



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

September 10, 2019

Re: Animal Welfare Assurance
A3079-01 [OLAW Case 3U]

Dr. Dawn A. Bonnell
Vice Provost for Research
University of Pennsylvania
1 College Hall, (b) (4)
Philadelphia, PA 19104-6303

Dear Dr. Bonnell,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 9, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Pennsylvania. According to the information provided, OLAW understands that animal activities were undertaken on a grant which had a restriction in place. Although Institutional Animal Care and Use Committee approval was subsequently obtained, the funding component and OLAW had not been notified and the restriction had not been lifted.

The corrective actions consisted of counseling the Principal Investigator (PI) on following appropriate procedures. The institutional Office of Research Services (ORS) developed a process to flag restricted grant awards in the central system and the Office of Animal Welfare will monitor PI's with animal grant restrictions regarding changes in the protocol. ORS will help PI's update grant applications with restrictions. The institution will work with the funding component regarding expenditures under the restricted award.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

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

cc: IACUC Chair
Director of Animal Welfare



Office of the Vice Provost for Research

September 9, 2019

Axel V. Wolff, MS, DVM
Deputy Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
RKL 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

University of Pennsylvania
A3079-01

Dear Dr. Wolff,

The University of Pennsylvania would like to report an administrative error for grant 5R01AR071340-02 from the National Institute of Arthritis and Musculoskeletal and Skin Diseases. The grant had a restriction on animal subjects research placed on it because at the time of the award, the IACUC protocols were not in place and were not needed at that time. At a later time, the PI submitted and modified IACUC protocols to be consistent with the grant. The IACUC approved a rat protocol 09/10/18 and the PI started a pilot rat study in January 2019, however the PI failed to update OLAW and NIAMS of the IACUC protocol approvals and to request the animal subject restriction be removed. Working with the PI, Penn's Office of Research Services (ORS) has been in communication with the Senior Grant Management Specialist at NIAMS regarding this matter, and Penn's Office of Animal Welfare (OAW) has contacted OLAW. The PI is very sorry about the error and has been counseled on proper procedures.

To prevent such an oversight in the future, Penn's Office of Research Services has developed a flagging process to identify restricted grants in Penn's master grant system. The ORS will share the list of Principal Investigators (PI) with animal subjects grant restrictions with the OAW to monitor the PIs for changes in their IACUC protocols. The ORS office will work with investigators to update grants regarding any restrictions.

The appropriate IACUC approval dates for the rat protocol is 9/10/2018, the swine protocol was initially approved on 10/26/2016 and last modified on 4/20/18. No work has been performed with swine. The OAW has confirmed these protocols are congruent with the grant. UPenn ORS will follow up with NIAMS on correcting any charging issues and restrictions on the grant.

Sincerely yours,
(b) (6)

Dawn Bonnell, PhD
Vice Provost for Research
Trustee Professor of Materials Science and Engineering
Institutional Official

CC: IACUC Chair, University of Pennsylvania
Attending Veterinarian and ULAR Director, University of Pennsylvania
Director of Animal Welfare, University of Pennsylvania

1 College Hall, Suite 118, Philadelphia, PA 19104-6381
Tel 215-898-7236 Fax 215-573-2108 <http://www.upenn.edu/research>

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, September 09, 2019 2:39 PM
To: Reinhard, Gregory R; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: U of Penn Self Reports

Thank you for providing these two reports Dr. Reinhard. We will send official responses soon.

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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From: Reinhard, Gregory R [mailto:reingr@upenn.edu]
Sent: Monday, September 09, 2019 12:14 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: U of Penn Self Reports

Dear OLAW,
Attached please find two self-reports to OLAW regarding an adverse facility event and a documentation oversight by a PI. (Both previously discussed with Axel.)
Please contact me if you any questions.
Regards
Gregory Reinhard

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