

DEPARTMENT OF HEALTH & HUMAN SERVICES

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

November 6, 2018

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR EXPRESS MAIL: Office of Laboratory Animal Welfare 6700B Rockledge Drive, Suite 2500 Bethesda, Maryland 20817 Telephene: (301) 496-7163 Facsimile: (301) 402-7065

Re: Animal Welfare Assurance A3231-01 [OLAW Case 1W]

Dr. Christopher Agnew Associate Vice President for Research Director, University Research Administration and Compliance Purdue University 610 Purdue Mall, West Lafayette, IN 47907

Dear Dr. Agnew,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 22, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Purdue University, following up on an initial report on October 18, 2018. According to the information provided, OLAW understands that mice were subjected to 20 training sessions although the protocol was approved for 10 and that the water deprived mice were group housed rather than singly housed as approved. No adverse effects were noted with the mice due to the extra sessions.

The corrective actions consisted of notifying the Principal Investigator (PI) about the unapproved activities, counseling the PI to submit a protocol amendment, and having the PI counsel the students to conduct animal activities as described in the protocol. A protocol amendment was subsequently submitted.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Sincerely,

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Axel Wolff, M.S., D.V.M. Deputy Director Office of Laboratory Animal Welfare

cc: IACUC Chair

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OFFICE OF THE EXECUTIVE VICE PRESIDENT FOR RESEARCH AND PARTNERSHIPS

ASSOCIATE VICE PRESIDENT FOR RESEARCH, REGULATORY AFFAIRS

October 22, 2018

Assurance #D16-00147

Dr. Axel Wolff Director, Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health RKL1, Suite 360, MSC 7982 6705 Rockledge Drive Bethesda, MD 20892-7982

Dear Dr. Wolff:

I am providing information to the Office of Laboratory Animal Welfare regarding a protocol noncompliance that occurred at Purdue University. This was originally reported to you in a letter dated October 18, 2018, and contained the information below. The PI asked that the information bolded below also be included in the report to you. These mice are covered under an approved IACUC protocol. The protocol number and title is 1408001112, "Experimental investigations of neural circuits function in cerebral cortex." Please be aware that the use of animals on this protocol is supported by the following funds:

NIH National Institutes of Mental Health 5R01MH116500-02, "Neural Mechanisms of predictive impairments in autism."

On Friday, October 5, 2018, it was discovered that the number of training sessions per mouse had been exceeded from the number approved on the protocol (20 training sessions completed when the protocol states that up to 10 sessions would be done) and that the water deprived mice were being group housed vs. singly housed as approved. Email communication from the IACUC office with the PI and the graduate student immediately commenced to inform them they were in non-compliance with their approved study. A follow-up meeting with the PI was held on October 15, with the IACUC Chair and Administrator in attendance, to further discuss the non-compliance and the need to submit an amendment to the protocol if the additional training sessions and group housing are necessary. The PI stated that he will submit an amendment to the protocol up to where it needs to be. The PI will also discuss with his graduate students the importance of following the approved protocol.

From the PI: As we discussed last week, there was an incident related to a mouse which was undergoing behavioral training. My graduate student forgot about the 10 days limit on water restriction in our protocol. We have immediately stopped the experiment as soon as we discovered this. During the water restriction period, the graduate student

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OFFICE OF THE EXECUTIVE VICE PRESIDENT FOR RESEARCH AND PARTNERSHIPS

ASSOCIATE VICE PRESIDENT FOR RESEARCH, REGULATORY AFFAIRS

October 18, 2018

Assurance #D16-00147

Dr. Axel Wolff Director, Division of Compliance Oversight Office of Laboratory Animal Welfare National Institutes of Health RKL1, Suite 360, MSC 7982 6705 Rockledge Drive Bethesda, MD 20892-7982

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The IACUC was informed of this non-compliance at their full committee meeting on Wednesday, October 17, 2018. The committee felt that the PI submitting an amendment (and that a meeting had already taken place with the PI) was adequate to correct the non-compliance and had no further recommendations or concerns.

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Dr. Axel Wolff Page 2 October 18, 2018

Purdue University would like to reaffirm its commitment to a strong animal care and use program. It is hoped that the actions being taken in response to this incident will serve to strongthen the program of animal care at Purdue University.

Please feel free to contact me if you require additional information.

Sincerely.

Christopkeł R. Agnew, Ph.D. Institutional Official Associate Vice President for Research, Regulatory Affairs

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cc: Dr. J. Kritchevsky, Chair, Purdue Animal Care and Use Committee

Dr. W. Ferner, Director, Laboratory Animal Program Interim Head, Dept. of Biological Sciences Dean, College of Science