



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) 402-7065

November 20, 2018

Re: Animal Welfare Assurance
#A3294-01 (OLAW Case 2I)

Dr. Jennifer Larsen
Vice Chancellor for Research
Louise and Morton Degen Professor
of Internal Medicine
University of Nebraska Medical Center
987878 University Nebraska Medical Center
Omaha, NE 68198-7878

Dear Dr. Larsen,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 13, 2018 letter reporting an adverse event involving a nonhuman primate at the University of Nebraska Medical Center. According to the information provided, OLAW understands that a rhesus macaque developed unexpected respiratory distress following nasogastric intubation. The monkey had received an experimental drug that is used in humans and had recovered well from anesthesia.

The immediate action taken in response was to have the veterinarians apply interventional procedures, but these were unsuccessful. The cause of death could not be determined but future intubations will use guided ultrasound and the intensive post-procedural monitoring phase will be extended.

Based on its assessment of this explanation, OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair

John Bradfield, D.V.M., Ph.D., Director, Comparative Medicine
Robert Gibbens, D.V.M., USDA-APHIS-AC

November 13, 2018

Axel V. Wolff, M.S., D.V.M., Director
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health
 Rockledge 1, Suite 360, MSC 7982
 6705 Rockledge Drive
 Bethesda, MD 20892-7982

RE: IACUC Case #2018-07 Final Report

Dear Dr. Wolff:

I am submitting this report in accordance with the requirements of the PHS Policy at IV.F.3. The IACUC has reviewed this incident described in this report determined it was reportable to OLAW.

1. **Animal Welfare Assurance Number:** A3294-01
2. **Grant or Contract Number:** NIH 5R01AI124965
3. **Species:** Nonhuman primates
4. **Effects on Programmatic or Physical Areas:** N/A
5. **Explanation of the Situation:**
 - a. One of four rhesus macaques that underwent a protocol-approved anesthesia to administer medication via nasogastric intubation by a veterinarian, developed unexpected respiratory symptoms after apparent normal recovery from anesthesia. The medication administered was a formulation approved for use in humans. Veterinarians immediately administered extensive rescue procedures but were unable to resuscitate the animal.
 - b. Post mortem evaluation of tissues (gross and histopathologic) found acute pulmonary inflammation and hemorrhage in peripheral lungs, of unknown cause.
 - c. As the cause of this adverse event is unknown, we will continue to be careful, and extend the period of intensive post-procedural monitoring for future animals undergoing this protocol, as well as employ routine ultrasound-guided intubation.
6. **Actions Taken by the IACUC:**
 - a. The IACUC Subcommittee reviewed this adverse event on October 5, 2018 and determined this to be a reportable incident.
7. **Implementation Schedule:**
 - a. Complete.

If you have any questions or require any further information, please do not hesitate to contact me.

Respectfully,

(b) (6)

Jennifer Larsen, MD
Institutional Official,
University of Nebraska Medical Center
Vice Chancellor for Research

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PH

(b) (6)

FAX

(b) (6)

email: jlarsen@unmc.edu

cc: Robert G. Bennett, Ph.D., IACUC Executive Chair

(b) (6)

John F. Bradfield, D.V.M., Ph.D. Attending Veterinarian/Director Comparative Medicine

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, November 14, 2018 10:18 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Initial Report UNMC/UNO IACUC Case #2018-07

Thank you for this report, (b) (6) I will send a response soon.

Axel Wolff

From: (b) (6)
Sent: Wednesday, November 14, 2018 9:19 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Larsen, Jennifer L <jlarsen@unmc.edu>; Bennett, Robert G <rgbennet@unmc.edu>; (b) (6)
(b) (6) Bradfield, John F <john.bradfield@unmc.edu>; IACUCORA, UNMC
<IACUCORA@unmc.edu>
Subject: Initial Report UNMC/UNO IACUC Case #2018-07
Importance: High

November 14, 2018

Axel V. Wolff, M.S., D.V.M., Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

RE: IACUC Case #2018-07

(b) (6)



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