

## 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

January 23, 2020

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

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 December 10, 2019 letter, received in our office on January 2, 2020, reporting an adverse event and a non-compliance within the animal care and use program at the University of Colorado - Boulder. According to the information provided, OLAW understands that on November 13, 2019 mice on an experiment to replicate behavioral effects of ovalbumin/alum sensitization and Mycobacterium vaccae died after receiving an overdose of alum. The alum had been improperly prepared for the i.p. injection. The PI has re-trained his staff by reviewing the instruction manual for preparation of the alum together and verifying accurate calculations. This activity was not PHS funded.

The second incident involved a post-doc performing tail-tip amputation for genotyping in mice after postnatal day 21 without anesthesia. This was a protocol violation. The IACUC Director met with the PI and personnel responsible to review the incident and recommend an amendment be submitted for the protocol in the event that genotyping beyond postnatal day 21 be needed in the future. This animal activity was PHS-funded and the funding agency will be notified of the situation.

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.

Sincerely,

(b) (6)

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

cc: IACUC Contact



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

A3646-16

jon reuter@colorado.edu

t 303 735-5809

No open cases

December 10, 2019

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 December 17th convened meeting where they were voted as a reportable incident.

Protocol: 2686

Spec

Species: Mice

Funds: VA BLR&D Merit award

11/13-19/19 - an adverse event occurred with mice dying in an experiment to replicate the behavioral effects of ovalbumin/alum sensitization and *Mycobacterium vaccae*. Upon investigation by the principle investigator it was concluded that the alum (adjuvant; Imject <sup>TM</sup>) was not prepared as specified by ThermoFisher and the mice had received an overdose of alum.

The principal investigator commissioned a commercial necropsy where results were consistent with an adverse innate immune response on serosal surfaces in the peritoneal cavity following an overdose of alum given via i.p. injection. Together, these findings led to the conclusion that an overdose of alum led to the deaths of mice.

The personnel responsible for dosing the animals was unaware of an instruction manual for the dosage of alum. Since the incident occurred the principle investigator has retrained his staff by reviewing the instructional manual together and verifying accurate calculations.

Protocol: 2590 Species: Mice Funds: NIH R01HD081562, 3 R01 HD081562-04S1, R01HD081117

11/29/19 – At a convened IACUC meeting the committee voted to report this as non-compliance. A post-doc genotyped mice after postnatal day 21 neglecting to use anesthesia. Upon investigation it was determined that their protocol was not approved for tail tip amputation beyond postnatal day 21, putting the lab in direct deviance from their approved protocol. The IACUC Director met with the principal investigator and personnel responsible to go over the incident and to recommend that an amendment be submitted to their protocol in the event the need arose to genotype beyond postnatal 21 in the future. The Grants and Contract Office will also be notified where in turn the funding agency will be apprised of the situation.

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Grants & Contracts Office

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 Remens

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