



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

September 13, 2017

Re: Animal Welfare Assurance
#A3260-01 (OLAW Case Q)

Dr. Christopher A. Roman
Institutional Official
Executive Vice Chair
SUNY Downstate Medical Center
450 Clarkson Avenue, MSC 112
Brooklyn, NY 11203

Dear Dr. Roman,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 30, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the State University of New York Downstate Medical Center, following up on an initial telephone report on August 16, 2017. According to the information provided, OLAW understands that twelve mice were given a medicated diet although this had not been approved by the Institutional Animal Care and Use Committee (IACUC).

The corrective action consisted of amending the protocol and counseling the investigator to obtain IACUC approval prior to conducting animal activities and to consult the veterinary staff for any medical conditions in animals. The primary grantee was notified about the incident.

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.

Sincerely,

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

cc: IACUC Chair



SUNY
DOWNSTATE
Medical Center

University Hospital of Brooklyn
College of Medicine
School of Graduate Studies
School of Public Health
College of Nursing
College of Health Related Professions

Institutional Animal Care and Use Committee

August 30, 2017

Acting Director, Division of Compliance Oversight
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

Animal Welfare Assurance Number: D16-00167(A3260-01)

Dear Dr. Morse,

I'm writing to advise you of a protocol non-compliance. On July 17, 2017, twelve mice were started on a medicated diet to ameliorate their genetically occurring diabetic condition prior to receiving IACUC approval. This is associated with a PHS-funded project through Columbia University, a portion of which has been subcontracted to SUNY Downstate Medical Center. The animal care staff identified the use of the medicated diet within the animal room, the Attending Veterinarian and Office of Animal Welfare (OAW) staff coordinated submission of an amendment with the PI, and the IACUC approved the amendment on July 26, 2017. There was no negative impact on the health or welfare of the animals by providing the medicated diet. The IACUC Chair and Director, OAW met with the PI to review the non-compliance, and the PI will obtain IACUC approval prior to initiating changes in study and contact the veterinary staff to evaluate treatment of medical conditions moving forward. The primary grant awardee institution has been notified of the event and provided information related to the animal costs associated with the period of non-compliance. During the preliminary verbal report of the non-compliance to OLAW, we were advised that the amount of animal-related costs is below the threshold for reimbursement to the NIH. Please let us know if you need additional information on this matter.

Best,

Christopher A. Roman, PhD
Institutional Official

telephone #
telephone #



Initial Report of Noncompliance

By: 

Date: 8/16/17

Time: 1:45

Name of Person reporting: Julie Sharp DVM

Telephone #: 

Fax #: 

Email: 

signature

Name of Institution: SUNY Downstate

Assurance number: A3260

Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): No. See*

What happened? Medicated diet w/o approval to 12 mice.

Species involved: Mice

Personnel involved: Researcher

Dates and times: 7/17/17

Animal deaths: No

Projected plan and schedule for correction/prevention (if known): _____

Protocol amendment approved on 7/26/17

*Columbia U. will be notified

Projected submission to OLAW of final report from Institutional Official:

Soon *Advised not to contact NIH grants due to low \$.

OFFICE USE ONLY

Case # _____