



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) 402-7065

November 21, 2019

Re: Animal Welfare Assurance
#A3456-01 [OLAW Case 8R]
UMN IACUC #35960A

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 November 7, 2019 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 ten chinchillas on an approved protocol were not properly monitored following recovery from anesthesia, and one animal subsequently died.

The immediate action taken upon discovery of the anesthetized animals consisted of Research Animal Resources (RAR) taking over care and monitoring vital signs. Nine chinchillas were recovered successfully and RAR staff worked with the investigators during the treatment phase and up to euthanasia. The Principal Investigator suspended all animal activities until the laboratory staff had been retrained. The Institutional Animal Care and Use Committee (IACUC) placed the laboratory under enhanced post-approval monitoring.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy.

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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, November 22, 2019 7:33 AM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6)
Subject: RE: Report of non-compliance

Hi (b) (6)

In this situation we do not need to wait until everyone has completed the training. A second letter would only be necessary if the proposed corrective actions have not been completed. This applies to most proposed corrective actions. We assume they will be carried out as stated and would only need to be notified if this is not done. This is to ensure that the case file report, which becomes a federal record, is correct and accurate. I will finalize the case and send the response shortly.

Axel Wolff

From: (b) (6)
Sent: Thursday, November 21, 2019 1:17 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: Re: Report of non-compliance

Hello Dr. Wolff,

Thank you for your reply.

We initially thought that OLAW might want to have a secondary letter to ensure that all the training was completed. If you do not need a secondary letter for this incident and are ok with the actions of the Committee to have further training of the PI and their staff prior to resuming work with animals, we will not submit a secondary letter. I hope this helps. Please let me know if you have any additional questions.

Best regards,

(b) (6)

On Thu, Nov 21, 2019 at 10:12 AM (b) (6) wrote:

Thank you-I am copying (b) (6) from our IACUC office to get clarification on this point.
(b) (6)

On Thu, Nov 21, 2019 at 10:06 AM OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> wrote:

Hi (b) (6)

I began responding to this letter but then noted that the last sentence said: "A secondary letter will be sent once all training is completed and the Committee discusses any final steps."

As such, the case is still open and the letter is in draft format.

If no further information is forthcoming, please let me know and I will finalize it.

Axel Wolff

From: (b) (6)
Sent: Thursday, November 21, 2019 9:43 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Re: Report of non-compliance

Hello Dr. Wolff,

I am checking in to see if there was a response sent for this report #35960A and I have missed it. Please let me know.

Thank you,

(b) (6)

On Tue, Nov 12, 2019 at 11:40 AM OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> wrote:

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

Axel Wolff, M.S., D.V.M.

Deputy Director, OLAW

From: (b) (6)
Sent: Tuesday, November 12, 2019 9:48 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Brian Crooker <crook001@umn.edu>; Lynn Impelluso <impell@umn.edu>; Chris Cramer <cramer@umn.edu>
Subject: Report of non-compliance

Hello Dr. Wolff,

On behalf of Vice President for Research, Christopher J. Cramer, attached please find a report of non-compliance. Please let me know if you have any questions.

Thank you,

(b) (6)

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(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: 612-626-6081
iacuc@umn.edu
www.research.umn.edu/iacuc

November 7, 2019

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: 1R41HD097038-01A1
 UMN IACUC #35960A

Dear Dr. Wolff,

In keeping with the terms of our assurance, please be informed that we are making an initial report of non-compliance of an IACUC approved, NIH funded study involving chinchillas. The basis of this report results from a self-reported incident. The report outlined that ten chinchillas undergoing intra-bullar injections of bacteria were not properly monitored and recovered after anesthesia on October 30, 2019. Research Animal Resources (RAR) staff identified the problem and intervened to take over the care of the animals at which time vital signs of the animals were taken (temperature, pulse and respiration), finding that the animals had low pulses and temperatures. While animals recovered and were given additional hay to encourage eating, one animal died overnight. This animal was submitted for necropsy.

Over subsequent days, RAR supervised and worked directly with the lab during the treatment phase and euthanasia of the remaining chinchillas.

This non-compliance was reviewed by the Committee on the November 5, 2019 IACUC meeting. As such, the Committee requested that additional training be coordinated and completed with appropriate UMN specialists at the IACUC office, controlled substances, and RAR. The PI has voluntarily suspended all animal work until such training can be completed.

The Committee expects that the corrective action should prevent further non-compliance. The University of Minnesota IACUC will continue to monitor this research group and ensure that they comply with all IACUC requirements. A secondary letter will be sent once all training is completed and the Committee discusses any final steps.

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: Brian Crooker, Chair, IACUC
 Lynn Impelluso, Director and Attending Veterinarian

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, November 12, 2019 12:40 PM
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 send a response soon.

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

From: (b) (6)
Sent: Tuesday, November 12, 2019 9:48 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Brian Crooker <crook001@umn.edu>; Lynn Impelluso <impell@umn.edu>; Chris Cramer <cramer@umn.edu>
Subject: Report of non-compliance

Hello Dr. Wolff,

On behalf of Vice President for Research, Christopher J. Cramer, attached please find a report of non-compliance. Please let me know if you have any questions.

Thank you,

(b) (6)

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(b) (6)