DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive - MSC 7982
Bethesda, Maryland 20892-7982
Home Page: http://grants.nih.gov/grants/olaw/olaw.htm

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

November 28, 2017

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

Dr. (b) (6)
Chairman, IACUC
Armed Forces Radiobiology Research Institute
8901 Wisconsin Avenue
Bethesda, MD 20814

Dear Dr. (b) (6),

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 27, 2017 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at the Armed Forces Radiobiology Research Institute, following up on an initial report on December 28, 2016. According to the information provided, OLAW understands that five mini-pigs were found outside of their cages in two separate animal rooms. The cause was due to human error in failing to secure the latches. There were no adverse effects on the animals due to the escape.

The corrective actions consisted of counseling the animal caretakers involved, assigning alternative staff to the area, retraining all caretakers, using two individuals to double check sanitation and door closure, alternating personnel, and servicing the door latches.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Sincerely,

(b) (6)

(b) (6), M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: Mr. (b) (6) Institutional Official

27 Nov 17

From: (b) (6) Chairman, IACUC, Armed Forces Radiobiology Research Institute, Bethesda, MD 20852
To: Dr. (b) (6), Division of Compliance Oversight, Bethesda, MD 20892

SUBJ: Final Report ICO Animal Welfare Assurance A4176-01{OLAW Case R}

1. The AFRRI IACUC reviewed the mini-pig incident at the monthly IACUC meeting held on January 26, 2017. MAJ (b) (6) informed the IACUC that mini-pigs were found outside the cages during the Christmas weekend by the Principal Investigator (PI) staff. No animals were injured, the animals (mini-pigs) had not been irradiated, but VAP surgeries had been conducted on them 9-10 days prior to the incident. An investigation was conducted and the animal care staff were notified about the incident (details below). The animal care technicians were retrained and a recheck system was mandated by the Veterinary Sciences Division (VSD) for the staff. The IACUC discussed the cause of the incident and the corrective actions taken by the PI and VSD. The IACUC unanimously agreed with the actions taken by the PI and the staff of VSD.

- I (MAJ (b) (6) have investigated the incident situation and interviewed six people independently regarding the scenario that took place. I also investigated the caging involved and have come to the following conclusions that have contributed to the events involved:

- Veterinary Sciences Department of the Armed Forces Radiobiology Research Institute provides this preliminary report concerning the escape of 5 pigs from their home caging involved in a protocol titled "DEVELOPMENT OF WELL-CHARACTERIZED MINIPIG (*Sus scrofa domestica*) MODELS OF GI- AND H-ARS". This incident occurred on December 24, 2015 and was reported to the attending veterinarian and the IACUC Chair on December 28, 2016. The study Principle Investigator (PI) contacted the IACUC Chair and a staff veterinarian who conducted a root cause investigative inquiry. Information gathered from the direct investigation and interviews of six different staff members revealed no harm had come to any of the five study animals that were reported to be found loose in two separate animal rooms. Further investigation and inquiry by a staff veterinarian revealed two caretakers were on duty that morning and sanitized all swine caging early that morning and likely human error failed to fully engage the latching on the swine caging. It was also discovered the latching mechanisms on some of the swine caging present in both rooms close but need more than normal force to close. The following measures have recently been employed to prevent this incident from happening:

- A formal counselling has taken place for both caretakers involved in the incident
- Alternate staff have temporarily been assigned to the care of swine in those animal spaces until proper retraining has been conducted

- Caretaker personnel have been retrained on a single common method to deliver sanitation services in swine rooms
- A two person system is now employed to allow for a proper recheck of delivered sanitation and ensure the proper closure of pen doors
- Alternate groups or combinations of personnel are now employed to reduce systematic human error and group tendencies.
- Caging has been adjusted and oiled to reduce mechanical friction of latching mechanisms

- A full IACUC board is scheduled to meet 26 JAN 2016 to further discuss the incident and solutions to prevent future escape from occurring.

2. Please contact me at (b) (6) or at (b) (6) if you have any additional comments or concerns.

(b) (6)

Chair, IACUC

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

From: (b) (6) (NIH/OD) [E]
Sent: Tuesday, November 28, 2017 7:46 AM
To: (b) (6)
Subject: RE: OLAW report

Thank you for this report, Dr. (b) (6) I will respond shortly.
(b) (6)

From: (b) (6)
Sent: Tuesday, November 28, 2017 7:17 AM
To: (b) (6)
Subject: RE: OLAW report

Dr. (b) (6)

Please find attached the final report. I am sorry that I did not get this to you on Friday. (b) (6) (b) (6) and it escaped my attention.

Please let me know if you have any questions.

Thank you,

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

(b) (6)
(b) (6)

From: (b) (6)
Sent: Monday, November 20, 2017 11:34 AM
To: (b) (6)
Subject: RE: OLAW report

Ok, thank you.

From: (b) (6)
Sent: Monday, November 20, 2017 11:25 AM
To: (b) (6)
Subject: RE: OLAW report

Dr. (b) (6)

Thank you and my apologies. I will send a final report.

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

(b) (6)
(b) (6)

From:
Sent: Monday, November 20, 2017 11:17 AM
To: (b) (6)
Subject: OLAW report

Hello Dr. (b) (6),

I am following up on a preliminary report from 12/28/16 regarding escaped mini-pigs. There was a follow up report on 1/24/17 but we never received the final. Please provide an interim or final report by the end of the week so this can be closed out.

Thank you.

(b) (6) M.S., D.V.M.
Deputy Director, OLAW

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

A4176

From: (b) (6) (NIH/OD) [E]
Sent: Tuesday, January 24, 2017 11:04 AM
To: (b) (6)
Subject: RE: MINI-PIG INCIDENT

Thanks for this update, Dr. (b) (6). It appears you have found the cause of the escapes. I will add this information to the file and will await the final report from the IACUC.
(b) (6)

From: (b) (6)
Sent: Tuesday, January 24, 2017 10:57 AM
To: (b) (6)
Subject: MINI-PIG INCIDENT

Dr. (b) (6)

I am following-up on the subject line regarding an incident at AFRRI involving several mini-pigs. MAJ (b) (6) AFRRI Veterinarian, conducted an investigation and provided the following information:

I (MAJ (b) (6)) have investigated the incident situation and interviewed six people independently regarding the scenario that took place. I also investigated the caging involved and have come to the following conclusions that have contributed to the events involved:

Veterinary Sciences Department of the Armed Forces Radiobiology Research Institute provides this preliminary report concerning the escape of 5 pigs from their home caging involved in a protocol titled "DEVELOPMENT OF WELL-CHARACTERIZED MINIPIG (*Sus scrofa domestica*) MODELS OF GI- AND H-ARS". This incident occurred on December 24, 2015 and was reported to the attending veterinarian and the IACUC Chair on December 28, 2016. The study Principle Investigator (PI) contacted the IACUC Chair and a staff veterinarian who conducted a root cause investigative inquiry. Information gathered from the direct investigation and interviews of six different staff members revealed no harm had come to any of the five study animals that were reported to be found loose in two separate animal rooms. Further investigation and inquiry by a staff veterinarian revealed two caretakers were on duty that morning and sanitized all swine caging early that morning and likely human error failed to fully engage the latching on the swine caging. It was also discovered the latching mechanisms on some of the swine caging present in both rooms close but need more than normal force to close. The following measures have recently been employed to prevent this incident from happening:

1) A formal counselling has taken place for both caretakers involved in the incident
2) Alternate staff have temporarily been assigned to the care of swine in those animal spaces until proper retraining has been conducted
2) Caretaker personnel have been retrained on a single common method to deliver sanitation services in swine rooms
3) A two person system is now employed to allow for a proper recheck of delivered sanitation and ensure the proper closure of pen doors
4) Alternate groups or combinations of personnel are now employed to reduce systematic human error and group tendencies.
5) Caging has been adjusted and oiled to reduce mechanical friction of latching mechanisms

A full IACUC board is scheduled to meet 26 JAN 2016 to further discuss the incident and solutions to prevent future escape from occurring.

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

(b) (6)
(b) (6)

From: (b) (6)
Sent: Wednesday, December 28, 2016 10:29 AM
To: (b) (6)
Subject: RE: UNEXPECTED EVENT USING AFRRI SARRP

Thank you for this preliminary report, Dr. (b) (6) I will open a new case file and look forward to receiving the final report after the IACUC has completed its investigation.

(b) (6)

From: (b) (6)
Sent: Wednesday, December 28, 2016 9:53 AM
To: (b) (6)
Cc: (b) (6)
(b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6) (b) (6)
Subject: RE: UNEXPECTED EVENT USING AFRRI SARRP

Dr. (b) (6)

Please find attached an incident report involving several mini-pigs. This was brought to my attention yesterday afternoon, with the PI following-up with an incident report. This appears to be an animal welfare issue and is currently under investigation. Appropriate action will be taken and I will follow-up with an after-action report.

Thank you for your review.

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

(b) (6)
(b) (6)

A4176-5

ARMED FORCES RADIOBIOLOGY RESEARCH INSTITUTE
8901 WISCONSIN AVENUE
BETHESDA, MARYLAND 20889-5603

Dec 28, 2016

MEMORANDUM TO: Dr. (b) (6) PhD, Chair, AFRRI IACUC Committee
LTC (b) (6), DVM, Head, VSD
AFRRI IACUC Committee

SUBJECT: Incident Report on cage doors left open in minipig rooms (b) (4) and (b) (4)

REFERENCES: (1) Protocol: P-2016-03-005

Purpose. This memo provides the AFRRI IACUC Chair, Attending Veterinarian, and the IACUC Committee with a brief description of the events that occurred on Dec 24, 2016.

Events: On Dec 24th 2016, VSD morning caretaker(s) left some of the cages open, after washing down the room. Five (5) animals got out, and were free to roam in the room until the HJF caretaker on my staff came for his pm rounds. He found several signs of scratch and bites. The same incident occurred in November, when 2 animals escaped from their cages.

This is concerning for several reasons:

- MP can get hurt while jumping off the cage, and may break a limb.
- if left able to freely interact, the MP will bite and scratch each other until they establish dominance
- the animals from last Saturday had just undergone surgery; we found no damage or infection at the wound site, but this is a fortunate coincidence
- if irradiated animals get wounded, they may die just because of infection or bleeding to the wound and not radiation damage. In this case, they would have to be dropped from the study.

How can this issue be avoided in the future?

Very Respectfully,

(b) (6)

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

From: (b) (6) (NIH/OD) [E]
Sent: Wednesday, December 28, 2016 10:29 AM
To: (b) (6)
Subject: RE: UNEXPECTED EVENT USING AFRRI SARRP

Thank you for this preliminary report, Dr. (b) (6) I will open a new case file and look forward to receiving the final report after the IACUC has completed its investigation.

(b) (6)

From: (b) (6)
Sent: Wednesday, December 28, 2016 9:53 AM
To: (b) (6)
Cc: (b) (6) (b) (6)
(b) (6) (b) (6)
(b) (6)
(b) (6)
Subject: RE: UNEXPECTED EVENT USING AFRRI SARRP

Dr (b) (6)

Please find attached an incident report involving several mini-pigs. This was brought to my attention yesterday afternoon, with the PI following-up with an incident report. This appears to be an animal welfare issue and is currently under investigation. Appropriate action will be taken and I will follow-up with an after-action report.

Thank you for your review.

v/r

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

(b) (6)
(b) (6)