April 23, 2019

Re: Animal Welfare Assurance
#A4100-01 (OLAW Case 2D)

Dr. Paul R. Sanberg
Vice President for Research and Innovation
University of South Florida - Tampa
3702 Spectrum Blvd., (b) (4)
Tampa, FL 33612-9444

Dear Dr. Sanberg,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 5, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of South Florida, following up on an initial telephone report on March 26, 2019. According to the information provided, OLAW understands that ten mice were subjected to an approved surgical procedure but had not been given post-operative analgesics. There was no documentation of the surgery or peri-operative care and the surgeon was not listed on the protocol.

The corrective actions consisted of having the research staff re-read the protocol and being retrained on surgical recordkeeping. The protocol was amended to add the surgeon. The Institutional Animal Care and Use Committee counseled the Principal Investigator (PI) to ensure that all staff is listed on the protocol and provided the PI with rodent surgery recordkeeping forms. The PHS grant was not charged for any unauthorized animal activities.

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.

Sincerely,

(b) (6)

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

cc: IACUC Chair

USF / RESEARCH & INNOVATION

April 5, 2019

Brent Morse, D.V.M., Acting Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Dr.
Bethesda, MD 20892-7982

Dear Dr. Morse:

The University of South Florida (USF) in accordance with Assurance D16-00589 (A4100-01) and PHS Policy IV.F.3, is reporting an event previously discussed by telephone with the Office of Laboratory Animal Welfare (OLAW) on March 26, 2019.

On March 6, 2019, Comparative Medicine (CM) husbandry staff in the Stabile Research Facility discovered ten mice housed on behalf of IACUC protocol 5599 entitled "Development of New Casein Kinase 1 Inhibitor for the Treatment of Brain Cancers" that appeared to have had recent surgery. However, no documentation for the surgery or post-operative care/analgesia plan was available in accordance with USF policy. The veterinarian contacted the Principal Investigator who stated that the ten mice had undergone surgery on March 4, 2019. It was confirmed that while the surgery was approved on the protocol, the mice had not received post procedural analgesics as described. In addition, the scientist performing the surgery was not listed on the approved protocol.

On March 7, 2019, the Principal Investigator self-reported the non-compliance to the IACUC. The PI indicated that corrective actions were taken that included all research staff re-reading the protocol and being retrained on surgical recordkeeping in accordance with USF SOPs. Additionally, he indicated the research scientist who performed the surgeries was IACUC certified, however, was inadvertently left off of the IACUC protocol and subsequently submitted an amendment to add the researcher on March 18, 2019, which was approved.

On March 22, 2019, the report of noncompliance was reviewed by the IACUC during its regular monthly meeting. The IACUC discussed regulatory requirements with the PI at the meeting, including principles that require securing IACUC approval of all staff associated with the protocol and provided him with appropriate recordkeeping forms for rodent surgery.

At its meeting, the IACUC determined the previously completed and upcoming scheduled corrective actions, as well as the long-term assessments and plans, were sufficient to prevent recurrence.

Research Integrity & Compliance
Institutional Animal Care and Use Committee
PHS No. D-16-00589 (A4100-01) • AAALAC 000434 • USDA No. 58-R-0015
University of South Florida • 3702 Spectrum Blvd., Suite 165 • Tampa, FL 33612
813-974-5638 • Fax 813-974-7091

Although IACUC protocol 5599 is supported by a federal grant award, all costs incurred during this period of noncompliance were paid from other nonfederal sources; no federal funds were used in support of this noncompliance.

The University of South Florida is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Dr. Jay Dean, IACUC Chair, at (b) (6)   or via email at jdean@health.usf.edu.

Sincerely,

(b) (6)

Paul R. Sanberg, Ph.D., D.Sc.
Senior Vice President for Research,
   Innovation & Knowledge Enterprise
Institutional Official

cc: AAALAC International
         Brian Springer, Moffitt Cancer Center, Vice President, Research Administration
         (b) (6)

         Jay Dean, Ph.D., Professor, Chairperson, IACUC
         (b) (6)

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From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, April 11, 2019 8:21 AM
To: RSCH IACUC; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Dean, Jay; RSCH Comparative Medicine
Subject: RE: 2019-4-5-OLAW report- follow-up to OLAW reportable item-Mice -deviation from post surgical care procedures- University of South Florida-PHS no D16-00589 (A4100-01)

Thank you for providing 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

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: RSCH IACUC [mailto:IACUC@research.usf.edu]
Sent: Tuesday, April 09, 2019 11:03 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: RSCH IACUC <IACUC@research.usf.edu>; Dean, Jay <jdean@health.usf.edu>; RSCH Comparative Medicine <compmed@admin.usf.edu>
Subject: 2019-4-5-OLAW report- follow-up to OLAW reportable item-Mice -deviation from post surgical care procedures- University of South Florida-PHS no D16-00589 (A4100-01)

Dear Dr. Morse,

The University of South Florida (USF) hereby submits a final report to a notification of an incident, reported originally on March 26, 2019. Attached is the Adobe PDF document of the report.

Let me know if you have any questions or if the transmission of the attached document does not come through.

Thank you for your time.

Sincerely,

(b) (6)

1

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3702 Spectrum Blvd,
Suite (b) (4)
Tampa, Florida 33612

(b) (6)

Visit our website: http://www.research.usf.edu/dric/
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2

A 4100-2D

Initial Report of Noncompliance

By: *(illegible)*

Date: 3/26/19   Time: 10:10

Name of Person reporting: (b) (6)
    Telephone #: (b) (6)
    Fax #:
    Email:

Name of Institution: U of South Florida
Assurance number: A 4100

Did incident involve PHS funded activity? Yes
    Funding component: NCI
    Was funding component contacted (if necessary): _____

What happened?

Surgery done & 1 mouse died, person not on protocol
Didn't fill out necessary paperwork. No post op analgesia

Species involved: Mouse
Personnel involved:
Dates and times:
Animal deaths: 1

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

Retrain

Mice are fine

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
    Case #_____