



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

December 20, 2017

Re: Animal Welfare Assurance
#A4100-01 (OLAW Case 1Y)

Dr. Paul R. Sanberg
Vice President for Research and Innovation
University of South Florida - Tampa
3702 Spectrum Blvd., Suite 175
Tampa, FL 33612-9444

Dear Dr. Sanberg,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 7, 2017 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at the University of South Florida. According to the information provided, OLAW understands that an animal care employee did not report to work on a weekend day and therefore the daily animal health checks and environmental monitoring were not performed or documented.

The corrective actions consisted of checking all animals and noting no morbidity or mortality, including among animals on restricted feed. The individual responsible was reprimanded and the standard operating procedure for daily checks was revised to include redundant oversight. An on-call supervisor will now be assigned on weekends and holidays along with the on-call veterinarian, and this supervisor will communicate with the animal care staff. Staffing schedules will be posted and the staff has been trained on these revised procedures.

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 institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Sincerely,

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

cc: IACUC Chair



UNIVERSITY OF
SOUTH FLORIDA

December 7, 2017

Brent Morse, DVM, 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 and PHS Policy IV.F.3, provides this report of noncompliance, originally reported by telephone to the Office of Laboratory Animal Welfare (OLAW) on November 1, 2017.

On Monday, October 23, 2017, Comparative Medicine (CM) reported to the IACUC chairperson an incident of non-compliance. On Sunday, October 22, a CM staff failed to show for work, therefore, there was no daily oversight of animals housed at the College of Medicine (COM) vivarium. Consequently, no daily animal health or environmental monitoring checks were performed or recorded for that day in the COM vivarium as required by the *Guide* and USF SOP.

On Monday, October 23, the day following the incident, a thorough review of all animals, rooms, and records determined that there was no animal morbidity or mortality that occurred associated with this incident.

Additionally, on Monday, October 23, four animals on measured daily feed offerings, including two rabbits involved with antisera production, on IACUC protocol 2810S and in accordance with SOP 100 – Rabbit Husbandry, and two rats on IACUC protocol 1425R, were found to be active and alert. When fresh feed was offered and consumed, and body weights were measured, their weights were found to be within the limits approved in the IACUC protocols. All other animals COM facility-wide were on ad libitum feed offering and still had feed available in each primary enclosure.

Costs associated with this noncompliance have been removed from all CM charge-backs to COM-based protocols housed on Sunday, October 22, therefore, no federal funds were used in support of this noncompliance.

The following corrective and preventive action plan has been implemented.

1. The CM staff member who failed to show up for work on Sunday, October 22, 2017, has been reprimanded for their negligence. This reprimand has also been reported to USF Human Resources.
2. SOP 006 entitled "Animal Health & Environmental Surveillance" has been revised. It now requires:
 - a. Redundant oversight by CM staff on all weekends and holidays.
 - b. In addition to the on-call veterinarian, an on-call supervisor is now assigned to each weekend and holiday.

RESEARCH INTEGRITY & COMPLIANCE

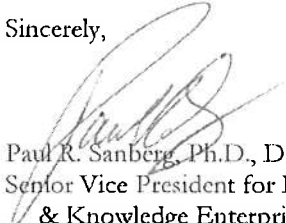
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- c. Communication between the on-call supervisor and the scheduled CM staff scheduled for each weekend and holiday is required. The on-call supervisor will acknowledge the scheduled staff's arrival and departure, and reporting animal health or environmental concerns.
- d. Uniform posting is now required in each of the three-principle vivarium regarding weekend and holiday CM staffing, on-call supervisor, and on-call veterinarian schedules.
- e. CM staff received documented retraining of revised SOP 006 – Animal Health and Environmental Surveillance.

During its November 17, 2017, meeting, the IACUC reviewed the corrective actions implemented in response to this event and found them acceptable. The IACUC now considers this matter resolved.

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 telephone # or via email at jidean@health.usf.edu.

Sincerely,


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

PRS:fim

cc: Jay Dean, Ph.D., Chairperson, USF IACUC
[Redacted] Senior Associate Vice President, Research & Innovation
Robert W. Engelman, D.V.M., Ph.D., Assistant Vice President, Comparative Medicine
[Redacted] Associate Director, Comparative Medicine
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[Redacted] Assistant Director, Comparative Medicine
[Redacted] IACUC Program Coordinator, USF Research Integrity & Compliance

Ward, Joan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, December 15, 2017 7:55 AM
To: [REDACTED]
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW reportable item-December 2017-Report of missed weekend daily animal health/environmental monitoring incident- University of South Florida-PHS D-16-00589 (A4100-01)

Thank you [REDACTED] for this report. Dr. Morse will respond soon.

Regards,
Joan

From: [REDACTED] [mailto:[REDACTED]@usf.edu]
Sent: Thursday, December 14, 2017 5:17 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: RSCH IACUC <IACUC@research.usf.edu>
Subject: OLAW reportable item-December 2017-Report of missed weekend daily animal health/environmental monitoring incident- University of South Florida-PHS D-16-00589 (A4100-01)

Dear Dr. Morse,

The University of South Florida (USF) hereby submits a final report to a notification of missed weekend daily animal health/environmental monitoring incident- reported originally on November 1, 2017. Attached is an 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.

Sincerely,
[REDACTED]

[REDACTED]
IACUC Program Manager & Institutional Biosafety Officer
Research Integrity & Compliance



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