



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
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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
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December 26, 2017

Re: Animal Welfare Assurance
A3224-01 [OLAW Case 1N]

Dr. John Bixby
Vice Provost for Research
Miller School of Medicine-Vice Provost for Research
University of Miami
1400 N.W. 10th Avenue - 1200, Dominion Tower
Miami, Florida 33136

Dear Dr. Bixby,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 20, 2017 letter reporting the suspension of all animal use privileges for a Principal Investigator (PI) at the University of Miami. According to the information provided, OLAW understands that the Institutional Animal Care and Use Committee (IACUC) took this action after determining that 36 animals were subjected to unapproved spinal cord surgeries, 14 animals were used as unapproved controls, no surgical records or anesthetic monitoring sheets were maintained, analgesia was not provided, depth of anesthesia was not monitored, drug logs were incomplete, and animals survived for 10 weeks not for 24 hours as stated in the protocol. The same PI was determined not to be providing adequate oversight on a previous protocol.

The corrective actions consisted of the IACUC suspending the PI's animal use privileges on all protocols for four months, having the individual remain PI on the grant, assigning a different PI who is familiar with the work, and having the surgeon stop further activities and undertake retraining.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. In future, please remember to state the species involved. Thank you for keeping OLAW apprised on this matter.

Sincerely,

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

cc: IACUC Chair

UNIVERSITY
OF MIAMI
OFFICE of RESEARCH



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Vice Provost for Research

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December 20, 2017

Axel V. Wolff, M.S., D.V.M.
Deputy Director, Office of Laboratory Animal Welfare
National Institutes of Health
Bethesda, MD 20892-7982

RE: Suspension of PI on animal use protocols 15-087, 15-163, 16-086
Sponsor: NINDS

Assurance #: A3224-01

Dear Dr. Wolff,

I am writing to inform OLAW of noncompliance in an animal research program at the University of Miami. These violations occurred on a non-PHS funded project; however, the PI, who has NIH funding, has been suspended from working with animals as described below. This is a follow up to the verbal report that we made regarding the following violations:

1. There were 36 animals unapproved for spinal cord surgeries.
2. Fourteen animals were used as unapproved controls.
3. There were no surgical records or anesthetic monitoring sheets for the short survival post-surgery animals. These records were especially important for these animals, since they were anesthetized and therefore not administered analgesia. Although the staff reported that they monitored anesthesia and it that was appropriate, there is no written record justifying the lack of analgesia.
4. Surgical records for the longer survival animals were inadequate with no monitoring for the depth of anesthesia.
5. Although the drug logs confirmed that analgesic drug was administered post-surgery, the corresponding surgical records were incomplete regarding this drug administration.
6. Animals that were supposed to survive for 24 h were kept for 10 weeks.

The IACUC has decided the following:

1. Overall, these violations showed a lack of proper recordkeeping and oversight of the protocols. This PI had a major noncompliance incident on another protocol within the past year in which a "lack of oversight" determination was also made. As a result, the PI has been suspended from personally working with animals and from being PI on any animal protocol for a period of four months (He remains PI on the research projects and the corresponding grants).
2. The person responsible for the surgeries has stopped working and has been re-trained by the University of Miami IACUC; this individual must also attend an IACUC 101 class prior to restarting work.
3. The animal studies are going forward with a different PI. The new PI is either a co-investigator or multiple PI on each of the funded projects, and thus is intimately familiar with and able to oversee the animal studies.

I have been kept apprised of these issues, and I am in agreement with the decisions of the IACUC. I hope that these actions help to assure OLAW that UM takes seriously its responsibility to comply with regulations designed to protect the welfare of its animal research subjects.

Sincerely,

signature

John L. Bixby, Ph.D.
Vice Provost for Research
Institutional Official

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, December 20, 2017 3:09 PM
To: Secondary Individual; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Bixby, John L; Secondary Individual; Secondary Individual
Subject: RE: noncompliance report

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

Regards, Brent Morse

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

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: Secondary Individual [mailto:Secondary Individual@med.miami.edu]
Sent: Wednesday, December 20, 2017 1:13 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Bixby, John L <jbixby@med.miami.edu>; Secondary Individual @med.miami.edu; Secondary Individual @med.miami.edu
Subject: noncompliance report

Dear Dr. Wolff

Attached please find a letter following up on our earlier preliminary report of a noncompliance. Please let me know if you have any questions.

Secondary Individual
Director of Compliance, IACUC /IBC /ESCRO
University of Miami