



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

May 23, 2018

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

Dr. Paul Feustel
Director of Research Affairs
Albany Medical College
47 New Scotland Avenue, MC #1
Albany, NY 12208-3479

Dear Dr. Feustel,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 22, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Albany Medical College, following up on an initial report on April 27, 2018. According to the information provided, OLAW understands that a Principal Investigator (PI) was using a special chamber to expose mice to chronic hypoxia and this device required daily monitoring. However, the laboratory staff failed to conduct daily monitoring for two days. There was no harm to the mice or the study due to this failure.

The corrective actions consisted of revoking animal facility access for the Research Associate (RA) responsible and having the PI personally check the chamber. The Institutional Animal Care and Use Committee subsequently allowed the RA to check the chamber again, directed the PI to train other co-investigators how to check the chamber and serve as back-ups, and to have the PI ensure that checks are conducted daily. If future problems occur with chamber monitoring, the study will be terminated. The animal resources staff will verify the daily documentation of chamber monitoring.

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 institution to comply with the PHS Policy.

Sincerely,

(b) (6)

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

cc: IACUC Chair



Research Office • Mail Code #1 • 47 New Scotland Avenue, Albany, NY 12208
Phone: (518) 262-5182 • Fax: (518) 262-5890

Albany Medical College

22 May 2018

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

To Whom It May Concern

As Institutional Official of Albany Medical College (AMC), I am submitting this follow up report to a previously reported incident on April 26th 2018.

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

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

ACUP # and Title ACUP # 17-03003 Ryanodine receptors and hypoxic pulmonary hypertension

Grant Number: R01 HL122865-04 Novel Signaling in Chronic Hypoxic Responses in Pulmonary Arteries

Impact on PHS-Supported Activities: None.

Explanation for Incident (previously reported): Incident was a failure to adhere to an IACUC approved protocol. The protocol involves the use of a special chamber designed to expose mice to chronic hypoxia. The approved protocol required daily monitoring of the chamber by lab personnel to assure proper chamber operation. On April 10th it was discovered that personnel had failed to check the chamber on Saturday April 7th. Individuals involved were notified and reminded that daily monitoring was required. On Friday, April 20th, documentation of chamber monitoring was again absent for April 19th. Upon questioning, the individual responsible admitted that monitoring was not done. On April 20th the Animal Facility Director in consultation with the IACUC Chair removed facility access for the individual, and the PI was informed that either the animals had to be immediately removed from the chamber or someone else from his lab had to be assigned the chamber monitoring task. On the same day, the PI responded that he would daily check the chamber himself. Furthermore, the PI was informed that the issue would be further discussed at the next IACUC meeting (May 17th) and his presence was requested. No animals were harmed in this incident and there was no apparent effect on the experiment as chamber operation was apparently normal.

Corrective Actions (previously reported): Access was terminated for the individual responsible for the chamber monitoring. The PI is currently performing that task. We expect a more complete corrective action plan to be drafted and agreed upon at the next IACUC meeting. A definitive plan will

be presented at the next IACUC next meeting.

Corrective Actions (NEW): At the May 17th IACUC meeting, the committee met with the Research Associate (RA) who had failed to do the required monitoring. The RA apologized to the committee and admitted that he had become too involved with other lab activity and had neglected to check the chamber. The IACUC was convinced that this individual was unlikely to repeat that mistake and the RA was again given access to the barochamber room. Further, the IACUC required that the PI 1) assign and train other co-investigators listed on the approved ACUP to perform the inspections should the RA be unable and 2) put in place a procedure which insures that the checks are performed daily should the RA be unable to do it. The IACUC stressed that it is the PI who bears ultimate responsibility for overseeing all of his ACUP's. Should any further deviations from the barochamber observation schedule occur, the IACUC will terminate barochamber experiments. The PI agreed and responded in writing on May 21st. Animal resources staff will continue to verify daily documentation of chamber monitoring.

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.

Sincerely,

(b) (6)

Paul J. Feustel, Ph.D.
Institutional Official
Director, Office of Research Affairs
Phone: (b) (6)
e-mail: feustep@amc.edu

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, May 23, 2018 6:05 AM
To: Feustel, Paul
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of Non-compliance

Thank you for this report, Dr. Feustel. We will send a response shortly.
 Axel Wolff

From: Feustel, Paul [mailto:FeusteP@amc.edu]
Sent: Tuesday, May 22, 2018 4:00 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: RE: Report of Non-compliance

Dear Dr. Wolff,
 Please find attached the follow up on the previously reported incident of non-disclosure. Please let me know if anything further is required.

Thanks,
 Paul

Paul J. Feustel, Ph.D.
 Institutional Official
 Director, Research Administration, Basic Science
 Office of Research Affairs, [REDACTED] Mail Code 1
 Albany Medical College
 Albany NY 12208
 phone: [REDACTED] (b) (6) (ORA), [REDACTED] (b) (6) (direct)
 feustep@mail.amc.edu



Albany Medical College

From: OLAW Division of Compliance Oversight (NIH/OD) [mailto:olawdco@od.nih.gov]
Sent: Friday, April 27, 2018 12:12 PM
To: Feustel, Paul <FeusteP@amc.edu>
Cc: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: RE: Report of Non-compliance

STOP! THINK! External Email!

Thank for this preliminary report, Dr. Feustel. I will open a new case file and look forward to receiving the final report after the IACUC has completed its investigation.

Axel Wolff, M.S., D.V.M.
 Deputy Director, OLAW

From: Feustel, Paul [mailto:FeusteP@amc.edu]
Sent: Friday, April 27, 2018 11:58 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)@amc.edu>
Subject: Report of Non-compliance

I am the new IO for Albany Medical College. What follows is a preliminary disclosure of an incident of non-compliance at AMC (the attached pdf is the same). Please let me know if any further information is required.

26 Apr 2018

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

To Whom It May Concern

As Institutional Official of Albany Medical College (AMC), I am submitting a report of noncompliance regarding an animal welfare issue.

Name of Institution: Albany Medical College, Albany, NY 12208
Animal Welfare Assurance Number: D16-00062 (A3099-01)
ACUP # and Title ACUP # 17-03003 Ryanodine receptors and hypoxic pulmonary hypertension
Grant Number: R01 HL122865-04 Novel Signaling in Chronic Hypoxic Responses in Pulmonary Arteries
Impact on PHS-Supported Activities: None.

Explanation for Incident: Incident was a failure to adhere to IACUC approved protocol. The protocol involves the use of a special chamber designed to expose mice to chronic hypoxia. The approved protocol required daily monitoring of the chamber by lab personnel to assure proper chamber operation. On April 10th it was discovered that personnel had failed to document checking the chamber on Saturday April 7th. Individuals involved were notified and reminded that daily monitoring was required. On Friday, April 20th, documentation of chamber monitoring was again absent for April 19th. Upon questioning, the individual responsible admitted that monitoring was not done. On April 20th the Animal Facility Director in consultation with the IACUC Chair removed facility access for the individual and the PI was informed that either the animals had to be immediately removed from the chamber or someone else from his lab had to be assigned the chamber monitoring task. On the same day, the PI responded that he would daily check the chamber himself. Furthermore, the PI was informed that the issue would be further discussed at the next IACUC meeting (May 17th) and his presence was requested. No animals were harmed in this incident and there was no apparent effect on the experiment as chamber operation was apparently normal.

Corrective Actions: Access was terminated for the individual responsible for the chamber monitoring. The PI is currently performing that task. We expect a more complete corrective action plan to be drafted and agreed upon at the next IACUC meeting. A definitive plan will be presented at the next IACUC next meeting.

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.

Sincerely,

Paul J. Feustel, Ph.D.

Institutional Official
Director, Office of Research Affairs
Phone: (b) (6)
e-mail: feustep@amc.edu

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