



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, MD 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

January 6, 2020

Re: Animal Welfare Assurance  
A3079-01 [OLAW Case 3W]

Dr. Dawn A. Bonnell  
Vice Provost for Research  
University of Pennsylvania  
1 College Hall, (b) (4)  
Philadelphia, PA 19104-6303

Dear Dr. Bonnell,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 18, 2019 letter reporting an adverse event within the animal care and use program at the University of Pennsylvania. According to the information provided, OLAW understands that despite its FDA approval for humans, published canine dosages and performance of a pilot study without issues, a dog unexpectedly died during a subsequent study of a drug being used as an adjunct therapy to treat a naturally occurring genetic disease in canines. In response to this event the IACUC protocol was modified to include a gradually rising dose of the drug as well as more frequent drug blood level monitoring. The animal was assigned to a protocol funded by the PHS.

The prompt consideration of this matter by the University of Pennsylvania was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to prevent recurrence were appropriate. We appreciate being informed of this unfortunate matter and find no cause for further action by this office at this time.

Sincerely,

(b) (6)

Brent C. Morse, DVM  
Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC contact  
Dr. Robert M. Gibbens, USDA, APHIS, AC



**Office of the Vice Provost for Research**

December 18, 2019

Brent Morse, DVM, DACLAM  
 Director of Compliance Oversight  
 Office of Laboratory Animal Welfare  
 National Institutes of Health  
 RKL 1, Suite 360, MSC 7982  
 6705 Rockledge Drive  
 Bethesda, MD 20892-7982

University of Pennsylvania

A3079-01

Dear Dr. Morse,

The University of Pennsylvania would like to report an unexpected drug adverse event on an IACUC approved study. The study was to investigate an adjunct therapy to treat a naturally occurring genetic disease in canines. The drug which was used is FDA approved for humans and the drug did have published canine dosages in the literature. A pilot dosing study was performed without issues. However, in the subsequent study an unexpected terminal adverse event did occur with one subject on study. The IACUC, veterinary staff and IACUC compliance group were informed and reviewed the incident. Working with the PI on the study, the IACUC protocol was modified to include a gradually rising dose of the drug to allow acclimatization, as well as, more frequent drug blood level monitoring to adjust the dosing per individual animal. The clinical and the research veterinary staff have coordinated their collaboration to ensure strong oversight and documentation of the study.

The study was funded by R01-AR-071975-01.

Sincerely yours,

(b) (6)

Dawn Bonnell, PhD  
 Vice Provost for Research  
 Trustee Professor of Materials Science and Engineering  
 Institutional Official

CC: IACUC Chair, University of Pennsylvania  
 Attending Veterinarian and ULAR Director, University of Pennsylvania  
 Director of Animal Welfare, University of Pennsylvania

**Morse, Brent (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Thursday, January 02, 2020 12:34 PM  
**To:** Reinhard, Gregory R; OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: UPenn Adverse event report

Thank you for providing this report of an adverse event Dr. Reinhard. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM  
Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

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**From:** Reinhard, Gregory R [mailto:reingr@upenn.edu]  
**Sent:** Thursday, January 02, 2020 11:36 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** UPenn Adverse event report

Enclosed is an adverse event report  
Regards  
Greg

Gregory R. Reinhard, MBA, DVM, DACLAM, CPIA  
Director of Animal Welfare  
University of Pennsylvania  
3800 Spruce St., (b) (4) OVQ  
Philadelphia, PA 19104  
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