



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

March 20, 2020

Re: Animal Welfare Assurance
A3627-01 [OLAW Case G]

Dr. Jason Carter
Vice President for Research and
Economic Development
Montana State University
P O Box 17460, Montana Hall, (b) (4)
Bozeman, MT 59717

Dear Dr. Carter,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 11, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Montana State University, following up on an initial telephone report on February 25, 2020. According to the information provided, OLAW understands that 50 mice were given iron in their drinking water and were subjected to submandibular blood collection, although neither activity was described in the approved protocol. No adverse events were reported with the mice.

The corrective actions consisted of amending the protocol to include the procedures, requiring the Principal Investigator and staff to undertake retraining on relevant topics, and placing 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 institution to comply with the PHS Policy. Please ensure that the NIH grant is not charged for any unauthorized animal activities. 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



A3627-G

March 11, 2020

Brent Morse, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
7505 Rockledge Drive
Bethesda, MD 20892

Dear Dr. Morse:

Montana State University (MSU), Animal Welfare Assurance #D16-00379, provides this report of noncompliance in accordance with PHS Policy IV.F.3 regarding the following incidents:

- Implementation of significant changes to the protocol prior to IACUC approval. Specifically, research personnel administered iron in water and mice underwent submandibular blood collection which are not described in the protocol.

The above noncompliance incidents both occurred under the Principal Investigator's (PI) IACUC protocol entitled "Understanding the Contributions of Commensal Bacteria to Human Iron Metabolism". These incidents were first reported to OLAW on February 25 via phone call by Mr. Kirk Lubick, M.S., Director, Office of Research Compliance (ORC).

A review of billing records showed that all direct costs associated with procurement, care, and use of the animals in the studies under the PI's IACUC protocol were paid from NIH Grant NIH 5 R21 DK 114607 02.

On February 21, 2020 the IACUC received information of the above noncompliance incidents. No animals died or experienced any adverse events. A total of 50 mice were involved in these experiments.

Mr. Lubick met with the PI on February 24, 2020 regarding the incident and indicated that exclusion from the IACUC protocol was an unintentional oversight.

To address the noncompliance incidents, the following corrective action plan will be implemented:

1. A protocol modification has been submitted to include the procedures that were inadvertently omitted.
2. The PI and the research staff will be trained again on measures to prevent these incidents from occurring in the future. The training, will encompass:
 - MSU protocol review/amendment processes
 - CITI Course Modules
 - About the IACUC
 - Federal Laws Policies and Guidelines

Office of Research and
Economic Development
207 Montana Hall
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- Making Changes to an Approved Animal Use Protocol
- Personnel and Their Welfare
- Planning Research and Completing the Protocol Form
- Procedures: Surgery, Antibody Production and Blood Collection
- Reporting Animal Use Concern
- Working with the IACUC
- Post Approval Monitoring

3. The IACUC protocol will undergo Post Approval Monitoring, when experimental procedures are occurring on a periodic basis.

MSU is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this matter, please contact Kirk Lubick, M.S., Director of ORC.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Jason Carter

Vice President for Research and Economic Development & Graduate Education
Montana State University
P O Box 17460, Montana Hall, (b) (4)
Bozeman, MT 59717

Cc: Kirk Lubick, Director ORC

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, March 16, 2020 7:42 AM
To: Lubick, Kirk
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report to OLAW (Montana State University - A3627-01)

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

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

From: Lubick, Kirk <kirk.lubick@montana.edu>
Sent: Friday, March 13, 2020 5:31 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: Report to OLAW (Montana State University - A3627-01)

Dear Dr. Morse,

Please find attached MSU's final report, per PHS Policy IV.F.3, to OLAW. In the attached report you will find a detailed explanation of the circumstances and a corrective action plan, along with all of the pertinent details as required by OLAW. In addition, a preliminary report to OLAW was submitted, via telephone, on February 25th, 2020 describing the incident and the proposed corrective action plan.

Thanks and please let me know if you have any additional questions or concerns.

Kirk

Kirk Lubick
Director, Office of Research Compliance
Montana State University
Office: (b) (6)
Cell: (b) (6)



Initial Report of Noncompliance

By: Neene Gogge

Date: 2-25-20

Time: 4:02 PM

Name of Person reporting: Kirk Lybick (Director of Research Compliance)
 Telephone #: [REDACTED] (b) (6)
 Fax #:
 Email:

Name of Institution: Montana State University
 Assurance number: 016-00379

Did incident involve PHS funded activity? Yes - R21-DK-114607-02

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

Use of unapproved blood collection route and addition of water in the water without IACUC approval

Species involved: 50 micePersonnel involved: Research staff

Dates and times:

Animal deaths: None

Projected plan and schedule for correction/prevention (if known): _____

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____