



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

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Office of Laboratory Animal Welfare
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Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
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May 7, 2018

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

Dr. Philip R. Cunningham
Associate Vice President for Research
Wayne State University
5057 Woodward Avenue, (b) (4)
Detroit, MI 48201

Dear Dr. Cunningham,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 3, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Wayne State University, following up on an initial report on December 22, 2017. According to the information provided, OLAW understands that a laboratory conducting a study using rats with Adeno-associated Virus (AAV) did not follow institutional biosafety procedures and failed to post signage on the animal room door and failed to label the cages. The Principal Investigator (PI) had been advised previously about the requirements. The same PI was involved in other previous noncompliant incidents consisting of using an unapproved room for animal work, failing to cool rats after their temperatures rose following drug administration, repairing a dehiscence incision without consulting the veterinarian, failing to follow procedures regarding guillotine use, failing to remove mice from experimental chambers at the correct time, and failing to follow the approved analgesic regimen for post-operative rats.

The corrective actions consisted of decontaminating the areas in the vivarium affected by the AAV and counseling the laboratory manager on posting appropriate biosafety signage. The PI suspended animal activities and was counseled by the Attending Veterinarian, Institutional Animal Care and Use Committee chair, and Institutional Official. The protocol was amended to provide greater detail, the laboratory staff was counseled on safety procedures, and necessary documents were submitted to the Office of Environmental Health and Safety. Animal activities resumed and the compliance and biosafety officer observed the laboratory staff successfully performing approved biohazard procedures. An approved location was identified for extended overnight animal housing.

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



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

(313) 577-9064
philc@wayne.edu

May 3, 2018

Animal Welfare Assurance Number: A3310-01

Brent Morse, DVM, DACLAM
Acting 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
olawdco@mail.nih.gov

RE: NIH Award Number 5 RO1 DA034783-05: "Proteasome and Parkin as Drug Targets
Against Methamphetamine Toxicity"

Dear Dr. Morse,

This is a follow-up to an initial report on Dec 22, 2017 of an IACUC-determination of serious and continuing non-compliance.

Background: At the time of initial report – we laid out the following generalized plan of action for resolution for the unapproved housing location, and lack of biohazard notifications/postings involving animals within the vivarium. These recent events coupled with 6 previous minor non-compliance events occurring within the most recent 3-year period (2014-2017) were the basis for the IACUC's "serious and continuing non-compliance" determination:

"Both the Attending Veterinarian and IACUC Chair will meet with the researcher to discuss and assist with implementation of proactive animal care and associated safety practices for this lab, with ongoing input and oversight provided by OEHS. The researcher has voluntarily suspended animal research until the meeting occurs. This was confirmed by the AV. A follow-up report will be filed following the meeting with the researcher".

Current status: The Institutional Official (IO) discussed with the PI the need for proactive resolution including the importance of following the institution's safety regulations regarding biohazard use. The Attending Veterinarian (AV) and IACUC Chair met with the PI on January 17, 2018, to develop an action plan to resume *in vivo* studies under IACUC protocol 16-03-067; specifically – the PI submitted an amendment to update the protocol to cover study details, met with lab staff to review safety procedures, and submitted needed safety filings with WSU OEHS.

The Research Compliance Officer and OEHS Biosafety Officer observed laboratory staff successfully carrying out IACUC approved biohazard procedures on January 18, 2018. The AV and IACUC Chair agreed to assist the PI with identifying an appropriate location for extended overnight housing for the PI's next study. The AV and IACUC Chair inspected and approved the final site in February 2018.

Wayne State University works to maintain the highest standards in our missions. We believe the actions described above are appropriate but we would appreciate any guidance on this event that you feel might be helpful.

Please contact me at the address above.

Sincerely,

(b) (6)

Philip R. Cunningham, Ph.D.
Institutional Official

c.c. Dr. James Swearengen, Global Director, AAALAC International, accredit@AAALAC.org
Dr. Kristopher Bough, Program Official, boughk@mail.nih.gov
Dr. Lisa Anne Polin, IACUC Chair

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, May 04, 2018 7:02 AM
To: Philip Cunningham
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Follow-up noncompliance report

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

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

From: Philip Cunningham [mailto:philc@wayne.edu]
Sent: Thursday, May 03, 2018 3:00 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: accredit@AAALAC.org; Bough, Kristopher (NIH/NIDA) [E] <boughk@nida.nih.gov>; Lisa Polin <ac8694@wayne.edu>;
(b) (6)
Subject: Follow-up noncompliance report

Please see the attached follow-up to our initial report of serious and continuing noncompliance. Please contact me if you have any questions.

Sincerely,
Phil

Philip R. Cunningham, Ph.D.
Associate Vice President
Research Integrity
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Animal Welfare Assurance Number: A3310-01

December 22, 2017

Brent Morse, DVM, DACLAM
Acting 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
olawdco@mail.nih.gov

RE: NIH Award Number 5 RO1 DA034783-05: "Proteasome and Parkin as Drug Targets
Against Methamphetamine Toxicity"
Initial Report

Dear Dr. Morse,

I am writing to report an incident of serious and continuing non-compliance. A researcher at Wayne State University (WSU) failed to follow WSU policy and Federal regulations which led to serious deviation from the provisions of the *Guide* with respect to the proper care and use of animals in research. The incident occurred on protocol 16-03-067.

During semiannual inspection in August of 2017, Office of Environmental Health and Safety (OEHS) inspectors asked Division of Laboratory Resources (DLAR) personnel if a specific lab had been working with Adeno-associated Virus (AAV). Neither the DLAR leader, nor building veterinarian had received biohazard notification from this researcher. During a follow-up OEHS inspection, it was discovered that the lab conducted work with AAV but had not alerted DLAR by posting the required signage on the animal room door, or by labeling cages when AAV injected rats were returned to the animal facility. When contacted by a WSU Senior Research Compliance Specialist, the PI replied that they had been working with AAV since 2010, but were not aware of Wayne State posting requirements for working with biohazards. However, it was noted that the investigator had received instructions at the time of protocol approval from the OEHS which were outlined in the required posting of "Animal Hazardous Agents Form". In addition, the PI was reminded of the requirements during Post Approval Monitoring on at least one occasion in July 2016.

The WSU veterinarian for the building had the DLAR leader perform decontamination of

affected spaces within the vivarium. The laboratory manager has since met with WSU's Attending Veterinarian who explained what is clearly outlined for the lab's OEHS "Animal Hazardous Agent Form". In the future, they will post the appropriate signs and stickers, both on the door and on cages, as required.

On October 25, 2017 the incident was reported to the IACUC at a convened meeting. The committee was also informed of the PI's non-compliance history comprising six minor off protocol events since 2013: During semiannual inspection in 2017, it was discovered that the PI was using a room for animal work that was not included on the approved animal protocol. In February of 2017, laboratory staff failed to initiate indirect cooling as indicated in the protocol when rat temperatures reached 40°C after methamphetamine administration. In August of 2016, a lab member anesthetized a rat to repair an incision that had dehisced without veterinary consultation. In November of 2014, AAALAC visited the lab and found that a guillotine did not have a maintenance log and its described use was not in agreement with the AVMA Guidelines on Euthanasia, or the WSU IACUC requirements. In September of 2014, four mice were housed in operant conditioning chambers for 12hrs longer than approved in protocol. At the December 2013 IACUC meeting, it was reported that this PI did not follow the protocol approved analgesic regimen for rats undergoing performed survival surgeries.

The IACUC voted that the above described non-compliant events coupled with most recent situation represents serious and continuing non-compliance. Both the Attending Veterinarian and IACUC Chair will meet with the researcher to discuss and assist with implementation of proactive animal care and associated safety practices for this lab, with ongoing input and oversight provided by OEHS. The researcher has voluntarily suspended animal research until the meeting occurs. This was confirmed by the AV. A follow-up report will be filed following the meeting with the researcher.

Please let me know if you would like additional information.

Sincerely,

(b) (6)

Philip R. Cunningham, Ph.D.

c.c. Dr. James Swearingen, Global Director, AAALAC International,
accredit@AAALAC.org
Dr. Kristopher Bough, Program Official, boughk@mail.nih.gov
Dr. Lisa Anne Polin, IACUC Chair

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, December 26, 2017 7:26 AM
To: 'Philip Cunningham'
Subject: RE: Initial report of serious and continuing non-compliance

Thank you for this preliminary report, Dr. Cunningham. We will start a new case file and look forward to receiving the final report after the IACUC has completed its actions.

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

From: Philip Cunningham [mailto:philc@wayne.edu]
Sent: Friday, December 22, 2017 4:08 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: International Aaafac <accredit@aaafac.org>; Bough, Kristopher (NIH/NIDA) [E] <boughk@nida.nih.gov>; Lisa Polin <ac8694@wayne.edu>; (b) (6)
Subject: Initial report of serious and continuing non-compliance

Please see the attached initial report of serious and continuing noncompliance. A follow-up report will be filed as described in the report. If you have any questions, please do not hesitate to contact me.

Regards,
Phil

Philip R. Cunningham, Ph.D.
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July 3, 2018

Animal Welfare Assurance Number: A3310-01

Brent Morse, DVM, DACLAM
Acting Director, Division of Compliance Oversight
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olawdco@mail.nih.gov

RE: Approval of new protocol – lifting of suspension

Principal Investigator: Mark Ming-Cheng Cheng, Ph.D.

NSF Grant: Parity-Time Symmetric Wireless Telemetry Systems for Implantable
Microsensors (proposal number 1711409)

Dear Dr. Morse,

This is a follow-up to an initial report on December 22, 2017 and final report on May 3, 2018. The Principal Investigator involved in the reported non-compliance that led to protocol suspension has secured approval of a new protocol (17-05-278) to replace the one (A 03-05-15) that expired during the suspension period. On June 8th, 2018 the Attending Veterinarian and IACUC Chair met with PI to discuss arrangements for the ongoing monitoring of animal studies once work resumes. On June 27th, 2018 the IACUC met and reviewed the suspension concerns, and the proposed plan of action for ongoing monitoring of studies, and voted to formally lift the suspension with the understanding that the Principal Investigator will be working closely with the Attending and Clinical Veterinarians when he is ready to begin animal work again.

Sincerely,

(b) (6)

Philip R. Cunningham, Ph.D.

c.c. Dr. James Swearengen, Global Director, AAALAC International, accredit@AAALAC.org
Dr. Shubhra Gangopadhyay, sgangopa@nsf.gov, NSF Program Official
Jessie Richardson, jrichard@nsf.gov, NFS Grant Official

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, July 05, 2018 7:19 AM
To: Philip Cunningham; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Gangopadhyay, Shubhra; jrichard@nsf.gov; Lisa Polin; (b) (6)
Subject: RE: Suspension update

Thank you for this update Dr. Cunningham. We will add it to the closed case file.

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: Tuesday, July 03, 2018 6:16 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: accredit@AAALAC.org; Gangopadhyay, Shubhra <sgangopa@nsf.gov>; jrichard@nsf.gov; Lisa Polin <ac8694@wayne.edu>; (b) (6)
Subject: Suspension update

Please see the attached update to a prior notification of protocol suspension. If you have any questions, please don't hesitate to contact me.

Best regards,
Phil

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