



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, 2020

Re: Animal Welfare Assurance
A3646-01 [OLAW Case 1H]

Dr. Jon Reuter
Assistant Vice Chancellor for Research Integrity and Compliance
University of Colorado – Boulder
3100 Marine Street, UCB 563 Office 25
Boulder, CO 80309

Dear Dr. Reuter,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 1, 2020 letter reporting two non-compliances within the animal care and use program at the University of Colorado - Boulder. According to the information provided, OLAW understands that on February 19th and 20th mice were injected intraperitoneally with a mixture of ovalbumin dissolved in saline and an adjuvant. During cage changes eight out of forty-eight mice were found deceased. The remainder of the mice completed the experiment. The attending veterinarian performed a necropsy on the carcasses finding signs of serosal hemorrhaging in the GI tract indicative of a needle prick during injections. Two of the four mice that died were sent for histopathology. One animal had "very mild colitis and hepatic lipidosis". The other animal only had mild epicardial mineralization which is likely related to the strain. The report also stated that there was no evidence of toxic or tissue changes associated with the IP injection noted on the histologic evaluation. This activity was not PHS funded.

Corrective and preventive actions included scheduling additional training closer to the time that the lab initiates another experiment. In future studies involving i.p. injections by the researcher involved in this instance the lab will utilize the assistance of the Office of Animal Resources Veterinary Technician until a new agreement has been met with the IACUC.

The second incident occurred on February 3, 2020 when the vet staff recommended euthanizing a moribund male mouse with the lab's approval. At that time, there were 2 adult mice and 1 relatively young litter within the cage. On 2/18/20 the lab checked on the surviving animals and found only 1 adult animal in the cage (the surviving adult animal had eaten the pups). It was realized that the previously reported male mouse was a female mouse, and the incorrect sexing of the animal led to the loss of the litter. This activity was PHS funded.

Corrective and preventive actions included retraining of the Office of Animal Care technician involved in appropriate sexing of mice and the importance of double checking to provide accurate information.

OLAW believes that the corrective and preventive measures by the University of Colorado - Boulder are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals for institutional self-monitoring and self-reporting. We appreciate being informed of these matters and find no cause for further action by this office.

*Page 2 – Dr. Reuter
June 11, 2020
OLAW Case A3646-1H*

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C. Morse

-S

Date: 2020.06.11 11:04:43 -04'00'

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



University of Colorado
Boulder

Jon Reuter, Assistant Vice Chancellor for
Research Integrity and Compliance
3100 Marine St, UCB 563, Office 25
Boulder, CO 80309

jon.reuter@colorado.edu

t 303 735-5809

A3646-1H

June 1, 2020

Brent Morse, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500 MSC 6910
Bethesda, MD 20892

Dr. Morse,

The University of Colorado Boulder, Assurance No. D16-00388, provides the following reports discussed by the IACUC at the March convened meeting where they were voted as a reportable incident. Due to COVID-19 and the closure of the University investigative results were delayed because personnel were on extended leave. We are sending these reports as all the information has been presented to the IACUC now.

Protocol : 2686

Species: Mice

Funds: VA BLR&D Merit award

2/19-/02/20/20 Mice were injected intraperitoneally with a mixture of ovalbumin (OVA) dissolved in saline (0.2mg/mL), and Imject Alum, an adjuvant that consists of aluminum hydroxide (40mg/mL), magnesium hydroxide (40mg/mL), and inactive stabilizers. During cage changes eight out of forty-eight mice were found deceased. The remainder of the cohort resulted in a successfully completed experiment with endpoints collected. Prior to initiation of the experiment, stock concentrations and administered doses were determined by the researcher, and reviewed by the PI (these doses had proven successful in a previous experiment). The attending veterinarian performed a necropsy on the carcasses finding signs of serosal hemorrhaging in the GI tract indicative of a needle prick during injections. No signs of peritonitis were found in any of the mice that had a necropsy performed. Two of the four mice that died on 2/19/20 were sent to IDEXX for histopathology. One animal had "very mild colitis and hepatic lipidosis". The other animal only had mild epicardial mineralization which is likely related to the strain. The IDEXX report also stated that there was no evidence of toxic or tissue changes associated with the IP injection noted on the histologic evaluation. The PI was notified where additional training will be scheduled closer to the time that the lab initiates another experiment, although the restrictions due to COVID-19 may further delay the training. In future studies involving i.p. injections by the researcher involved in this instance the lab will utilize the assistance of the Office of Animal Resources Veterinary Technician until a new agreement has been met with the IACUC.

Protocol: 2516

Species: Mice

Funds: NIH AR049446, NIH AR069955

On 2/3/20 an animal care technician reported a male mouse in the colony room as moribund where the vet staff recommended euthanizing the animal with the lab's approval. At that time, there were 2 adult mice and 1 relatively young litter within the cage. On 2/18/20 the lab checked on the surviving animals and found only 1 adult animal in the cage (the surviving adult animal had eaten the pups). It was realized that the previously reported male mouse was actually a female mouse, and the incorrect sexing of the animal led to the loss of the litter. The Office of Animal Care technician involved was retrained in appropriate sexing of mice and the importance of double checking to provide accurate information.

CU Boulder maintains its commitment to the health and welfare of animals used in research.

Should you have any questions regarding this report, please contact Christopher A. Lowry, PhD, IACUC Chair at christopher.lowry@colorado.edu or Althea R. Lantron, IACUC Director, at althea.lantron@colorado.edu.

Sincerely,

DocuSigned by:
(b) (6)

Jon Reuter, Assistant Vice Chancellor of Research Integrity and Compliance

Cc: Christopher A. Lowry, IACUC Director

Althea R. Lantron, Director, IACUC

Sara Hashway, Director, Office of Animal Resources

Walker, Keri (NIH/OD) [C]

From: Morse, Brent (NIH/OD) [E]
Sent: Thursday, June 4, 2020 12:45 PM
To: Walker, Keri (NIH/OD) [C]
Cc: Wolff, Axel (NIH/OD) [E]
Subject: FW: A3646-01-University of Colorado-Boulder-Reportable Incident
Attachments: OLAW Report 2020-0601.pdf

Hi Keri,

Please use this email and the attached letter to open a case file. Please let me know the case # and you can put the file in my mailbox. Thanks.

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: Morse, Brent (NIH/OD) [E]
Sent: Thursday, June 04, 2020 12:43 PM
To: Althea Lantron <Althea.Lantron@Colorado.EDU>
Subject: RE: A3646-01-University of Colorado-Boulder-Reportable Incident

Thank you for providing this report of these incidents. We'll send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: Althea Lantron <Althea.Lantron@Colorado.EDU>
Sent: Thursday, June 4, 2020 10:52 AM
To: OLAW Division of Assurances (NIH/OD) <olawdoa@od.nih.gov>
Subject: A3646-01-University of Colorado-Boulder-Reportable Incident

Please see the attached letter. Due to COVID-19 and the closure of the University investigative results were delayed because personnel were on extended leave. We are sending these reports as all the information

has been presented to the IACUC now.

Althea R. Lantron

Director, Institutional Animal Care and Use

University of Colorado - Boulder

2860 Wilderness Pl, (b) (4)

Boulder, CO 80301

Email: althea.lantron@colorado.edu

Phone: (b) (6)

NOTE: Due to COVID-19 mitigation efforts, IACUC staff are working remotely at this time. IACUC staff will be monitoring all emails and phone messages during normal business hours while also processing protocols. We appreciate your patience as we adapt to this ongoing situation.