



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

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Office of Laboratory Animal Welfare
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Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

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March 30, 2018

Re: Animal Welfare Assurance
A3875-01 [OLAW Case H]

Ms. Mary Emmons Bergaas
Vice President of Operations
Minneapolis Medical Research Foundation, Inc.
(b) (4) Shapiro Building
914 South Eighth St.
Minneapolis, MN 55404

Dear Ms. Bergaas,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 15, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Minneapolis Medical Research Foundation. According to the information provided, OLAW understands that a previous amendment to an approved protocol to add cricothyrotomy to a terminal surgery on sheep was not included when the protocol was renewed in July 2017. Six more sheep subsequently received the procedure while anesthetized and then euthanized immediately after the cricothyrotomy. It is understood that the animal activity was not funded by the PHS.

Corrective and preventive measures include sending a letter of explanation to the PI. In addition, future use of non-recovery animals for extra procedures should be approved as separate protocols to more accurately track the animal use.

OLAW believes that the corrective and preventative measures put in place by the Minneapolis Medical Research Foundation are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

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

cc: IACUC Contact



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Re: Unapproved animal activities

From: Mary Bergaas IO
Minneapolis Medical Research Foundation
Animal Welfare Assurance D16-00504

Date: March 15, 2018

This letter describes unapproved animal activities that occurred July 2016 through December 2017. The support for this work is department funds and not a federal grant.

An amendment had been approved to a protocol involving non-recovery procedures on anesthetized sheep. The amendment added a single procedure comparing two methods of cricothyrotomy just prior to euthanasia of the sheep. The original protocol was renewed in July of 2017; however, the amendment cricothyrotomy procedures were not included in the renewal.

After the renewal of the protocol was instituted, 6 more cricothyrotomy procedures occurred. All sheep were already anesthetized for the approved procedures from the renewed protocol and euthanized immediately after the cricothyrotomy. No extra sheep were ordered and used. The cricothyrotomy project was complete in December 2017.

In February 2018 these extra procedures were discovered during routine records review. The IO and IACUC leadership were notified and the incident was described to the IACUC at the regularly scheduled March meeting. The violation and future requirement will be explained to the PI via letter.

The committee agreed that any future additions to this protocol that make use of non-recovery animals for extra procedures should be approved as separate protocols rather than amendments. Animals must be transferred to the new protocol number so that tracking of the number of animals is more accurate and transparent.