



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) 480-3377

July 28, 2020

Re: Animal Welfare Assurance
A3377-01 [OLAW Case 7K]

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 June 24, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Florida. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the University of Florida Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure to perform daily health checks/environmental monitoring, failure to maintain appropriate animal related records, failure to follow IACUC protocol and University of Florida policies and use of expired materials. The final report states unannounced IACUC inspections were performed in the principal investigator (PI) managed axolotl facility between May 14-18, 2020. Findings from the inspection revealed animal health and environmental monitoring records were being pre-filled for future dates. Also, deviations from husbandry SOPs were discovered in addition to expired isopropyl alcohol.

The IACUC full committee voted on June 16, 2020 that this incident was a noncompliance and required the following corrective actions:

- Long Term, Animal Care Services (ACS) will assume responsibility for the husbandry and clinical care of the axolotl colony in an ACS facility.
- Within 24h after receipt of this report the PI must add a time column to the daily husbandry log. The time logged must match the ACS sick list report timestamp within ~30min. This action is to assure animal welfare is not compromise during transition to axolotl husbandry by ACS in an ACS facility.
- Within 1 wk a report must be submitted to the IACUC with a provisional plan for ensuring husbandry care standards are upheld until the transition to ACS husbandry.
- Within 2wk the PI must meet the IACUC staff to review SOPs associated with the animal protocol to ensure husbandry practices accurately reflect lab protocols.

It is noted that this research is supported by PHS funds. Based on its assessment of this explanation, OLAW understands that the University of Florida has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. We appreciate being informed of these matters and find no cause for further action by this Office.

Page 2 – Dr. Norton
July 28, 2020
OLAW Case A3377-7K

Sincerely,

Jacquelyn T. Tubbs -S
Digitally signed by
Jacquelyn T. Tubbs -S
Date: 2020.07.28
12:27:52 -04'00'

Jacquelyn T. Tubbs, DVM
Animal Welfare Program Specialist
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

June 24, 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 non-compliance regarding axolotls and failure to perform daily animal health checks/environmental monitoring, failure to maintain appropriate animal-related records, failure to follow IACUC protocol and University of Florida Policies, and use of expired materials.

Between May 14, 2020 and May 18, 2020 unannounced IACUC inspections were performed of the Principal Investigator (PI) managed axolotl facility. Findings from the inspection indicated that animal health and environmental monitoring records were being pre-filled for future dates. In addition, deviations from the husbandry SOP's were found as well as expired isopropyl alcohol in the room. These issues were found during a period when on-campus activities were greatly curtailed due to the COVID-19 pandemic

The IACUC full committee voted on June 16, 2020 that this incident was a non-compliance and the following corrective actions are required:

1. Long term, Animal Care Services (ACS) will assume responsibility for the husbandry and clinical care of the axolotl colony in an ACS facility. In order to do that, within 60 days, the PI must initiate discussions with an ACS vet to outline a plan to move the axolotls into an ACS facility. The plan must be completed within 90 days and must include a reasonable timeline for the move.
2. In order to assure animal welfare is not compromised during the transition to axolotl husbandry by ACS in an ACS facility, the following corrective actions must be implemented: Within 24 hours after receipt of this report the PI must add a time column to the daily husbandry log. The time logged must match the ACS sick list report time-stamp within ~30 minutes.
3. Within 1 week a report must be submitted to the IACUC with a provisional plan for ensuring husbandry care standards are upheld until the transition to ACS husbandry.
4. Within 2 weeks the PI must meet with IACUC staff to go over all SOP's attached to the animal protocol to ensure husbandry practices accurately reflect lab protocols.

The Foundation for The Gator Nation

An Equal Opportunity Institution

Non-compliance Report
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This study is funded by the following grant:
National Institutes of Health: R01DK105916 *Axolotl Hematopoiesis: A Regeneration Model*

The NIH funding components have been notified of the noncompliance.

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, July 24, 2020 7:20 AM
To: Mahoney, Michael P
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of noncompliance (00927725)

Thank you for this report, Dr. Mahoney. We will respond soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: Mahoney, Michael P <mmahoney@ufl.edu>
Sent: Wednesday, July 22, 2020 6:15 PM
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: Report of noncompliance (00927725)

Dr. Morse,

I am sending the attached report of noncompliance from the University of Florida.

The protocol involved is funded by NIH and the applicable officials have been cc'd 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
Grinter Hall (b) (4)
PO Box 115500
Gainesville, FL 32611-5500
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