



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

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Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
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August 29, 2017

Re: Animal Welfare Assurance
A3049-01 [OLAW Case 1M]

Mr. Thomas Coggins
Director, Office of Research Compliance
University of South Carolina
Room #Byrnes Building
Columbia, SC 29208

Dear Mr. Coggins,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 29, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of South Carolina. According to the information provided, OLAW understands that two rats were subjected to a subcutaneous implantation via trocar although this activity was not covered by an approved protocol, was not performed as described in a pending amendment, and was performed by an individual involved in a prior unauthorized surgery. Also, unapproved post-procedure suturing was performed, analgesia was not provided, and the veterinary staff was not consulted. The institutional animal protocol transfer had not been properly conducted.

The corrective actions consisted of counseling the investigator to follow the animal protocol transfer procedures before using animals, having the individual responsible undertake retraining, resubmitting a revised detailed protocol amendment, and confirming proficiency of staff performing the trocar implantation procedure.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of the problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy. Please notify the funding components for grants #R01 DA013137 and R01 MH 106392 that no charges will be made for any unauthorized animal activities. Thank you for informing OLAW about this matter.

Sincerely,

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

cc: IACUC Chair
Pamela Fleming, Chief GMO, NIDA
Rebecca Claycamp, Chief GMO, NIMH

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, August 29, 2017 8:59 AM
To: 'COGGINS, TOMMY'
Subject: RE: Report of Non-Compliance - A3049 (D16-00028)

Thank you for this report, Mr. Coggins. We'll respond soon.
Axel Wolff

From: COGGINS, TOMMY [mailto:TCOGGINS@mailbox.sc.edu]
Sent: Tuesday, August 29, 2017 8:56 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: [REDACTED]@mailbox.sc.edu>; [REDACTED]@uscmed.sc.edu; [REDACTED]@mailbox.sc.edu>; [REDACTED]@mailbox.sc.edu>; [REDACTED]@mailbox.sc.edu>
Subject: Report of Non-Compliance - A3049 (D16-00028)

August 29, 2017

Axel Wolff, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Dear Dr. Wolff:

The University of South Carolina, in accordance with Assurance D16-00028 and PHS Policy IV.F.3., provides this report regarding a recent case of non-compliance. The non-compliance occurred on PHS-funded, NIH grant numbers R01 DA013137 and R01 MH106392 .

On July 7, 2017, DLAR staff discovered two rats being held in cages marked "Pilot Project" and they appeared to have undergone a procedure which was not covered by the relevant animal use protocol (AUP). Subsequently, the PI submitted a transfer request to move the animals onto what was, ostensibly, the correct AUP. A subcommittee of the IACUC was appointed to review the incident. The subcommittee requested that the PI provide detailed information about the procedures, including how they fit within the approved AUP. The requested information was provided on August 2, 2017.

At its meeting on August 3, 2017, the IACUC fully reviewed all correspondence and evidence connected with this matter and concluded the following:

1. The procedure in question (subcutaneous implantation via trocar) was not approved on either of the protocols in question.
2. The procedure was performed by the same individual who performed a prior unauthorized surgery.
3. The procedure was not performed as described in a pending amendment to AUP #2205 or according to the PI's email message of August 2, 2017.

4. Post-procedure suturing constitutes an additional unapproved procedure, compounded by failure to provide appropriate care. It was performed without veterinary consultation or provision of analgesia.

Based on these findings the IACUC required the following corrective actions:

1. The established procedure for transferring animals to protocols must be followed. All transfers must be requested and approved prior to animal use on the receiving protocol.
2. The individual who performed the procedure must undergo compliance training as follows; complete or re-take the following AALAS Learning Library modules before September 15, 2017 or his approval to work with animals and his facility access will be revoked:
 - a. PHS Policy on Humane Care & Use of Laboratory Animals
 - b. Animal Welfare Act Regulations
 - c. 8th Edition of the Guide for the Care & Use of Laboratory Animals
 - d. Working with the IACUC (not the refresher)
 - e. Common Compliance Issues
 - f. Pain Management in Laboratory Animals
3. The pending amendment to AUP 2205-100886-082114 cannot be approved. It must be re-submitted and include the following information:
 - a. A complete description of the procedure, including information regarding suturing;
 - b. The type of anesthesia, if any, that will be used for the procedure;
 - c. Description of what will be injected, including doses and volumes as appropriate.
4. All protocol associates who will perform subcutaneous implantation via trocar must demonstrate proficiency in the procedure via observation by appropriate DLAR staff before conducting the procedure on any approved protocols.

The University of South Carolina is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions concerning this report, please do not hesitate to contact me.

Sincerely,

Thomas Coggins
Institutional Official
Director, Office Research Compliance
University of South Carolina

Phone Number