checks by multiple personnel; and regular meetings for planning and process improvements.

The committee will be updated after each anesthetic event involving cats as to any animal welfare concerns as well as the cooperation of the PI and lab staff with veterinary staff. The requirement for supervision will be lifted only when the committee is satisfied that the investigator and lab staff have both the technical skills and culture of compliance required to ensure the welfare of the cats. In addition to the supervision requirement, post-approval monitoring by compliance staff will be conducted at regular intervals.

Any future concerns related to animal welfare in this lab will be investigated by the IACUC and action taken, including suspension if deemed appropriate by the committee.

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]

---

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, July 8, 2022 7:31 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: [EXTERNAL] IACUC #37090A, #36898A, OLAW #A3456-9Y

Thank you for this report, (b) (6) We will review carefully and send a response soon.

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

---

**From:** (b) (6)  
**Sent:** Wednesday, July 6, 2022 5:53 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:** [EXTERNAL] IACUC #37090A, #36898A, OLAW #A3456-9Y

Dear Dr. Wolff,

Attached please find an update and final report regarding the suspension of a UMN PI.  
Please let me know if you have any questions,

(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.



**McCoy, Devora (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, June 8, 2022 8:48 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Response to IACUC ##37090A, #36898A

Good morning (b) (6)

I'm contacting you regarding an incident that occurred in August 2021 leading to the suspension of a UMN PI protocol. The most recent update sent to us was in October 2021, so please let us know if there have been any recent developments with this case (OLAW case# A3456-9Y).

Thanks,  
Devora

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

**From:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Sent:** Wednesday, October 6, 2021 6:57 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** RE: Response to IACUC ##37090A, #36898A

Thank you for this thorough update from the IO. I will place it in the file and await the next update or final following the meetings with the PI.  
Axel Wolff

**From:** (b) (6)  
**Sent:** Monday, October 4, 2021 12:18 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6) Richard Bianco  
<bianc001@umn.edu>; Lynn Impelluso <impell@umn.edu>  
**Subject:** Response to IACUC ##37090A, #36898A

Dear Dr. Wolff,

Attached please find the response to IACUC ##37090A and #36898A. Please let me know if you have any questions.  
Thank you,

A3456-9Y

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

---

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, October 6, 2021 6:57 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Response to IACUC ##37090A, #36898A

Thank you for this thorough update from the IO. I will place it in the file and await the next update or final following the meetings with the PI.

Axel Wolff

**From:** (b) (6)  
**Sent:** Monday, October 4, 2021 12:18 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6) Richard Bianco  
<bianc001@umn.edu>; Lynn Impelluso <impell@umn.edu>  
**Subject:** Response to IACUC ##37090A, #36898A

Dear Dr. Wolff,

Attached please find the response to IACUC ##37090A and #36898A. Please let me know if you have any questions.

Thank you,

(b) (6)

(b) (6)

I acknowledge that the University of Minnesota Twin Cities stands on Miní Sóta Makhóche, the traditional, ancestral, and contemporary Homelands of Dakhóta Oyáte. The University occupies land that was cared for and called home by Dakota peoples from time immemorial.



# 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)

September 30, 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 Numbers: R01MH111413, R01MH111447, and 1R01NS118330-01  
UMN IACUC #37090A, #36898A

Dear Dr. Wolff,

The following is an interim report regarding the suspension of a University of Minnesota PI that was originally reported to you on August 26, 2021. We can confirm that the funding components have been informed of the suspension, that any existing animals were placed on a holding protocol during the suspension, that no animal activities were performed during the suspension and that the grants were not charged.

The UMN IACUC reviewed and discussed a preliminary response from the PI during an FCR meeting held on 9/7/21. At that time all of the PI's animal work had been suspended. The PI specifically asked for reinstatement of his rodent protocol. With regard to the rodent study (UMN IACUC #36898A), the PI pointed out that for over 20 years, their rodent research has not had any animal welfare issues. Although the committee was adamant that the PI needed to improve his laboratory culture, it felt that with the following proposed improvements, he could resume his rodent work. The PI agreed to implement the following planning, preparation and monitoring procedures. These procedures are summarized below:

- All lab members conducting animal studies will review the relevant protocols and SOPs before each study/experiment to understand their own responsibility and all aspects of the experimental procedures relevant to the particular animal preparation related to the study;
- The responsible parties including animal technician and researcher(s) will check the relevant drugs/supplies/medications and equipment/devices before each study/experiment to ensure their availability and proper condition/function for the planned study;
- For all drugs or agents used in the study, their dosages will be pre-calculated and double checked according to the approved protocol, study design and the body weight of the animal, and confirmed by all personnel (at least two people) conducting the study. The correct concentration of the infusion solution and/or infusion pump setting will also be confirmed by the study personnel (at least two people);
- All lab members conducting animal studies will learn to recognize signs of abnormal animal physiology on the monitoring equipment and know how to make proper adjustment to bring the animal and its physiological parameters back to the normal range if it is out of the range; if the adjustment could not successfully reset/improve the animal condition, the planned experiment will be stopped immediately and the animal will be allowed for recovery; if needed we will seek RAR support.

- All lab members conducting animal work will meet regularly to plan experiments and discuss any issues or questions they might have, and review study results for further improvement in animal preparation and monitoring procedures.
- All lab members conducting animal studies will work together whenever needed to achieve the best anesthesia practice and maintain normal physiology condition of the animals, and always have a proper mindset to ensure the animal welfare.

The committee was satisfied with these responses and the lab's history specifically related to their use of rodents and voted unanimously to reinstate the investigator's rodent protocol at this meeting. The rodents were released from the holding protocol on 9/7/21.

The committee, however, was not satisfied that even if these procedures were applied to the cat protocol, they would sufficiently correct the issues and voted to retain suspension of that protocol. The PI was sent several questions to address and asked to develop a detailed plan for going forward. The committee is presently working with the PI and consulting with the veterinary staff and other experts in the area of cat anesthesia to help address the ongoing study issues and develop a more robust corrective action plan for the cat study.

Beyond IACUC requirements, I am requiring the PI and lab director to meet with me and the controlling Associate Vice President for Research so that we may discuss the importance of leadership and culture as regards compliance and research ethics more generally. I will articulate my expectations and ensure a corrective action plan is executed in this regard.

We will keep you updated on this progress. Please let us know when another update is required.

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]

---

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Tuesday, September 21, 2021 7:09 AM  
**To:** Farber, Greg (NIH/NIMH) [E]; OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** Bennett, Yvonne (NIH/NIMH) [E]; Weiss, Heather (NIH/NIMH) [E]; Kirker, Robert (NIH/NIMH) [E]  
**Subject:** RE: Cat Research Project funded by NIH BRAIN Initiative R01 Grant

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

Hello Dr. Farber,

OLAW has received the notification about this matter from the university and we have opened a compliance case. I will add this communication to the file, which will probably be open for some time as this is a very serious situation. The PI correctly informed you about the suspension which is required under NIH Grants Policy and the Animal Welfare Act. At this time there should be no conduct of animal activities on this grant and there should be no charges made to the grant unless permission is given by NIMH for expenditures for basic husbandry and veterinary care.

<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>.

OLAW will keep you informed as to the progress and resolution, when (or if) the suspension will be lifted. Mr. Kirker should be able to advise on the status of the grant codes or you can contact OPERA. Thank you for contacting OLAW about this matter.

Axel Wolff, M.S., D.V.M.  
Deputy Director, OLAW  
Office of Extramural Research  
Office of the Director, NIH

**From:** Farber, Greg (NIH/NIMH) [E] <farberg@mail.nih.gov>  
**Sent:** Tuesday, September 21, 2021 5:06 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Bennett, Yvonne (NIH/NIMH) [E] <yvonne.bennett@nih.gov>; Weiss, Heather (NIH/NIMH) [E] <heather.weiss@nih.gov>; Kirker, Robert (NIH/NIMH) [E] <robert.kirker2@nih.gov>  
**Subject:** FW: Cat Research Project funded by NIH BRAIN Initiative R01 Grant

Hello OLAW Division of Compliance Oversight,

A program officer, Yvonne Bennett who is copied on this e-mail, received this troubling e-mail yesterday. The grant number is R01MH111413 and the PI is Wei Chen who sent the e-mail. The vertebrate animal code is currently 30. The grant is in a no cost extension, and the current budget end date is 6/30/2022.

Do we need to modify the vertebrate animal code on this grant award while waiting for the decision of the University of Minnesota IACUC? If the IACUC does allow experiments to resume, do we need to document that decision in any way? Are there any other actions we need to take related to dealing with this significant change in the grant award?

Gregory K. Farber, Ph.D.  
Director, Office of Technology Development and Coordination

National Institute of Mental Health  
National Institutes of Health

**From:** Wei Chen <[chenx075@umn.edu](mailto:chenx075@umn.edu)>

**Sent:** Sunday, September 19, 2021 4:37 PM

**To:** Bennett, Yvonne (NIH/NIMH) [E] <[yvonne.bennett@nih.gov](mailto:yvonne.bennett@nih.gov)>

**Cc:** Richard Bianco <[bianc001@umn.edu](mailto:bianc001@umn.edu)>;

(b) (6)

(b) (6) Wei Chen <[chenx075@umn.edu](mailto:chenx075@umn.edu)>

**Subject:** Cat Research Project funded by NIH BRAIN Initiative R01 Grant

Dear NIH Program Officer Dr. Yvonne Bennett:

My name is Wei Chen, a professor in the Department of Radiology at the University of Minnesota (UMN), and I am also the PI of a NIH BRAIN Initiative R01 grant funded by your institute, which is now in the NCE stage (MH111413, Project Title: Integrated fMRI Methods to Study Neurophysiology and Circuit Dynamics at Laminar and Columnar Level). This project involves conducting functional MRI (fMRI) and neural recording studies to understand the neuro-vascular relationship at the laminar and columnar level using the cat model.

My laboratory has established cat models since 2003. In the past two decades, we have maintained an excellent record of animal research using rodent and cat models at the University of Minnesota. During the past year, however, we faced several unprecedented challenges: the COVID-19 pandemic and university lockdown; the retirement of our animal surgeon who had been handling all animal preparations in my lab for the last 20 years; and the difficulty of recruiting new animal technician and training lab personnel on the cat procedures for continuing the cat projects. By working closely with UMN RAR veterinarians and staff, we developed SOPs for cat studies, which were reviewed/approved by IACUC, and had two lab members complete the cat anesthesia training provided by the RAR training team. However, earlier this year during the actual cat studies, three kittens developed respiratory complications after the fMRI scans and had to be euthanized later, even though the animal preparations were following the cat SOPs and supervised by RAR and IACUC members. Nevertheless, we have figured out the problem and made significant progress in preventing such complications in subsequent cat studies.

Unfortunately, on Aug 05, 2021 during a cat fMRI study, the animal was mistakenly given 4.5 times the expected dose of a paralytic drug due to a human error in setting the infusion pump rate by a newly hired animal technician. Despite immediate intervention by laboratory personnel and RAR veterinarians, the animal was humanely euthanized due to concerns about its condition and difficulty in recovery. We reported this unfortunate incident to IACUC and the committee decided to temporarily suspend all animal work in my lab starting from Aug 24, 2021. Right after this accident, I had serious discussions with all lab members who work with animals on how to prevent such errors from happening again. A detailed correction plan has been formulated and submitted to IACUC. Last week, we also had a meeting with IACUC members to answer their questions and discuss how to reinstate the suspended IACUC protocol so we can resume our research project as soon as possible.

Our university has reported this incident and IACUC's decision to the NIH OLAW office. According to the OLAW policy, I am writing to inform you of the status of the referenced project. Currently, we have no animal on the cat protocol since we are waiting to obtain new kittens for the planned studies. As soon as the IACUC removes the suspension, we will resume the cat fMRI experiments and continue to make progress on this project funded by your institute.

Thank you for your attention and understanding. Your advice will be greatly appreciated.

Sincerely,

Wei Chen, Ph.D.

Preliminary

## UNIVERSITY OF MINNESOTA

Twin Cities Campus

Institutional Animal Care and Use Committee (IACUC)

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D-528 Mayo Memorial Building  
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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)

August 26, 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 Numbers: R01MH111413, R01MH111447, and 1R01NS118330-01  
UMN IACUC #37090A, #36898A

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 a cat. The basis of this report results from a self-report. The report outlined that a cat accidentally received an overdose of vecuronium during an fMRI scan. The paralytic was infused intravenously at 0.1mg/kg at 2ml/min versus the intended rate of 2ml/hour. Fourteen minutes into the infusion, anesthesia monitoring showed airway deficit. At this point, the vecuronium infusion was stopped and the animal was given the reversal (Neostigme/Atropine). Two veterinarians examined the cat and recommended euthanasia due to mild lung sounds consistent with pulmonary edema and the concern of hypovolemia and hypoxemia resulting in organ damage. This incident occurred on August 5, 2021.

We want to inform you that due to ongoing issues regarding animal welfare in this laboratory, the IACUC has formally suspended this PI's animal research program indefinitely until an adequate plan for correction is submitted and approved by the IACUC. Additionally, the committee will verify that 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. Suspension of research activities occurred during a convened IACUC meeting held on August 24, 2021.

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]

---

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, August 30, 2021 7:26 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Report of non-compliance

Thank you for this report, (b) (6) We will accept this as a preliminary report and await the results of the following:

- A copy or summary of the PI's corrective action plan
- The results of the IACUC's assessment of the correction plan
- Confirmation that the funding component was informed of the suspension
- Confirmation that the animals were placed on a holding protocol during the suspension, that no animal activities were performed during this time, and that the grant was not charged
- A detailed explanation regarding how depth of anesthesia is assessed during application of the paralytic agent
- Status of the suspension. Was it made permanent or was the study reinstated?
- Details of post-approval monitoring if the study was reinstated
- Any additional relevant information such as an explanation of "ongoing issues regarding animal welfare in this laboratory"

Feel free to contact me should you have any questions. Please send an interim or final report **October 1, 2021**.

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

---

**From:** (b) (6)  
**Sent:** Saturday, August 28, 2021 8:46 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Lynn Impelluso <impell@umn.edu>; Richard Bianco <bianc001@umn.edu>  
**Subject:** Report of non-compliance

Dear Dr. Wolff,  
On behalf of interim Vice President Michael Oakes, attached please find a report of non-compliance.  
Please let me know if you have any questions.  
Thank you,  
(b) (6)

