



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

March 20, 2017

Re: Animal Welfare Assurance
A3519-01 [OLAW Case E]

Dr. Ronald J. Lukas
Vice President of Research, Director
Saint Joseph's Hospital – Medical Center
350 West Thomas Road
Phoenix, Arizona 85013

Dear Dr. Lukas,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 17, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Saint Joseph's Hospital and Medical Center, following up on an initial telephone report on February 10, 2017. According to the information provided, OLAW understands that mice had been used in a surgical procedure not approved by the Institutional Animal Care and Use Committee (IACUC). Also, neonatal mice were euthanized by decapitation alone to collect tissue, although the protocol included use of isoflurane.

The postdoctoral fellow responsible was directed to stop the unauthorized activities. The Principal Investigator (PI) was informed and it was determined that the postdoctoral fellow had not been included in communications with the PI, Attending Veterinarian, or IACUC. The fellow will now be included in these communications, will become completely familiar with the content of the protocol, and will undertake retraining. The protocol was amended and it along with the surgical protocol were reviewed and approved by the IACUC. All PIs were reminded to ensure that all protocols are available to staff and that staff is familiar with the procedures.

OLAW understands that the protocol involved was not PHS-supported, but concurs that the incidents were serious and supports the actions taken by the IACUC. The establishment and application of policies and practices that are consistent with the provisions of the PHS Policy at Saint Joseph's Hospital and Medical Center are commendable and avoid the perception of a double standard. Thank you for keeping OLAW apprised on this matter.

Sincerely,

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

cc: IACUC Chair

BARROW
Neurological Institute



St. Joseph's Hospital
and Medical Center
A Dignity Health Member

March 17, 2017

Axel Wolff, M.S., D.V.M.
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Re. Incidence of Noncompliance with PHS Policy
St. Joseph's Hospital and Medical Center
Animal Welfare Assurance Number A3519-01

Dear Dr. Wolff,

We wish to report incidents of noncompliance with PHS Policy on Humane Care and Use of Laboratory Animals at our institution. An interview with a postdoctoral fellow during the IACUC's semiannual facilities inspection last month revealed that he had used several mice in a surgical procedure that had not been approved by the IACUC. Although a protocol for this procedure had been submitted to the IACUC for review, the review had not been completed. In further discussion with the postdoctoral fellow, it was determined that the euthanasia of neonatal mice to collect tissue for another project had not been performed according to IACUC approved procedures. In this instance, the IACUC had approved euthanasia of mature and neonatal mice by decapitation following isoflurane anesthesia, but the euthanasia was performed on neonates by decapitation alone. Neither project in question is related to a PHS-supported activity. A preliminary report was given to you by phone conversation on February 10, 2017.

The postdoctoral fellow was instructed during the laboratory inspection to immediately stop performing the unapproved procedures, and the Principal Investigator was notified the same day and instructed that the procedures must stop until IACUC approval had been obtained. A meeting was arranged between the IACUC Chair, the Attending Veterinarian, the Principal Investigator and the postdoctoral fellow. At this meeting, it was determined that the postdoctoral fellow had assumed responsibility for day-to-day management of the laboratory after departure of a more senior postdoctoral fellow. However, the postdoctoral fellow had not been included in communications between the Principal Investigator, the IACUC, and the Attending Veterinarian and his staff. Also, although the postdoctoral fellow had access to copies of approved animal-use protocols in the lab, he was not completely familiar with their content. At the time of the meeting it was agreed that the postdoctoral fellow would be included in all written communications between the principal investigator, the IACUC and the Attending Veterinarian and his staff.

It was also agreed that the postdoctoral fellow would thoroughly familiarize himself with the approved animal use protocols used by the lab and would retake training offered through the CITI Program on the IACUC and regulations governing the use of laboratory animals. The Principal Investigator was asked to submit an amendment to revise the procedure for euthanasia of neonatal animals of less than 10 days age to decapitation without prior isoflurane anesthesia.

The circumstances of these instances of non-compliance and the measures taken to address them were considered by the IACUC during its semiannual program review conducted on February 22, 2017. The items of noncompliance were presented, and the meeting with the Principal Investigator and postdoctoral fellow summarized. The requirements to halt use of unapproved procedures at the time of discovery, training and protocol review for the postdoctoral fellow, inclusion of the fellow in communications, and submission of a protocol amendment in addition to ongoing review of the surgical protocol were all noted. At this time, the postdoctoral fellow has completed his CITI training and review of approved protocols. He has been included in communications between the Principal Investigator, IACUC and Attending Veterinarian. The surgical protocol has been reviewed and approved by the IACUC. The amendment for euthanasia of neonatal mice has been submitted and reviewed and approved by the IACUC. In addition, the IACUC Chair has reminded all Principal Investigators to have copies of approved protocols readily available to their laboratory staff members and to ensure that all staff members engaged in animal use are familiar with the procedures in the approved protocols.

Sincerely,



Thomas M. Hamm, Ph.D.
Chairperson, IACUC
St. Joseph's Hospital and Medical Center

Through the office of:



Ronald J. Lukas, Ph.D.
Vice President for Research and Institutional Official
St. Joseph's Hospital and Medical Center

cc. ondary Indivi Integrity and Compliance Officer

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Monday, March 20, 2017 7:52 AM
To: Secondary Individual
Subject: RE: OLAW Report of Incident

Thank you for this report, Secondary Individual. We will respond soon. In future, please send all final reports to olawdco@od.nih.gov

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

From: Secondary Individual [mailto:Secondary Individual@DignityHealth.org]
Sent: Friday, March 17, 2017 5:34 PM
To: Wolff, Axel (NIH/OD) [E] <WolffA@OD.NIH.GOV>
Cc: Hamm, Thomas - SJHMC <Thomas.Hamm@DignityHealth.org>; Secondary Individual
 <Secondary Individual@DignityHealth.org>
Subject: OLAW Report of Incident

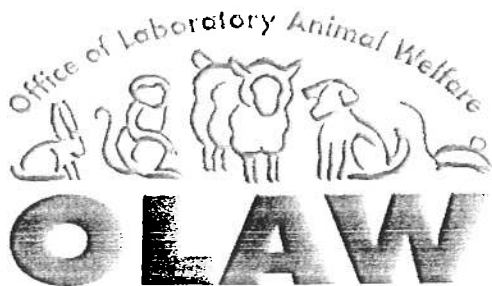
Dr. Wolff,
 Please find attached our report of noncompliance with PHS Policy on Humane Care and Use of Laboratory Animals at our institution. If you have any questions please feel free to contact Dr. Tom Hamm, thank you.

Secondary Individual
 IACUC/IBC Program Manager
 Research Administration

Dignity Health
 St. Joseph's Hospital and Medical Center
 350 W. Thomas Road
 Phoenix, AZ 85013

(O)
 Phone Number (F)
 Secondary Individual@DignityHealth.org

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Initial Report of Noncompliance

By: ACDate: 2/10/17Time: 2:00Name of Person reporting: Tom HAM

Telephone #:

Phone Number

Fax #:

Email:

Name of Institution:

St Joseph Hospital

Assurance number:

A3519Did incident involve PHS funded activity? Not

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

stroke model in mice, not approvedSpecies involved: micePersonnel involved: Post Doc

Dates and times:

Animal deaths:

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

stop work, retrain

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____