



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

April 14, 2020

Re: Animal Welfare Assurance
A3377-01 [OLAW Case 6Y]

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

Dear Dr. Norton,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 6, 2020 letter reporting an adverse event within the animal care and use program at the University of Florida. According to the information provided, OLAW understands that on January 3, 2020 it was self-reported that several axolotls had become sick and one required euthanasia due to low water pH. The building tap water had been used previously without incident. The study is PHS funded.

Corrective and preventive actions included the PI submitting a protocol amendment and SOP change to include testing of the tap water before use.

OLAW believes that the actions taken by the University of Florida are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals for institutional self-monitoring and self-reporting. It is understood that the funding component has been informed of the non-compliance. OLAW appreciates being informed of this issue and finds no cause for further action by this office.

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C. Morse

-S
Date: 2020.04.14 09:30:52 -04'00'

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



Office of the Vice President for Research

223 Grinter Hall
PO Box 115500
Gainesville, FL 32611-5500
352-392-1582

March 6, 2020

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 (A3377-01) and PHS Policy IV.F.3., provides this report of an adverse event regarding the death of an axolotl due to low water pH.

On January 3, 2020 it was self-reported to the IACUC that multiple young axolotls appeared sick resulting in one young axolotl requiring euthanasia due to low water pH. The laboratory has historically used building tap water without issue.

On January 9, 2020 a committee member/ACS veterinarian met with the PI to discuss the incident. After evaluating the water parameters of the tap water, it appeared that the issue had been resolved. Going forward they discussed modifying the current practice to include testing of the tap water prior to its use.

On January 15, 2020 an IACUC staff member met with the PI to discuss the details of the incident and corrective actions. The PI has submitted a modification to update the IACUC protocol and laboratory SOP to indicate that tap water will be tested prior to its use.

The IACUC full committee voted on January 21, 2020 that this incident was an adverse event and was reportable through the IO to regulatory agencies.

This study is supported by the following grant:

- NIH NIDDK R01DK105916: Axolotl Hematopoiesis: A Regeneration Model

The NIH funding components have been notified of the adverse event.

The University of Florida is committed to protecting the welfare of animals used in

The Foundation for The Gator Nation

An Equal Opportunity Institution

Obtained by Rise for Animals. Uploaded 08/24/2020

Retrieved from Animal Research Laboratory Overview (ARLO)

Re: NIH NIDDK R01DK105916
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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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, April 10, 2020 7:12 AM
To: Mahoney, Michael P
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reportable adverse event (00715372)

Thank you for this report. We will respond soon.
Axel Wolff

From: Mahoney, Michael P <mmahoney@ufl.edu>
Sent: Thursday, April 9, 2020 10:50 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Ly, Diana (NIH/NIDDK) [E] <diana.ly@nih.gov>; Bishop, Terry (NIH/NIDDK) [E] <bishopt@extra.niddk.nih.gov>
Subject: Reportable adverse event (00715372)

I am sending the attached report of an adverse event from the University of Florida. UF did not send a preliminary report for this event.

The protocol involved in this adverse event is funded by NIH and I have cc'd the applicable Program Officials on this email.

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

-Michael

Michael Mahoney
Director of Research Operations and Services
University of Florida | UF Research | PO Box 115500
Grinter (b) (4) PH: (b) (6) | <http://research.ufl.edu>