



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 11, 2021

Re: Animal Welfare Assurance
#A3456-01 [OLAW Case 9Q]
UMN IACUC #37029A

Dr. J. Michael 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 May 5, 2021 letter in response to OLAW's April 2, 2021 request for information regarding an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Minnesota. According to the information provided, OLAW understands that there were no direct animal welfare concerns due to the noncompliance and no additional interventions were required. Animals did not show overt signs of distress and have been euthanized per approved study endpoints.

OLAW appreciates the prompt consideration of this matter by the University of Minnesota which is consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate steps have been taken to investigate this incident. We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely,
Nicole L.
Lukovsky-
akhsanov -S

Digitally signed by Nicole
L. Lukovsky-akhsanov -S
Date: 2021.06.11 14:58:32
-04'00'

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
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
www.research.umn.edu/iacuc

May 5, 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: R01 HL135046, R01 DK117425
UMN IACUC #37029A

Dear Dr. Wolff,

Thank you for your response to our report of non-compliance of an IACUC approved, NIH funded study involving rats (UMN IACUC #37029A). We are sorry for our delay in responding to your letter. We understand that you are requesting the following additional information:

- Please provide information regarding direct animal welfare concerns related to the surgical and analgesia noncompliances referenced in this report including any required medical interventions (e.g. treatments, euthanasia) and animal disposition.

In response, there were no direct animal welfare concerns related to the noncompliances. No additional treatments or medical interventions were required. The animals did not show any overt signs of distress and have now been euthanized per approved study endpoints.

Sincerely,

(b) (6)

Christopher J. Cramer, Ph.D.
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, May 7, 2021 7:26 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Response for UMN IACUC #37029A

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

From: (b) (6)
Sent: Wednesday, May 5, 2021 12:32 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: Response for UMN IACUC #37029A

Dear Dr. Wolff,
Attached please find the response letter for UMN IACUC #37029A.
Thank you,
(b) (6)

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(b) (6)



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April 2, 2021

Re: Animal Welfare Assurance
#A3456-01 [OLAW Case 9Q]
UMN IACUC #37029A

Dr. Christopher Cramer
Vice President for Research
Institutional Official
University of Minnesota
(b) (4) Johnston Hall - 101 Pleasant St., SE
Minneapolis, MN 55455

Dear Dr. Cramer,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 9, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Minnesota. According to the information provided, OLAW understands that on September 23, 2020 and October 22, 2020, two vascular heart surgical procedures were performed on rats that were not described and approved in the protocol. Analgesia was provided for the approved surgeries on this protocol however they were not administered at the timing described and approved in the protocol. Additionally, a staff member conducting the approved non-survival surgery was not approved as staff on the protocol. This study was PHS funded.

As a corrective measure, the principal investigator will be amending the protocol to include vascular heart transplants as the current protocol includes various transplant models however it does not currently include the vascular heart transplant. The staff member was added to the protocol and will not do any further work until approved. The lab also indicated that following will be performed: lab meetings to discuss findings and any additions or modifications to protocols, reviewing analgesia plans for each procedure and ensuring required pharmaceuticals are available, reviewing IACUC protocols, and ensuring everyone on the protocol has copy and is trained to perform procedures in addition to adding a section to lab training records to require sign off on procedure training.

OLAW appreciates the prompt consideration of this matter by the University of Minnesota which is consistent with the philosophy of institutional self-regulation.
Based on the information provided, OLAW requests the following information:

- Please provide information regarding direct animal welfare concerns related to the surgical and analgesia noncompliances referenced in this report including any required medical interventions (e.g. treatments, euthanasia) and animal disposition.

We look forward to your responses to the to the additional information request by **April 30, 2021**. Please contact us with any further questions or concerns.

Page 2 – Dr. Cramer
A3456-9Q
April 2, 2021

Sincerely,

Nicole L. Lukovsky-
akhsanov -S

Digitally signed by Nicole L.
Lukovsky-akhsanov -S
Date: 2021.04.02 07:59:20
-04'00'

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact

Wolff, Axel (NIH/OD) [E]

From: (b) (6)
Sent: Thursday, April 1, 2021 8:06 AM
To: OLAW Division of Compliance Oversight (NIH/OD); Walker, Keri (NIH/OD) [E]
Subject: Re: Report of Non-Compliance
Attachments: UMN IACUC #37029A.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Hello Dr. Wolff,
We are following up on this report #37029A as we haven't received a response yet. Please let me know the status.
Thank you,
(b) (6)

On Wed, Mar 10, 2021 at 6:11 AM OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> wrote:

Thanks for this report, (b) (6) We will send a response soon.

Axel Wolff

From: (b) (6)
Sent: Tuesday, March 9, 2021 2:43 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: Report of Non-Compliance

Hello Dr. Wolff,
On behalf of VP Chris Cramer, attached please find a letter with a report of non-compliance.
Please let me know if you have any questions.
Thank you,

(b) (6)

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(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
www.research.umn.edu/iacuc

DATE: March 9, 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: (b) (4)
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 surgical inspection. The report outlined that two surgical procedures, vascular heart transplants, were conducted on September 23, 2020 and October 22, 2020 and were not described and approved in the protocol. Additionally, while analgesics were given for the surgeries approved in the protocol, they were not given at the timing described and approved. This deviation occurred on the dates of December 23, 2020 and January 4, 2021. Both deviations were covered under NIH funding number (b) (4).

Further, a staff member that conducted an approved non-survival surgery on the above referenced study was not approved as staff on the protocol. This deviation was covered under grant number (b) (4).

We want to inform you that we consider this matter closed. The response from the PI indicated the protocol will be amended to include the vascular heart transplants. Currently, the protocol includes various transplant models, but the vascularized heart had not been added. The staff member was added to the protocol and will not do any further animal work until he is approved, and the analgesic will be given as currently outlined in the protocol.

Further, to prevent recurrence of these incidents, the lab indicated that they will do the following: have a lab meeting to discuss the report and findings, review the analgesia plan for each procedure and ensure that needed pharmaceuticals are available and that administration performed as per protocol approval, review IACUC protocols and ensure everyone has a copy to ensure that all personnel who are planning to perform procedures are trained and listed on those

protocols, add a section to our lab training records to sign off on training on the protocol procedures and discuss in advance any additions or modifications to protocols that might be needed to reflect revised experimental plans.

Sincerely,

(b) (6)

Christopher J. Cramer, Ph.D.
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: Wednesday, March 10, 2021 7:11 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of Non-Compliance

Thanks for this report, (b) (6) We will send a response soon.

Axel Wolff

From: (b) (6)
Sent: Tuesday, March 9, 2021 2:43 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: Report of Non-Compliance

Hello Dr. Wolff,
On behalf of VP Chris Cramer, attached please find a letter with a report of non-compliance.
Please let me know if you have any questions.
Thank you,

(b) (6)

