



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
Facsimile: (301) 402-7065

April 25, 2019

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

Mr. Thomas Coggins
Director, Office of Research Compliance
University of South Carolina
(b) (4) Byrnes Building
Columbia, SC 29208

Dear Mr. Coggins,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 12, 2019 email reporting two instances 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 the first incident was discovered on March 8, 2019 and involved an ultrasound procedure being performed on three mice before being added to the protocol. The procedure was performed under a surgical plane of anesthesia in accordance with an IACUC-approved SOP but had not yet been approved in the protocol by the IACUC. The PI was reminded that no procedures can be performed until approved by the IACUC. It was stated that the animals were supported by PHS funding.

The second incident occurred on March 22, 2019 and involved four cages of mice on a breeding-only protocol that had been injected with disulfiram nanoparticles. Two cages of mice were found dead on March 22nd. This was considered an unapproved "Category E" procedure that potentially endangered the health and safety of DLAR staff and other personnel. It was stated that the animals were supported by PHS funding. The PI stated that he counseled his lab personnel on adhering to the approved protocol and would accompany them in designing and conducting future experiments. The IACUC also required that the PI attend a training workshop.

The consideration of these matters by the University of South Carolina was consistent with the philosophy of institutional self-regulation. Similarly, the additional actions taken to resolve the issues and prevent recurrence were appropriate. We appreciate being informed of these matters and find no cause for further action by this office.

Sincerely,

(b) (6)

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

cc: IACUC Contact

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, April 25, 2019 9:51 AM
To: COGGINS, TOMMY: OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6)
Subject: RE: Report of Non-Compliance - A3049 (D16-00028)

Thank you very much for this additional information Mr. Coggins. We will send you a response to your final report soon.
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: COGGINS, TOMMY [mailto:TCOGGINS@mailbox.sc.edu]
Sent: Thursday, April 25, 2019 9:15 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
(b) (6)
Subject: RE: Report of Non-Compliance - A3049 (D16-00028)

Dear Dr. Morse,

The following information is provided in response to your question regarding our previously reported deviation.

Three mice were anesthetized with isoflurane and cardiac ultrasounds were performed under a surgical plane of anesthesia in the University's core animal imaging facility with a VEVO 3100 ultrasound unit. The mice recovered uneventfully. The ultrasound imaging was performed in accordance with an IACUC-approved SOP for the procedure, but a DLAR veterinary technician later discovered the imaging procedure was not described in the Animal Use Protocol for those three mice.

Please let me know if additional information is required.

Thomas Coggins
Director
Office of Sponsored Awards Management & Research Compliance
University of South Carolina
(b) (6)

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Wednesday, April 17, 2019 3:52 PM
To: COGGINS, TOMMY <TCOGGINS@mailbox.sc.edu>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: (b) (6)

(b) (6)

Subject: RE: Report of Non-Compliance - A3049 (D16-00028)

Good afternoon Mr. Coggins,

After reviewing the report, OLAW will need additional information regarding only the first incident. Please include the species and number of animals involved and the name or a short description of the unapproved procedure. Thank you.

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: COGGINS, TOMMY [mailto:TCOGGINS@mailbox.sc.edu]

Sent: Friday, April 12, 2019 4:06 PM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Cc: (b) (6)

(b) (6)

Subject: Report of Non-Compliance - A3049 (D16-00028)

April 12, 2019

Dear Dr. Morse:

The University of South Carolina, in accordance with Assurance D16-00028 and PHS Policy IV.F.3., provides this report regarding two recent incidents of non-compliance which were reviewed at the April 4, 2019, meeting of the IACUC.

The first incident involved an individual performing an unapproved procedure on live animals. The incident was discovered by DLAR staff on March 8, 2019. The procedure performed had been submitted as an amendment, but had not been approved. At the time of the April meeting, the amendment had been approved. The IACUC Administrator contacted the PI and reminded him that procedures may not be performed until approved by the IACUC. He provided assurance that this would not occur again. The federal grant numbers for the protocol are R01HL116626, P01AT003961, and R01CA218578.

The second incident occurred on March 22, 2019 and involved the discovery, by DLAR staff, of two cages containing dead animals. The cage cards indicated that the animals were part of a breeding colony; however, they appeared to have received an unknown experimental treatment. The PI confirmed that a student had administered disulfiram nanoparticles on breeding colony animals scheduled to be euthanized. The IACUC discussed the incident and concluded the following:

1. An unapproved Category E procedure was performed on four cages of mice from a breeding-only protocol.
2. No compound or experimental information was listed on the cages, potentially endangering the health and safety of DLAR staff and other personnel who may have required specific personal protective equipment (PPE).

3. The student in question should have known that both the procedure and compound could not be administered to any animals on any protocol because it had not been approved by the IACUC.
4. The PI stated that he counseled his lab personnel on adhering to the approved protocol and would accompany them in designing and conducting future experiments.

The IACUC remained concerned about the level of training and supervision provided to laboratory personnel and required that the PI attend a training workshop at his earliest opportunity and at his own expense. The PI must provide the IACUC with a certificate of attendance from the workshop. The federal grant funding work on this protocol is 2P01-AT003961.

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
(b) (6)
tcoggins@mailbox.sc.edu