



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

June 7, 2018

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

Dr. Christopher Agnew
Associate Vice President for Research
Purdue University
703 Third Street
West Lafayette, IN 47907-2040

Dear Dr. Agnew,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 31, 2018 letter reporting an incident of noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at Purdue University. According to the information provided, OLAW understands that on May 8, 2018 eight mice were found dead in their cages by animal care staff. It was subsequently determined that the PI's graduate student had increased the dose of BI 6727 and changed the route of administration without prior review and approval of the IACUC. It was stated that this protocol non-compliance most likely resulted in the adverse event of the mice dying prior to being euthanized. It was noted that the activity was supported with PHS funds.

After notification, the PI responded that they would not continue the study at the higher dose. The IACUC directed that a meeting be held between the IACUC Administrator, the PI and the graduate student to further stress that changes cannot be made to a study without first being reviewed and approved by the IACUC. The PI has discussed with the entire lab the importance of maintaining compliance. A follow-up meeting of the lab with the IACUC Administrator was also scheduled.

OLAW believes that the corrective and preventive measures put in place by Purdue University are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate being informed of this incident and find no cause for further action by this office.

Sincerely,

(b) (6)

Brent C. Morse, DVM
Acting Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



OFFICE OF THE EXECUTIVE VICE PRESIDENT FOR
RESEARCH AND PARTNERSHIPS

ASSOCIATE VICE PRESIDENT FOR RESEARCH,
REGULATORY AFFAIRS

Assurance #D16-00147

May 31, 2018

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. Wolf:

I am providing information to the Office of Laboratory Animal Welfare regarding an adverse event and protocol non-compliance that occurred at Purdue University resulting in the death of several mice. These mice were covered under an approved IACUC protocol with Prof. Xiaoqi Liu as the Principal Investigator. The protocol number and title is 1111000133, "The role of Plk1 in cancer progression and treatment." Please be aware that the use of these animals was supported by the following funds:

NIH National Cancer Institute R01CA157429
NIH National Cancer Institute R01CA192894
NIH National Cancer Institute R01CA196835
NIH National Cancer Institute R01CA196634

On Tuesday, May 8, 2018, eight (8) mice were found dead in their cages by animal care staff. The IACUC office was alerted that morning of the deaths via email. Communication between Purdue's IACUC Administrator and a graduate student of Prof. Liu's resulted in the determination that the student had increased the dose of BI 6727 and changed the route of administration without prior review and approval of the IACUC. This protocol non-compliance most likely resulted in the adverse event of the mice dying prior to being euthanized. Communication was sent by the IACUC Administrator to the graduate student and Prof. Liu, on May 8, stating that the study was in non-compliance and that they could not continue dosing at the higher concentration. It was explained that changes to a study cannot be made without being reviewed and approved by the IACUC. A response was received that they would not continue the study at the higher dose.

This incident was discussed at a full committee meeting of the IACUC on May 16. The IACUC directed that a meeting be held between Purdue's IACUC Administration, the PI, and the graduate student to further stress that changes cannot be made to a study without first being reviewed and approved by the IACUC. A meeting was held between [REDACTED] (b) (6) and the PI, Prof. Liu on Tuesday, May 29. Prof. Liu indicated during this meeting that he was unaware that the graduate student had increased the dose and changed the route of administration on the study until he was informed of the deaths of the mice by the IACUC office. Prof. Liu was reminded that he must submit an

amendment to his protocol should he and the graduate student wish to pursue dosing the mice at a higher concentration. He has discussed with his entire lab the importance of maintaining compliance. He also asked (b) (6) to attend his next lab meeting to meet with all of his students to discuss the seriousness of adverse events and protocol non-compliance. (b) (6) will be meeting with the lab on Monday, June 4. Information obtained during the meetings on May 29 and June 4 will be communicated to the full IACUC at their meeting on June 20 and this will resolve the issue.

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 strengthen the program of animal care at Purdue University.

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

Sincerely,

(b) (6)

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

cc: Dr. Xiaoqi Liu, Professor, Department of Biochemistry
Dr. J. Kritchevsky, Chair, Purdue Animal Care and Use Committee
(b) (6)
Dr. W. Ferner, Director, Laboratory Animal Program
(b) (6)

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, June 04, 2018 7:48 AM
To: Agnew, Christopher R; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Liu, Xiaoqi; Kritchevsky, Janice E; (b) (6) Ferner, William T.; (b) (6)
(b) (6)
Subject: RE: Adverse event and protocol non-compliance report

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

Best regards, 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: Agnew, Christopher R [mailto:agnew@purdue.edu]
Sent: Friday, June 01, 2018 4:48 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Liu, Xiaoqi <liu8@purdue.edu>; Kritchevsky, Janice E <sojkaje@purdue.edu>; (b) (6)@purdue.edu>;
Ferner, William T. <ferner@purdue.edu>; (b) (6)@purdue.edu>; (b) (6)
(b) (6)@purdue.edu>; (b) (6)@purdue.edu>
Subject: Adverse event and protocol non-compliance report

See attached report regarding an adverse event and protocol non-compliance here at Purdue, and the actions we have taken in light of the event.

Thank you,

Chris Agnew
Institutional Official, Purdue University

Christopher R. Agnew, Ph.D.
email: agnew@purdue.edu

Professor, Department of Psychological Sciences
<http://www.purdue.edu/hhs/psy/>

Associate Vice President for Research, Purdue University
<https://www.purdue.edu/research/>