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A3310-1N

Philip R. Cunningham, Ph.D.
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Animal Welfare Assurance Number: D16-00198
AAALAC Unit Number: 000393

January 31, 2018

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 R01 EY010869: "Molecular Regulation of Corneal Wound Healing"

Dear Dr. Morse,

I am writing to report an incident of serious 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* and PHS Policy with respect to the proper care and use of animals in research. The incident occurred on WSU protocol 16-04-070.

On December 20, 2017, two mice received injections of Resiniferatoxin (RTX) into their corneas. RTX was not approved in the protocol, and caused acute adverse symptoms requiring the mice to be euthanized per veterinary recommendation.

When contacted, the PI assumed responsibility for the situation, but stated that he had three new fellows recently added to his protocol. He said that without his prior knowledge, they wanted to use RTX to desensitize corneal sensory nerves to determine the total effects of neuropeptides.

The PI discussed the compliance issue with the fellows and provided a copy of his protocols to them for review before they were allowed to continue work with animals. He instructed them to verify protocol approval for any agent that will be administered to animals. He also reminded them that if they would like to use other agents for the study, an amendment to the protocol must be approved by the IACUC prior to initiating the procedure. The PI also requested that his laboratory staff meet with a WSU Research Compliance Specialist for a post-approval monitoring review of his protocol. This was completed on January 5, 2018.

The PI has submitted an amendment for the use of RTX under protocol 16-04-070. He stated that Resiniferatoxin only causes temporary pain and is currently under clinical trial for treating human chronic pain. The amendment is currently under IACUC review.

At a convened meeting on January 24, 2018, the IACUC voted that injecting an unapproved agent (RTX) into mouse corneas under the circumstances described above constituted serious non-compliance.

The IACUC also acknowledged the swift proactive approach taken by the Principal Investigator to resolve the situation, which included an immediate corrective course of action in re-enforcing staff awareness of the IACUC protocol and the proper steps to initiate changes in experimental designs, and in his voluntary request for a PAM. Due to these steps already taken, the IACUC was satisfied that this off-protocol event has been resolved and further remedial actions were not needed.

Please let me know if you would like additional information.

Sincerely,

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Philip R. Cunningham, Ph.D.

c.c. Dr. George A. McKie, Program Officer, National Eye Institute (NEI),
mckiegeo@mail.nih.gov
Dr. James Swearengen, Global Director, AAALAC International,
accredit@AAALAC.org
Dr. Lisa Anne Polin, IACUC Chair

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, January 31, 2018 3:40 PM
To: Philip Cunningham; OLAW Division of Compliance Oversight (NIH/OD)
Cc: McKie, George (NIH/NEI) [E]; Lisa Polin; (b) (6)
Subject: RE: Report of noncompliance

Thank you for this report Dr. Cunningham. We will send an official response soon.

Sincerely, Brent Morse

Brent C. Morse, DVM, DACLAM
Acting 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, January 31, 2018 1:12 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: McKie, George (NIH/NEI) [E] <george.mckie@nih.gov>; accredit@AAALAC.org; Lisa Polin <ac8694@wayne.edu>; (b) (6) @wayne.edu
Subject: Report of noncompliance

Please see the attached report of serious non-compliance. If you have any questions, please do not hesitate to contact me.

Sincerely,
Phil

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