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

July 21, 2021

Re: Animal Welfare Assurance
A4117-01 [OLAW Case 1B]

(b) (6)
Commander
WRAIR/NMRC
503 Robert Grant Avenue
Silver Spring, MD 20910

Dear (b) (6),

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 7, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Walter Reed Army Institute of Research, following up on an initial telephone report on February 5, 2021. According to the information provided, OLAW understands that in a ferret study of traumatic brain injury, a laboratory member failed to consult with the veterinary team and did not provide analgesics as described in the approved protocol. The animal had been examined by the individual and its condition remained unchanged from an earlier check and no subsequent check was performed. There were inconsistencies in the pain score chart and medical records and the animal's medical records were not in the designated location for veterinary review.

The ferret was subsequently found to be in pain/distress and was given analgesics. To ensure appropriate monitoring and care, after hours checks will now be conducted by more than one individual or by the veterinary team. The person responsible was retrained on assessing pain and filling out the relevant records and the records will be kept in a defined location. The pain score sheet was modified to better accommodate this protocol and the number of health checks needed.

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.

Sincerely,

(b) (6)

Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair

DEPARTMENT OF THE ARMY
WALTER REED ARMY INSTITUTE OF RESEARCH
503 ROBERT GRANT AVENUE
SILVER SPRING, MD 20910-7500

REPLY TO
ATTENTION OF

MCMR-UWZ

7 July 2021

MEMORANDUM FOR Director, Division of Compliance Oversight, Office of Laboratory Animal Welfare, National Institutes of Health, Bethesda, MD 20892

SUBJECT: Final Report to preliminary report provided on 5 February 2021 from Facility A4117-01 (Walter Reed Army Institute of Research/Naval Medical Research Center)

1. The WRAIR/NMRC Animal Care and Use Program, in accordance with Assurance A4117-01 and PHS Policy IV.F.3., provides this report of noncompliance regarding actions taken by a member of the investigative team from NMRC protocol 19-OUMD-09, "Individualized medicine in a Ferret (*Mustela putorius furo*) model of TBI polytrauma through the continuum of care". This incident was first reported to the office of (b) (6) (b) (6) OLAW, on February 05, 2021 via a telephone call by (b) (6) IACUC Chair and Director, Animal Research Compliance Office. The funding for this protocol is not NIH.

2. On January 29, 2021, the Animal Research Compliance Office received information that a member of the investigative team did not appropriately consult the Veterinary Services Program team and subsequently did not administer analgesic as prescribed in the protocol. At the time of the discovery, the animal was demonstrating signs of pain and distress and was immediately administered the prescribed analgesia.

3. On 29 January 2021, the Chair identified a subcommittee of three IACUC members to investigate the incident. They found the provided allegation to be accurate and identified three findings and made the corresponding recommendations.

a. Finding: The investigative member in question did in fact evaluate the animal during and evening check but determined that the animal's condition had not changed from an earlier check and it was too soon after the previous dose of analgesia to provide the succeeding dose. The member planned to return a few hours later to recheck the animal but unfortunately, did not return or notify anyone from the investigative team or veterinary services personal to conduct the evaluation. Recommendation: For animal evaluations conducted after normal business hours, more than one individual should be present from the investigative and/or the veterinary services team. This will create a safeguard to ensure accountability that the appropriate course of action for animal care will be implemented.

b. Finding: There were inconsistencies in the pain score chart and medical records with respect to animal evaluations and the pain score sheet was not designed adequately to capture increased frequency of observations. Recommendation: The

investigative team member needs to be retrained on proper assessment and completion of the pain score chart and medical record. Additionally, the pain score chart should be reformatted for this protocol to allow space for annotating additional animal checks beyond the required occurrences.

c. Finding: The animal's medical record was not in the designated location, thus impeding the veterinary services personnel evaluation during morning rounds. Recommendation: A defined location for keeping medical records in each corridor in the vivarium should be determined and research staff need to be trained on the importance of leaving the medical records in identified location.

4. The subcommittee reported these findings and recommendations to the IACUC on 18 March 2021. The IACUC concurred with the findings and recommendations. The PI was notified of the outcome and has made the necessary procedural changes and has confirmed the required training has been completed. Of note, the subcommittee uncovered no evidence of maliciousness on the part of any individual pertaining to this complaint. On the contrary, all participants in this investigation appeared to be open, honest, and forthcoming. The PI and investigative team member were fully compliant to the recommendations. The IACUC determined that this was an isolated incident and not a programmatic failure.

5. The WRAIR/NMRC Animal Care and Use Program 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 report, please contact (b) (6) , IACUC Chair ((b) (6) @mail.mil or (b) (6)) or (b) (6) Attending Veterinarian ((b) (6) @mail.mil or (b) (6)). Thank you for your consideration of this matter.

(b) (6)

COL, MC
Commanding

1B

Office of Laboratory Animal Welfare

OLAW

Initial Report of Noncompliance

By: (b) (6) [redacted]

Date: 2/5/21 Time: 11:00

Name of Person reporting: (b) (6) [redacted]
Telephone #: (b) (6) [redacted]
Fax #:
Email:

Name of Institution: Walter Reed Army Inst of Research
Assurance number: A4117

Did incident involve PHS funded activity? No
Funding component: _____
Was funding component contacted (if necessary): _____

What happened?
Traumatic brain injury study ~ ferrets, 1 didn't get analgesic at night. PI staff responsible but didn't give drug as contract req.

Species involved: Ferret
Personnel involved:
Dates and times:
Animal deaths:

Projected plan and schedule for correction/prevention (if known): _____
Vet provided care, counsel

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
Case #_____