



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) 402-2803

July 5, 2017

Re: Animal Welfare Assurance
A3099-01 [OLAW Case X]

Mr. Michael A. Falzano
Executive Assistant Dean and
Institutional Official for Animal Welfare
Albany Medical College
47 New Scotland Avenue
Albany, NY 12208-3479

Dear Mr. Falzano,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 29, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Albany Medical College. Your letter supplemented the information contained in your initial telephone report on April 13, 2017. According to the information provided, OLAW understands that due to multiple protocol violations and animal health issues resulting from improper maintenance of mice in metabolic cages, your IACUC suspended a PI's animal care and use protocol on April 12, 2017. The animals were transferred to an institutionally supported holding protocol and the NIH funding component was notified. These violations were subsequent to a previous IACUC intervention that specifically withdrew the approval of the use of metabolic cages. The involved animals were supported by PHS funding.

Corrective actions, in addition to the protocol suspension, included access to the vivarium being restricted for the PI and all of his personnel. The protocol was amended to include procedures for the appropriate use of the metabolic cages. The PI and his lab will be subject to increased oversight including regular reports to the IACUC. The lab personnel must retake training and demonstrate competency with metabolic cage monitoring.

The prompt consideration of this matter by Albany Medical College 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



ALBANY MEDICAL COLLEGE

47 New Scotland Avenue, Albany, New York 12208-3479

June 29, 2017

Axel Wolff, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892

RE: Protocol suspension due to protocol violation
Name of Institution: Albany Medical College, Albany, NY 12208
Animal Welfare Assurance Number: D16-00062 (A3099-01)

Dear Dr. Wolff,

This is a follow-up to a telephone communication I had with you on April 18, 2017. What follows is a detailed description of the incident and the corrective actions implemented.

As we discussed, Dr. Wenzheng Zhang's use of animals at Albany Medical College was suspended on April 12, 2017. Dr. Zhang is Principal Investigator (PI) on NIH Grant R01 DK080236; Epigenetic Control of Kidney Fibrosis; and the AMC animal protocol (#15-07009) of the same title. This Animal Care and Use Protocol (ACUP) was officially suspended for protocol violations at a convened meeting of the Institutional Animal Care and Use Committee (IACUC) on April 12, 2017. This action resulted in a cessation of all live animal related work on this grant. Mice and their associated housing costs were transferred to an institutional holding protocol. The IACUC's action was immediately reported to OLAW by phone and to NIH by email. Full restoration of activity occurred on June 15, 2017, although partial restoration of activity occurred sooner (details below).

History: Prior to the incident, in February (reported at IACUC meeting 2/16/17) Animal Resources Facility (ARF) staff noted animal health issues that could have been attributable to inappropriate maintenance and use of mouse metabolic caging used to measure urine output. Specifically, lab personnel used pelleted food rather than powdered; placed food containers improperly so that animal may not have been able to access food consistently; failed to replenish food daily; failed to decontaminate cages according to the schedule detailed in the protocol and manufacturers instructions; and failed to weight animals every 1 to 3 days as specified in the ACUP. The IACUC voted to withdraw specifically the approval of the use of metabolic caging until the PI could address these issues. The ARF Director sent an email to the PI, "The committee voted unanimously to place one portion of the protocol, the use of metabolic caging on hold for the next several weeks. The IACUC would like you and all those individuals

associated with this ACUP to attend the next IACUC meeting on March 16, 2017." The PI agreed to this, but he failed to appear. The IACUC then communicated (3/16/17) that the cages were not to be used until issues surrounding their use were addressed with the IACUC.

At the beginning of April, ARF staff reported that metabolic cages were missing from the facility. The ARF Director visited the PI's lab on April 6th to inquire about the cages and found three metabolic cages on the lab floor. Two cages contained mouse feces indicating that the previously clean cages must have been used in the laboratory despite the IACUC having withheld approval of their use. This also suggested that animals had been housed (>12 hrs) in the laboratory in violation of not only the IACUC communications of 2/16/17 and 3/16/17, but also the ACUP and IACUC policy on animal housing.

The ARF director then immediately terminated the PI's and his staff's swipe card access to the ARF and notified the IACUC that a serious protocol violation had likely occurred and needed to be discussed (4/6/17). The ARF staff took over caring for the mouse colony at the PI's expense.

On April 12, 2017 an IACUC emergency meeting was held. The IACUC unanimously voted to suspend the ACUP. A letter was sent to the PI on 04/12/16 stating his ACUP # 15-07005 was suspended. His mice were transferred to the ARF holding protocol. No animal related activity could be performed. He was also asked to submit a breeding protocol (so breeding colonies could be maintained) along with a plan of correction. He and his staff were also required to be present at the April 21 IACUC meeting.

On April 21, 2017, the PI and his staff appeared before the IACUC. Their plan of correction was not approved. A communication reiterated the neither the PI nor any of his staff could perform any experiments. The IACUC required a new protocol be submitted and approved along with a plan of correction revised to reflect IACUC requirements. Feeding and cleaning directions were discussed and detailed for the cages.

At the same meeting on April 21, 2017, the IACUC also approved a protocol which allowed for continued breeding of the PI's animals. This action assured continuity in his complex and extensive breeding program for the production of genetically modified mice required for experiments. However, animal related activity was restricted to breeding; no experiments could be performed until a revised protocol was submitted and a detailed corrective plan of action approved.

On May 24, 2017, the PI's new ACUP was approved by the IACUC. This allowed the vast majority of his animal activity to proceed. However, the use of metabolic cages was still restricted while details of animal husbandry in those cages continued to be worked out by the PI in collaboration with ARF staff.

On June 15, 2017, the IACUC approved a protocol amendment including a standard procedure for the appropriate use of the metabolic cages with IACUC required modifications in the way food was supplied to animals assuring access and enhanced husbandry documentation. The corrective plan of action together with the amendment procedures required retraining of all lab

staff with demonstration of competence in the procedures, thorough documentation of daily metabolic cage monitoring, enhanced oversight of metabolic caging procedures by the PI with reporting to the IACUC, and periodic ARF staff monitoring. This fully restored all aspects of Dr. Zhang's grant-related activity and NIH was so notified.

Please let me know if you need further information.

Sincerely,



Michael A. Falzano, MS

Albany Medical College

Dean's Office

Executive Assistant Dean

- Director, Office of Research Affairs, Administration and Compliance
- Institutional Official (IACUC and IBC)

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Initial Report of Noncompliance

By: 

Date: 4/13/17

Time: 2:00

Name of Person reporting: Doug Cohn, DVM, A/V + Mike Falzano, I.D.

Telephone #:

Phone Number

Fax #:

Email:

Name of Institution: Albany Med. Coll.

Assurance number: A3099

Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? PI notified to not use met. cages due to issues w/ sanitation and to appear at IACUC mtg. Did not come to meeting + continued to use cages + house mice in lab. Protocol suspended by IACUC on 4/12/17

Species involved: Mouse

Personnel involved: PI

Dates and times:

Animal deaths:

Projected plan and schedule for correction/prevention (if known):

Told to notify funding component.

PI to appear at next IACUC mtg.

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____