



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, MD 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

October 26, 2021

Re: Animal Welfare Assurance
A3914-01 [OLAW Case 1R]

Dr. Timothy Denning
Vice President for Research and Economic Development
Georgia State University
100 Auburn Ave NE, (b) (4)
Atlanta, GA 30303

Dear Dr. Denning,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 1, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Georgia State University. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the Georgia State University Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: unauthorized personnel conducting animal activities, failure to adhere to the IACUC-approved protocol, and the conduct of animal-related activities without prior IACUC review and approval. The final report states the clinical veterinarian was notified that a post-doc fellow in Dr. Stern's laboratory performed unapproved stereotaxic surgery and administered a viral vector to mice. The mice were provided by Dr. Mabb and it was determined the animals were not properly transferred to Dr. Stern's protocol. It was also determined the post-doc fellow did not provide post-operative (post-op) care and monitoring and did not provide post-op analgesia to animals. In response, the clinical veterinarian administered post-op analgesics and the mice were later euthanized by the veterinarian. The report states Dr. Stern's protocol did not include survival surgery procedures and the post-doc fellow did not follow DAR policy. The policy requires researchers to complete a DAR surgery/anesthesia record and place stickers on cages, indicating animals underwent a surgical procedure.

It is understood the clinical veterinarian discussed the requirement to be listed on an IACUC-approved protocol and to perform approved procedures to the post-doc. It was also emphasized that it is necessary to provide post-op care and monitor animals until recovery from anesthesia. Dr. Mabb implemented the following corrective actions to prevent future recurrence:

- In the future, she will request written confirmation from a Principal Investigator (PI) that they and their personnel have IACUC approval before moving forward with the transfer of mice. She will also confirm with the DAR that the requesting PI and personnel are IACUC-approved. Upon confirmation, she will initiate the transfer of mice in the DAR portal to the PI's approved IACUC protocol number.
- She discussed the noncompliance incident with her lab technician and described the proper procedure to transfer mice to other labs. Dr. Mabb will directly handle all future mouse transfers to other investigators to avoid miscommunication.

Following discussions by the IACUC on August 27, 2021, the committee agreed with Dr. Mabb's corrective action plan. Additional corrective actions include the following:

- Dr. Stern must submit an amendment to his existing IACUC protocol or submit a new protocol to include surgical procedures in mice and list the post-doc fellow as authorized personnel to work with mice.
- The post-doc fellow must cease procedures in rats until (b) (6) proficiency can be evaluated. He must coordinate and schedule veterinarian oversight before he performs procedures in rats.
- The IACUC office will conduct post-approval monitoring (PAM) in conjunction with veterinarian oversight.

It is noted that this research is supported by PHS funding. Based on its assessment of this explanation, OLAW understands that the Georgia State University has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

Jacquelyn T.
Tubbs -S

Digitally signed by
Jacquelyn T. Tubbs -S
Date: 2021.10.26 14:15:38
-04'00'

Jacquelyn Tubbs, DVM, DACLAM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

A3914-1R

Mailing Address:
P.O. Box 3999
Atlanta, GA 30302-3999

In Person:
Centennial Hall, Suite 532
100 Auburn Ave NE
Atlanta, GA 30303

Phone 404-413-3517
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October 01, 2021

To: Brent Morse, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Re: Non-Compliance of IACUC Protocol A19048
PI: Angela Mabb, PhD
Entitled "Ubiquitin Pathway Disruption in Mouse Models of Neurological Disorders"
Funding Source: NIH #R21NS116760, "Insights into Gordon Holmes syndrome by substrate profiling of Triad3A and Chip using Orthogonal Ubiquitin Transfer"

Additional PI Involved: Javier Stern, PhD

Georgia State University IACUC (PHS Assurance Number D16-00527 (A3914-01)) investigated a non-compliance that was brought to their attention by the Clinical Veterinarian on August 12, 2021.

The factual background of this matter is as follows:

- The Clinical Veterinarian was informed by animal care staff that a postdoctoral fellow in Dr. Stern's laboratory performed unapproved stereotaxic surgery and administered a viral vector into mice.
- The mice were provided by Dr. Mabb from her approved IACUC protocol A19048. The animals were not properly transferred over to Dr. Stern's protocol.
- The [REDACTED] (b) (6) failed to perform required post-operative care and monitoring. Specifically, (b) (6) did not provide a heating source to animals during recovery and placed mice back in their home cage while partially anesthetized. (b) (6) did not provide analgesics post-surgery, citing that they were not needed. Analgesics were later administered by the Clinical Veterinarian. Animals were later euthanized by the Clinical Veterinarian.

- (b) (6) failed to follow an approved IACUC protocol and performed unapproved surgical procedures on mice. Neither (b) (6) nor survival surgery procedures are approved on Dr. Stern's mouse protocol A19010. (b) (6) is not listed as approved personnel on protocol A19048. Per Dr. Mabb's statement, the addition of (b) (6) as personnel onto her protocol had never been discussed.

(b) (6) failed to follow DAR policy which requires researchers to complete a DAR surgery/anesthesia record and place green surgery stickers on cage cards to indicate that mice underwent surgical procedures.

The Clinical Veterinarian discussed with (b) (6) the requirement to be listed on an approved IACUC protocol and to conduct approved procedures. She also reiterated the necessity to provide post-operative care and monitor animals until recovery from anesthesia. (b) (6) was asked to cease performing any additional animal surgeries until further notice. The Clinical Veterinarian spoke with both Dr. Mabb and Dr. Stern regarding the incident.

Dr. Stern and Dr. Mabb cooperated with the veterinary staff and the IACUC in the investigation of this matter and in developing corrective actions.

Dr. Mabb took the following corrective actions in response to these events:

- In the future, she will request written confirmation from a PI that they and their personnel have IACUC approval before moving forward with the transfer of mice. She will also confirm with the DAR that the requesting PI and personnel are IACUC approved. Upon confirmation, she will initiate the transfer of mice in the DAR portal to the PI's approved IACUC protocol number.
- She discussed the noncompliance incident with her lab technician and described the proper procedure to transfer mice to other labs. Dr. Mabb will directly handle all future mouse transfers to other investigators to avoid miscommunication.

The IACUC discussed the aforementioned facts during the August 27th IACUC meeting and determined the following:

- Failure to follow an approved IACUC protocol, provide adequate post-operative care and adhere to standard operating policies constituted noncompliance on the parts of both Principal Investigators and their research personnel.
- The IACUC agreed with Dr. Mabb's corrective action plan and requires no further action by this PI.
- Dr. Stern must submit an amendment to his existing IACUC protocol or submit a new protocol to include surgical procedures in mice and list (b) (6) as authorized personnel to work

with mice. (b) (6) must cease all mouse work until approval of the amendment or protocol.

- (b) (6) must cease procedures in rats until (b) (6) proficiency can be evaluated. (b) (6) must coordinate and schedule veterinarian oversight before he performs procedures in rats. The IACUC office will conduct post-approval monitoring (PAM) in conjunction with veterinarian oversight.

The investigators are aware that further violations of IACUC protocols or failure to implement corrective actions as set forth by the IACUC may result in additional sanctions, including permanent suspension of all IACUC protocols..

Please note that IACUC protocol A19048 lists NIH as a source of funding. This incident meets the criteria for reporting to the Office of Laboratory Animal Welfare (OLAW), under the directive of OLAW Notice #: NOT-OD-05-034, "Examples of reportable situations:

- conditions that jeopardize the health or well-being of animals, including natural disasters, accidents, and mechanical failures, resulting in actual harm or death to animals.
- failure to adhere to IACUC-approved protocols.

If you have any questions concerning these issues, please feel free to contact the IACUC office.

Sincerely,

(b) (6)

Timothy L. Denning, Ph.D.
Vice President for Research and Economic Development
Distinguished University Professor

Cc: IACUC file
IACUC Chair
Attending Veterinarian
AAALAC

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, October 15, 2021 8:35 AM
To: Institutional Animal Care and Use Program
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW Final Notification GSU (Assurance #A3914-01)- IACUC Protocol-NC- Final Report

Thank you for this report. We will send a response soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: Institutional Animal Care and Use Program <iacuc@gsu.edu>
Sent: Thursday, October 14, 2021 12:46 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Tubbs, Jai (NIH/OD) [E] <jacquelyn.tubbs@nih.gov>; 'accredit@aaalac.org' <accredit@AAALAC.org>
Cc: Timothy Luke Denning <tdenning@gsu.edu>; (b) (6)
(b) (6)
Subject: OLAW Final Notification GSU (Assurance #A3914-01)- IACUC Protocol-NC- Final Report

Good Afternoon,
Please see the attached final report from Georgia State University. Please contact GSU's Office for questions or concerns.

Sincerely,

(b) (6)