

August 24, 2017

DEPARTMEN'I JF HEALTH & HUMAN SERVICES

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

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

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

Mr. Michael A. Falzano Executive Assistant Dean Albany Medical College 47 New Scotland Avenue, MC-34 Albany, NY 12208-3479

Dear Mr. Falzano,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 23, 2017 letter reporting two instances of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Albany Medical College. According to the information provided, OLAW understands the following about the incidents and the corresponding corrective actions:

1) Approximately 600 mice were transferred to a holding protocol because the research protocol had expired and was not yet renewed. The mice were not to be handled by the research staff, however a post-doctoral student euthanized two cages of mice.

Corrective action: The Institutional Animal Care and Use Committee (IACUC) chair informed the Principal Investigator about the incident and warned him that further noncompliance could result in the suspension of animal use privileges.

2) Live neonatal mice were found in the carcass freezer due to a failure to ensure death following exposure to CO2 for euthanasia. A secondary method of euthanasia had not been used on many adult cadavers.

Corrective action: A post-doctoral student working for the same PI of the previous incident, was found to be responsible. The student was denied access to the vivarium and all laboratory staff was retrained on the appropriate conduct of euthanasia. The student's animal use privileges were subsequently restored.

Based on its assessment of this explanation, OLAW understands that measures have been implemented in both situations to correct and prevent recurrence of the problem. OLAW concurs with the actions taken by the IACUC 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



A3099-Y



ALBANY MEDICAL COLLEGE

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

August 23, 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

Dear Dr. Wolff,

As Institutional Official of Albany Medical College (AMC), I am submitting a report of noncompliance.

Explanation for Incidents:

1. On August 8, 2017, protocol # 14-06003 expired. Dr. Yong-Xiao Wang is the Principal Investigator (PI) and the protocol is funded by NIH, number R01 HL064043.

Because the protocol expired, 600+ mice were transferred to a mouse holding protocol. Dr. Wang did not submit a renewal protocol in time for consideration by the IACUC. Dr. Douglas Cohn, Director of the Animal Resources Facility and Attending Veterinarian is the PI on the Mouse Holding Protocol. On August 11, 2017, Dr. Cohn sent an email to Dr. Wang with a copy to the IACUC that the transferred cages (with new cage cards containing the new protocol number) could not be handled by any of his staff. On August 13, 2017, a post-doctoral student of Dr. Wang's admitted to Dr. Cohn that he had euthanized all the mice in two cages that were labeled with Dr. Cohn's protocol number and name. The student claimed that Dr. Wang did not inform him that he could not touch those cages. The Chair of the IACUC wrote Dr. Wang a letter stating that his post-doctoral student euthanized mice from another PI's protocol without authorization and that further infractions of this nature may result in the suspension of his research.

2. On Friday, August 11, 2017, a research technician reported to the Director of the Animal Resources Facility and Attending Veterinarian, Dr. Douglas Cohn, that she found neonatal mice alive in the freezer of the necropsy room. Dr. Cohn inspected the freezer to verify the observation, and read the name of last person who euthanized mice using CO2. That person had euthanized 81 mice within the previous hour. Upon further inspection of the freezer he noted that many of the adult mouse cadavers did not have a second method of death verification. The animal user was a post-doctoral student who was working under the approved

protocol # 15-03002 of Dr. Yong-Xiao Wang, funded by the <u>financial information</u> Dr. Cohn then called the student into his office and questioned her about her method of euthanasia. She admitted that she did not perform euthanasia of mice in accordance to federal and institutional regulations. Dr. Cohn pulled her access to the vivarium, and informed Dr. Wang of the infraction and that all personnel in his lab must undergo retraining in the proper methods of euthanasia. The instruction was copied to the IACUC. The retraining was completed on August 17, 2017. Dr. Cohn returned swipe card access to the post-doctoral student on Friday, August 18, 2017.

We are confident that the above-stated actions are in line with the expectations of OLAW. Thank you for your kind attention.

Name of Institution: Albany Medical College, Albany, NY 12208

Animal Welfare Assurance Number: D16-00062 (A3099-01)

Reporting Requirement:

Serious non-compliance regarding directions from ARF Director regarding expired protocol # 14-06003 entitled, "Ryanodine receptors and hypoxic pulmonary hypertension".

Serious deviation from animal care and use protocol # 15-03002 entitled, "Ca2+ release in diabetic cerebral artery myocytes".

Corrective Actions: Access to Animal Facility vivarium was taken away from post-doctoral student.

ACUP #: 14-06003 Grant Number: NIH # R01 HL064043

ACUP#: 15-03002 Grant Number: Not Applicable.

Impact on PHS-Supported Activities: Not applicable.

The Albany Medical College is committed to assuring the welfare of all animals used in research. This report provides and describes the circumstances and actions taken.

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

Thank you for your consideration in this matter.

Sincerely,

Mulia Ul. Tolano, M.S. Michael A. Falzano, MS

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)
- HIPAA Privacy Officer for the Albany Medical College
- Research Integrity Officer
- Instructor Med Students Year I

Telephone: Phone Number

E-mail: falzanm@mail.amc.edu

Wolff, Axel (NIH/OD) [E]

From:	Wolff, Axel (NIH/OD) [E]
Sent:	Wednesday, August 23, 2017 11:43 AM
	econdary Individua
Subject:	RE: Assurance# D16-00062 animal incident

Sensitivity:

Confidential

Thank you for this report, condary Individ We will send a response soon

Axel Wolff

From: condary Individu [mailto dary Ind@mail.amc.edu] Sent: Wednesday, August 23, 2017 11:31 AM To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov> Subject: RE: Assurance# D16-00062 animal incident Sensitivity: Confidential

Dear Dr. Wolff,

I am the administrative coordinator for Michael A. Falzano, MS, Institutional Official for Albany Medical College's Institutional Animal Care and Use Committee. Attached to this email is a report of noncompliance and an animal incident that occurred.

Please see the attached report.

Respectfully,

 Secondary Individual
 Administrative Coordinator

 on behalf of
 Michael A. Falzano, MS

 Institutional Official
 Albany Medical College

 Dean's Office
 47 New Scotland Avenue MC # 34

 Albany, NY
 12208

 Telephone:
 Phone Number

 Email:
 falzanm@mail.amc.edu

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