



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

October 17, 2019

Re: Animal Welfare Assurance
A3270-01 [OLAW Case 1I]

Dr. Laurie Locascio
Vice President for Research
University of Maryland – College Park
(b) (4) Lee Building – 7809 Regents Drive
College Park, MD 20742

Dear Dr. Locascio,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 3rd, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Maryland, College Park. Your letter supplements the information provided in a preliminary telephone report on May 2nd, 2019. According to the information provided, OLAW understands that a series of non-compliance concerns related to guinea pigs left in a non-housing room for >12 hours post-operatively. These including insufficient water, overcrowding, unapproved and unskilled staff, missing or incorrect animal identification, unapproved source and breeding of animals, lack of evidence that post-operative analgesia was provided, and missing documentation related to surgery, housing, husbandry and housing. These issues were discovered during IACUC inspection of a PI-operated facility on April 3rd and April 23rd. The study was not supported by NIH funding.

Corrective actions by the institution included halting of study and immediate intervention by the Attending Veterinarian (AV) to correct animal health and welfare, suspension of two protocols by the IACUC and removal of unapproved staff. Staff retraining was conducted online via AALAS learning library consisting of 20 varied topics and face-to-face training by DLAR and the AV was conducted on regulations, general animal user training, husbandry, documentation practices, facility operations, protocol-specific concerns and regarding the role and responsibility of the PI. Additionally, the PI hired staff to assist in maintaining the facility and ensuring protocol compliance, all protocols updates (SOP, amendments) were completed, new caging systems purchased and implemented, centralized management and oversight of the facility operations including staff implemented, a permanent facility veterinarian appointed and on-going additional oversight by the Post Approval Monitor coordinator and the AV.

OLAW appreciates the prompt consideration of this matter by University of Maryland, College Park, which is consistent with the philosophy of institutional self-regulation. We understand that the institution additionally noted that USDA will be contacted to report the concern. Based on the information provided and due to the programmatic nature of the concern, a progress report describing ongoing activities as related to the non-compliance resolutions is requested to be included with the OLAW Annual report due January 31, 2020. Please ensure to identify case #A3270-1I in the documentation for ease of reference. We appreciate being informed of this matter and as always, do not hesitate to contact us with any questions or concerns.

Page 2 – Dr. Locascio
October 17, 2019
OLAW Case A3270-11

Sincerely,

(b) (6)

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact

cc: Dr. Robert M. Gibbens, USDA, APHIS, AC



DIVISION OF RESEARCH

OFFICE OF THE VICE PRESIDENT FOR RESEARCH

2133 Lee Building
College Park, Maryland 20742-5125
301.405.4175 TEL 301.405.8386 FAX

October 3, 2019

Dr. Brent Morse, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

RE: Animal Welfare Assurance Number: **D16-00172 (A3270-01)**

Dear Dr. Morse:

The University of Maryland, College Park has finalized an issue that was previously self-reported to OLAW on May 2, 2019. Non-compliances related to the care and use of guinea pigs were noted during the IACUC inspection of a PI-operated facility on April 3rd and further identified during a subsequent unannounced visit by an IACUC subcommittee on April 23rd. No PHS funds supported this work.

Non-compliances

- Items associated with surgical procedures included: Animal left in non-housing room for >12 hours after surgical procedures; no surgical, anesthesia, post-operative records available. No evidence that post-surgical analgesia had been administered.
- Items associated with animal housing included: overcrowding, insufficient water, unapproved/undocumented single housing, lack of enrichment for single housing, incorrect or missing animal identification, husbandry logs, and USDA records; unapproved breeding and animal source.
- Items associated with training: Staff demonstrated incomplete knowledge of pertinent documents and procedures including the protocol, surgical procedures, SOPs, and procedures associated with record keeping. Some personnel participating in animal care had not been approved by the IACUC for work on these animal studies.

Corrective Actions

- All animal activities within this facility were halted and animals transferred to a holding protocol. The Attending Veterinarian took immediate steps to correct issues related to animal health and welfare.
- Two protocols associated with the above non-compliances were suspended via a majority vote of a convened quorum of the IACUC on April 30th.
- All unapproved staff were removed from the rotation, and oversight by the Department of Laboratory Animal Resources (DLAR) was immediately put into place. This oversight remained in place during the entire period of suspension.
- Staff received face-to-face retraining by DLAR staff and the Attending Veterinarian on the following: institutional animal care and use regulations, general animal user training, general husbandry and animal care documentation, and facility operations.

- Face-to-face training was also provided on protocol-specific animal husbandry, surgical procedures, record keeping and post-operative monitoring. The IACUC Administrator provided face-to-face training regarding the roles and responsibilities of the Principal Investigator (PI).
- Online training via the AALAS Learning Library included 20 modules covering the topics above as well as other topics such as aseptic technique, surgical instruments and materials, working with controlled substances, and others. Training on the ethical conduct of research was also provided via an online course offered through the Office of Research Integrity, HHS.
- The Principal Investigator and staff were very cooperative throughout this process, and directly addressed questions from the IACUC.

In addition to near-term corrective actions, the following additional actions have also been taken:

- The PI hired additional staff to assist with managing the facility and ensuring protocol compliance and worked closely with the Attending Veterinarian and DLAR staff to bring all procedures and processes into compliance. All required amendments and updates to the protocol and SOPs have been completed.
- The department has purchased and implemented use of new animal caging. In addition, the department has restructured the oversight of the facility, staff and the care of the animals such that management is more centralized. Finally, the department has appointed a permanent facility veterinarian to oversee the care and use of all animals for the unit.
- The Post Approval Monitoring coordinator and Attending Veterinarian are providing ongoing additional oversight, to ensure that any issues that arise are dealt with promptly and appropriately.

On June 20, 2019, after careful consideration of corrective actions completed, and at a convened meeting of the IACUC, a majority of the quorum present voted to reinstate the two protocols associated with the non-compliances above. Ongoing post-reinstatement monitoring is in place via the Post-approval monitor, Attending Veterinarian and other DLAR staff.

Sincerely,

(b) (6)

Laurie E. Locascio
Vice President for Research
and Institutional Official

cc:

(b) (6)

Catherine Carr, Chair, Institutional Animal Care and Use Committee
Shannon Stutler, University Attending Veterinarian

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, October 3, 2019 1:56 PM
To: Pamela Jean Lanford
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: UMD finalized report

Thank you for this report, Dr. Lanford. Dr. Morse will send a response shortly.

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

From: Pamela Jean Lanford <planford@umd.edu>
Sent: Thursday, October 3, 2019 1:51 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Laurie Locascio <lcl@umd.edu>; (b) (6) Catherine Carr <cecarr@umd.edu>; Shannon A. Stutler <sstutler@umd.edu>; (b) (6)
Subject: Re: UMD finalized report

Dear Dr. Morse,

Please find attached a letter from the University of Maryland, College Park Institutional Official, Dr. Laurie Locascio, finalizing an animal care issue previously self-reported to the Office of Laboratory Animal Welfare on May 2nd, 2019.

Please let us know if you have questions or concerns.

Sincerely,

Pam Lanford

Pamela Lanford MS, PhD, CPIA
Director of Animal Research Support & Administrator, IACUC
Chair, University Senate
(b) (4) A James Clark Hall
8278 Paint Branch Drive
University of Maryland
College Park, MD 20742
t: (b) (6)
pronouns: she/her



Initial Report of Noncompliance

By: gmDate: 5/2/19Time: 1:10Name of Person reporting: Pam Lanford, PhDTelephone #: (b) (6)Fax #: (b) (6)Email: (b) (6)Name of Institution: U. MD-College ParkAssurance number: A3270Did incident involve PHS funded activity? No

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? 2 protocols suspended on 4/30/19 due to:

animal care issues; post-op care & monitoring issues; surgical records; Housing & husbandry issues.

Species involved: G.P.Personnel involved: Researcher including E.E. issues.Dates and times: 4/30/19Animal deaths: No

Projected plan and schedule for correction/prevention (if known): _____

Will notify USDA

Projected submission to OLAW of final report from Institutional Official: _____

OFFICE USE ONLY

Case # _____