



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, Maryland 20892-6910
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

October 26, 2018

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

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

Dear Dr. Sanberg,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 22, 2018 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 August 27, 2018. According to the information provided, OLAW understands that one rat, two mice, and 89 reptiles were being housed in a room without Institutional Animal Care and Use Committee (IACUC) approval and without certification of the staff involved. The reptiles had been wild caught and the rodents had been acquired at a pet store, which is not compliant with university policy. The housing room had not been approved as a satellite facility. No animal welfare concerns were noted.

The corrective action consisted of the IACUC directing the investigator to stop all animal activities, to obtain certification for staff involved, and to submit a protocol. The veterinarian counseled the investigator on the institutional policies for obtaining animals, provided record keeping forms for daily animal and environmental observations, and explained the requirements for satellite housing. All staff was reminded that all animal activities require prior approval from the IACUC. A protocol was submitted and subsequently approved by the IACUC, IACUC personnel certification was completed, but the housing of rodents in the satellite facility was not approved and these animals were removed from the protocol. The laboratory was subjected to post-approval monitoring.

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,

[REDACTED] (b) (6)

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

cc: IACUC Chair

(b) (4)

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The veterinarian (1) instructed the faculty member to cease all animal use activities, (2) reminded him of the requirements of securing IACUC personnel certification and protocol approval prior to housing or using vertebrate animals in research or teaching, (3) guided him to established processes for requesting IACUC approval of animal use, (4) reminded him that animals must be procured via or reported as captured in the wild to Comparative Medicine, and (5) provided him with appropriate recordkeeping forms for logging daily oversight of animal and environmental conditions (e.g., animal health, feeding, environmental conditions) in accordance with SOP 006 entitled "Animal Health and Environmental Surveillance", and (6) reviewed IACUC Principle III.32 regarding the requirements of a vertebrate animal satellite housing site.

On September 10th, a university wide, program specific email notification was sent to faculty, administrators and staff regarding IACUC requirements, responsibilities, and policies, reiterating that research, testing, and teaching/instructional activities utilizing live vertebrate animals requires IACUC review & approval prior to animal procurement or wild vertebrate capture, and that animal procurement must be via USF Comparative Medicine.

On September 28th, IACUC protocol 5565 entitled "Early Hatching in Reptiles" was reviewed by the IACUC during its regular monthly meeting, and found to "Require Modification to Secure Approval via Designated Member Review". It was determined by the IACUC that the proposed rodent housing and use could not be effectively implemented in accordance with established procedures at the proposed satellite facility.

The IACUC was also concerned that the proposed satellite housing of uncharacterized rodents would introduce an unacceptable risk by possibly harboring rodent opportunistic infectious agents therein, serving as a source of fomite-transmission of such agents to well-characterized rodent inventories housed in central university-managed facilities, thereby invalidating research.

The IACUC also determined that Post Approval Monitoring (PAM) was required for the satellite reptile facility as well as for protocol 5565. At its September 28th 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.

On October 1st, a subcommittee of the IACUC reviewed the satellite facility, determined that the pet rodents have been removed, and made recommendations for improvements, which have now been incorporated by the PI and research staff.

On October 2nd, the Principal Investigator (PI) completed IACUC personnel certification.

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Subsequently, the PI removed the proposed satellite housing and the use of rodents from protocol 5565, acknowledging the aims of the research were preserved by the use of a surrogate predator (i.e., egg shaking), or insect or reptile predator.

On October 19th, protocol 5565 was approved by the IACUC.

Post Approval Monitoring of the satellite reptile facility as well as protocol 5565 has been scheduled.

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

(b) (6)

Jay Dean, Ph.D., Professor, Chairperson, IACUC

(b) (6)

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, October 24, 2018 1:07 PM
To: RSCH IACUC; OLAW Division of Compliance Oversight (NIH/OD)
Cc: RSCH Comparative Medicine
Subject: RE: 2018-10-22-OLAW report- follow-up to reportable item-1) Use of lizards at St Pete campus 2) use of Beta fish University of South Florida-PHS A4100-01

Thank you for providing these final reports. We will send official responses 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: Wednesday, October 24, 2018 12:33 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: RSCH IACUC <IACUC@research.usf.edu>; RSCH Comparative Medicine <compmed@admin.usf.edu>
Subject: 2018-10-22-OLAW report- follow-up to reportable item-1) Use of lizards at St Pete campus 2) use of Beta fish University of South Florida-PHS A4100-01

Dear Dr. Morse,

The University of South Florida (USF) hereby submits a final report to a notification of two incidents, reported originally on August 27, 2018. Attached are two 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,
(b) (6)

(b) (6)



Initial Report of Noncompliance

By: aw

Date: 8/22/18

Time: 9:00

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: U of South Florida

Assurance number: A4100

Did incident involve PHS funded activity? No

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? 29

3
Reptiles, amphibians, rodents housed w/out protocol

Species involved:

Personnel involved:

Dates and times:

Animal deaths:

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

I Amc Counseling PI, put on protocol

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____