



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

July 31, 2019

Re: Animal Welfare Assurance
A3168-01 [OLAW Case O]

Dr. Ping Wang
Chief Scientific Officer
Feinstein Institute for Medical Research
350 Community Drive
Manhasset, NY 11030

Dear Dr. Wang,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 24, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Feinstein Institute for Medical Research. According to the information provided, OLAW understands that a mouse that had undergone surgery was not properly monitored post-operatively as required by the protocol, in part due to an intervening holiday. This animal activity was not supported by funds from the PHS or NSF.

Corrective and preventive actions included reminding the responsible party that arrangements for technical assistance can be made with the CCP if needed. Post-approval monitoring for this protocol was increased and the responsible party retrained. The PI will be included in the email notifications from the CCP. Backup emergency contact phone numbers from study personnel will be included and forms and procedures updated.

The prompt consideration of this matter by the Feinstein Institute for Medical Research was consistent with the philosophy of institutional self-regulation. OLAW concurs that the incident warranted reporting. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident, make corrections, and prevent recurrence. 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
Director, Animal Welfare Office

VIA E-MAIL

July 24, 2019

Dr. Axel Wolff
Director, 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
E-mail: olawdco@mail.nih.gov

PHS Assurance Number: D16-00107 (A3168-01)

Dear Dr. Wolff:

I am writing to inform the Office of Laboratory Animal Welfare of an incident of serious non-compliance that occurred at the Center for Comparative Physiology (CCP) at the Feinstein Institute for Medical Research. While the research in question is not federally funded we are reporting this as non-compliance under the terms and conditions of our federal assurance.

A surgical procedure was performed on mice on 7/2/19. After IACUC investigation, it was determined that post-operative monitoring was not conducted by study personnel in accordance with the approved protocol. Post-operative monitoring was documented for 7/3/19 however it was not conducted on post-op day 2 (7/4/19). While post-operative monitoring was conducted on day 1, the frequency was inconsistent with the protocol. Post-operative monitoring resumed on post-op day 3 and was verified as being conducted in accordance with the protocol.

The responsible party was previously trained, is familiar with program process. This was purely an oversight in arrangements made for back up coverage during the holiday. CCP staff followed all program processes.

Corrective Actions:

1. Program resources are available to mitigate this issue. If study personnel are incapable of providing post-procedural monitoring of animals as described in the protocol and consistent with program guidelines, arrangements can be made with the CCP for technical assistance.
2. Increased post-approval monitoring for this protocol, specifically, post-surgical.
3. Responsible party will undergo retraining to ensure understanding and compliance with the corresponding IACUC protocol, IACUC approved animal care and use guidelines, and in the completion and documentation of records.
4. The Principal Investigator will be included in the email notifications from the CCP. PI bears responsibility of animals under study and should be afforded the opportunity to make alternate arrangements should study personnel fail to meet their assigned responsibilities.
5. Study personnel will be required to include a backup emergency contact with phone numbers on surgical documentation.
6. Revise instructions on all program forms to include the term "holiday", as applicable.
7. Technical request instructions will be revised to ensure consistency throughout every program document, policy, and guideline.
8. If the PI or study teams fails to meet their responsibility to monitor post-operatively, and a CCP staff member identifies this, the CCP will notify the PI and study team via email and call them at phone contact numbers provided. A response deadline will be established. If the study team fails to respond, CCP will conduct the check and the PI will be charged for this service. Consistent with IACUC policy,

July 24, 2019

these incidents will be promptly be reported to the Animal Welfare Office. Repeat incidences may result in an individual's privileges being temporarily or permanently revoked.

Please contact me with any questions or concerns.

Sincerely,

(b) (6)

Ping Wang, MD
Chief Scientific Officer
Institutional Official

cc: Dr. Kathryn Bayne, Chief Executive Officer, AAALAC International, kbayne@aaalac.org; Dr. Max Brenner, IACUC Chairman
mbrenner@northwell.edu; Michelle Aparicio, Director, Animal Welfare Office iacuc@northwell.edu

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, July 24, 2019 3:01 PM
To: Aparicio, Michelle; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Wang, Ping - MD; Brenner, Max; IACUC
Subject: RE: Report to OLAW D16-00107

Thank you for providing this report. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: Aparicio, Michelle [mailto:MAparici@northwell.edu]
Sent: Wednesday, July 24, 2019 2:57 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Wang, Ping - MD <PWang@northwell.edu>; kbayne@aaalac.org; Brenner, Max <MBrenner@northwell.edu>; IACUC <IACUC@northwell.edu>
Subject: Report to OLAW D16-00107

Dear Dr. Wolff,

Attached please find a report of non-compliance including a full explanation of circumstances and actions taken consistent with NOT-OD-05-034.

Please advise if you have any questions or require additional information.

Thank you.

Michelle Aparicio, CPIA
Director, Animal Welfare Office
Institutional Animal Care & Use Committee (IACUC)
Institutional Biosafety Committee (IBC)
Feinstein Institute for Medical Research-Northwell Health
Vice-Chair, PRIM&R CPIA Council (CCPIA®)
125 Community Drive
Great Neck, NY 11021
Tel: (b) (6)
Email: maparici@northwell.edu
IACUC General Email: iacuc@northwell.edu
IBC General Email: ibc@northwell.edu
<http://www.feinsteininstitute.org/>



The information contained in this electronic e-mail transmission and any attachments are intended only for the use of the individual or entity to whom or to which it is addressed, and may contain information that is privileged, confidential and exempt from disclosure under applicable law. If the reader of this communication is not the intended recipient, or the employee or agent responsible for delivering this communication to the intended recipient, you are hereby notified that any dissemination, distribution, copying or disclosure of this communication and any attachment is strictly prohibited. If you have received this transmission in error, please notify the sender immediately by telephone and electronic mail, and delete the original communication and any attachment from any computer, server or other electronic recording or storage device or medium. Receipt by anyone other than the intended recipient is not a waiver of any attorney-client, physician-patient or other privilege.