

From: [Gibbens, Robert - APHIS](#)
To: [McKinnie, Carolyn - APHIS](#); [Rhyner, Aaron A - APHIS](#)
Subject: FW: OLAW Case A3031-1A
Date: Wednesday, May 27, 2020 9:54:18 AM
Attachments: [SIGNED Compliance Letter University of Utah 1A.pdf](#)

fyi

From: Walker, Keri (NIH/OD) [C] [mailto:keri.walker@nih.gov]
Sent: Wednesday, May 27, 2020 7:11 AM
To: andy.weyrich@utah.edu
Cc: Gibbens, Robert - APHIS <robert.m.gibbens@usda.gov>; iacuc@ocm.utah.edu;
(b) (6)
Subject: OLAW Case A3031-1A

Dear Dr. Weyrich,

Attached please find Dr. Tubbs' final response to OLAW Case A3031-1A.

If you have any questions, feel free to contact us by phone or by e-mail.

Best Regards,
Keri

*Keri Walker
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DEPARTMENT OF HEALTH & HUMAN SERVICES

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May 26, 2020

Re: Animal Welfare Assurance
A3031-01 [OLAW Case 1A]

Dr. Andrew S. Weyrich
Vice President for Research
The University of Utah
(b) (4) Park Building
Salt Lake City, UT 84112

Dear Dr. Weyrich

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 7, 2020 letter reporting an adverse event with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Utah (U of U) following up on an initial March 2, 2020 notification by email.

According to the information provided, this Office understands that the U of U Animal Care and Use Committee (ACUC) determined that an adverse event occurred with respect to: the death of an adult marmoset. The final report provides a summary of the event that occurred on February 1, 2020. The summary states an adult marmoset underwent a surgical procedure (bilateral craniotomies and small durotomies) as approved per the protocol on January 29, 2020. No complications occurred during the procedure, the animal recovered well and was left in the incubator overnight. The following day, the Attending Veterinarian (AV) documented post-operative observations of the animal and the treatment plan. On January 31, 2020 the summary states an OCM tech noticed nasal discharge, and treatment was prescribed by the clinical veterinarian. On February 1, 2020 treatment plan was adjusted based on the observations of the animal's lack of appetite, decrease activity level and body temperature. The summary states the animal declined rapidly on February 1st and was euthanized, followed by a necropsy. Following the event, the principal investigator (PI) requested a meeting with the AV, clinical veterinarian, and the PI's lab manager to discuss cause for early termination of the animal. While no definitive cause could be identified, 3 possible causes and potential actions to avoid future recurrence were discussed. They included the following:

- Potential viral infections- Nasal swabs will be taken in all animals that will be anesthetized prior to a procedure to determine whether a viral infection may be present in the colony.
- Stress- Efforts will be made to maintain consistency in the personnel that interacts daily with the animals and improve the training of those people. Factors include minimizing contact with unknown personnel, reducing stress postoperatively and possible hiring of an animal technician by the PI dedicated to taking care of the marmoset colony.
- Drugs- Consideration was given that Alfaxalone may have led to respiratory difficulty when paired with administration of Buprenex. It was discussed that a review of previous records would be done to determine whether other animals administered this same drug combo exhibited respiratory difficulty.

The report states the OCM veterinarian clarified that discussion included concerns by the clinical veterinarians about the ventilator/anesthesia machine setup. It is stated the veterinary staff has been repeatedly concerned about the ventilation of these animals during surgery. It was further clarified that the animal began showing signs of respiratory difficulty/abnormality during the recovery from anesthesia on the day of the procedure. The Institutional Veterinarian stated that in reviewing the history of the last several marmosets, ventilator associated lung injury is a reasonable differential diagnosis and has ordered a new ventilator that is used for marmoset anesthesia by some of the primate centers.

The IACUC discussed the event at the March 26, 2020 convened meeting. A corrective action letter was sent to the PI and at the appeal of the PI the committee again reviewed the events of the matter and additional study related events leading up to the adverse event above and pathology report. Ultimately the IACUC required the following additional actions to be implemented immediately and they include the following:

- A ventilator that is approved by the OCM clinical veterinarian must be used for all surgery/procedures that require anesthesia.
- Surgery procedures that require anesthesia must be scheduled with the OCM clinical veterinarian and must be at a time when veterinary oversight support can be readily available to observe, train and provide study oversight as often the veterinarian deems necessary and must continue for each procedure until the clinical veterinarian is confident of proper equipment function and procedure adherence.
- In consultation with the clinical veterinarian additional sanitation safeguards must be implemented for entry into the IACUC approved surgical suite from the animal facility corridor.
- The IACUC requires surgical progress reports for each animal that includes a description of surgical outcome, animal welfare, and any health status reports on survival surgical studies after recovery.

The report states the IACUC determined the pathology report indicated that endotracheal tissue damage, causing swelling, most likely lead to the early termination of the study animal. The PI stated that recently a change in supplier for the ET tubes had occurred and the outside diameter of the tube was unknowingly larger between suppliers. The size of the ET tube has been corrected per the report.

It is noted that this research is PHS funded. Based on its assessment of this explanation, OLAW understands that the University of Utah 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
Jacquelyn T. Tubbs, DVM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

Digitally signed by Jacquelyn
T. Tubbs -S
Date: 2020.05.27 09:01:12
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cc: IACUC Contact
Robert M. Gibbens, DVM, Director, Animal Welfare Operations