



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

February 21, 2017

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

Dr. John Bixby
Vice Provost for Research
Miller School of Medicine Vice Provost for Research
University of Miami
1400 N.W. 10th Avenue - (b) (4) Dominion Tower
Miami, Florida 33136

Dear Dr. Bixby,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 6, 2017 letter reporting the suspension of an animal activity at the University of Miami, following up on an initial telephone report on December 8, 2016. According to the information provided, OLAW understands that the Institutional Animal Care and Use Committee (IACUC) took this action after determining that seventeen rats failed to receive post-surgical analgesia as described in the approved protocol and nine rats received analgesia later than approved. The surgery was part of a pilot study supported by NIH grant #1R01NS089443-01A1.

The corrective actions consisted of the IACUC suspending the protocol and the animal use privileges of the student responsible. The student was counseled by the Institutional Official and must undergo retraining along with the other investigators in the laboratory. Upon resumption of animal activities, the laboratory will be under enhanced IACUC post-approval monitoring. The surgeries and student will be closely monitored by the investigators.

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. Note that suspensions of animal activities on PHS-supported studies must be reported to the funding component. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair
Tijuanna DeCoster, NINDS Chief GMO

UNIVERSITY OF MIAMI

OFFICE of the VICE PROVOST for RESEARCH



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

February 6, 2017

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

RE: Suspension of animal use protocol for NIH grant 1R01NS089443-01A1

Assurance #: A3224-01

Dear Dr. Wolff,

I am writing to inform OLAW of an issue of noncompliance in an animal research program at the University of Miami. This is a follow-up to our earlier verbal report regarding this violation. A student involved in a pilot project funded by the above-mentioned NIH grant committed serious noncompliance on a rat protocol. The student did numerous surgeries over a two-day period, but did not administer post-procedural analgesia as per the protocol. In total, 17 animals received no analgesia subsequent to surgery and 9 animals received analgesia later than what was approved in the protocol.

Because of these violations, the student has been suspended from working with animals for a period of three months. In addition, this protocol, which covered a pilot project, has been suspended for the same period. The investigators, including the student, must undergo additional internal IACUC training, and, once they recommence animal work, must perform [self] post-approval monitoring of the protocol every month for 6 months, sending monthly reports of their findings to the IACUC. In addition, the student was required to meet with me to discuss the seriousness of this violation. The investigators have instituted an action plan that includes greater monitoring of the surgeries as well as weekly meetings with this student.

Please note that these surgeries were part of a pilot study utilizing a different model of traumatic brain injury; there have been no issues with the separate protocol that contains the other funded studies in this project. Thus, the remainder of the project continues without interruption. These investigators have an excellent track record for

compliance with all rules and regulations and have complied with and agreed to each of the imposed sanctions.

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,

(b) (6)

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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, February 07, 2017 1:24 PM
To: 'Kapsalis, Ellen'
Subject: RE: OLAW letter for A3224-01

Thank you for this letter, Dr. Kapsalis. We will send a response soon.
Axel Wolff

From: Kapsalis, Ellen [mailto:EKapsali@med.miami.edu]
Sent: Tuesday, February 07, 2017 11:38 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Bixby, John L <jbixby@med.miami.edu> (b) (6)
(b) (6)
Subject: OLAW letter for A3224-01

Dear Dr. Wolff,

Please see the attached letter from Dr. Bixby, the University of Miami's Institutional Official regarding a noncompliance event for which we gave a preliminary report.

Please do not hesitate to contact me if you have any questions or need additional information.

Ellen

Ellen Kapsalis, Ph.D., CHRC, CPIA
Director of Compliance, IACUC /IBC /ESCRO



Initial Report of Noncompliance

By: _____

(b) (6)

Date: 12/8/16

Time: 11:00

Name of Person reporting: Ellen Kapsalis

Telephone #: _____

(b) (6)

Fax #: _____

Email: _____

Name of Institution: U. Miami

Assurance number: A3224

Did incident involve PHS funded activity? Yes, will copy funding component on final report.

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? No buprenorphine to 17 an. + some not given per protocol. 26 animals total.

Species involved: Rats

Personnel involved: Grad. student

Dates and times: Notified Nov 28th

Animal deaths: _____

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

Suspended protocol + student
on Dec. 1st

Projected submission to OLAW of final report from Institutional Official: _____

OFFICE USE ONLY

Case # _____