



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

March 6, 2019

Re: Animal Welfare Assurance
A3096-01 [OLAW Case G]

Dr. Andres Gil
Vice President for Research
Florida International University
1120 SW 8th Street
University Park –MARC 430
Miami, FL 33199

Dear Dr. Gil,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 1, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Florida International University. According to the information provided, OLAW understands that mice on a surgical study were inadvertently given a dose of analgesic at five times the prescribed dose. Seven of 11 sham surgery mice died while no mice that received an ovariectomy did. It is possible that the ovariectomy had a protective effect.

The corrective actions consisted of retraining the graduate student responsible on anesthesia, surgery, and on calculating drug dosages.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Sincerely,

(b) (6)

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

cc: IACUC Chair



March 1, 2019

Brent C. Morse, DVM, DACLAM
 Director, Division of Compliance Oversight
 Office for Laboratory Animal Welfare
 National Institutes of Health
 Rockledge 1, Suite 360, MSC 7982
 6705 Rockledge Drive
 Bethesda, MD 20892

RE: Unexpected Deaths and Deviation in Protocol

Dear Dr. Morse,

Florida International University (FIU), in accordance with Assurance #A3096-01 and PHS Policy IV.F.3, is providing this report regarding an incident involving unexpected animal deaths related to the IACUC protocol referenced below:

- Project Title: "Small molecule modulators of relaxin receptors"
- FIU IACUC Approval Number: IACUC-19-009
- Grant or Contract Number(s): 1R01DK110167-01A1 and 1R01AR070093-01
- Effect on PHS-Supported Activities: This incident did not affect any PHS-supported activities other than the project referenced above.
- Compliance with Terms and Conditions of Award: This incident did not have a negative impact on the terms and conditions of the grant award, so this issue was not reported to the funding component.

Summary

On February 14, 2019, the FIU Office of Research Integrity received an adverse event report from the principal investigator of the above referenced project. The adverse event report explained that 7 out of 11 sham mice had died post-surgery of a bilateral ovariectomy in a transgenic mouse model for human relaxin gene. It was noted that no ovariectomized mice had died. Following necropsy, it was discovered the animals were in good condition, the only finding was gastric dilatation but no volvulus, and a smaller amount of ingesta than normal in the intestine.

Following an investigation from the Attending Veterinarian, it was determined that the graduate student involved in the procedure miscalculated the NSAID dose used for post-procedural pain control and the animals received a 5 fold dose increase x 3 days. However, this does not explain why only the sham animals were affected. It has been hypothesized that the ovariectomy has a protective effect and the relaxin transgene is a risk factor.

Brent C. Morse, DVM, DACLAM
Director, Division of Compliance Oversight
Office for Laboratory Animal Welfare
March 1, 2019
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Corrective Action Plan

On February 21, 2019, the FIU IACUC reviewed the adverse event at a Full Board meeting. The IACUC determined that additional training is needed for the graduate student on anesthesia and surgery to ensure that the correct dose of the NSAID is being used. The Attending Veterinarian has since provided the graduate student with additional training and the correct dose has now been properly calculated.

FIU is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard.

I am available to answer any questions that you may have. Thank you for your consideration of this matter.

Best regards,

(b) (6)


Andrés G. Gil, Ph.D.
Vice President for Research & Economic Development
Institutional Official
Florida International University

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, March 4, 2019 6:36 AM
To: Christopher Grayson
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Adverse Event Report from FIU

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

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: Christopher Grayson <graysonc@fiu.edu>
Sent: Friday, March 1, 2019 3:06 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Andres Gil <gila@fiu.edu>
Subject: Adverse Event Report from FIU

Dear OLAW Division of Compliance Oversight,

Attached is an adverse event report from Florida International University (#A3096-01).

Please let us know if you have any questions or require any further information.

Thank you,
Chris

Christopher Grayson, MBA, CIP, CIM
Director, Research Integrity
Office of Research and Economic Development
Florida International University
Phone: (b) (6)
Fax: (b) (6)