



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) 402-7065

August 29, 2018

Re: Animal Welfare Assurance
A3310-01 [OLAW Case 1O]

Dr. Phillip Cunningham
Associate Vice President for Research
Wayne State University
5700 Cass Ave., (b) (4)
Detroit, MI 48202

Dear Dr. Cunningham,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 23, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Wayne State University. Your final report supplements the information in a prompt preliminary telephone report on July 27, 2018 and your letter submitted to this office on August 1, 2018. According to the information provided, OLAW understands that on July 26, 2018 an investigator was directed by a veterinarian to euthanize a group of mice due to profound and persistent vestibular disturbance. Due to various circumstances the investigator failed to euthanize the mice and instead housed them in a lab overnight without IACUC approval. The animals were returned to the animal facility the next day and then euthanized. This animal activity is funded by the PHS.

Corrective and preventive measures included suspension on July 27, 2018 of all protocols under the PI. Animal welfare and study-related procedures will be overseen by the IACUC and the Division of Laboratory Animal Resources (DLAR) including unannounced visits to the lab. Meetings will be held between the PI, DLAR staff and IACUC members as needed. Veterinarians will be provided prior notification of planned procedures that have the potential to cause adverse symptoms. The PI will also provide veterinarians with updates of research activities involving biohazard and chemical hazards. Periodic updates will be provided to the IACUC. The protocol suspension was lifted on August 8, 2018. OLAW confirms that this incident was reported by your institution to the funding component at NIH.

The prompt consideration of this matter by Wayne State University was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to resolve the issue were appropriate and the on-going oversight to prevent recurrence is expected to be effective. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

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

cc: IACUC Contact



Philip R. Cunningham, Ph.D.
Assoc. Vice President for Research
Wayne State University
5057 Woodward Avenue, Suite 2317
Detroit, MI 48202

(b) (6)

philc@wayne.edu

Animal Welfare Assurance Number: D16-00198

August 23, 2018

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892
olawdco@mail.nih.gov

RE: Follow-up regarding the suspension of three WSU animal protocols

Dear Dr. Morse,

I am writing to report that the suspension of WSU animal protocols 18-01-0457, 17-05-265 and 17-11-0387 initially reported to you on August 1, 2018 was lifted on August 8, 2018. Protocol 18-01-0457 is associated with the NIH grant R01DC013275; *Regeneration of auditory synaptic contacts using stem cell-based approaches*. The IACUC also made the official determination that the incident listed below constituted serious non-compliance with the provisions of the *Guide*:

- Failure to follow veterinarian's order to euthanize animals experiencing profound, persistent and unresolvable vestibular disturbances.
- Housing said animals overnight in lab space not IACUC approved for overnight housing.

The following corrective actions have been implemented:

- 1) Animal welfare and study-related procedures will be overseen by DLAR and/or IACUC personnel. This includes unannounced visits to the lab space.
- 2) Periodic meetings and discussions will be held among the PI, DLAR staff and members of the IACUC as needed. The IACUC acknowledged that the PI has already proactively initiated the first such interactive meeting on August 6, 2018 and agreed this was a positive step going forward on the part of the PI.
- 3) The PI will provide veterinarian(s) with prior notification of planned procedures that have the potential to cause adverse symptoms (including ouabain injection related studies, surgeries, etc.). The IACUC is hopeful that this will further enhance positive interactions among the PI, lab staff and DLAR, and will also help re-establish a relationship of mutual trust and collaboration.

- 4) The PI will provide DLAR veterinarians with updates of research activities involving biohazard and chemical hazards. The IACUC requires this to ensure the personal safety of all who work within this lab space, and those who may visit unannounced (as per requirement #1). The PI subsequently met with DLAR and IACUC representatives on August 13, 2018 and provided the requested information.
- 5) Periodic updates will be provided to the IACUC at convened meetings to review the findings from unannounced visits and periodic meetings held with the PI, lab staff and DLAR/IACUC.

Please contact me know if you would like additional information.

Sincerely,

(b) (6)

Philip R. Cunningham, Ph.D.

c.c. Dr. Nancy Freeman, Program Official, NIH, freemann@nidcd.nih.gov
Dr. James Swearingen, Global Director, AAALAC International, accredit@AAALAC.org
Dr. Lisa Anne Polin, IACUC Chair, ac8694@wayne.edu

(b) (6)

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(b) (6)

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Monday, August 27, 2018 7:43 AM
To: Myrbeck, Edward (NIH/NIDCD) [E]
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: suspension Ifited: R01 DC013275

Good morning Mr. Myrbeck,

Thank you for contacting OLAW. We have received the final report from Wayne State regarding this issue. I have reviewed the corrective and preventive measures put in place by the University and they are acceptable. I will send them an official response within the next few days. You can lift the restriction at any time.

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: Myrbeck, Edward (NIH/NIDCD) [E]
Sent: Friday, August 24, 2018 2:26 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Subject: suspension Ifited: R01 DC013275

Hi Dr. Morse -

NIDCD received the attached letter from Wayne State University. They lifted the animal suspension on R01 DC013275, PI: Zhengqing Hu. Kindly verify NIDCD can now revise the award to lift the vertebrate animal restriction.

Thanks -
Eddie Myrbeck
NIH/NIDCD Grants Mgmt
301-435-1405



A3310 -10
Prelim.

Philip R. Cunningham, Ph.D.
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Animal Welfare Assurance Number: D16-00198

August 1, 2018

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892
olawdco@mail.nih.gov

RE: Suspension of three WSU animal protocols: Initial report

Dear Dr. Wolff,

I am writing to report the suspension of WSU animal protocols 18-01-0457, 17-05-265 and 17-11-0387. Protocol 18-01-0457 is associated with NIH grant R01DC013275; *Regeneration of auditory synaptic contacts using stem cell-based approaches*. A researcher at Wayne State University (WSU) failed to follow WSU policy and federal regulations which led to deviations from the provisions of the *Guide* with respect to the proper care and use of animals in research.

The investigator failed to follow veterinary instructions on 7/26/18 to euthanize a group of animals experiencing profound and persistent vestibular disturbance. In addition, the investigator housed the animals in his laboratory, a location that lacks IACUC approval for overnight housing, where temperatures fell to 64 °F. Two additional cages (each with a singly housed, healthy, male mouse) were also found housed in the laboratory space. Upon discovery by DLAR staff the following morning (7/27/18), the animals were immediately removed from the laboratory and transferred back to the animal facility where they were assessed by a veterinarian and found to be alive but without improvement in the original condition.

When asked, the PI indicated that he agreed with the original recommendation for euthanasia and stated that he wished to additionally determine the potential cause for the unexpected vestibular disturbances and had planned to harvest tissue in the evening of 7/26/18. When he finally prepared to perform the euthanasia and harvest he could not readily locate the needed fixative and decided to wait until the next morning when fixative was available. DLAR staff or veterinarians were not contacted though cell phone numbers are posted at the vivarium entrance. When asked why he did not return the mice to the animal facility, he indicated a lack of access to the animal room (his technician had the key) as well as concern about the response of DLAR staff upon finding the animals in the morning. The veterinarian allowed the PI to collect tissues from the animals after they were euthanized as originally directed.

The same day (7/27/18) the AV and IACUC Chair met with the P.I., discussed the off-protocol concerns as summarized above, and then reported them to the IACUC at a meeting specifically convened to discuss the issues. Following a thorough discussion, the IACUC voted unanimously to suspend all of the active protocols under the P.I. until an appropriate corrective action plan can be developed and implemented that will assure the protection and wellbeing of the research animals.

We will provide a follow-up report when these issues have been resolved.

Please contact me if you would like additional information.

Sincerely,

(b) (6)

Philip R. Cunningham, Ph.D.
Institutional Official

c.c. Dr. Nancy Freeman, Program Official, NIH, freemann@nidcd.nih.gov
Dr. James Swearingen, Global Director, AAALAC International, accredit@AAALAC.org
Dr. Lisa Anne Polin, IACUC Chair, ac8694@wayne.edu

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, August 02, 2018 7:27 AM
To: Philip Cunningham; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Freeman, Nancy (NIH/NIDCD) [E]; Lisa Polin; (b) (6)
Subject: RE: Initial report of protocol suspension

Thank you for this prompt initial report Dr. Cunningham. We will open a case file and await further information.

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: Philip Cunningham [mailto:philc@wayne.edu]
Sent: Wednesday, August 01, 2018 6:02 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Freeman, Nancy (NIH/NIDCD) [E] <freemann@mail.nih.gov>; accredit@AAALAC.org; Lisa Polin <ac8694@wayne.edu>; (b) (6)
Subject: Initial report of protocol suspension

Please see the attached initial report of protocol suspension. Please contact me if you would like additional information at this time.

Regards,
Phil

Philip R. Cunningham, Ph.D.
Associate Vice President
Research Integrity
Wayne State University
5057 Woodward Avenue, (b) (4)
Detroit, MI 48202

Phone: (b) (6)
FAX: (b) (6)
Email: philc@wayne.edu



Initial Report of Noncompliance

By: AW

Date: 7/27/18

Time: 4:00

Name of Person reporting: Lisa Pollens

Telephone #: [REDACTED] (b) (6)

Fax #:

Email:

Name of Institution: WAYNE STATE

Assurance number: A3310

Did incident involve PHS funded activity?

Funding component:

Was funding component contacted (if necessary):

What happened?

Animals housed in lab overnight, disregard vet orders

Species involved:

Personnel involved:

Dates and times:

Animal deaths:

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

Suspend protocol

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case #