



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive - MSC 7982
Bethesda, Maryland 20892-7982
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
Facsimile: (301) 402-7065

January 25, 2017

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

Dr. Phillip Cunningham
Assistant Vice President for Research
Wayne State University
5700 Cass Ave., Room #
Detroit, MI 48202

Dear Dr. Cunningham,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 17, 2017 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 your interim report submitted to this office on October 28, 2016. According to the information provided, OLAW understands that on September 28, 2016 the IACUC determined that issues pertaining to the management of a researcher's mouse breeding colony had constituted continuing non-compliance. These issues included delayed weaning and overcrowding and the loss of a newborn litter and one pup in another newborn litter. In addition, at least one incidence of laboratory personnel not following veterinary medical orders was documented. It was stated that these activities were funded by the PHS. Note: OLAW records document non-compliance concerning this lab dating back to 2014.

Corrective and preventive measures included having DLAR employees perform breeding colony management and having regular meetings between the PI and an institutional veterinarian. Appropriate Program Officials at NIH have been notified of these incidents by your institution.

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 and prevent recurrence were appropriate. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse, DVM
Animal Welfare Program Specialist
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

(313) 577-9064
philc@wayne.edu

January 17, 2017

Animal Welfare Assurance Number: A3310-01

Axel V. Wolff, MS, 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
olawdco@mail.nih.gov

RE: Follow-up for report of continuing non-compliance: Dr. Jian-Ping Jin, Grants:
Regulation of Troponin I in Cardiac Adaptation & Failure (1 R01 HL127691-01A1); Role
of Troponin T Isoforms in Nemaline Myopathy (5R01AR048816-11)

Dear Dr. Wolf,

I am writing to provide an update to our initial correspondence on October 28, 2016 reporting continuing non-compliance. At the time of the initial report, the P.I. had been traveling and was planning to appeal the finding. At a regularly convened meeting of the IACUC on November 16, 2016, the P.I. explained the nature of his research and discussed the situation in his laboratory. The IACUC subsequently voted to let the finding of continuing non-compliance stand but also agreed to work with the P.I., lab members, veterinarians and staff to address the issues occurring in the P.I.'s laboratory. Since then, and with the cooperation of the P.I. and his staff, several measures have been implemented to address the issues that led to non-compliance. We delayed filing this report until enough data were collected to evaluate the success of these corrective actions.

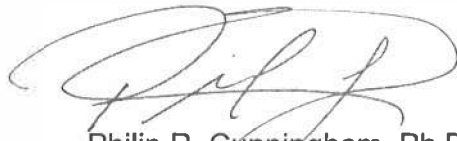
Since the initial report, several of the remedies specified at that time have been implemented to good effect. The Division of Laboratory Animal Resources (DLAR) is continuing to perform breeding colony management services to ensure that timely weaning occurs and that housing densities in individual cages are in compliance with the Wayne State University IACUC and national guidelines. This process has

eliminated any litter loss associated with overcrowding in the past two months. DLAR staff are also participating daily in the assessment of litters and providing delayed weaning or support for litters when this is not possible. The transition of these colony management duties to DLAR staff has increased communication with the lab which, coupled with monthly in-person meetings between the PI and an institutional veterinarian, have improved communication significantly.

These remedies, DLAR management of the colony, and regular meetings with the PI will continue for the foreseeable future with regular updates to the IACUC at the monthly meetings. Colony management services including weaning are provided at no cost to the investigator and will continue indefinitely. In the future, colony management could be transferred back to the laboratory if the PI chooses to hire trained personnel or train existing laboratory personnel to perform these duties. This training and evaluation would occur in cooperation with DLAR staff, though at this time there are no imminent plans. Similarly, the in-person meetings will continue until such time as the veterinarian and the IACUC determine that they are no longer necessary.

If you have any questions or suggestions, please do not hesitate to contact me.

Sincerely,



Philip R. Cunningham, Ph.D.

c.c. Dr. Renee P. Wong, Program Official, NIH, wongr2@nhlbi.nih.gov
Dr. Glen H. Nuckolls, Program Official, NIH, nuckollg@mail.nih.gov
Secondary Individual Global Director, AAALAC International,
accredit@AAALAC.org

Secondary Individual Secondary Individual Secondary Individual Secondary Individual

Room #

Phone Number
Phone Number



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

(313) 577-9064
 philc@wayne.edu

October 28, 2016

Animal Welfare Assurance Number: A3310-01

Axel V. Wolff, MS, 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
 olawdco@mail.nih.gov

RE: Interim report of continuing non-compliance: Dr. Jian-Ping Jin, Grants: *Regulation of Troponin I in Cardiac Adaptation & Failure* (1 R01 HL127691-01A1); *Role of Troponin T Isoforms in Nemaline Myopathy* (5R01AR048816-11)

Dear Dr. Wolff,

I am writing to report continuing and serious non-compliance. A researcher at Wayne State University (WSU) has 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.

At a convened meeting on September 28, 2016, the IACUC voted that the issues summarized below represent continuing non-compliance.

After an IACUC determination of minor noncompliance associated with breeding colony management in March 2016, the committee requested that animal care communications between the Division of Laboratory Animal Resources (DLAR) and the Principal Investigator be monitored and reported to the IACUC on a monthly basis. The IACUC noted positive efforts on behalf of the laboratory staff to improve mouse breeding colony management for an initial 3 month period. Over the subsequent 3-month period, however, several incidents of delayed weaning and overcrowding requiring DLAR intervention occurred. The overcrowding and delayed weaning appear to have

contributed to the loss of a newborn litter of pups on Sept 5th and 1 pup in a newborn litter on Sept 12th.

To help resolve these issues, the IO, IACUC chair, and Attending Veterinarian met with the PI on September 27th to discuss the implementation of measures to minimize further losses from occurring. The PI acknowledged difficulties with ongoing management of a complex and very active breeding colony; noted that some transgenic strains may be more fragile and therefore require extra time with dam before weaning, and that his staff was trying to provide the pups with that extra time.

Veterinarians noted that the intensive breeding schemes currently employed by the lab are counterproductive for fragile litters needing delayed wean times, because a litter may be born before the older pups can be removed, resulting in the loss of younger litters. The importance of communicating with veterinary staff about ongoing colony needs was also stressed, because without such consults and an approved request for variance in the protocol, delayed weaning constitutes an off protocol event. The IACUC Chair offered to assist the PI in drafting an amendment to allow a delay in weaning that would meet the IACUC SOPs and the *Guide's* housing requirements and the IO recommended a number of options in terms of management software that may assist with tracking weaning dates, etc.

On September 28th, with the determination of continuing non-compliance, the IACUC requested that the Division of Laboratory Animal Resources (DLAR) assume responsibility for weaning litters on behalf of the PI until a permanent plan is in place. Additional recommendations were made: 1) PI should consider hiring support staff with specific training in colony management; 2) IACUC Chair and Veterinarians meet with the PI to devise a suitable plan to remedy ongoing housing density and breeding concerns; 3) DLAR permanently assume all breeding colony management responsibilities (contingent on availability of sufficient DLAR resources).

On the morning of October 13th a DLAR veterinarian examined a mouse and determined that it should be euthanized by the end of the day due to dehydration, reduced activity, and wound complications. The laboratory decided not to euthanize the mouse and initiated treatment of the animal without consulting with the veterinarian. At a convened meeting on October 26, 2016, the IACUC voted that this constituted serious non-compliance.

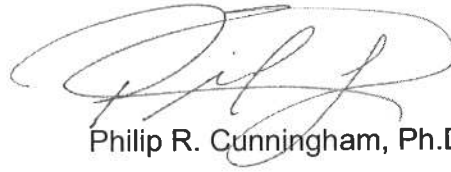
The PI was traveling and unavailable when some of the above activities occurred but discussions with him have resumed and are currently underway. In addition, the PI will appear before the IACUC on November 16th to discuss the incidents and appeal the Committee's determinations.

Thus, we are submitting this as an interim report. An update will be provided once the course of action has been finalized, and the appropriate amendment(s) have been reviewed and approved by the IACUC. We anticipate that a final report will be sent to you by the end of November. In the meantime, DLAR is assuming the responsibility of

performing timely weanings and assisting the PI and laboratory staff with maintaining appropriate housing density for animals currently enrolled on study to assure the welfare of the PI's colony.

Wayne State University works to maintain the highest standards in our missions. We believe the actions we are taking are appropriate. We would appreciate further guidance on this event, should you feel that it is appropriate.

Sincerely,



Philip R. Cunningham, Ph.D.

c.c. Dr. Renee P. Wong, Program Official, NIH, wongr2@nhlbi.nih.gov
Dr. Glen H. Nuckolls, Program Official, NIH, nuckollg@mail.nih.gov
Secondary Individual  Global Director, AAALAC International,
accredit@AAALAC.org

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, October 31, 2016 9:19 AM
To: 'Philip Cunningham'; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Secondary Individual
Subject: RE: Initial incident report

Thank you for this report Dr. Cunningham. We will open a case file and await the final report.

Sincerely, Brent Morse

Brent C. Morse, DVM, DACLAM
 Animal Welfare Program Specialist
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health

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-----Original Message-----

From: Philip Cunningham [<mailto:philc@wayne.edu>]
Sent: Friday, October 28, 2016 6:44 PM
To: OLAW Division of Compliance Oversight (NIH/OD)
Cc: Wong, Renee (NIH/NHLBI) [E]; Nuckolls, Glen (NIH/NINDS) [E]; accredit@AAALAC.org; Secondary Individual
Subject: Initial incident report

Dear Dr. Wolff,

Please see the attached Initial incident report. A follow-up report will be filed in November.

Please don't hesitate to contact me if you have any questions.

Best regards,
 Phil

Philip R. Cunningham, Ph.D.
 Associate Vice President
 Research Integrity
 Wayne State University
 5057 Woodward Avenue, Room #
 Detroit, MI 48202

Phone: Phone Number
 FAX: Phone Number
 Email: philc@wayne.edu