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

January 10, 2022

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

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

Dear (b) (6)

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 3, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Walter Reed Army Institute of Research, following up on an initial report on March 24, 2021. According to the information provided, OLAW understands that following euthanasia of a nonhuman primate on an approved protocol, an employee was directed to secure the unused controlled substances. Despite receiving instructions from several individuals, the drugs were not appropriately secured. The individual responsible indicated that insufficient training had been provided on appropriately handling controlled drugs.

The immediate action taken upon discovery consisted of other staff members appropriately securing the drugs. The employee originally tasked with the assignment was terminated. Corrective actions consisted of implementing a process to validate that individuals are competent to perform specific tasks unsupervised following training. A trained individual must now acknowledge that they are capable of performing a specific task and this will be documented. It was verified that no contaminated drugs are ever re-used.

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

3 September 2021

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

SUBJECT: Final Report of Incident Subsequent to Preliminary Report Communicated to OLAW on 24 March 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 final report regarding accusations made by a previous contract employee of the Henry Jackson Foundation in support of Naval Medical Research Command. This incident was first reported to the office of (b) (6) (b) OLAW, on March 24, 2021 via an e-mail from (b) (6) IACUC Chair and Director, Animal Research Compliance Office. The funding for this protocol is not NIH.

2. On 12 March, the Animal Research Compliance Office received a letter from a (b) (6) making an accusation (b) was used as a 'scapegoat' for an incident involving controlled drugs not having been secured in a drug locker overnight and ultimately 'fired" even though (b) did not received proper instruction or training.

3. On 16 March, the IACUC Chair identified a subcommittee of three IACUC members, to investigate the incident. While it is not the place of this subcommittee nor the IACUC to investigate matters of personnel actions regarding "being used as a scapegoat", they found there were some training practices on the part of the investigative team that should be improved. The following addresses the three specific allegations made by (b) (6) and the findings and recommendations of the subcommittee, of which two address said training practices.

a. "(b) did not received proper instruction or training."

Findings: Through extensive interviews and provided documentation, it appears (b) (b) (6) did in fact receive instruction and training on the handling of controlled drugs along with other tasks. However, there was no process in place to validate from the individual that the task had been mastered. For this task, even though (b) (6) had previously demonstrated the ability to manage controlled drugs in her possession, it was completed under circumstances that allowed for assistance from co-workers or supervisors during the process. In the situation under review, (b) (6) did not receive this type of assistance or support and subsequently the task was not completed.

Recommendation: The NMRC investigate team should implement a process to validate that individuals can in fact accomplish tasks unsupervised before they are left alone to implement said task.

b. (b) further claimed that (b) has concern that "people intended to use tainted drugs left in syringes".

Finding: The intent for leaving drugs in syringes is for proper accountability upon return to the drug locker custodian. The drugs were ultimately returned to the drug custodian, properly accounted for and discarded (see attachment 1). The subcommittee determined there was no intention to use "tainted drugs". The practice of re-using contaminated drugs in not consistent with current NMRC Policy.

Recommendation: No recommendations as the NMRC investigative team currently follows the policy to not re-use contaminated drugs.

c. "Request for training were 'ignored and/or denied'".

Finding: While requests for training were not ignored and/or denied, they were not addressed to the extent to make (b) (6) self-assured in her ability to perform the task without direct supervision by the leadership. The requests from (b) (b) (6) were met with suggestions from leadership for self-study via online courses and additional didactic training. However, leadership should have identified that (b) (6) was not prepared to perform the management of controlled substances and they should have provided more experiential type hands-on training to solidify (b) capability before asking (b) to accomplish this task independently. Additionally, with the potential negative consequences for unaccounted controlled substances, the investigative team leadership should have a system in place to ensure the senior person on site can confirm the completion of all critical tasks such as securing controlled substances.

Recommendation: NMRC Investigative team should implement a system of documentation that completes the circle of training by having the trained individual acknowledge in writing that they are capable to perform the tasks on which they have been trained. Additionally, the investigate team leadership should positively identify the senior person responsible for the completion of critical tasks when personnel are rotated for long procedures and subsequently have methods in place to confirm the completion of critical tasks such as the final disposition of controlled substances at the completion of the procedure.

4. The subcommittee reported these findings and recommendations to the IACUC on 15 July 20201. The IACUC concurred with the findings and recommendations. The PI was notified of the outcome and has made the necessary procedural changes. The PI and investigative team members were fully compliant to the recommendations. The IACUC

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determined that this was an isolated incident and not a programmatic failure. No animals were harmed as a result of this incident.

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 at (b) (6) (b) (6) @mail.mil or (b) (6) Attending Veterinarian at (b) (6) @mail.mil. Thank you for your consideration of this matter.

(b) (6)

Chair, WRAIR/NMRC Institutional Animal Care and Use Committee

Reviewed by WRAIR/NMRC Acting Institutional Official

(b) (6)

COL, MC
CF:
NMRC CO ((b) (6) MSC)

12 Mar 21

MEMORANDUM

From: LCDR (b) (6), Department Head ECD
To: Commanding Officer
Via: (1) Controlled Substances Inventory Board
(2) Executive Officer (acting)

Subj: CONTROLLED SUBSTANCE INCIDENT

Ref: (a) NAVMEDRSCHCENINST 6710.1N

Encl: (1) NONE

1. On 10 Mar 21 there was a controlled substances incident during which a contract employee in the En Route and Critical Care Department, (b) (6) (b) (6), left several controlled substances unattended in the surgical suites of the vivarium overnight which were discovered by another member of our department the following morning.

2. A detailed report of the incident has been compiled from the statements of department members (b) (6) (b) (6)

a. At 1130 on 10 Mar 21 a NHP model terminated and following euthanasia of the animal (b) (6) was tasked by (b) (6) with securing the remaining controlled substances that were not used. This included 110 mL Fentanyl (Schedule 2), 97.5 mL Euthanasia (Schedule 3), and 302 mL Alfaxan (Schedule 4). (b) reported that (b) did not know how to do this and requested instruction. (b) was given specific instructions by (b) (6) to waste any fentanyl in the syringe pump and return any unused drugs to (b) (6) then ensure they were secured in the drug locker. (b) asked for additional instruction and was referred to (b) (6) who had left following (b) overnight shift with the animal who explained the same procedure. (b) (b) (6) confirmed that (b) understood what (b) was asked and both (b) (6) and (b) (6) have stated that there was no ambiguity in the task or requested actions.

b. The next morning at 1030, (b) (6) went to start preparations in the operating suite. When (b) was moving a cart (b) found the unused drugs still sitting on a cart in the operating suite. The amount of drugs found matched the volumes listed above. (b) reported this immediately to (b) (6) and the drugs were secured.

3. (b) (6) was placed on administrative leave on the afternoon of 11 Mar 2021 and actions to terminate (b) employment through (b) were initiated. (b) was dismissed for breech of safety protocol and lack of professionalism and (b) access to base has been shut off. (b) (2) (b) (2)

Very respectfully,

(b) (6)

MC USN