



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) 480-3387

June 13, 2022

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

Dr. Jon Reuter  
Assistant Vice Chancellor for Research Integrity and Compliance  
University of Colorado - Boulder  
3100 Marine Street, UCB 563 (b) (4)  
Boulder, CO 80309

Dear Dr. Reuter,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 4, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Colorado- Boulder, following up on an initial report on January 26, 2022. According to the information provided, OLAW understands that an unapproved experimental agent was used in six rats and three animals experienced unanticipated problems and were euthanized.

The corrective actions consisted of counseling the Principal Investigator to adhere to the approved protocol. The three surviving rats were used in behavioral testing that was approved in the protocol. The protocol was amended to include the behavioral testing as a pilot study to determine future steps in this study.

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 institution to comply with the PHS Policy. We recommend involvement of the veterinarian and Institutional Animal Care and Use Committee to determine whether additional actions can be taken to minimize/eliminate the unanticipated adverse events or whether these need to be included as potential outcomes. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair



University of Colorado  
Boulder

Jon Reuter, Assistant Vice Chancellor for  
Research Integrity and Compliance  
4845 Pearl East Circle, room 206 (UCB 563)  
Boulder, CO 80309

jon.reuter@colorado.edu

t 303 735-5809

February 4, 2022

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 non-compliance report outlined below. Please note a preliminary report was provided on 1/26/2022 by

(b) (6)

Protocol: 2611

Species: Rats

Funds: NIH RMH050479G & NIH RMH116353A

On 1/26/22 an unapproved agent was given during an approved surgery. After the surgery the animals experienced unanticipated adverse effects that resulted in three of the six animals being euthanized. The three remaining animals were closely monitored and returned to normal health. The lab was repeating an experiment done in years prior in order to collect additional data, and the PI did not realize the agent had been removed from the protocol.

The IACUC office discussed with the principal investigator the importance of reviewing the protocol to be sure all procedures and agents are approved. The PI requested to continue to use the three remaining animals for planned non-invasive behavioral testing following the surgery. The behavioral testing is an approved procedure on the protocol. The IACUC met in a special meeting to discuss the PI's request. After discussion, the committee determined that letting the PI continue to use these animals as a pilot study and subsequently utilize the histology to determine what occurred in this cohort would be useful to the lab. The PI has submitted an amendment for a pilot study of the behavioral testing portion of the experiment. Pending the results of the pilot, the PI can submit an amendment to add the study with the agent to the protocol to be performed to supplement historical data.

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](mailto:christopher.lowry@colorado.edu) or (b) (6)

(b) (6)

Sincerely,

(b) (6)

Jon Reuter, Assistant Vice Chancellor of Research Integrity and Compliance

Cc:

Christopher A. Lowry, IACUC Chair

(b) (6)

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, February 7, 2022 7:15 AM  
**To:** IACUC Office  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Reportable Incident

Thank you for this report. We will send a response soon.

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

**From:** IACUC Office <iacucoffice@colorado.edu>  
**Sent:** Friday, February 4, 2022 12:08 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Jon D Reuter <Jon.Reuter@Colorado.EDU>; (b) (6) Christopher Lowry  
<christopher.lowry@colorado.edu>; (b) (6)  
**Subject:** [EXTERNAL] Reportable Incident

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.

Dear OLAW,

Please find attached the final report for an incident that we have found reportable. A preliminary report was sent on 1/26/2022.

Thank you.

(b) (6)

**Ward, Joan (NIH/OD) [E]**

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**From:** IACUC Office <iacucoffice@colorado.edu>  
**Sent:** Wednesday, January 26, 2022 5:20 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** (b) (6)  
**Subject:** [EXTERNAL] Preliminary Report on a Non-Compliance

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

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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.

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Good Afternoon,

I am (b) (6) I am emailing to provide preliminary information on a non-compliance. The non-compliance involved the use of an experimental agent that was not approved in the current protocol during an approved procedure. Due to the condition of the animals following the procedure the Attending Veterinarian required euthanasia of the animals involved. We are currently still investigating this non-compliance and gathering information. Our IACUC committee will convene in February to review the findings from the investigation. After the committee convenes a letter will be sent to OLAW with further information and the resolution.

CU Boulder's Assurance number is D16-00388 (A3646-01)

Thank you,

(b) (6)

A large rectangular area of the email body is completely redacted with a solid grey fill. The redaction covers the signature and any additional text that might have been present.