



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) 402-7065

January 7, 2019

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

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

Dear Dr. Agnew,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 30, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Purdue University. According to the information provided, OLAW understands that one specific step in a mouse cancer study was conducted but had not been described in the approved protocol.

The corrective action consisted of the Institutional Animal Care and Use Committee (IACUC) contacting the Principal Investigator and graduate student responsible about the incident and having them stop the unapproved animal activity. The protocol was amended and subsequently approved by the IACUC.

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 IACUC to comply with the PHS Policy. Please ensure that the PHS grant is not charged for any unauthorized animal activities. Thank you for informing OLAW about this matter.

Sincerely,

[REDACTED] (b) (6)

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

cc: IACUC Chair

November 30, 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 non-compliance that occurred at Purdue University. The mice are covered under an approved IACUC protocol. The protocol number and title is 1110000037, "Analysis of transgenic and knock-out mouse lines." Please be aware that the use of animals on this protocol is supported by the following funds:

5 R01DK055489-18 "Pancreas Transcription Factors and Disease Model Systems"
5 R01CA124586-10 "Kras-induced Cellular Plasticity in Pancreatic Cancer"

Sub-awards from Cincinnati Children's Hospital:

5 R01CA211098-02 "Thrombin -Dependent Mechanisms of Pancreatic Ductal Adenocarcinoma Disease"
1 U01HL143403-01 "Targeting the Plasminogen Activation System to Limit Pancreatic Cancer Progression and Associated Thrombosis"

On October 26, 2018, it was discovered that an experiment was conducted that involved an orthotopic study implanting mouse pancreatic cancer cells into the pancreas of C57Bl/6 mice. In the past, study personnel have genetically engineered the cells prior to injecting so that WT cells grow aggressive tumors but mutant cells grow much smaller tumors. Study personnel added a test to ask if adding in an anti-sense oligonucleotide (ASO) for a target gene would slow tumor growth. Unfortunately, both the PI and the graduate student forgot that they had not submitted this particular detail in the protocol. They have permission to do the exact study with gemcitabine but not with ASOs and for that the PI took complete responsibility.

Email communication from the IACUC office with the PI and the graduate student commenced to inform them they were in non-compliance with their approved study. The PI immediately terminated the experiment upon learning of the non-compliance. An amendment has been submitted by the PI and approved by the IACUC to correct the non-compliance.

Dr. Axel Wolff
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The IACUC was informed of this non-compliance at their full committee meeting on Wednesday, November 28, 2018. The committee felt that the PI submitting an amendment (and that communication had already taken place with the PI) was adequate to correct the non-compliance and had no further recommendations or concerns.

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. J. Kritchevsky, Chair, Purdue Animal Care and Use Committee

(b) (6)

Dr. W. Ferner, Director, Laboratory Animal Program

(b) (6)

Cincinnati Children's Hospital, 3333 Burnet Avenue, Cincinnati, OH 45229