DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH

FOR EXPRESS MAIL:
Office of Laboratory Animal Welfare
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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

September 21, 2017

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

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 September 19, 2017 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 mice were not monitored for several days following a procedure. Failure to conduct the required monitoring led to a negative impact on animal welfare.

The corrective actions consisted of euthanizing the mice and retraining the laboratory staff on monitoring, humane endpoints, and euthanasia. Animals on a progressive disease study are to be monitored at least daily, observations are to be documented, animal care staff is to notify research staff if animals are identified requiring euthanasia, and if the research staff does not respond the animal care staff will notify the attending veterinarian and euthanize the animals. The protocol was amended to clearly address humane endpoints, early euthanasia, and any clinical manifestations that negatively impact animal welfare.

OLAW understands that the protocol involved was not PHS-supported, but concurs that the incidents were serious and supports the actions taken by the institution. The establishment and application of policies and practices that are consistent with the provisions of the PHS Policy at the Feinstein Institute for Medical Research are commendable and avoid the perception of a double standard. Thank you for informing OLAW about this matter.

Sincerely,

Axel Wolff, M.S., D.V.M.

Deputy Director

Office of Laboratory Animal Welfare

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cc: IACUC Chair

Ping Wang, MD
Chief Scientific Officer
Institutional Official
350 Community Drive

Manhasset, NY 11030

Email: pwang@northwell.edu

Tel: 516-562-3411



VIA E-MAIL

September 19, 2017

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.

On August 30, 2017, NYSDOH Inspector issued a violation (code section 55-1.5A) of a study for failure to monitor animals post-procedurally as necessary to ensure well-being. The affected species were mice. It is estimated animals were not monitored daily for several days. Study lab staff members were immediately notified and discussed the finding with the NYSDOH inspector. Animals were euthanized at the time of the inspection.

Corrective Action:

Lab staff members were retrained by veterinary services supervisor and CCP Director on 9/8/17. Retraining emphasized post-procedural monitoring, study endpoints and when an animal should be euthanized. Observations of a progressive disease model should be at minimum daily and documented. It was further determined if animal facility staff notice an animal is in a state requiring early euthanasia, they will immediately notify study lab personnel. If study personnel do not euthanize animals within 24 hours of said notification, animal facility staff will notify the attending veterinarian and euthanize animals in accordance with the approved protocol.

The corrective action plan was communicated to the Principal Investigator and study personnel verbally by the Director of the CCP on 8/31/17 and 9/8/17. The IACUC convened with a quorum present on September 11, 2017 to discuss this finding and endorsed the corrective action plan. The IACUC Director further communicated in writing to the PI that an amendment to the study must be submitted to clarify criteria to be used to identify moribund or distressed animals requiring early euthanasia and clinical or physiologic alternations that will adversely affect animal health or well-being.

Please contact me with any questions or concerns.

Sincerely,

Ping Wang, MD Chief Scientific Officer Institutional Official

CC:

Secondary individua

Chief Executive Officer, AAALAC International

Wolff, Axel (NIH/OD) [E]

From:

Wolff, Axel (NIH/OD) [E]

Sent:

Thursday, September 21, 2017 9:45 AM

To:

IACUC Member

Subject:

RE: Report to OLAW

Thank you. I'll send the response shortly.

From: IACUC Member [mailto CUC Mem@northwell.edu]

Sent: Thursday, September 21, 2017 9:27 AM

To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>

Subject: RE: Report to OLAW

Good morning Dr. Wolff,

This activity is not federally funded.

Regards, CUC Memb

From: Wolff, Axel (NIH/OD) [E] [mailto:wolffa@od.nih.gov]

Sent: Thursday, September 21, 2017 7:21 AM

To: IACUC Member

Subject: [EXTERNAL] RE: Report to OLAW

External Email. Use Caution.

Thank you for this report, ACUC Membe If this was PHS-supported, please send me the grant number and I'll include it in the case file.

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

From: IACUC Member [mailto CUC Mem@northwell.edu]

Sent: Wednesday, September 20, 2017 2:13 PM To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>

Cc: OLAW Division of Compliance Oversight (NIH/OD) < olawdco@od.nih.gov >; 'kbayne@aaalac.org'

<kbayne@aaalac.org>; Wang, Ping - MD < PWang@northwell.edu>

Subject: Report to OLAW

Dr. Wolff -

It was a pleasure speaking with you yesterday. Thank you for your feedback on this matter.

In follow up to our conversation and in compliance with PHS Policy, IV.F.3, attached find a report I am submitting on behalf of the animal research program at the Feinstein Institute.

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

Thank you.

IACUC Member

Director, IACUC & IBC
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