



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 22, 2020

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

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 March 20, 2020 letter reporting an incident of non-compliance with the PHS Policy on Humane Care and Use of Laboratory Animals within the animal care and use program at the University of Florida. According to the information provided, OLAW understands that issues with either catheter implantation surgeries at the animal vendor or lab dosing procedures led to catheter infections in rats resulting in euthanasia. The animals involved in this incident were on a study funded by the PHS.

Corrective and preventive actions included the lab deciding to perform the catheterization in-house. The lab is being retrained in procedures related to correct handling of drugs and equipment. An SOP has been developed related to the preparation, storage and general processes related to the IV drug administration. A weeks supply of sterilized tubing will be available at any one time and labeling of the tubes will include the name of the person responsible.

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 notified of the noncompliance. OLAW appreciates being informed of this issue and finds no cause for further action by this office.

Sincerely,

(b) (6)

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 20, 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 rats developing catheter-related infections.

Between October 2019 and February 2020, 61 rats received surgery for jugular vein catheter and vascular access button implantation at Envigo and were then shipped to UF for a drug self-administration study. Within days to weeks following surgery at the vendor, rats developed catheter-related infections and systemic abscessation leading to a progressively increasing number of animals requiring euthanasia. Ongoing discussions with Envigo have revealed that other institutions are currently having the same issue with these pre-catheterized rats.

After the colony was culled, additional investigation into lab procedure space and practices revealed potential sources of infection related to drug administration technique and daily cleaning of equipment for IV injection. The laboratory practices failed to follow the *UF Policy for Use of Anesthetic Cocktails and Diluted Drugs in Laboratory Animals*. A direct link between the PI's procedures and the catheter-related infections has not been made, nor is it possible to firmly identify to what extent the infections may have originated at the vendor.

The laboratory has initiated the following corrective actions:

1. Envigo has offered to send eight pre-catheterized rats with a different brand of implant free of charge. The lab is running a trial to see if they continue to see catheter-related infections with the new implant. The intent is for Envigo to provide more replacement animals if no catheter-related infections are found.
2. The lab has decided not to order pre-catheterized rats from Envigo, pending the results of the trial using the animals with the alternative catheter type. Alternatively, the lab will perform the surgical implantation of catheters in-house.

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)

3. Retraining of the lab on correct methods for sterile handling of drugs and equipment by vet staff is currently in progress and will be completed prior to initiation of the next animal study. Vet staff provided the first training session 02/25/20.
4. An SOP was developed regarding preparation, storage, and general processes related to the IV drug administration. This will aid in training of personnel.
5. All tubes will be labeled with date, name of drug, name of vehicle, and person who is responsible.
6. A week supply of sterilized tubing will be available at all times, gas sterilization will be used between uses.

The IACUC full committee voted on March 10, 2020 that this incident was non-compliance and was reportable through the IO to regulatory agencies. The IACUC has required the PI to designate someone in the laboratory to be responsible for IACUC compliance within the laboratory.

This study is funded by the following grant:

National Institutes of Health: UG3DA048353 *Opioid use disorders: UF Pharmacy medications discovery and development.*

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: Wednesday, April 15, 2020 8:50 AM
To: Mahoney, Michael P
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of noncompliance (00762395)

Thank you for all of these reports, Dr. Mahoney. I realize these are unique times, but if at all possible, do not "batch" the reports. Please send a preliminary report as soon as possible after the incident occurred followed by a final after the IACUC has completed its investigation.

Axel Wolff

From: Mahoney, Michael P <mmahoney@ufl.edu>
Sent: Monday, April 13, 2020 10:01 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Bucheimer, Amy (NIH/NIDA) [E] <bucheimera@mail.nih.gov>; Acri, Jane (NIH/NIDA) [E] <jacri@nida.nih.gov>
Subject: Report of noncompliance (00762395)

Dr. Morse,

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

The protocol involved in this noncompliance 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>

Wolff, Axel (NIH/OD) [E]

From: Mahoney,Michael P <mmahoney@ufl.edu>
Sent: Wednesday, April 15, 2020 8:57 AM
To: OLAW Division of Compliance Oversight (NIH/OD)
Subject: Re: Report of noncompliance (00762395)

Dr. Morse,

Will do.

-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>

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Wednesday, April 15, 2020 8:49 AM
To: Mahoney,Michael P
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report of noncompliance (00762395)

[External Email]

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Michael Mahoney
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