



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive B MSC 7982
Bethesda, Maryland 20892-7982
Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

February 25, 2019

Re: Animal Welfare Assurance
#A4309-01 (OLAW Case D)

Dr. Joel W. Martin
Provost and Dean of the Faculty
Franklin and Marshall College
Post Office Box 3003
Lancaster, PA 17604

Dear Dr. Martin,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your February 19, 2019 letter reporting a serious deviation from the provisions of the *Guide for the Care and Use of Laboratory Animals* at Franklin & Marshall College, following up on an initial telephone report on December 21, 2018. According to the information provided, OLAW understands that mouse cages were frequently overcrowded due to significantly delayed weaning of pups.

The corrective actions consisted of retraining the Principal Investigator on colony management, amending the protocol to include a detailed description of the weaning procedures and cage density, having the PI provide monthly updates on the breeding colony to the Institutional Animal Care and Use Committee (IACUC), having the animal care staff report noncompliance to the IACUC and Attending Veterinarian, and developing institutional policies addressing mouse breeding colony management and housing densities. The PI subsequently chose to disband the breeding colony, the mice were transferred to a holding protocol, and then were euthanized.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy on Humane Care and Use of Laboratory Animals. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

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

cc: IACUC Contact

FRANKLIN & MARSHALL COLLEGE

February 19, 2019

Axel Wolff, DVM
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. Wolff:

Franklin & Marshall College, in accordance with Assurance D16-00661 (A4309-01) and PHS Policy IV.F.3, provides this report of an incident of noncompliance regarding mouse colony management under the IACUC-approved protocol 57N(CODAS) "A mouse model of CODAS syndrome." The research covered by this protocol is not federally funded and the noncompliance does not impact any federally funded work. Dr. Marcus W. Thomsen, Associated Dean of the Faculty and Chair of our IACUC, initially informed me as the Institutional Official of this matter on or shortly after December 3, 2018. This noncompliance was first reported to OLAW by Dr. Thomsen on December 21, 2018 by telephone. Subsequent to this first notification Dr. Thomsen reported the progress on resolving this matter to you on February 5, 2019 by telephone.

On December 3, 2018 an employee of the College reported mouse management practices that may have resulted in issues of noncompliance under the protocol noted above. The initial communication was done by email to the Chair of the IACUC, and he confirmed this information with the employee by telephone between December 4 and December 11. The specific concerns were related to late weaning of mouse pups and overcrowding in cages.

On December 12, 2018, when the IACUC was informed of this situation, the Committee determined that more information was required and directed Dr. Thomsen and Dr. Tiffany Whitcomb, the Attending Veterinarian (AV), to conduct an inquiry.

The employee who had made the initial report provided additional detailed statements in writing on January 1, 2019 to the IACUC chair, who in turn shared them with AV. On January 11, the IACUC chair and the AV interviewed the employee about the details of late weaning and overcrowding.

On January 16 the IACUC chair and the AV interviewed the vivarium staff members about the late weaning and overcrowding. They also conducted an inspection of the facility where the mice on protocol 57N were housed.

Between January 17 and January 18 the PI was invited three times to meet with the IACUC chair and the AV to discuss these issues of noncompliance so that the PI might provide relevant information. The PI declined all three invitations.

At its January 21 meeting the IACUC considered the information from the inquiry and unanimously determined that the PI was in noncompliance by weaning pups at ages significantly past the ages given in the protocol and by housing mice at a density greater than what was described in the protocol and at a density inconsistent with best practices in the *Guide*. The IACUC put forth the following corrective actions for the PI:

- a) The PI will receive re-training for colony management, regulations pertaining to animal welfare and non-compliance, and the expectations for mouse colony management outlined in *the Guide*.
- b) The PI must amend the animal care and use protocols involving mice to provide: 1) A description of the weaning process including weaning date, and a scientific justification for delayed weaning (28 days) if there is a need to do so, 2) the maximum number of mice per cage that matches the performance standards provided by the cage manufacturer and complies with *the Guide*, including the maximum number of litters allowed per cage and a description of the breeding strategy (pairs vs. trios, intensive vs. non-intensive) and a justification for the strategy.
- c) The PI will provide the IACUC a monthly report of the breeding colony that clearly illustrates that weaning has been performed according to the protocol, that mice are housed at densities that comply with the amended protocol, and that sick animals are being cared for in a timely fashion (within 1 business day of notification). These monthly reports will continue until the IACUC can demonstrate to OLAW that the PI is capable of managing the colony in a manner consistent with the protocol and *the Guide*, with a minimum of 6 months.
- d) The animal care staff will report any non-compliance (delayed weans, overcrowded cages, sick animals not attended to within 2 business days) directly to the IACUC through the chair and the Attending Veterinarian (AV).
- e) A team of stakeholders (PIs, AV, clinical veterinarian, animal care staff) will work together to develop Policies and/or SOPs for mouse breeding colony management and housing densities. These documents should be presented to the IACUC no later than the May 2019 IACUC meeting and should address all matters related to these non-compliance events.

In my role as the IO, I was informed verbally of the IACUC decision on January 22 and was given the reviewed and approved meeting minutes on January 24.

On January 28 the PI was invited to have a conversation with Dr. Thomsen, Chair of the IACUC, and Dr. Whitcomb, the AV, in order to review the issues of noncompliance and the outlined corrective actions. The PI declined the invitation for a conversation pending the PI's receipt of a written summary. Dr. Thomsen sent the PI a written summary on January 31. The PI responded on the same date that he would be closing his mouse colonies on February 14, 2019.

The members of the IACUC and I were informed of the PI's decision by email from the Chair of the IACUC.

The PI's mouse colonies were transferred to the Vivarium's holding protocols on February 12. Subsequently the mice were euthanized as per the holding protocol.

Franklin & Marshall College is committed to upholding guidelines and procedures to protect the welfare of animals used in research and teaching conducted by our faculty, professional staff and students. The assistance provided by you in handling this matter was greatly appreciated. If you have any questions regarding this report, please contact Marcus W. Thomsen, Ph.D., Associate Dean of the Faculty and Chair of the F&M College IACUC (marcus.thomsen@fandm.edu or (b) (6)).

Sincerely,

(b) (6)


Joel W. Martin, Ph.D.
Institutional Official
Provost and Dean of the Faculty

cc: M. Thomsen

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, February 20, 2019 10:20 AM
To: Marcus W. Thomsen; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Reporting Noncompliance Incident

Follow Up Flag: Follow up
Flag Status: Flagged

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

Best regards, Brent Morse

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

From: Marcus W. Thomsen <marcus.thomsen@fandm.edu>
Sent: Wednesday, February 20, 2019 9:47 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Reporting Noncompliance Incident

Dear Dr. Wolff,

A report of an incident of noncompliance from Franklin & Marshall College is attached.

If you have difficulty downloading or reading the file, please let me know.

Sincerely
Marcus W. Thomsen
Chair of the IACUC

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Marcus W. Thomsen, Ph.D.
Associate Dean of the Faculty
Office of the Provost
Franklin & Marshall College

**Initial Report of Noncompliance**By: *aw*Date: *12/21/18*Time: *9:25*Name of Person reporting: *MARCUS Thompson*Telephone #: (b) (6)

Fax#:

Email:

Name of Institution: *FRANKLIN + Marshall College*Assurance number: *A4309*Did incident involve PHS funded activity? *NO*

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

*Mice overcrowded due to late weaning*Species involved: *Mice*

Personnel involved:

Dates and times:

Animal deaths: *no*

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

*Counsel PI**PI will stop breeding colony, update SOPs*

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____