



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
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Bethesda, Maryland 20892-6910  
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

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Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
Facsimile: (301) 402-7065

October 10, 2018

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

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 September 27, 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 September 18, 2018. According to the information provided, OLAW understands that tumor transplant procedures were performed in mice although this activity had not been described in the approved protocol. This occurred due to inadequate supervision and training of laboratory staff.

The corrective actions consisted of euthanizing the mice and suspending the vivarium access for the Principal Investigator (PI) and staff. The PI assured the Institutional Animal Care and Use Committee (IACUC) that unapproved procedures would not be performed, that copies of the protocol would be available, and that staff is familiar with the content, that staff is familiar with relevant regulations, and that all protocol amendments would be submitted by the PI.

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 NIH grant was not charged for any unapproved animal activities. Also note that the data acquired during the time the protocol was not approved usually cannot be published. Thank you for keeping OLAW apprised on this matter.

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

27 September 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 Sept 18, 2018.

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

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

**ACUP # and Title** ACUP # 17-04003 In vivo SMG7 regulation of the nonsense-mediated mRNA decay and the p53 pathway in tumor suppression and DNA damage response

**Grant Number:** R01 GM112085 EST1C Regulation of the p53 Pathway in Stress Response

**Impact on PHS-Supported Activities:** Delay of one month in a limited set of experiments.

**Explanation for Incident:** On August 28<sup>th</sup>, it was discovered by Animal Resources Facility (ARF) staff that research was being performed that was not authorized by the IACUC. Specifically, an investigator was subcutaneously transplanting tumors that developed spontaneously in transgenic mice into recipient mice. Initially it was thought that the recipient mice had been irradiated but this was not the case. Nevertheless, this specific procedure was not included in the PI's approved protocol.

**Corrective Actions (previously reported):** The investigators access to the facility was removed. With supervision, the investigator euthanized 23 mice that were involved in the unapproved activity on August 29<sup>th</sup>. The principle investigator and all staff in his lab had ARF access removed and they were allowed to continue only with breeding activity under direct ARF staff supervision.

**Corrective Actions (NEW):** The approved protocol involved both the use of irradiation in mice and the breeding and use of mice in which spontaneous tumor appearance was expected. At the 20 Sept IACUC meeting, the PI stated that he had instructed a post-doctoral fellow to prepare an amendment for the new procedures, the amendment had been prepared but that it never been submitted due to a miscommunication within the lab.

The IACUC requested the PI submit a written response that includes a corrective action plan to assure that such an incident does not occur in the future. The conclusion was that there was not adequate

supervision of lab activities or training of lab staff.

The PI's corrective action plan was submitted on 24 Sept. The PI's plan included: *"I will take full responsibility to ensure that my lab personnel do not perform unapproved procedures. First, I will make sure that my active ACUPs are available to lab members who participate animal research. Second, I will review the ACUPs with the lab personnel on a regular basis, so they clearly know the IACUC-approved procedures prior to initiation of any animal study. Third, I will make sure that lab personnel are familiar with the OLAW regulations and laws regarding IACUC review requirements and fully aware that they can only perform IACUC-approved procedures. Lastly, since the incident occurred because of a miscommunication about submission of an amendment, in the future I will solely be responsible for submitting amendment to IACUC for review and assure that any new animal procedure proposed in the amendment must be approved by the IACUC."* The PI's plan was circulated to the committee, approved, and ARF access restored on 27 Sept.

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

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Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

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**From:** Feustel, Paul [mailto:FeusteP@amc.edu]  
**Sent:** Tuesday, September 18, 2018 10:12 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Ferland, Russell <FerlanR@amc.edu>; (b) (6)  
**Subject:** Preliminary report

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 preliminary report of noncompliance regarding an animal welfare issue.

Explanation for Incident: This is a preliminary report of an incident at Albany Medical College. On August 28<sup>th</sup> it was discovered that research was being performed that that was not authorized by the IACUC. Specifically, an investigator was transplanting tumors that developed spontaneously in knock out mice into recipient mice that have been irradiated beforehand. This specific procedure was not included in the PI's approved protocol. The investigators access to the facility was removed. With supervision, the investigator euthanized a limited number of animals that were involved in the unapproved activity. The investigator was allowed to continue only with his breeding protocols under ARF staff supervision. The IACUC needs to meet to consider further action pending a meeting to be held on 20 Sept. A final report will be submitted after that meeting.

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

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

Corrective Actions: to be determined

Grant Number: R01GM112085

Impact on PHS-Supported Activities: To be determined

The Albany Medical College is committed to assuring the welfare of all animals used in research. This preliminary report provides and describes the circumstances but not the actions taken. If you have any questions, please do not hesitate to contact me.

Thank you for your consideration in this matter.

Sincerely,

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)  
[feustep@amc.edu](mailto:feustep@amc.edu)

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