



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

April 29, 2019

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

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 April 17, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Florida International University, following up on an initial report on February 14, 2019. According to the information provided, OLAW understands that two investigators conducted surgery on two HIV infected mice without following biosafety procedures, without administering post-operative analgesia, and without maintaining post-operative care records.

The corrective actions consisted of euthanizing the mice, suspending the investigators' animal use privileges, and terminating the protocol. If animal activities resume under a new protocol, an experienced technician must monitor the major cranial surgery, all laboratory staff must certify understanding of the protocol, a copy of the protocol and records must be kept in the laboratory, and monthly updates must be submitted to the Institutional Animal Care and Use Committee (IACUC). The IACUC further required the Principal Investigator (PI) to hire an experienced technician, placed the PI on two year probation, permanently revoked the animal use privileges of the two investigators responsible, prohibited a co-investigator from serving in this capacity for the PI unless included on the grant, and having new staff hires approved by upper administration. The laboratory was placed under enhanced post-approval monitoring by the IACUC and safety department. The NIH funding component was notified about the incident and the grant was not charged for any unauthorized animal activities.

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



April 17, 2019

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

RE: Deviation from IACUC Approved Protocol – Final Report

Dear Dr. Morse,

Florida International University (FIU), in accordance with Assurance #A3096-01 and PHS Policy IV.F.3, is providing its final report regarding a serious or continuing noncompliance with the PHS Policy in relation to the Institutional Animal Care and Use Committee (IACUC) protocols referenced below:

- Project Title: "Cocaine in the Neuropathogenesis of HIV Infection: Role of HDAC2"
- FIU IACUC Approval Number: IACUC-16-076
- Grant or Contract Number: 1R01DA034547-01
- 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: The funding component will be provided with a copy of this final report for notification purposes. All charges associated with the animal activities during the noncompliant period have been removed from the grant.

Summary:

On February 8, 2019, the Director of Laboratory Animal Research was notified of possible violations of an IACUC (Institutional Animal Care and Use Committee) protocol and possible laboratory safety violations. Upon further inspection, it was determined that two researchers from FIU's Herbert Wertheim College of Medicine had violated an IACUC protocol by conducting surgical procedures on mice (two of which were HIV infected) without proper BSL-2 containment procedures, without administering post-operative analgesics, and without documenting any post-operative care records.

On February 12, 2019, the Office of Research Integrity (ORI) placed an administrative hold on all laboratory activities and animal activities conducted by the two researchers involved in the incident.

On February 21, 2019, the IACUC convened a meeting to review the animal research protocol deviation submitted by the Principal Investigator (PI) related to the violations listed above.

On March 7, 2019 the IACUC submitted to me a memorandum delineating the requirements for addressing deviations of the animal research protocol that were sent to the PI, as well as, their recommendations for actions they deemed necessary.

IACUC Requirements for the PI:

Current IACUC Protocol

- Protocol IACUC-16-076 will be closed out and should the PI wish to continue animal activities a new application must be submitted and approved by the IACUC.

New IACUC Protocol

- All major cranial surgeries will need to be supervised by a technician that has extensive experience in conducting major cranial surgeries.
- All personnel involved in the animal studies will need to read the approved IACUC protocols. The protocols need to be printed out and maintained in the animal labs with a coversheet. The coversheet will need to have all the study personnel's signatures attesting that they have read the protocol(s).
- For all lab inspections, lab books/records will need to be readily available for review.
- Monthly progress reports must be submitted to the IACUC on the first day of every month for a period of 2 years, which includes daily event logs.

IACUC Recommendations to the Institutional Official (IO):

Principal Investigator

- The PI should be put on probation for a period of two years.
- The PI will need to hire an experienced and qualified technician with the approval of the Attending Veterinarian and EH&S Director prior to hiring.

Researchers # 1 and #2

- Researcher #1 should be banned from conducting animal and lab research at FIU for a period of five years. Researcher #2 should be banned from conducting animal at FIU for a period of two years.

Co-Investigator

- Although the two researchers did not notify the Co-Investigator (Co-I) of their intent to begin surgeries, the protocol clearly indicates that the Co-I would be providing oversight on the surgeries. Therefore, the Committee felt the Co-I should be placed on a one-year probation. Furthermore, the Co-I should no longer supervise or be a Co-I on any protocol outside of her work.

PI's Research Labs

- Recommended ongoing oversight of the PI's laboratories to ensure safety compliance.

IO Actions/Plans to Address the Problem:

Based on the seriousness of the violations and the recommendation of the IACUC, I, as the IO, have determined that the following actions are warranted. These are listed separately for the different pertinent individuals and for specific areas below. The sanctions and corrective actions are listed separately below for the different groups of individuals based on their level of responsibility.

Principal Investigator

- The PI was not directly involved in the violations committed by the two researchers. However, as the IACUC pointed out, as the Principal Investigator of the research grant and the related IACUC protocol, he bears the ultimate supervisory responsibility. Therefore, I accept the recommendation from the Committee and place the PI under a two-year probation.
 - During this period, the PI's IACUC protocols will be reviewed bi-annually for adherence to protocols, and his laboratories will be inspected bi-annually by the ORI and EH&S and may also be inspected on an unannounced basis.
 - Monthly progress reports will need to be submitted to the IACUC on the first day of every month for a period of 2 years, which includes daily event logs.
 - Any additional compliance violation pertaining to animal research during this two-year period may result in escalating the severity of sanctions.

Researchers #1 and #2

- Both researchers are permanently banned from conducting animal and laboratory research at FIU. The IACUC recommended a five-year ban on Researcher #1 (vs. a two-year ban on Researcher #2). However, the sanction of a permanent ban on research is based on the severity of these violations, particularly the fact that the non-identification of HIV-infected mice placed the safety of staff from the Animal Care Facility at risk. Moreover, the researchers failed to follow basic practices and safety protocols.

Co-Investigator

- The Committee recommended a one-year probation for the Co-I due to the fact that she was designated as the individual providing oversight on surgeries conducted by the two researchers. However, there are additional factors that were considered in determining the Co-I's responsibility. First, as required, she provided the training to both researchers. Second, the researchers conducted the surgery without informing the Co-I. Third, being the Co-I of the IACUC protocol without having a role in the research grant makes her ability to supervise limited. Given all of these factors, the Co-I will not be placed on probation; but, as recommended by the IACUC, she will no longer be permitted to supervise or be a Co-I on any animal research protocol for this PI, unless she is a member of the research team on the grant associated with the animal research protocol.

PI's Research Labs

- During the next two years, these laboratories will have ongoing oversight to ensure safety compliance, including bi-annual or unannounced inspections by the IACUC and EH&S.

Requirements in the Recruitment of Staff and Research Scientists for PI's Laboratories:

- For a period of five (5) years, the hiring of any laboratory staff, non-tenure track research faculty, or postdoctoral scholars for the PI's laboratories must be approved by the Dean of the Herbert Wertheim College of Medicine, the Vice President for Research, and the Associate Provost for Planning and Finance.

Closing:

The use of live vertebrate animals in research is a privilege, and carries with it the responsibility to follow applicable law, policies, and procedures developed by the federal government and FIU. The research compliance violations deviate from the ethical standards that have been set at FIU, and which are expected of all its research faculty, staff and students. FIU's commitment to safe and humane animal research practices is

Brent C. Morse, DVM, DACLAM
Director, Division of Compliance Oversight
Office for Laboratory Animal Welfare
April 17, 2019
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exemplified by FIU's accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC).

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

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, April 18, 2019 1:40 PM
To: Christopher Grayson; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Andres Gil
Subject: RE: Preliminary Report from FIU

Thank you for this final report. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: Christopher Grayson [mailto:graysonc@fiu.edu]
Sent: Thursday, April 18, 2019 9:03 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Andres Gil <gila@fiu.edu>
Subject: RE: Preliminary Report from FIU

Dear Dr. Morse,

Attached is our final report on this case.

Please let me know if you have any questions or require any additional information.

Regards,
Chris

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

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Thursday, February 14, 2019 10:36 AM
To: Christopher Grayson <graysonc@fiu.edu>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Andres Gil <gila@fiu.edu>
Subject: RE: Preliminary Report from FIU

Thank you for submitting this preliminary report Mr. Grayson. We will open a case file and await the final report as noted in your email.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: Christopher Grayson [mailto:graysonc@fiu.edu]
Sent: Thursday, February 14, 2019 9:19 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Andres Gil <gila@fiu.edu>
Subject: Preliminary Report from FIU

Dear OLAW Division of Compliance Oversight,

Florida International University (FIU) is providing a brief preliminary report relating to a deviation from protocol. The details of this preliminary report are outlined below.

Animal Welfare Assurance Number: #A3096-01

Grant or Contract Number: 1R01DA034547-01

Effect on PHS-Supported Activities: Based on our preliminary findings, the situation only appears to have impacted the above referenced grant.

Full Explanation of the Situation: The FIU Office of Research Integrity recently discovered that two researchers had conducted experiments involving several mice (two of which were HIV infected) without proper BSL-2 containment procedures, without administering post-operative analgesics, and without documenting any post-operative care records.

Description of Actions Taken by the Institution: The Institutional Official (IO), the Attending Veterinarian (AV) and the Biosafety Officer have been notified of the incident. Animal Care Facility access and laboratory access have been temporarily revoked for both researchers. In addition, all of their animal activities and laboratory activities have been placed on administrative hold. The Principal Investigator has been asked to submit a deviation report to the IACUC. The IACUC will be scheduling a special meeting to review the deviation report.

Description of Corrective Plans and Implementation Schedule: The affected mice have been euthanized. Further details about the corrective action plans and implementation schedule will be provided in a final report from the Institutional Official, once the IACUC has reviewed the deviation report.

Please let me know if you require any additional information at this time.

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)