



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, Maryland 20892-6910  
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare  
6700B Rockledge Drive, Suite 2500  
Bethesda, Maryland 20817  
Telephone: (301) 496-7163  
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January 3, 2019

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

Dr. Paul Fuestel  
Director of Research Administration,  
Basic Science  
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 20 December 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Albany Medical College. Your letter supplements your prompt preliminary email report made on December 7, 2018. According to the information provided, OLAW understands that on November 15, 2018 your IACUC was notified of animal welfare issues regarding a laboratory. A new post-doc had weaned mouse pups too early, at just 2 weeks of age, and they were found dead the next day. Two days later, five neonates were found dead in a cage which this post-doc had weaned the day before where no Napa Nectar or food pellets were placed on the cage floor. The Attending Veterinarian (AV) subsequently removed access for the post-doc to the ARF but the next day another member of the lab allowed the post-doc into the ARF where he instilled novel substances into the nostrils of mice without protocol-required anesthesia. The AV contacted the PI and made it clear that this post-doc could no longer enter the ARF or work with animals, pending IACUC action. The activity was not supported with PHS funds.

The PI informed the committee that the post-doc would no longer be allowed to work with live animals in her lab at AMC and that the post-doc's employment at AMC is terminating January 31, 2019. The PI submitted a corrective action plan to prevent such incidents from occurring in her lab. The plan consisted of three major parts: Training, in which instruction is provided to lab members regarding IACUC review requirements, and training on ACUP protocols; Supervision, wherein the PI and other qualified lab members form a supervising team to provide and evaluate the training and to be available for consultation to other lab members, and; Incidents handling.

The prompt consideration of this matter by Albany Medical College and the PI was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to correct the issue and prevent recurrence were appropriate. OLAW advises that the IACUC is ultimately responsible for evaluating that personnel are appropriately qualified and trained in procedures to be conducted on animals and that under "Incidents handling" there should be recognition early in the process that the IACUC must be notified of the possible animal welfare or ACUP compliance issue. Although this activity was not PHS funded, the application of the standards of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. We appreciate being informed of this matter and find no cause for further action by this office.

*Page 2 – Dr. Fuestel*  
*January 3, 2019*  
*OLAW Case A3099-1E*

Sincerely,

(b) (6)

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

cc: IACUC Contact



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

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Albany Medical College

20 December 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 an incident previously reported on 7 December, 2018.

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

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

**ACUP # and Title** ACUP # 16-01006 Early Innate Lymphoid Cell Development

**Grant Number:** None (this was previously reported to be associated with K22AI116728 but it was later determined that the project was funded by institutional funds; NIH funds were not involved)

**Impact on PHS-Supported Activities:** None.

**Explanation for Incident (previously reported):** Incident was a failure to adhere to IACUC approved protocol.

On November 15, 2018, animal welfare issues were reported to the IACUC committee regarding this laboratory.

On the previous Monday, a new post-doc weaned pups too early at just 2 weeks of age, and they were subsequently found dead the next day. On Wednesday, five neonates were found dead in a cage that this post-doc had weaned the day before, in which no Napa Nectar or food pellets were placed on the cage floor. The PI was contacted and agreed to provide assistance and training for the new post-doc. On Thursday, the Attending Veterinarian removed swipe card access to the ARF for the post-doc. The Attending Veterinarian stated that he would return the post-doc's ARF access once he and the PI were confident that the post-doc was performing all duties as trained and in agreement with approved Animal Care and Use Protocol (ACUP).

On Friday, it was reported to the Attending Veterinarian that another person from the same lab allowed the post-doc into the ARF and left him on his own to do procedures. It was also reported that the post-doc was only using manual restraint on the mice prior to the installation of novel substances into the nostrils of mice. The approved protocol requires that isoflurane anesthesia be used to instill substances into the nostrils of mice. The Attending Veterinarian contacted the PI and made it clear that this post doc could no longer enter the ARF or work with animals pending IACUC action. Given these incidents and violations, the IACUC concluded the Attending Veterinarians actions were justified and that there was not adequate supervision of this ACUP by the PI. The IACUC directed that the PI and the post-doc appear at the next IACUC meeting (December 20) and present a corrective action plan. At a minimum,

the corrective action plan must include: 1) re-training of laboratory staff regarding NIH/OLAW regulations and laws regarding IACUC review requirements, 2) regularly scheduled review of active ACUPs with lab personnel so all are aware of IACUC allowed procedures and limitations; 3) a provision so that active ACUPs are available in the lab at any time for consultation by staff prior to initiation of any study, and 4) plans to ensure new animal users in your lab are supervised.

**Corrective Actions (previously reported):** Access was terminated for the individual responsible for violations of the protocol. He was not permitted to enter the ARF or work with live animals pending a more complete corrective action plan to be drafted and agreed upon at the 20 Dec IACUC meeting.

**Corrective Actions (NEW):** The PI attended the IACUC meeting on the 20<sup>th</sup> of December. The PI had previously submitted to the committee a detailed corrective action plan. Items in the plan included:

- 1) The PI informed the committee she would no longer allow the involved post-doctoral researcher to work with live animals in her lab at AMC. She indicated that this ban is permanent. The post-doctoral researcher's employment at AMC is terminating January 31, 2019.
- 2) The PI also proposed a corrective action plan to assure that such incidents involving other individuals will not occur in her lab in the future. The plan consisted of three major parts: training, supervision and incidents handling (below is abstracted from the submitted plan).
  - (1) *Training - In addition to the training provided by the AMC animal facility, additional training will be provided to members of the lab either by the PI or a qualified member of the laboratory.*
    - a) *Regarding IACUC review requirements*
      - i. *Training content: NIH/OLAW/AMC regulations regarding IACUC review requirements, particularly the importance of the regulations and laws and compliance.*
      - ii. *Trainer: PI or a qualified laboratory member.*
      - iii. *Trainee: new members of the laboratory, all members of the laboratory*
      - iv. *Training schedule: upon joining of the laboratory for new members, and as necessary for all other laboratory members.*
    - b) *ACUP protocols training*
      - i. *Training content: active ACUP protocols in the laboratory, particularly their allowed procedures and limitations.*
      - ii. *Trainer: PI or a qualified laboratory member.*
      - iii. *Trainee: every laboratory member that will perform approved ACUP protocol procedures.*
      - iv. *Training schedule:*
        1. *Initial training: a laboratory member new to an ACUP protocol is required to be trained on the specific procedure before the procedure can be performed by the member independently.*
        2. *refresher training: active members of an ACUP protocol will be trained on the protocol to refresh their memory and training whenever necessary.*
      - v. *Training assessment and follow up*
        1. *Based on the training results, the PI will decide whether to allow the trainee to perform a specific ACUP approved procedure or additional training is needed.*
        2. *To ensure that an ACUP protocol will be followed correctly by a trainee upon completion of the initial training, the first time the trainee performing a procedure of the protocol independently it shall be supervised. If the trainee fails to comply with the protocol, another round of training and supervised performing of the procedure will be conducted.*
  - (2) *Supervision*

*To ensure that sufficient supervision is provided for laboratory members who perform animal research,*

    - a) *The PI and other qualified laboratory members will be forming a supervising team that*

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**STOP! THINK! External Email!**

Dear Dr. Feustel,

Thank you for providing this prompt preliminary report. We will open a case file and await further information.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM  
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:** Friday, December 07, 2018 9:32 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <[olawdco@od.nih.gov](mailto:olawdco@od.nih.gov)>  
**Cc:** [REDACTED] (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.

**Name of Institution:** Albany Medical College, Albany, NY 12208  
**Animal Welfare Assurance Number:** D16-00062 (A3099-01)  
**ACUP # and Title** ACUP # 16-01006 Early Innate Lymphoid Cell Development  
**Grant Number:** K22AI116728 Early Innate Lymphoid Cell Development  
**Impact on PHS-Supported Activities:** Uncertain at this time.

**Explanation for Incident:** Incident was a failure to adhere to IACUC approved protocol.

On November 15, 2018, animal welfare issues were reported to the IACUC committee regarding this laboratory.

On the previous Monday, a new post-doc weaned pups too early at just 2 weeks of age, and they were subsequently found dead the next day. On Wednesday, five neonates were found dead in a cage that this post-doc had weaned the day before, in which no Napa Nectar or food pellets were placed on the cage floor. The PI was contacted and agreed to provide assistance and retraining for the new post-doc. On Thursday, the Attending Veterinarian removed swipe card access to the ARF for the post-doc. The Attending Veterinarian stated that he would return the post-doc's ARF access once he and the PI were confident that the post-doc was performing all duties as trained and in agreement with approved Animal Care and Use Protocol (ACUP).

On Friday, it was reported to the Attending Veterinarian that another person from the same lab allowed the post-doc into the ARF and left him on his own to do procedures. It was also reported that the post-doc was only using manual restraint on the mice prior to the installation of novel substances into the nostrils of mice. The approved protocol requires that isoflurane anesthesia be used to instill substances into the nostrils of mice. The Attending Veterinarian contacted the PI and made it clear that this post doc could no longer enter the ARF or work with animals pending IACUC action. Given these incidents and violations, the IACUC concluded the Attending Veterinarians actions were justified and that there was not adequate supervision of this ACUP by the PI. The IACUC directed that the PI and the post-doc appear at the next IACUC meeting (December 20) and present a corrective action plan. At a minimum, the corrective action plan must include: 1) re-training of laboratory staff regarding NIH/OLAW regulations and laws regarding IACUC review requirements, 2) regularly scheduled review of active ACUPs with lab personnel so all are aware of IACUC allowed procedures and limitations; 3) a provision so that active ACUPs are available in the lab at any time for consultation by staff prior to initiation of any study, and 4) plans to ensure new animal users in your lab are supervised.

**Corrective Actions:** Access was terminated for the individual responsible for violations of the protocol. We expect a more complete corrective action plan to be drafted and agreed upon at the next IACUC meeting Dec 20.

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

Paul J. Feustel, Ph.D.  
Institutional Official  
Director, Research Administration, Basic Science  
Office of Research Affairs, [REDACTED] Mail Code 1  
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Albany NY 12208  
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