



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Office of Laboratory Animal Welfare  
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Bethesda, Maryland 20817  
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DATE: January 15, 2019

TO: Michael M. Gottesman, M.D.  
Deputy Director for Intramural Research, NIH

FROM: Deputy Director, Office of Laboratory Animal Welfare

SUBJECT: Animal Welfare Investigation (#017-18) - Animal Welfare Assurance  
A4149-01 [Case 12S]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 4, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Rocky Mountain Laboratory of the National Institute of Allergy and Infectious Diseases, NIH. According to the information provided, OLAW understands that mice were used in study although this strain was not listed on the protocol.

The corrective actions consisted of counseling the Principal Investigator to adhere to the protocol and having the Animal Program Resource Manager verify all mouse strains on the shipping documents and check them against the protocol and amendments.

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.

(b) (6)

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

cc: Dr. Richard Wyatt  
Dr. Stephen Denny  
Dr. Steele-Mortimer



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health  
Bethesda, Maryland 20892

[www.nih.gov](http://www.nih.gov)

January 4, 2019

TO: Brent C. Morse, D.V.M.  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare

FROM: Deputy Director for Intramural Research, NIH

SUBJECT: Animal Welfare Investigation Report - Assurance A4149-01 (NIH Incident 017-18)

This correspondence conveys the results of an animal incident investigation conducted by the Rocky Mountain Laboratory (RML) ACUC of the National Institute of Allergy and Infectious Diseases, in accordance with Assurance A4149-01 and PHS Policy IV.F.3. The animal incident consisted of an investigator not following animal program and ACUC approved procedures when ordering and receiving a substrain of mice for use in an ACUC-approved study.

The event was first reported to the NIH Office of Animal Care and Use by the RML ACUC Coordinator on December 14, 2018. The details of the RML ACUC investigation and the corrective actions taken by the animal care program are outlined in the attached memorandum.

Please contact me or Dr. Stephen Denny, Acting Director, Office of Animal Care and Use, if additional information or clarifications are required.

(b) (6)

Michael M. Gottesman, M.D.

Attachment

cc: Dr. Wyatt  
Dr. Steele-Mortimer  
Dr. Denny



National Institute of  
Allergy and  
Infectious Diseases

ROCKY MOUNTAIN LABORATORIES

903 South 4th Street  
Hamilton, Montana 59840

December 31, 2018

Dr. Michael Gottesman, M.D.  
NIH Deputy Director for Intramural Research

Dear Dr. Gottesman,

The National Institute for Allergy and Infectious Diseases (NIAID) at Rocky Mountain Laboratories (RML), in accordance with Assurance A4149-01 and PHS Policy IV.F.3., provides this report of noncompliance, of a failure to follow ACUC administrative procedures. The incident was first reported to NIH's Office of Animal Care and Use on December 14, 2018.

This study uses Collaborative-Cross (CC) mice, which are a large collection of inbred mouse strains developed to aid the study of complex genetic traits and diseases. Availability of CC strains determines which strains will be used on the study, and this is often not known until the collaborators are ready to ship animals to RML. The RML ACUC decided that additional CC strains must be added to the approved protocol as an Administrative Change, since it does not affect the total animal numbers or any of the research described in the protocol. Thus, the PI must send an email to the ACUC coordinator listing any additional CC strains before using them. Recently the collaborating lab sent several CC strains that were used on the study although they were neither listed on the original protocol nor added by an amendment.

The RML ACUC reviewed the incident at a fully convened ACUC meeting held on December 21, 2018. The PI was not present at the meeting, but an overview was presented by a lab member. The committee agreed that this was a noncompliance issue due to lack of oversight, or carelessness, by the PI. The committee discussed corrective measures that could be implemented to prevent recurrence of an incident of this nature. The ACUC Chair will speak with the PI, who is special volunteer at RML, and the Responsible Individual on the protocol to discuss the importance of adhering to the protocol and the potential consequences for them if they are found to be out of compliance in the future. Additionally, going forward, the Animal Program Resource Manager will verify all strains listed on the shipping manifests from this collaborator, against the protocol and addenda.

Rocky Mountain Laboratories is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OACU in this regard. After reminding the investigator to closely follow the protocol, the Committee feels this action should reasonably ensure that additional issues of this nature will not occur in the future.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Olivia Steele-Mortimer, Ph.D.  
Chair RML ACUC



**Morse, Brent (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, January 09, 2019 1:47 PM  
**To:** Denny, Stephen (NIH/OD) [E]; OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: A4149-01 NIH Animal Incident Report (RML 017-18)

Thank you for providing this report Dr. Denny. We will 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.

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**From:** Denny, Stephen (NIH/OD) [E]  
**Sent:** Wednesday, January 09, 2019 1:09 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** A4149-01 NIH Animal Incident Report (RML 017-18)

Dear OLAW/DCO,

Final reports from the NIH Institutional Official and the National Institutes for Allergy and Infectious Diseases-Rocky Mountain Laboratory (NIAID-RML) ACUC addressing an animal incident reported to this office on December 14th are attached. The incident involved a principal investigator failing to follow the mouse procurement and identification procedures outlined in an NIAID-RML ACUC-approved animal study proposal and policy document.

If you have any questions please contact me via email or the phone number listed below. Thanks, Steve

STEPHEN L DENNY, DVM, MS, DACLAM | Acting Director, Office of Animal Care and Use | National Institutes of Health | Bldg 31-Rm B1C37, 9000 Rockville Pike, Bethesda, MD 20982 | Phone: (301) 496-5424 | <http://oacu.od.nih.gov>