



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

February 11, 2022

Re: Animal Welfare Assurance
A3377-01 [OLAW Case 8Y]

Dr. David P. Norton
Vice President for Research
University of Florida
(b) (4) Grinter Hall
Gainesville, FL 32611-5500

Dear Dr. Norton,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 26, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Florida. According to the information provided, OLAW understands that of fourteen rats which had undergone survival laparotomy surgery, two died and five required euthanasia due to dehiscence. Necropsy revealed that the skin clips had fallen out and the suture line did not have knots. It was determined that these failures were due to improper suture technique.

The corrective actions consisted of a veterinarian retraining the Principal Investigator on appropriate suture technique.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to reduce the likelihood of a recurrence. While OLAW concurs with the actions taken by the institution to comply with the PHS Policy, we note that the Institutional Animal Care and Use Committee is to determine in advance of staff conducting animal activities that "personnel conducting procedures on the species being maintained or studied will be appropriately qualified and trained in these procedures." OLAW also recommends that this laboratory be placed under enhanced post-approval monitoring to ensure that surgeries are now being correctly conducted.

Sincerely,

(b) (6)

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

cc: IACUC Chair



A3377-8Y

Office of the Vice President for Research

(b) (4) Grinter Hall
PO Box 115500
Gainesville, FL 32611-5500
(b) (6)

January 26, 2022

Axel Wolff, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892

Dear Dr. Wolff:

The University of Florida, in accordance with Assurance D16-00244 and PHS Policy IV.F.3., provides this report of an adverse event regarding adverse surgical outcomes leading to multiple rat euthanasia. A preliminary report was not sent to OLAW regarding this adverse event.

Survival laparotomy surgery was performed on 14 rats on December 21, 2021, as outlined in the IACUC protocol. The muscular layer was sutured with 4-0 vicryl suture, and metal clips were used to close the skin layer. There were no immediate peri- or post-operative issues, but on the morning following the surgery, one rat was found dead, and five had to be euthanized because of major dehiscence. Two rats had mild-moderate seroma formation with intact body wall and skin incisions. One of the two died on day 2 post-op, after overnight dehiscence.

The laboratory routinely performs this procedure and this is the first time that they have had such a large number of post-operative mechanical failures. The Animal Care Services (ACS) vet necropsy found clips had fallen out and vicryl 4-0 suture was found to be an appropriate length for an interrupted suture, but no knots remained on the interior layer. There was no obvious evidence of self-mutilation of the skin. The likely cause of the dehiscence was improper suture technique. The PI was retrained by an ACS veterinarian on suture technique following the incident.

The IACUC full committee voted on January 18, 2022 that this incident was an adverse event and was reportable through the IO to regulatory agencies.

The animals involved in this adverse event are funded by the following grant:

- National Institutes of Health-NIDDK-R01DK125890-*Consequence of mechanism of diet-driven vagal remodeling on gut-brain feeding behavior*

The University of 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 Daniel R. Brown, Ph.D., IACUC Chair.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

David Norton, Ph.D.
Vice President for Research
Institutional Official

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, February 4, 2022 6:53 AM
To: Research - IACUC
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: [EXTERNAL] Reportable Adverse Event (2022Jan01) [ref:_00D412ElGo._5001K15bQll:ref]

Thank you for this report. We will send a response soon.
Axel Wolff

From: Research - IACUC <iacuc-crm@research.ufl.edu>
Sent: Wednesday, February 2, 2022 10:59 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: drbrown@ufl.edu; (b) (6) Parsad, Charmaine (NIH/NIDDK) [E] <charmaine.parsad@nih.gov>; Maruvada, Padma (NIH/NIDDK) [E] <maruvadp@mail.nih.gov>
Subject: [EXTERNAL] Reportable Adverse Event (2022Jan01) [ref:_00D412ElGo._5001K15bQll:ref]

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To All Concerned,

Please see the attached report of an adverse event from the University of Florida (D16-00244). A preliminary report was not sent in regards to this adverse event.

The protocol involved in this adverse event is funded by the NIH and the applicable program official and grants management specialist are cc'd on this email.

Please acknowledge receipt and let me know if you have any questions.

(b) (6)

