



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

December 16, 2019

Re: Animal Welfare Assurance
#A3281-01 [OLAW Case 2J]

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 your December 12, 2019 letter 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 November 19, 2019. According to the information provided, OLAW understands that 57 mice underwent survival surgery but failed to receive preemptive long acting analgesia as described in the protocol. Two mice subsequently died and six were euthanized but the others recovered. Laboratory staff thought that the analgesic drug would negatively impact survival.

The corrective actions consisted of counseling the investigator and staff to follow the protocol, to contact veterinary staff regarding drug changes, and to ensure that staff provides analgesia. The laboratory manager will conduct spot inspections of surgeries and post-operative monitoring, the surgeon was given a copy of the protocol, and new surgeons will be observed by a veterinarian.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

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

cc: IACUC Chair
Director for the Animal Care and Use Program



VCU

Office of the Vice President for Research and Innovation

Office of the Vice President for
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Virginia Commonwealth University

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P. Srirama Rao, PhD
Vice President for Research and Innovation

December 12, 2019

Axel V. Wolff, M.S., D.V.M.,
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive
Suite 2500, MSC 6910
Bethesda, MD 20892
(301) 496-7163

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 failure to adhere to IACUC-approved protocol. Ms. Chuang, Director of Animal Care and Use Program reported it to you on November 19, 2019 via a telephone call.

Description of Incident:

On November 11th, it was self-reported to the IACUC by the investigator's lab manager that 57 mice had undergone bile duct ligation surgery and were not administered Buprenorphine SR Lab prior to surgery as described in the previously approved protocol. The new surgeon was trained to administer analgesia by the previously trained surgeon; however, they had a concern that the narcotic would have a detrimental effect on the survival of their animals so it was not administered. The mice were monitored hourly then daily until the end of the study (up to 14 days). They recovered as usual, eating and gaining activity after a day or so. Two out of 57 mice died, well within the approved 20% mortality rate, and six were pre-emptively euthanized. As soon as this was discovered, it was reported to the investigator. Since that time, Buprenorphine SR lab has been administered to all mice.

Corrective action plan:

- (1) On November 12th, the investigator, lab manager, new surgeon and lab assistant were counseled and told that they must follow the approved protocol. If they are concerned the analgesic will have a detrimental effect on the survival of the animals, they should consult with veterinarians and submit an amendment prior to implementation of any change in analgesic dosing or withdrawal.
- (2) The lab manager will be taking additional measures that this will not happen again, including:

- Spot inspections of surgeries by the lab manager to make sure that the protocol is being followed.
- Spot check monitoring of post-operative animals will be conducted by lab manager regularly.
- The new surgeon was given another copy of the protocol to study and follow.
- The lab will request a veterinary observation of all new surgeons in the future.

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*.

Best,

(b) (6)

P. Srirama Rao, PhD
Vice President for Research and Innovation



Initial Report of Noncompliance

By: *aw*

Date: *11/19/19*

Time: *9:20*

Name of Person reporting: *Amy Cheung*
 Telephone #: [REDACTED] (b) (6)
 Fax #:
 Email:

Name of Institution: *VIRGINIA Commonwealth U*
 Assurance number: *A3281*

Did incident involve PHS funded activity? _____
 Funding component: _____
 Was funding component contacted (if necessary): _____

What happened?
57 mice didn't get analgesia following surgery

Species involved: *Mice*
 Personnel involved:
 Dates and times:
 Animal deaths:

Projected plan and schedule for correction/prevention (if known): _____
Lab management monitor surgeons.

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
 Case # _____