



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

February 4, 2019

Re: Animal Welfare Assurance
A3654-01 [OLAW Case F]

Dr. Yoel Sadovsky
Director
Magee-Women's Research Institute
204 Craft Avenue
Pittsburgh, PA 15213

Dear Dr. Sadovsky,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 1, 2018 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at Magee-Womens Research Institute. According to the information provided, OLAW understands that nonhuman primates on an approved study were not socially housed. Due to miscommunication with the Principal Investigator (PI), the facility manager thought the protocol had a social housing exemption. On a rabbit study by the same PI, there was an approved social housing exemption but the rabbits were to have brief interactions in a pen but this was not done. The rabbits were however housed in pairs. Miscommunication between the PI and facility manager was also contributory.

The corrective actions consisted of the PI meeting with the Attending Veterinarian and Institutional Animal Care and Use Committee chair to establish an appropriate social housing plan for the two studies. The facility manager left the institution and a new individual has been hired.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of these problems. OLAW concurs with the actions taken by the institution to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. In future, please send all final noncompliance reports to olawdco@od.nih.gov. The reports should still be signed by the IO, scanned, and submitted to the electronic mailbox. Also, please indicate whether the study involved was PHS or NSF supported and provide the relevant grant number(s) if so. 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



December 1, 2018

Brent C. Morse, DVM, DACLAM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892

Dear Dr. Morse,

Magee-Womens Research Institute (MWRI), in accordance with Assurance A3654-01 and PHS Policy IV.F.3., provides this report of noncompliance regarding an incident involving failure to social house non-human primates for IACUC protocol titled "A Comprehensive Evaluation of Prolapse Meshes Using a Nonhuman Primate Model" for Principal Investigator, Dr. Pamela Moalli. On July 18, 2018 The IACUC office was notified that non-human primates were not being provided appropriate social housing. In this case there was a miscommunication between the PI and the facility manager, who erroneously believed the NHPs on this protocol had an exemption from social housing. With the assistance of the attending veterinarian, the facility husbandry staff, and Dr. Moalli's staff socialization procedures were immediately put into place. Shortly after this incident it was also determined that another protocol for Dr. Moalli, "Rabbit Model for Sacrocolpopexy Mesh Implantation" also had a noncompliance involving social housing. In this case the rabbits do have a protocol exemption from social housing following surgery but were to receive additional enrichment by being allowed interaction with other rabbits in a pen for 15 minutes a day beginning 14 days after surgery. The additional social enrichment was not being followed as described in the approved protocol but consisted of only pair social housing. The PI and her laboratory assistant met with the attending veterinarian and the IACUC chairperson, and a corrective plan was initiated to address social housing. Importantly, in both cases there was a miscommunication between the PI and the facility manager. The facility manager in this case has since left the institute, and a new facility manager has been hired.

At their meeting on September 26, 2018, the IACUC reviewed both incidents and voted to report both to the Office of Animal Welfare (OLAW). The Magee-Womens Research Institute is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Any questions regarding this report should be directed to the IACUC Chairperson, Robert Powers, PhD.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Yoel Sadovsky, MD
Institutional Official & Executive Officer
Magee-Womens Research Institute