

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 Henne Page: http://grants.nih.gov/grants/olaw/olaw.htm

July 11, 2018

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

Re: Animal Welfare Assurance A3381-01 [OLAW Case 2C]

Dr. Jennifer K. Lodge Vice Chancellor for Research Washington University in St. Louis 660 South Euclid Ave., Box 8108 St. Louis, MO 63130

Dear Dr. Lodge,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 9, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Washington University in St. Louis, following up on an initial telephone report on April 10, 2018. According to the information provided, OLAW understands that eight mice received injectable anesthesia although the protocol was approved for use of an inhalant agent. The monitoring documentation was incomplete, the surgeon was not listed, and the mice came from different protocols. No adverse events were reported with the animals.

The corrective actions consisted of retraining and counseling the surgeon and laboratory staff, amending the protocol, and transferring the mice to one protocol.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of these problems. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M. Deputy Director Office of Laboratory Animal Welfare

cc: IACUC Chair Meredith Moore, Ph.D., IACUC Director

Washington University in St. Louis

Institutional Animal Care and Use Committee

July 9, 2018 Assurance: D16-00245 (A3381-01)

Dr. Axel Wolff, DVM, MS Deputy Director, Office of Laboratory Animal Welfare National Institutes of Health Rockledge Drive Bethesda, MD 20892-7982

Initial Report: April 10, 2018 Protocol: 20170058 "Targeting lysosomes to improve outcomes in myocardial infarction and heart failure; diabetes and Alzheimer's Disease"

Dear Dr. Wolff,

Washington University in St. Louis (WU), in accordance with PHS Policy IV.F.3 and Assurance D16-00245, submits this final report for a non-compliant event initially reported by the IACUC Director on April 10, 2018.

Veterinary staff identified approximately 8 mice that participated in surgeries performed as part of a research collaboration and utilized ketamine/xylazine anesthesia when isoflurane is listed in the approved protocol. The post-operative monitoring cards contained incomplete information about the xylazine used and the appropriately trained surgeon was not included in the list of surgeons participating in the collaboration. Further discussion revealed that the parabiosis partners originated from different protocols. The noncompliance did not result in any animal welfare issues and no adverse clinical consequences were observed.

In response, the surgeon completed immediate retraining with members of the Quality Assurance/Quality Improvement staff. The entire lab will complete the animal welfare regulations module. The collaborating investigators discussed the incident with the IACUC office and clarified the roles and responsibilities of the participants. Protocol amendments to clarify surgical procedures, personnel, and collaborator responsibilities have been submitted and are under review by the IACUC. Participants will transfer both parabiosis partners to a single protocol before the experiments begin.

The PI is committed to following the approved protocol and identified factors that contributed to the breach in compliance including the complexity of the collaboration, number of labs involved, space limitations, and challenges navigating multiple facilities and procedural spaces with incompatible housing status (barrier vs. in-and-out facilities). The modifications included in the protocol amendments and consistent use of the animal transfer form will mitigate these issues and prevent future non-compliance.

The incident and corrective action plan were reviewed and approved by the IACUC at the April 24, 2018 meeting. The retraining was completed by June 22, 2018 and the required amendment was approved by the IACUC on June 18, 2018. The WashU IACUC considers the incident resolved.

Campus Box 1054, One Brookings Drive, St. Louis, MO 63130 (314)362-3229, Fax (314)747-6695, http://dx.wustl.edu A3381-2C

The protocol is supported by NIH funding (R01NS094692) but no specific costs were determined to be associated with the incident. In accordance with NIH Grants policy, any NIH funds directly associated with noncompliant events would be returned.

Please let me know if you have any questions or would like additional information.

Sincerely, (b) (6)

Jennifer K. Vodge, Ph.D. Institutional Official Vice Chancellor for Research

Obtained by Rise for Animals. Uploaded 07/07/2020

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A3381-2C office of Leboratory Animal Well Initial Report of Noncompliance By:: 4/10/18 Date: Time: Z: 00 Name of Person reporting: Mercante Moore (b) (6) Telephone #: Fax #: Email: Name of Institution: A 3381 Assurance number: Did incident involve PHS funded activity? <u>Yes</u> Funding component: Was funding component contacted (if necessary): What happened? 6= & pavis of paraliseis mice used ingedable instead of unhalant ansilleslip Species involved: Movie Personnel involved: Dates and times: Animal deaths:

Projected plan and schedule for corréction/prevention (if known):

Retrain

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY Case #_____