



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

November 30, 2017

Re: Animal Welfare Assurance
A3099-01 [OLAW Case 1A]

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 November 21, 2017 letter reporting an instance 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 that a protocol expired on August 24, 2017 despite multiple notices to the PI and the laboratory manager. On November 9, 2017 it was determined that seven mouse surgeries and eight mouse euthanasias had been conducted after the protocol had expired. During the IACUC's review of the matter it was determined that the IACUC SOP would be rewritten to state that the IACUC Chair would specifically notify the PI when a protocol expired in a Termination Notice and in the 30 day letter before expiration the IACUC Chair, the Attending Veterinarian and the Department Head would also be copied. The IACUC also counseled the PI to be "sure to respond properly on following continuation notices." The activity is not supported with PHS funds.

The prompt consideration of this matter by Albany Medical College was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to correct 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,

Signature

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

cc: IACUC Contact



ALBANY MEDICAL COLLEGE

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

13099 - 1A

November 21, 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 24, 2017, protocol # 15-08000 expired. Dr. Reynold Lopez-Soler is the Principal Investigator (PI) and the protocol is funded by departmental funds. The protocol was initially approved on August 24, 2016.

The IACUC Coordinator sent the PI an email on three separate occasions: 90 days, 60 days and 30 days before the protocol expired, requesting him to submit an annual renewal. The PI did not submit this renewal by this date, and the IACUC Coordinator made a note on the website that the protocol had expired.

2. On Monday, November 9, the Research Coordinator of the Animal Resources Facility completed training for a new animal user in the lab of the PI. She noted on the website that the protocol had expired in August. She contacted the Director of the Animal Resources Facility, [Secondary Individual] about this incongruity. He had no knowledge of the expiration of this protocol. He contacted the IACUC Coordinator, and she verified that she had terminated the protocol because of the PI's failure to submit the annual renewal. Neither the Chair of the IACUC, nor the PI knew that the protocol had expired. The PI had thought that his laboratory manager, who was copied on the three emails, took care of the submission, but obviously she had not. The PI admitted that since the protocol had expired, he had completed seven (7) surgeries on mice and eight (8) mouse euthanasia. The PI did complete and submit an annual renewal form to the IACUC, however [redacted] informed the PI that his access to the vivarium was being removed until the IACUC could meet formally to discuss the case on Thursday, November 16. The IACUC discussed this case at the regularly scheduled meeting. They

realized that the IACUC SOP did not specifically address who would be notified when a protocol expired. The IACUC rewrote the SOP to designate that the Chair would specifically notify the PI when a protocol expired in a Termination Notice. In the 30 day letter before expiration, the IACUC Chair, the Attending Veterinarian and the Department Head would also be copied. In this way, such an incident will be unlikely to occur again. The IACUC then formally voted to allow the PI's protocol to continue until Aug. 24, 2018, retroactive from Aug. 24, 2017.

We are confident that the above-stated actions are in line with the expectations of OLAW.

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

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

Reporting Requirement:

IACUC will report to PI formally that his protocol is approved. Today, November 21, the IACUC Chair sent a letter to the PI to have him be sure to respond properly on following continuation notices.

Corrective Actions:

Revision of the IACUC SOP

ACUP #: 15-08000

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,

Signature

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)
- Research Integrity Officer

Telephone: Phone Number

E-mail: falzanm@amc.edu

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Wednesday, November 22, 2017 8:34 AM
To: Secondary Individual
Subject: RE: Assurance# D16-00062 (2nd animal incident)

Thank you for these reports, Secondary Individual. We will send responses soon. In future please send all final reports to olawdco@od.nih.gov.
 Axel Wolff, M.S., D.V.M.
 Deputy Director, OLAW

From: Secondary Individual [mailto:Secondary Individual@amc.edu]
Sent: Tuesday, November 21, 2017 4:19 PM
To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Cc: Falzano, Michael <FalzanM@amc.edu>
Subject: RE: Assurance# D16-00062 (2nd animal incident)

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 second 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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