



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) 402-7065

December 20, 2019

Re: Animal Welfare Assurance
A4366-01 [OLAW Case 1G]

Dr. Steve Monroe
Associate Director, Office of Laboratory
Science and Safety
Centers for Disease Control and Prevention
1600 Clifton Road, NE
Clifton Building 21, Room 02306
Atlanta, GA 30329

Dear Dr. Monroe,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your letter received December 16, 2019 regarding noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals at your institution. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, our office understands that on September 12, 2019, it was discovered that a laboratory had been performing intradermal injections that were not part of the protocol approved by the Institutional Animal Care and Use Committee (IACUC). The IACUC Chair, Alternate Chair, and Compliance Officer counseled the laboratory's Principal Investigator (PI) on requirements to follow approved protocols as written, and to submit an amendment should changes be needed. An amendment was submitted which was approved by the IACUC.

Based on its assessment of this explanation, OLAW understands that measures have been taken to prevent recurrence of this problem. OLAW concurs with the actions taken by your institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate having been informed of this matter and at this time find no cause for further action by this office.

Sincerely,

Nicolette Petervary, VMD, DACAW
Animal Welfare Policy Specialist
Office of Laboratory Animal Welfare

cc: IACUC Contact

A4366-1G



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control and Prevention
National Center for Emerging and Zoonotic
Infectious Diseases
Division of Vector-Borne Diseases
3156 Rampart Road
Fort Collins, Colorado 80521

MEMORANDUM

To: Steve Monroe, PhD
Associate Director, Office of Laboratory Science and Safety
Institutional Official

From: Aaron Brault, PhD *Act*
Chairperson, CDC-Fort Collins Institutional Animal Care and Use Committee
on behalf of the IACUC

Subject: Report modified - CDC Fort Collins (OLAW Assurance #A4366-01)
DVBD Incident Report FY2019-009

Date: December 10, 2019

CC:

(b)(6)

Fort Collins Institutional Animal Care and Use Committee (IACUC)

This memorandum is to inform you of a reportable incident that occurred at the Division of Vector-Borne Diseases (DVBD) in Fort Collins, CO that the IACUC recommends reporting to OLAW.

On September 12, 2019, an animal care technician reported to the veterinary medical staff that four rabbits each had red swollen injection sites in the right lateral lower thoracic/upper lumbar area of their backs. The alternate Attending Veterinarian and clinical veterinarian noted that intradermal injections were not in the IACUC-approved protocol and reported this to the Chair and Compliance Officer.

The IACUC Chair and alternate Chair along with the Compliance Officer met with the PI and key associate on September 20, 2019 to discuss the digression. During that discussion the PI and associate apologized for the digression and agreed to submit a protocol amendment adding the use of intradermal injections. The Chair and alternate Chair along with the Compliance Officer counseled the PI and key associate on the need to follow the protocol and if a new procedure is needed, an amendment should be submitted and IACUC-approved before the new procedure can be performed. The IACUC was informed of this protocol noncompliance during the meeting held on October 8, 2019. The IACUC agreed this noncompliance should be reported to OLAW. The protocol amendment was also approved.

Because intradermal injections were not included in the IACUC-approved protocol, this is considered a noncompliance reportable to OLAW.

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, December 16, 2019 10:35 AM
To: Monroe, Steve (CDC/DDPHSS/OLSS/OD)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reportable incident: CDC-Ft. Collins

Thank you for this report, Dr. Monroe. We will respond soon.

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

From: Monroe, Steve (CDC/DDPHSS/OLSS/OD) (b)(6)
Sent: Monday, December 16, 2019 10:13 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Animal Care and Use Program Office (CDC) (b)(6)

(b)(6)

(b)(6)

; Monroe, Steve (CDC/DDPHSS/OLSS/OD)

(b)(6)

Subject: Reportable incident: CDC-Ft. Collins

Dr. Morse,

Attached is a report of an incident that occurred at the CDC facility in Ft. Collins, CO on 12 September 2019. The Ft. Collins IACUC reviewed the incident and provided guidance, as described in the attached memo.

Please contact me if you require any additional information regarding this incident.

Best,
Steve

Steve Monroe, PhD
Associate Director for Laboratory Science and Safety
Director, Office of Laboratory Science and Safety
Centers for Disease Control and Prevention (CDC)

(b)(6)

<http://www.cdc.gov/labs/>

OLSS Office of Laboratory
Science and Safety

Strengthening the culture of laboratory science and safety at CDC