



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

January 22, 2019

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

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, received in our office on January 11, 2019, reporting a noncompliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at the Magee – Womens Research Institute. According to the information provided, OLAW understands that on July 18, 2018 it was determined that non-human primates were not being socially housed per protocol requirements and there was no exemption from social housing in the protocol. On another protocol of the same PI, rabbits were also not being socially housed/enriched as described in the protocol. In both cases, the housing issues were caused by a miscommunication between the PI and the facility manager. The facility manager has since left the institute and a new facility manager has been hired. It was noted that the associated animal research activity was PHS funded.

The corrective action consisted of the Attending Veterinarian, the facility husbandry staff, and the protocol research staff working together to rectify the social housing/enrichment issues.

OLAW believes that the corrective measures by the Magee – Womens Research Institute are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals for institutional self-monitoring and self-reporting. In future reports please identify the approximate number of animals involved and the species of 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
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact



MAGEE-WOMENS RESEARCH INSTITUTE

204 Craft Avenue
Pittsburgh, PA 15213

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 A365401 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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, January 11, 2019 10:44 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: preliminary report

Thank you for this report, (b) (6) Dr. Morse will respond soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: (b) (6)
Sent: Friday, January 11, 2019 9:16 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Re: preliminary report

I sincerely apologize. That letter was supposed to have been sent quite a while go.
Please find the attached report.

Sincerely,

(b) (6)



From: "OLAW Division of Compliance Oversight (NIH/OD)" <olawdco@od.nih.gov>
Date: Thursday, January 10, 2019 at 12:52 PM
To: (b) (6) "OLAW Division of Compliance Oversight (NIH/OD)" <olawdco@od.nih.gov>
Subject: RE: preliminary report

Good afternoon,

OLAW doesn't have a record of receiving a final report for this incident. If one is available, please provide it in an email response to this message. If not, please provide an interim report ASAP. Thank you.

Sincerely, 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: (b) (6)
Sent: Tuesday, July 31, 2018 3:26 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: preliminary report

Name and contact information of person reporting: (b) (6)

Name of institution: Magee-Womens Research Institute

Assurance number (see list of domestic and foreign Assured institutions): A3654-01

Funding component and if contacted (for situations related to PHS-supported activities): National Institutes of Health (NIH)

Brief description of incident (e.g., species, category of personnel involved, dates, times, animal deaths): On July 18, 2018 The IACUC office was notified that non-human primates were not being provided social housing, and the approved IACUC protocol does not require exemption from social housing. The IACUC and attending veterinarian discussed the incident and requested a corrective action plan from the PI.

Plan and schedule for correction and prevention (if known): A socialization plan has been initiated with the assistance of the attending veterinarian, facility husbandry staff and the laboratory staff.

Timeframe for final report from the Institutional Official: Anticipate a final report from the Institutional Official by August 31, 2018

Respectfully,

(b) (6)

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13654-E

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, July 31, 2018 3:48 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: preliminary report

Thank you for this preliminary report (b) (6). We will open a case file and await further information.

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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Respectfully,

(b)(6)



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