



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

March 28, 2018

Re: Animal Welfare Assurance
A3292-01 [OLAW Case 1X]

Dr. Mark B. Taubman, M.D.
Dean, School of Medicine
University Vice President for Health Sciences
University of Rochester
601 Elmwood Avenue, Box 706
Rochester, NY 14642

Dear Dr. Taubman,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 21, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Rochester. According to the information provided, OLAW understands that animals were present on a protocol that had expired. The investigator had failed to transfer the animals from the old protocol to a new approved one. No research activities took place under the lapsed protocol.

To prevent a recurrence, the Institutional Animal Care and Use Committee (IACUC) will discourage a change in renewal protocol numbers and the IACUC staff will track animal census as necessary, and verify that no animals remain on a protocol that is ready to expire.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy. Please remember to state whether a noncompliant issue is PHS or NSF supported and provide the relevant grant number(s) if so, and also state the species involved. Thank you for informing OLAW about this matter.

Sincerely,

(b) (6)

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

cc: IACUC Chair

THE UNIVERSITY COMMITTEE ON ANIMAL RESOURCES

TO: Mark Taubman, M.D.
CEO, URM and UR Medicine
Dean, School of Medicine and Dentistry
University Vice President for Health Sciences

FROM: Chris Stodgell, Ph.D.
Chair, University Committee on Animal Resources

DATE: February 21, 2018

SUBJECT: Protocol Lapse

During the February 21, 2018, meeting, the University Committee on Animal Resources discussed an issue of a protocol that lapsed due to both lab PI and UCAR error, as a result, there were animals without an approved protocol.

The lab began the renewal process for the protocol months ahead of time. However, instead of renewing the original protocol which was quite lengthy, the decided to split the protocol into two new protocols. The lab was advised by UCAR that this would be acceptable, however it was their responsibility to maintain the original protocol until all animals were transferred onto the two new protocols.

The first protocol was approved well before the expiration date of the original protocol, but the investigator failed to transfer animals from the original protocol to the new protocol. The second of the two new protocols was returned to the PI with committee questions, but the PI failed to answer the question prior to the expiration of the original protocol. Because of this, there were animals on the PI's census without an approved protocol.

This event identified a "blind-spot" in UCARs monitoring process of animal's census counts for expiring protocols. Because, one of the new protocols was approved, and the other protocol was in review, UCAR did not identify the lapsing protocol as problematic.

To avoid future occurrences of this type, UCAR will actively discourage any change in renewal protocol numbers; if it is requested, the UCAR office staff will take precautions to track the census properly, and re-verify that no animal is still on the expiring protocol prior to its planned lapse.

The lab confirmed that no experimental procedures occurred during the time the protocol lapsed and the animals were transferred to their appropriate new protocols. At no time was the care of the animals interrupted and basic husbandry and health surveillance was maintained.

Copy: [REDACTED] (b) (6)

CS/jz

Mark B. Taubman, MD
CEO, University of Rochester Medical Center and UR Medicine
Dean, School of Medicine and Dentistry
Senior Vice President for Health Sciences



UNIVERSITY of
ROCHESTER
MEDICAL CENTER

MEDICINE of THE HIGHEST ORDER

March 12, 2018

Axel Wolf, M.S., D.V.M.
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
67005 Rockledge Drive – MSC 7982
Bethesda, Maryland 20892 – 7982

REF: Animal Welfare Assurance #D16-00188

Dear Dr. Wolff:

I am attaching a report from the University Committee on Animal Resources about a noncompliance issue.

Please do not hesitate to contact the Chair of the Committee, Dr. Chris Stodgell, if you wish further information. His contact information is: phone number (b) (6) email address is Chris_Stodgell@urmc.rochester.edu

Yours truly,

(b) (6)

Mark B. Taubman, M.D.

Attachment
MT/jz