



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

June 23, 2021

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

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 2, 2021 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: the conduct of animal-related activities without prior IACUC review and approval. The final report states laboratory staff surgically implanted abdominal windows on 6 non-survival and 7 survival mice. The surgery is not included in the approved protocol. It is understood that personnel performing the surgeries are listed on the protocol as performing surgery and have completed the required training. In response to the incident, all mice were euthanized. The IACUC voted that the matter as a noncompliance and required the following corrective actions:

- A modification has been submitted to add the abdominal window procedure.
- Within 2 weeks, the principal investigator (PI) must contact the IACUC office to schedule a post approval monitoring (PAM) visit.
- Within 2 weeks, the PI must submit a plan to the IACUC for ensuring protocol compliance. This should include a plan for onboarding of new staff as well as a plan for continuing compliance.
- Data obtained from animals that underwent unapproved procedures must not be used for any purpose.

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.

Sincerely,
Jacquelyn T.
Tubbs -S

Digitally signed by Jacquelyn T.
Tubbs -S
Date: 2021.06.23 12:42:08 -0400

Jacquelyn Tubbs, DVM, DACLAM
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
352-392-9605 Fax

June 2, 2021

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 a noncompliance regarding unapproved survival and non-survival surgical procedure performed in mice. A preliminary report was not sent to OLAW regarding this noncompliance.

Laboratory staff surgically installed abdominal windows on 6 non-survival and 7 survival mice. This surgery is not outlined in the approved protocol. Personnel performing the surgeries are listed on the protocol as performing surgery and have taken the required training. All mice have been euthanized.

The IACUC full committee voted on May 4, 2021 that these incidents were a noncompliance and the following corrective actions are required:

1. A modification has been submitted to add the abdominal window procedure.
2. Within 2 weeks, the PI must contact the IACUC office to schedule a post approval monitoring (PAM) visit.
3. Within 2 weeks, the PI must submit a plan to the IACUC for ensuring protocol compliance. This should include a plan for onboarding of new staff as well as a plan for continuing compliance.
4. Data obtained from animals that underwent unapproved procedures must not be used for any purpose.

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

- National Institutes of Health: R01DK121117: *Extramedullary Hematopoiesis and Splenic Niche*

The NIH funding components have been notified of the noncompliance.

Report of a non-compliance
June 2, 2021
Page 2

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: Wednesday, June 9, 2021 7:35 AM
To: Research - IACUC
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reportable noncompliance (2021Apr04) [ref:_00D412ElGo_5001K11lIMZ:ref]

Thank you. We will send a response soon.
Axel Wolff

From: Research - IACUC <iacuc-crm@research.ufl.edu>
Sent: Tuesday, June 8, 2021 12:26 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: drbrown@ufl.edu; (b) (6) Ly, Diana (NIH/NIDDK) [E] <diana.ly@nih.gov>; bishopt@extra.niddk.nih.gov
Subject: Reportable noncompliance (2021Apr04) [ref:_00D412ElGo_5001K11lIMZ:ref]

To All Concerned,

Please see the attached report of a noncompliance from the University of Florida (D16-00244). A preliminary report was not sent for this noncompliance.

The protocol involved in this noncompliance 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.

Best,

(b) (6)

