



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) 480-3387

September 15, 2021

Re: Animal Welfare Assurance  
#A3281-01 [OLAW Case 20]

Dr. P. Srirama Rao  
Vice President for Research and Innovation  
Virginia Commonwealth University  
Biotech One, (b) (4)  
PO Box 980568  
Richmond, VA 23298-0568

Dear Dr. Rao,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of the September 13, 2021 letter submitted in your behalf reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Virginia Commonwealth University, following up on an initial telephone report on September 8, 2021. According to the information provided, OLAW understands that twelve mice were subjected to research activities after the protocol had expired.

The corrective actions consisted of the Institutional Animal Care and Use Committee (IACUC) approving the protocol six days after expiration. The Principal Investigator and staff were counseled and informed that only IACUC approved animal activities may be conducted and that no animal research may be performed on an expired protocol. It was determined that the costs incurred by the conduct of these animal activities were minimal and did not require adjustment of the grant. Adjustments to the animal care and use program were made to prevent a similar incident occurring elsewhere.

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 remember to include the relevant PHS/NSF grant numbers and the species involved in the final noncompliance report. 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  
Amy Chuang, Director, Animal Care and Use Program



# VCU

## Office of Research and Innovation

September 13, 2021

Axel V. Wolff, M.S., D.V.M.,  
Deputy Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
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[IACUC@VCU.EDU](mailto:IACUC@VCU.EDU)

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Amy Chuang, M.S.  
Director of Animal Care and Use  
Program (ACUP)

**VCU Animal Welfare Assurance number D16-00180 (A3281-01)**

Dear Dr. Wolff:

Virginia Commonwealth University, in accordance with Assurance D16-00180 (A3281-01) and PHS Policy IV.F.3., provides this report of noncompliance regarding an animal activity performed beyond the protocol expiration date. I have discussed and reported to you via a telephone call and an email.

**Description of Incident:**

On August 19, 2021, it was noted during a post approval compliance monitoring visit that the head twitch behavior study (involving 12 animals) was conducted on June 17, 2021. The protocol expired on June 12, 2021 and the three year renewal was not approved until June 23, 2021. Therefore, the lab staff member has performed the animal related activity beyond the expiration date established by the IACUC.

**Corrective action plan:**

- (1) The Animal Care and Use Program (ACUP) leadership, including the IACUC Chair, Attending Veterinarian, and Director of ACUP, met with the investigator and his staff member on September 3, 2021. The primary purpose of this meeting was to emphasize that no animal related activities are allowed beyond the protocol expiration date.
- (2) The investigator will provide a response to the IACUC via the post approval compliance monitoring to ensure the following:
  - The investigator will counsel the lab staff member involved in this incident to ensure this will not happen again.

Axel V. Wolff, M.S., D.V.M.

September 13, 2021

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- The investigator will assure IACUC that all his staff members understand and adhere to “no animal activities will be allowed beyond the protocol expiration date.”

After a review of direct costs associated with the procurement, care, drugs and use of animals conducted on 12 animals, the monetary impact of the noncompliance is considered insignificant and as such it was not necessary to make an adjustment to the grant.

We regret that this incident occurred. Following our detailed investigation, we have deployed specific corrective actions to enhance our program and to minimize future occurrences. The IACUC will be advised of the above corrective actions at their next full committee meeting.

We appreciate your consideration of VCU's efforts to minimize future occurrences. VCU remains committed to animal welfare and recognizes its ethical responsibilities in ensuring the welfare of research animals and complying with the *PHS Policy* on the Humane Care and Use of Laboratory Animals.

Sincerely yours,

DocuSigned by:  
[Redacted Signature] (b) (6)  
3487C192480548F...

Amy Chuang, M.S., RQAP-GLP, CPIA  
Director, Animal Care and Use Program  
Office of Research and Innovation



### Initial Report of Noncompliance

By: [redacted] (b) (6)

Date: 9/8/21

Time: 6:30 AM

Name of Person reporting: Amy Chuena

Telephone #: [redacted] (b) (6)

Fax #: [redacted]

Email: [redacted]

Name of Institution: VIRGINIA COMMONWEALTH U

Assurance number: A3281

Did incident involve PHS funded activity? Yes

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

*Protocol expired, staff did procedures anyway*

*Mice on a head twitch behavior study*

Species involved:

Personnel involved:

Dates and times:

Animal deaths:

Projected plan and schedule for correction/prevention (if known): \_\_\_\_\_

*Terminate access to animal room*

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # \_\_\_\_\_