DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
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April 26, 2017

Re: Animal Welfare Assurance
A4176-01 [OLAW Case T]

Colonel (b) (6) [redacted]
Institutional Official and Director
Armed Forces Radiobiology Research Institute
8901 Wisconsin Avenue
Bethesda, MD 20889

Dear Colonel (b) (6) [redacted]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of a March 27, 2017 letter signed by Dr. (b) (6) [redacted] regarding an incident of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Armed Forces Radiobiology Research Institute. According to the information provided, OLAW understands that on February 20, 2017 two mice were found dead in a cage along with one live, but very weak cagemate. The cause was determined to be multifactorial and included: improper breakdown and replacement of caging by the investigative staff; improper documentation of this activity as well as other husbandry and technician activities, and; inadequate cross-training. It was not stated if the associated activity is supported by PHS funds.

Corrective actions to address the multifactorial root cause included retraining of husbandry, technical, and investigative support staff. Documentation requirements will be reviewed and forms modified.

The consideration of this matter by the Armed Forces Radiobiology Research Institute was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to resolve the issue and prevent recurrence were appropriate. We appreciate being informed of this matter and find no cause for further action by this office at this time.

Sincerely,

(b) (6) [redacted]

(b) (6) [redacted], DVM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

A 4176-T

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
ARMED FORCES RADIOBIOLOGY RESEARCH INSTITUTE
8901 WISCONSIN AVENUE, BUILDING 42
BETHESDA, MARYLAND 20889-5603

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC)
IACUC INVESTGICATION – MARCH 27, 2017

I. **PURPOSE:** An IACUC subcommittee was established to investigate and determine the contributing factors surrounding the death of two mice assigned to AFRRI study protocol 214-06-008 and recommend corrective actions to prevent future occurrence.

II. **BACKGROUND:** On February 20, 2017 two mice belonging to protocol 214-06-008 were discovered dead at approximately 1:30 pm by the Co-investigator and contracting technician due to a lack of food. One cagemate had survived but was found to be in very weak condition. On February 21, 2017 these findings were reported to a member of the veterinary technician staff by one of the protocol's senior technicians. After the Veterinary Sciences Department's (VSD) staff discovered the event, the incident was promptly reported to the Attending Veterinarian and AFRRI IACUC. The IACUC established a subcommittee to investigate this occurrence.

III. **FINDINGS:** A total of eleven people were interviewed by the IACUC subcommittee, husbandry and animal health status records from 2/14/17 through 2/27/17 were examined, and the study protocol was reviewed. The subcommittee determined that the adverse event's root cause was multifactorial. The following findings were discovered:

1. The primary contributing factor was the improper breakdown and replacement of cages by the investigative staff before the weekend; this was likely the last time food was placed in the cage (undocumented). This issue has also contributed to more potential animal welfare issues that week such as flooded caging.
2. The Co-Investigator was negligent in reporting the unexpected deaths to the Attending Veterinarian and the Principal Investigator.
3. The protocol study staff failed to maintain proper documentation to communicate with VSD staff about the cage breakdown and changing events before the weekend.
4. Some VSD technicians are not adequately cross-trained to exercise all necessary husbandry activities.
5. Some VSD staff members execute and document animal rounds and cage changes inconsistently.
6. Documentation of discovered notable animal events is not consistent.

IV. RECOMMENDATIONS:

1. All adverse events related to any AFRRI scientific study must be reported immediately to the Attending Veterinarian and responsible Principal Investigator. Communication should be made to the Co-Investigator to promote accurate, appropriate, and timely reporting in the future.
2. VSD husbandry and technician staff will undergo SOP training to reinforce the activities surrounding animal rounds and cage changing.
3. All investigative support staff involved with VSD related activities, will undertake documented training led by trained VSD technicians/caretakers to standardize methodologies and procedures for animal care.
4. All investigative staff will familiarize themselves with pertinent VSD SOPs to understand the coordination of animal care and necessary documentation as a part of a regular training program.
5. All Investigative staff will utilize VSD forms and/or animal records (SF 600s) to document all animal manipulations and health discoveries.
6. VSD forms will be modified to include the time when an animal manipulation or health status change/concern has occurred.

(b) (6)
[redacted]

Chair, IACUC

(b) (6) [redacted] **(NIH/OD) [E]**

From: (b) (6) [redacted] (NIH/OD) [E]
Sent: Friday, April 07, 2017 8:16 AM
To: (b) (6) [redacted]
Subject: RE: AFRRI IACUC INCIDENT AND INVESTIGATION

Thank you for this report, Dr. (b) (6) [redacted]. We will respond soon. In future, please send all final reports to (b) (6) [redacted]

(b) (6) [redacted], M.S., D.V.M.
Director, Division of Compliance Oversight
OLAW

From: (b) (6) [redacted]
Sent: Friday, April 07, 2017 8:04 AM
To: (b) (6) [redacted]
Cc: (b) (6) [redacted] (b) [redacted] (b) (6) [redacted] (b) (6) [redacted] (b) (6) [redacted]
Subject: AFRRI IACUC INCIDENT AND INVESTIGATION

Dear Dr. (b) (6) [redacted]

In February 2017, an AFRRI IACUC subcommittee was established to investigate and determine the contributing factors surrounding the unexpected death of two mice. Attached are the findings of the investigation and a list of recommended corrective actions to prevent future occurrence. We are now working to implement the corrective actions.

Please contact me if you have any questions or if you require additional information.

Thank you.

v/r
(b) (6) [redacted] Ph.D.
Deputy Director
Armed Forces Radiobiology Research Institute
Uniformed Services University of the Health Sciences
Bethesda, MD 20814

(b) (6) [redacted]