



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) 480-3387

June 10, 2021

Re: Animal Welfare Assurance
A3310-01 [OLAW Case 2D]

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 June 2, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Wayne State University following up on an initial May 20, 2021 notification by email.

According to the information provided, this Office understands that the Wayne State University Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure to adhere to the IACUC-approved protocol. The final report states on April 28, 2021, the IACUC voted the use of zebrafish larvae in a protocol approved only for use of adult fish constituted a serious and continuing noncompliance. The committee also voted to suspend the protocol due to concerns of inadequate supervision of laboratory personnel. Following a meeting on May 3, 2021, which involved a discussion of the suspension, the principal investigator (PI) proposed a corrective action plan. The plan included the following:

- A meeting with the lab staff to review the IACUC protocol the following week and every 6 months thereafter.
- A formal and documented approval process for review of experiments proposed by the members of the research group, and approved documents will be accessible to the entire staff and IACUC representatives.

The IACUC reviewed the plan and proposed the following additional action items:

- The PI and all lab staff will retake the "Working with the IACUC" course on the CITI Program website.
- The PI will provide a key to his laboratory and fish housing room to the IACUC to allow periodic unannounced inspections by an IACUC representative.

The report states the PI agreed to the additional action items and the IACUC accepted the revised corrective action plan and voted to reinstate the protocol on May 26, 2021. It is understood that this research is partially funded by PHS.

Page 2 – Dr. Cunningham
June 10, 2021
OLAW Case A3310-2D

Based on its assessment of this explanation, OLAW understands that the Wayne 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: 2021.06.10 14:40:19 -04'00'

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

cc: IACUC Contact



A3310

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

(b) (6)
philc@wayne.edu

Animal Welfare Assurance Number: D16-00198

June 2, 2021

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: Final Report Regarding Protocol Suspension

Dear Dr. Morse:

I am writing to provide you with a final report regarding an incident of serious non-compliance which led to a protocol suspension. The incident was initially reported to you in a letter dated May 20, 2021. The protocol is partly funded by NIH grant R01AI127390, entitled "Mechanisms for *Vibrio cholerae* colonization and pathogenesis in zebrafish".

Incident:

During a convened meeting on April 28, 2021, the IACUC voted that utilizing zebrafish larvae in a protocol that approved only adult fish constituted serious and continuing noncompliance. Due to concerns of inadequate supervision of laboratory personnel, the IACUC also voted to suspend the protocol.

Corrective Actions:

On May 3, 2021, the Principal Investigator, along with his chairperson, met with the IACUC chair, Attending Veterinarian, IACUC administrator and the I.O. (me) to discuss the suspension. Immediately following the meeting, the P.I. proposed a corrective action plan that included meeting with his entire lab staff to review the IACUC protocol in the following week and every six months thereafter. In addition, the corrective actions included a formal and documented approval process for review of experiments proposed by the members of his research group in which the approved documents will be accessible to the entire staff and IACUC representatives. The IACUC convened a meeting on May 18, 2021 to discuss the PI's plan and upon review, proposed additional action items: The P.I. will ensure that all laboratory personnel working with or providing husbandry for the fish are listed as personnel on the protocol; The P.I. and all the lab staff will retake the "Working with the IACUC" course on the Collaborative Institutional Training Initiative (CITI Program) website; And, the P.I. will provide a key to his laboratory and fish housing room to the IACUC to allow periodic unannounced inspections by an IACUC representative. The P.I. agreed to the additional corrective actions and incorporated them in a revised corrective action plan that was submitted for review.

Resolution:

During a convened meeting on May 26, 2021, the IACUC reviewed and accepted the revised corrective action plan and voted to reinstate the protocol.

Please contact me if you would like additional information.

Sincerely,

(b) (6)

Philip R. Cunningham, Ph.D.
Institutional Official

c.c. Shahida Baqar, Ph.D., Program Officer, NIAID, shahida.baqar@nih.gov
Gary L. Borkowski, D.V.M., M.S., AAALAC International, accredit@aaalac.org
Moh Malek, Ph.D., IACUC Chair, en7488@wayne.edu

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, June 4, 2021 7:21 AM
To: Philip Cunningham
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: suspension follow-up

Thank you for this update, Dr. Cunningham. We will respond soon.

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

From: Philip Cunningham <philc@wayne.edu>
Sent: Wednesday, June 2, 2021 4:05 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Baqar, Shahida (NIH/NIAID [E]) <shahida.baqar@nih.gov>; AAALac International <accredit@aaalac.org>; Moh Malek <en7488@wayne.edu>; (b) (6)
Subject: suspension follow-up

Please see the attached follow-up notice of a protocol violation and suspension. Please contact me if you would like additional information.

Best regards,
Phil

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

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FAX: (b) (6)
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Philip R. Cunningham, Ph.D.
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A3310-2D

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Animal Welfare Assurance Number: D16-00198

May 20, 2021

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: Report of Protocol Suspension

Dear Dr. Morse:

I am writing to report an incident of serious non-compliance which led to a protocol suspension. 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 protocol is partly funded by NIH grant R01AI127390, entitled "Mechanisms for *Vibrio cholerae* colonization and pathogenesis in zebrafish".

Incident:

During a semiannual inspection in March of 2021, an IACUC member noted discrepancies in a protocol utilizing zebrafish. According to the inspection report, experiments were being performed on larval zebrafish on a protocol that is only approved for adult fish.

Previous incidents of non-compliance included the following: In March of 2019 there was a finding of serious non-compliance with the same PI that involved housing two tanks of zebrafish for approximately 4 months after being exposed to *Vibrio cholerae* in a location that approved housing for up to 30 days and in April of 2020 there was an additional finding of serious non-compliance with the same PI that involved utilizing expired MS-222 to euthanize zebrafish.

PI Response:

When contacted by research compliance, the PI stated that his student performed one experiment with larvae that was taking place during the inspection, and that a previous protocol of his did include zebrafish larvae. The PI indicated that he would submit an amendment for the larval experiments and would halt further larval experiments until the amendment was approved by the IACUC.

IACUC Finding:

During the convened meeting on April 28, 2021 the IACUC voted that utilizing zebrafish larvae in a protocol that approved only adult fish constitutes serious and continuing noncompliance. Due to concerns of inadequate supervision of laboratory personnel, the IACUC also voted to suspend the protocol. The IACUC is currently working with the P.I. to address these concerns. I will provide a follow-up communication when that process is completed.

Please contact me if you would like additional information.

Sincerely,

(b) (6)

Philip R. Cunningham, Ph.D.
Institutional Official

c.c. Shahida Baqar, Ph.D., Program Officer, NIAID, shahida.baqar@nih.gov
Moh Malek, Ph.D., IACUC Chair, en7488@wayne.edu

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, May 20, 2021 2:09 PM
To: Philip Cunningham
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Notice of suspension

Thank you for this report, Dr. Cunningham, and for also reporting it to the NIH funding component.

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

From: Philip Cunningham <philc@wayne.edu>
Sent: Thursday, May 20, 2021 2:06 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Baqar, Shahida (NIH/NIAID [E]) <shahida.baqar@nih.gov>; Moh Malek <en7488@wayne.edu>; (b) (6)
(b) (6)
Subject: Notice of suspension

Please see the attached notice of serious non-compliance and protocol suspension. Please contact me if you would like additional information.

Best regards,
Phil

Philip R. Cunningham, Ph.D.
Associate Vice President
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Wayne State University
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