

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

August 27, 2019

EOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 <u>Telephone</u>: (301) 496-7163 <u>Faesimile</u>: (301) 402-7065

Re: Animal Welfare Assurance #A3283-01 (OLAW Case 2P)

Jay Walsh, Ph.D. Vice President for Research Northwestern University Office for Research Rebecca Crown Center 633 Clark Street Evanston, IL 60208

Dear Dr. Walsh,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your letter dated August 21, 2019 reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Northwestern University. According to the information provided, OLAW understands that on July 11, 2019 nineteen mice were injected with Complete Freund's Adjuvant (CFA) although that procedure and the laboratory member who conducted it were not approved in the animal study protocol. On July 12th two mice were found dead and thirteen had severely swollen right rear legs and were euthanized. On July 15th an additional cage of four mice with right rear leg swelling was identified by the laboratory. The lab member failed to euthanize the mice before placing the cage on the dirty cage cart. On July 16th the CCM found the mice on the dirty cage cart with access to food and water and the mice were euthanized. On July 17th another cage containing one mouse was found on the dirty cage cart. A laboratory member had transferred three mice from the cage to the euthanasia chamber, missing one mouse hidden behind the food hopper. It was suspended by its tail and did not have access to food or water. The mouse was euthanized. The animal activity was supported by NIH funds.

Corrective actions included the IACUC accepting the PI's corrective action plan which included: the PI halting all procedures conducted by both laboratory members involved in these incidents until retrained; reviewing appropriate euthanasia procedures with all laboratory members; euthanized animals will be inspected by another laboratory member prior to placing cage on the dirty cage cart; ensuring all personnel read and understand the protocol under which they will conduct procedures; ensuring procedures are not started prior to IACUC approval; conducting bi-weekly laboratory members and the PI to attend an IACUC Brown Bag to review pertinent IACUC policies and procedures, and; scheduling and completing a PAM visit.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken by Northwestern University to investigate this incident, provide corrective measures, and prevent recurrence. OLAW concurs that the incident warranted reporting. Please be sure that the referenced grants are not charged for any unapproved procedures. We appreciate being informed of this matter and find no cause for further action by this office. Page 2 – Dr. Walsh August 27, 2019 OLAW Case A3283-2P

Sincerely,

(b) (6)

Brent C. Morse, DVM Director Division of Compliance Oversight Office of Laboratory Animal Welfare

cc: IACUC Contact

A3283-2P

Northwestern | RESEARCH

Jay Walsh, PhD Vice President for Research Northwestern University Office for Research Rebecca Crown Center 633 Clark Street Evansten, Illinois 60208

vp-research@northwestern.edu Office 847. 491. 3485

August 21, 2019

Brent Morse, DVM, DACLAM, Acting Director Division of Compliance Oversight Office of Laboratory Animal Welfare OLAW Division of Assurance National Institutes of Health Suite 360 MSC 7982 6705 Rockledge Dr. Bethesda, MD 20817

Dear Dr. Morse:

I have been informed by the Northwestern University Institutional Animal Carc and Usc Committee (NU IACUC; Assurance #A3283-01) that a Principal Investigator (PI) reported to the NU IACUC that an unapproved research team member conducted procedures on animals that was not approved in the protocol and live animals were left on the dirty cage cart without conducting euthanasia procedures.

The projects are supported by federal funds (1 R01 AG062249-01 [17 mice] and 1 R01 AG057884-01 [3 mice]).

Nineteen mice underwent Complete Freund's Adjuvant (CFA) injection procedures on July 11, 2019. During the Center for Comparative Medicine (CCM) morning health checks on July 12, 2019, two mice were found deceased and thirteen mice had severely swollen right rear legs and were humanely euthanized. The CFA injection procedure and the laboratory member who conducted the procedures were not approved in the animal study protocols.

On July 15, 2019, an additional cage of four mice with right rear leg swelling was identified by the laboratory. While addressing the disposition of the mice, the laboratory member was distracted by an on-going experiment in the laboratory and failed to euthanize the mice before placing the cage on the dirty cage cart. On July 16, 2019, the CCM found the mice on the dirty cage cart with access to food and water and were humanely euthanized.

On July 17, 2019, another cage containing one mouse was found by the CCM on the dirty cage cart. After investigation of the matter, it was found that the mouse was left in the cage by another member of this same laboratory. The laboratory member transferred three of the mice to the euthanasia chamber, missing one mouse hidden behind the food hopper. The mouse was suspended by its tail from the top of the cage by the wire bar lid and did not have access to food or water. The mouse was humanely euthanized by the CCM.

At the August 15, 2019 NU IACUC meeting, the Committee discussed these incidents and reviewed the PI's corrective action plan, which included the following elements:

- Halt all procedures conducted by both laboratory members involved in these incidents until euthanasia retraining is complete and deemed competent in those procedures by the PI and laboratory manager.
- Review appropriate euthanasia procedures with all laboratory members.
- Ensure animals will be euthanized in their home cage and inspected by another laboratory member prior to placing cage on the dirty cage cart.
- Track and match protocol number and procedure for substances and supplies purchases.
- Ensure that all personnel read and understand the protocol under which they will conduct procedures.
- Ensure procedures are not started prior to IACUC approval by implementing an addenda sign off sheet to track addenda requests and sign off by the requesting laboratory member, the PI and laboratory manager.
- Conduct bi-weekly laboratory meetings to discuss any proposed changes and status of each amendment.
- Ensure that adequate supplies of an approved tissue adhesive are available prior to initiating surgical procedures.
- Require that all laboratory members, including the PI, attend an IACUC Brown Bag to review pertinent IACUC policies and procedures.
- Schedule and complete a PAM visit.

The Committee reviewed and accepted the PI's plan to prevent a recurrence of these errors.

Please let me know if you need any further information.

Sincerely,

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Jay Walsh, Ph.D. Vice President for Research Institutional Official

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cc:

C. Heckman, Ph.D., Chair-IACUC M. Kozlowski, MSL, CPIA, Director IACUC Office (b) (6)

Morse, Brent (NIH/OD) [E]

From:	OLAW Division of Compliance Oversight (NIH/OD)			
Sent:	Thursday, August 22, 2019 1:12 PM			
То:	VP Research; OLAW Division of Compliance Oversight (NIH/OD)			
Cc:	(b) (6) CJ Heckman; Mandy J Kozlowski; (b) (6)			
Subject:	RE: Correspondence from Northwestern University			

Thank you for providing this report. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM Director Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health

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From: VP Research [mailto:VP-Research@northwestern.edu] Sent: Thursday, August 22, 2019 1:03 PM To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> Cc:^{(b) (6)} CJ Heckman <c-heckman@northwestern.edu>; Mandy J Kozlowski <mkozlowski@northwestern.edu>; ^{(b) (6)}

Subject: Correspondence from Northwestern University

Dear Dr. Morse,

Attached please find correspondence from Jay Walsh, Vice President for Research Northwestern University.

(b) (6)			

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