



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) 480-3387

May 4, 2022

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

Dr. Erin Kobetz
Vice Provost for Research
University of Miami
1400 NW 10th Ave -
(b) (4) Dominion Towers
Miami, FL 33136

Dear Dr. Kobetz,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 26, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Miami. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the University of Miami Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: conditions that jeopardized the health/well-beings of animals that resulted in harm to animals. The final report states a survival surgery was performed on a baboon (*Papio hamadryas*) in late 2021. The animal recovered from the surgery without incident, but then developed decreased appetite and elevated temperature one week later. Diagnostics were performed, and the animal was given antibiotics as treatment. Additional diagnostics were performed, and radiographs revealed a metal instrument located within the inguinal region where a firm mass had been palpated.

A laparotomy was performed, and a hemostat and gauze were identified and removed from the abdomen. The items were determined to be from a previous surgery. The exploratory surgery determined the colon was not compromised and no other foreign bodies were present. Per the report, the animal recovered from the procedure and her involvement in the study was not affected. In response to the finding, the Principal Investigator (PI) submitted a report and action plan to the IACUC to use new forms to account for all surgical instruments prior to and after surgery.

The IACUC acknowledged the exemplary compliance history of the research team and their years of experience with the animal model. The committee voted to accept the action plan and mandated the following additional action items for the PI:

- Conduct an assessment of the protocol with attention towards other areas where a change could be made to limit the possibility of future errors.
- Explore the methods used in human surgeries that could be adopted to help ensure that no additional errors are made that may lead to adverse events.

It is noted that this research is supported by PHS funding. Based on its assessment of this explanation, OLAW understands that the University of Miami has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy.

Page 2 – Dr. Kobetz
May 4, 2022
OLAW Case A3224-1Q

We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

Jacquelyn
T. Tubbs -S

Digitally signed by
Jacquelyn T. Tubbs -S
Date: 2022.05.04
11:43:24 -04'00'

Jacquelyn Tubbs, DVM, DACLAM
Senior Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

Robert M. Gibbens, DVM, Director, Animal Welfare Operations



OFFICE OF THE VICE PROVOST FOR
RESEARCH & SCHOLARSHIP

A3224-1Q

April 26, 2022

Dr. Axel Wolff, Deputy Director
Office of Laboratory Animal Welfare
Rockledge One, Suite 2500
6700B Rockledge Drive – MSC 6910
Bethesda, MD 20892-7982

Re: NIH project 1R21AI156131-01
Assurance number: A3224-01

Dear Dr. Wolff,

We wish to report an adverse event that occurred during a survival surgery on a *Papio hamadryas*.

The animal had an uneventful survival surgery in late 2021, after which she recovered without incident. With a sudden decrease in appetite and elevated temperature one week later, the University clinical veterinary staff immediately took blood samples and found a mild elevation in the counts of white blood cells. The animal was treated with antibiotics.

After a week of antibiotic treatment with no change in the animal's appetite, the clinical veterinarian palpated a firm mass in the left inguinal region and determined it to be moveable and dense. A radiograph that day confirmed a metal instrument. The same day, the veterinarian performed a laparotomy and removed a hemostat and gauze left from the previous surgery. The abdomen was explored and lavaged before closure to ensure no other foreign bodies were present and that the colon was healthy and not compromised. The animal completely recovered, and her use in the study was not affected. The principal investigator immediately put in a report and action plan to the IACUC about this event to use new forms to account for all surgical instruments before and after surgery.

During the IACUC discussion of this incident, the committee noted the exemplary compliance history of the research team and the many years of experience with the animal model. Further, they noted that the research team immediately engaged the clinical veterinarian for medical assessment and intervention. As such, the IACUC voted to accept the action plan and mandated that the principal investigator:

- Conduct an assessment of the protocol with attention towards other places where a change could be made to limit the possibility of future errors.
- Explore methods used in human surgeries that could be adopted to help ensure that no additional errors are made that can lead to adverse events.

At the February 3, 2022, IACUC meeting, the principal investigator reported that the assessment had been conducted. Additionally, the surgery forms were modified to account for the number of gauzes and clarified that three counts would be conducted. The IACUC voted to accept the expanded action plan.

At the University of Miami, we strive to take excellent care of our animals and we are very upset that this adverse event occurred. We are confident that with this additional level of instrument counting, this type of situation will not reoccur.

Sincerely,

(b) (6)

Erin Kobetz, PhD, MPH

Vice Provost for Research + Scholarship

Associate Director, Population Sciences and Cancer Disparity, Sylvester Comprehensive Cancer Center
John K. and Judy H. Schulte Senior Endowed Chair in Cancer Research

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, April 27, 2022 7:36 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Adverse event report: Assurance number A3224-01

Thank you for this report, (b) (6) We will send a response soon.

Axel Wolff

From: (b) (6)
Sent: Tuesday, April 26, 2022 2:51 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) ekobetz <ekobetz@med.miami.edu>
Subject: [EXTERNAL] Adverse event report: Assurance number A3224-01

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

To whom it may concern

Attached please find an adverse event report for the University of Miami Miller School of Medicine, Assurance number A3224-01.

With kind regards,

(b) (6)