



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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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

February 22, 2017

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

Mr. Thomas Coggins
Director, Office of Research Compliance
University of South Carolina
Room 1 Byrnes Building
Columbia, SC 29208

Dear Mr. Coggins,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 20, 2017 letter reporting the suspension of an animal activity at the University of South Carolina. According to the information provided, OLAW understands that the Institutional Animal Care and Use Committee (IACUC) took this action after determining that an investigator failed to comply with an IACUC requirement for amending a HIV transgenic rat protocol to include newly developed humane clinical endpoints (a new IACUC policy). All other investigators with similar protocols complied.

The action taken by the IACUC in response to the investigator's willful and repeated failure to comply consisted of suspending all of the investigator's protocols and placing the rats on a holding protocol. The PHS grant #R01 DA013137 will not be charged for any animal activities during the period of suspension.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to address the problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy. Please also inform the NIH funding component about the suspension and provide OLAW with an update once a determination has been made as to the final status of the protocol (i.e., termination or reinstatement). Thank you for informing OLAW about this matter.

Sincerely,

Axel Wolff, M.S., D.V.M.
Director
Division of Compliance Oversight

cc: IACUC Chair
Pamela Fleming, NIDA Chief GMO

Wolff, Axel (NIH/OD) [E]

A3049-1I

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, February 21, 2017 7:50 AM
To: 'COGGINS, TOMMY'
Subject: RE: Report of Non-Compliance - A3049 (D16-00028)

Thank you for this report, Mr. Coggins. We will respond soon.

Axel Wolff

From: COGGINS, TOMMY [mailto:TCOGGINS@mailbox.sc.edu]
Sent: Monday, February 20, 2017 2:57 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Secondary Individual @mailbox.sc.edu; lary In @uscmed.sc.edu; Secondary Individual ndary Indiv @mailbox.sc.edu; Secondary Individual @mailbox.sc.edu
Subject: Report of Non-Compliance - A3049 (D16-00028)

February 20, 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 and subsequent suspension of an Animal Use Protocol (AUP). The non-compliance occurred on studies funded by a PHS-funded grant, number R01 DA013137. After a series of sick animal reports, the IACUC, at its August meeting, began considering what are appropriate humane endpoints for HIV transgenic rats. With external input from scientists and veterinarians who are familiar with these animals, the IACUC developed a set of humane clinical endpoints to ensure the health and welfare of these rats. In December 2016, protocols using these animals underwent interim review and all PIs holding such protocols were directed to modify their current AUPs to adopt the IACUC-approved endpoints. The principal investigator of the referenced NIH grant did not respond to the IACUC's request.

In January 2017, the IACUC sent a follow-up letter requesting that AUPs involving these HIV transgenic rats be amended to become congruent with the endpoints, now adopted as IACUC policy. The PI was directed to amend her current AUPs to conform to the IACUC's prior request and its humane endpoint policy. Such an amendment required only that the investigator remove previously described endpoints and replace with those approved by the IACUC. Again, the PI did not respond with the requested amendments. All other PIs using these animals complied with the request.

At its February meeting, the IACUC voted to suspend the AUPs based on the PI's repeated and willful failure to comply with directives involving IACUC-approved humane endpoint criteria. The PI was sent a letter on February 13, 2017, stating that, if not amended by close of business on February 16, 2017, the AUPs would be suspended. The AUPs were not amended; therefore, the AUPs were suspended which resulted in the PI being denied access to the animals and placing them on the institutional holding protocol. During the period of suspension, all expenses associated with these animals will be paid from non-federal institutional funds.

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