



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
Rockledge One, Suite 360  
6705 Rockledge Drive - MSC 7982  
Bethesda, Maryland 20892-7982  
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

August 10, 2017

Re: Animal Welfare Assurance  
#A3281-01 [OLAW Case 1Z]

Francis L. Macrina, PhD  
Vice President for Research  
Virginia Commonwealth University  
Biotech One, Room #  
PO Box 980568  
Richmond, VA 23298-0568

Dear Dr. Macrina,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 9, 2017 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 July 27, 2017. According to the information provided, OLAW understands that eight rats were subjected to two non-survival surgeries not described in the approved protocol.

The corrective actions consisted of counseling the investigator not to implement significant changes without Institutional Animal Care and Use Committee approval, amending the protocol, ensuring that laboratory staff will adhere to the protocol, keeping a copy of the protocol in the laboratory, and having the Principal Investigator meet with staff regularly to provide updates on protocols and amendments.

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,

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

cc: IACUC Chair

condary Individ Assoc. Dir. for Animal Research

**VCU**

August 9, 2017

Axel V. Wolff, M.S., D.V.M., Director  
Division of Compliance Oversight  
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macrina@vcu.edu

Francis L. Macrina, PhD  
Edward Myers Professor of Dentistry and  
Vice President for Research and Innovation

**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. The investigator implemented a significant change to his IACUC-approved protocol without prior IACUC approval. Two non-survival surgical experiments were mistakenly carried out with a total of eight rats according to the procedure once approved on another of the same investigator's protocol. This incident was reported to you on July 27, 2017 via a telephone call by **secondary Individual** Associate Director for Animal Research, Office of Research Subjects Protection (ORSP).

**Description of Incident**

It was noted during a laboratory post approval compliance monitoring visit that two non-survival surgical experiments were mistakenly carried out with a total of eight rats. The protocol was approved for the use of commercially pre-catheterized rats and serial blood sampling through the catheter without the use of an anesthetic, in order to characterize pharmacokinetics of the novel anticoagulant molecules. The two experiments were mistakenly carried out with eight normal rats instead of catheterized rats, and blood samples were taken directly from the jugular vein using syringes under urethane anesthesia throughout. Upon investigation, the investigator had confused this protocol with another protocol on which these procedures were previously approved.

**Corrective action plan:**

The following corrective action plan was implemented:

1. The investigator has been counseled and assured that he will not implement any significant changes to his protocol without prior IACUC approval.
2. The PI will submit an amendment to include the use of rats in a non-survival surgical procedures with repeated syringe based sampling under urethane anesthesia. No experiments will be carried out until the amendment is approved by the IACUC.

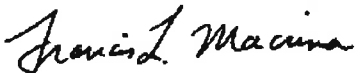
3. The PI assured the IACUC that all research staff will carefully review and adhere to the approved IACUC protocol.
4. The PI assured that he and his staff have reviewed the most recently approved protocol and that it will be kept in an easily accessible place for all research staff within the lab.
5. The PI will meet with his staff regularly to apprise them of the status of each protocol and amendments.

After a phone consultation with Dr. Morse with OLAW and a review of direct costs associated with the procurement, care, drugs and use of animals related to the experiments conducted on the 8 rats, the monetary impact of the noncompliance is considered insignificant and, as such it is 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.

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,



Francis L. Macrina, Ph.D.  
Institutional Official  
Edward Myers Professor of Dentistry and  
Vice President for Research and Innovation

**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, August 09, 2017 12:40 PM  
**To:** Secondary Individual  
**Subject:** RE: Follow-up letter (VCU Assurance# D16-00180)

Thanks [redacted] We'll send a response soon.  
Axel

**From:** [redacted] [mailto:[redacted]@vcu.edu]  
**Sent:** Wednesday, August 09, 2017 11:53 AM  
**To:** Wolff, Axel (NIH/OD) [E] <Wolffa@OD.NIH.GOV>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>; Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>  
**Cc:** Francis L Macrina <macrina@vcu.edu>; [redacted] Secondary Individual [redacted]@vcuhealth.org>  
**Subject:** Follow-up letter (VCU Assurance# D16-00180)

Dear Dr. Wolff,

Attached please find the follow-up reporting letter signed by Dr. Macrina, VCU Institutional Official. The incident was reported to you by phone on July 27th. The written report includes a detailed explanation of the incident and actions taken by VCU.

We have reviewed this incident thoroughly and deployed specific corrective actions designed to enhance our animal program and to prevent future occurrences. We appreciate your consideration and VCU recognizes its responsibilities to comply with the Public Health Service Policy on the Humane Care and Use of Laboratory Animals and the Guide, and also remains committed to animal welfare.

Should you have any questions regarding this matter, please do not hesitate to contact me at [redacted] Phone Number [redacted] or email to: [redacted] Secondary Individual [redacted]@vcu.edu.

*Best Regards,*

[redacted]  
Secondary Individual

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Associate Director for Animal Research  
Office of Research Subjects Protections  
Virginia Commonwealth University  
Box 980568  
800 E. Leigh St., Suite 3000  
Richmond, VA 23298  
[redacted] Phone Number [redacted]  
[redacted] Secondary Individual [redacted]@vcu.edu

Animal Research website: <https://www.vcu.edu/research/acup/index.htm>  
Animal Care and Use Program Blog: <http://wp.vcu.edu/acup/>



## Initial Report of Noncompliance

By: *aw*Date: *7/27/17*Time: *9:40*

Name of Person reporting: **Secondary Individual**  
 Telephone #: **Phone Number**  
 Fax #:  
 Email:

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?  
*3 rats - surgery done to implant catheter - not on protocol*

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

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

*Amend protocol, certify to follow protocol*

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY  
 Case # \_\_\_\_\_