



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

May 3, 2017

Re: Animal Welfare Assurance  
A3222-01 [OLAW Case M]

Aleister Saunders, Ph.D.  
Senior Vice Provost for Research  
Drexel University  
3180 Chestnut Street, Suite Room #  
Philadelphia, PA 19104

Dear Dr. Saunders,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 2, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Drexel University, following up on an initial telephone report on April 14, 2017. According to the information provided, OLAW understands that two rats were subjected to surgery by a medical student although this activity was not described in the approved protocol.

The immediate action taken upon discovery consisted of euthanizing the rats. The laboratory staff members were given copies of the approved protocols, a copy of the protocol was placed in the laboratory, and staff was retrained on approved surgeries and counseled that surgeries approved for mice may not be approved for rats. The Principal Investigator was directed to maintain better oversight of the research animals used by staff. The student responsible was removed from the protocol and prior to working with animals again must undergo retraining and be approved by the Institutional Animal Care and Use Committee.

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



May 2, 2017

Axel Wolff, DVM  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360  
6705 Rockledge Drive  
Bethesda, MD 20892

Dear Dr. Wolff:

Drexel University, in accordance with Assurance A-3222-01 (New D16-00138) and PHS Policy IV.F.3., provides this report of noncompliance regarding a surgical procedure performed in two rats, an activity not reviewed and approved by the IACUC in a Principal Investigator's (PI) animal study protocol, entitled "Role of intracellular ion channels in cardio protection and cardiac function." The work performed on this protocol is supported by Drexel University College of Medicine internal funding.

On April 6th, 2017, the Office of Research Compliance received information that two rats were found with bilateral surgical incisions in the inguinal area. The facility manager reviewed the protocol and noted that no surgical procedures were approved for rats under this protocol. The Chair contacted the PI to request a written report and response to this animal welfare concern for discussion at the April IACUC meeting.

The PI submitted correspondence to the IACUC, dated April 6, 2017, apologizing for the noncompliance incident and stated that the unapproved surgery was an oversight. Surgical technique was often practiced in dead mice using the femoral area. A medical student performed the practice surgery on a live rat without realizing that this procedure was unapproved. These two rats were immediately euthanized by the research group after being informed of the violation. The PI assured the IACUC that an incident of such nature would not occur again.

The following corrective actions were implemented immediately by the Investigator in response to the initial contact from the Chair:

- Copies of approved protocols were provided to all the workers in the laboratory;
- All team members were retrained on the surgeries which are approved with explicit instruction that surgeries approved for mice are not necessarily approved to be performed on rats;
- A copy of the protocol is available in the laboratory for everyone to read.

The written report and response was submitted for the April 10<sup>th</sup> IACUC meeting, and the IACUC voted to accept the following resolution plan:



1. The PI must assure the IACUC that he will have better oversight of the use of research animals by his laboratory staff.
2. The student will be removed from the protocol.
3. Prior to allowing the student involved to work with animals, the following must occur:
  - a. Student must retake all required CITI training modules
  - b. A personnel amendment adding the student must be submitted to the IACUC once CITI Training has been completed.
  - c. IACUC will have the option to approve or deny approval of the student to do further animal research once retraining occurs

Drexel University 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 regarding this report, please contact Tim Cunningham, PhD, IACUC Chair or Richard Huneke, DVM, attending veterinarian.

Thank you for your consideration of this matter.

Sincerely,

Aleister Saunders, Ph.D.  
Senior Vice Provost for Research  
Institutional Official

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, May 03, 2017 10:49 AM  
**To:** Secondary individual  
**Subject:** RE: Final Report - Drexel University - D16-00138

Thank you for this report. Secondary individual We will respond soon.

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

**From:** Secondary individual @drexel.edu]  
**Sent:** Wednesday, May 03, 2017 9:19 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Aleister Saunders <Aleister.Saunders@drexel.edu>  
**Subject:** Final Report - Drexel University - D16-00138

Hello,

Please find attached the Final Report for a noncompliance initially reported on April 14, 2017.

Please let me know if you have any questions.

Thank you,

Secondary individual

*IACUC Administrator  
Office of Research*

**Drexel University**

Bellet Building  
10<sup>th</sup> Floor, Office Room #  
Philadelphia, PA 19102  
Tel telephone #  
[www.drexel.edu/research](http://www.drexel.edu/research)



## Initial Report of Noncompliance

By: *aw*Date: *4/14/17*Time: *12:00*

Name of Person reporting:

Secondary individual

Telephone #:

telephone #

Fax #:

Email:

Name of Institution:

*Drexel U*

Assurance number:

*A3222*Did incident involve PHS funded activity? *No*

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

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

What happened?

*Rat used for exp but protocol only approved for mice*Species involved: *Rats*

Personnel involved: \_\_\_\_\_

Dates and times: \_\_\_\_\_

Animal deaths: \_\_\_\_\_

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

*Euthanized rats. Take student off protocol,**counsel student, Retrain if would again. Increased oversight.*Projected submission to OLAW of final report from Institutional Official: *Training log.*

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