

Office of the Vice President for Research

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March 23, 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 animal death due to equipment failure.

On February 15, 2020, a total of 15 chickens were found dead in an isolation unit. The cause of mortalities was attributed to the disconnection of the air handling unit of the isolator.

During the investigation concerns over the laboratory's Infectious Biological Agents standard operating procedures, specifically involving the laboratory's sanitation practices were found. The laboratory has been working closely with Environmental Health and Safety (EHS) to resolve these concerns. Additional concerns were found involving the laboratory's general husbandry and animal care practices, as these were not properly outlined in the animal protocol. The laboratory has been working closely with Animal Care Services (ACS) to develop an SOP and update the protocol as it pertains to husbandry practices.

Following the incident, the laboratory implemented the following corrective actions:

- The air supply line was further secured to air handling.
- 2. ACS and laboratory personnel were trained to inspect air supply line and air handling units. Monitoring of the air supply handling unit will be done at least 2x/day by laboratory personnel, 10-14 hours apart. This will be documented on a log in the animal room. The laboratory is also looking into an alarm system to alert remotely that a unit is not functioning properly.
- A modification to the protocol has been approved further clarifying EHS and husbandry practices.

The Foundation for The Gator Nation

OLAW Letter March 23, 2020 Page 2

The IACUC full committee voted on March 10, 2020 that this incident was an adverse event and was reportable through the IO to regulatory agencies.

This study is not PHS funded.

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,

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

Wolff, Axel (NIH/OD) [E]

OLAW Division of Compliance Oversight (NIH/OD) From: Wednesday, April 15, 2020 8:39 AM Sent: Mahoney, Michael P To: OLAW Division of Compliance Oversight (NIH/OD) Cc: RE: Report of adverse event (00762895) Subject: Thank you for this report. We will respond soon. Axel Wolff From: Mahoney, Michael P < mmahoney@ufl.edu> Sent: Monday, April 13, 2020 4:30 PM To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov> Subject: Report of adverse event (00762895) Dr. Morse, 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 not PHS funded. 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