



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 – 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

December 18, 2017

Re: Animal Welfare Assurance  
#A4309-01 (OLAW Case C]

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 December 15, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Franklin & Marshall College, following up on an initial telephone report on October 24, 2017. According to the information provided, OLAW understands that animal activities continued after the annual renewal date had lapsed and there was no approval by the Institutional Animal Care and Use Committee (IACUC). Specifically, twenty four mice were subjected to genotyping or euthanasia and tissue harvest. The Animal Welfare Assurance describes the use of annual protocol review and approval.

The immediate action taken upon discovery consisted of stopping additional animal activities. A new protocol was submitted by the Principal Investigator (PI) and approved by the IACUC. The activity was not PHS-supported and the PI was allowed to use the data. The IACUC amended the language in the PI renewal notices to clearly indicate the three annual renewal dates, PIs will be reminded of the anniversary dates at one and two months prior to expiration, all PIs have been notified about these changes, and the PI involved was asked to provide information on prevention of the incident to the IACUC.

Based on its assessment of these explanations, 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 and suggests that the committee consider amending the Assurance to have a *de novo* review at the three year date with continuing review being conducted at appropriate intervals as determined by the IACUC. Although the protocol in question was not PHS-supported, there could still be complications in submitting to a journal, data acquired without an active protocol in place. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

Signature

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

cc: IACUC Contact

A4309-01

# FRANKLIN & MARSHALL COLLEGE

December 15, 2017

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 A4309-01 and PHS Policy IV.F.3, provides this report of noncompliance regarding an incident of research procedures that were conducted after an IACUC-approved protocol for "Functional studies of rare alleles associated with inherited disorders of the nervous system" had lapsed; i.e., the PI failed to renew the protocol prior to the second annual renewal date of March 30, 2017. Dr. Marcus W. Thomsen, Associated Dean of the Faculty and Chair of our IACUC, initially informed me of this matter on October 12, 2017. This incident was first reported to OLAW ([olawdco@mail.nih.gov](mailto:olawdco@mail.nih.gov)) by Dr. Thomsen on October 17, 2017 by email. Subsequent to this notification Dr. Thomsen reported the incident to you on October 18, 2017 and to Dr. Brent Morse, OLAW, on or about October 23, 2017 through telephone calls.

On October 11, 2017 the PI reported that his protocol for "Functional studies of rare alleles associated with inherited disorders of the nervous system" had lapsed because he had not submitted a renewal request to the IACUC before the protocol's second anniversary date, which was March 30. (Thus, the protocol had lapsed more than six months before the PI's report to the IACUC.) Associate Dean Thomsen, Chair of IACUC, asked the PI to voluntarily stop any research activities associated with the protocol, and the PI responded that he had already done so.

Upon the request of Associate Dean Thomsen the PI provided the following information about related research activity in his laboratory. Between March 30, 2017 and October 11, 2017 twenty-four mice were used for this study after the lapse in protocol. Six of the 24 mice were either ear-punched or tail-biopsied for genotyping following the procedures approved under the lapsed protocol at or under p21 (post-natal day 21), returned to their cages with their mother until they were weaned (p21-28), and then used for research. The remaining 18 mice were either

genotyped prior to 3/30/17 or at the time of use after they were sacrificed as described in the next sentence. All 24 of the mice were anesthetized and sacrificed according to the SOP associated with the approved mouse protocols to harvest whole brains for histological staining and protein biochemistry as approved under the lapsed protocol. The only person who handled these 24 mice for research activities after the lapse of protocol was the PI. The College's Vivarium staff handled the mice for the purpose of routine care.

The College's Animal Welfare Assurance statement on file with OLAW indicates that all protocols are subject to annual review and approval. If an annual report with a request for renewal is not received prior to the anniversary date of a protocol, then it automatically lapses, and as a result the PI would need to submit a *de novo* protocol to continue the same research. Because research activity was conducted after the associated protocol had lapsed, a condition of noncompliance existed.

The IACUC discussed this incident at its November 8, 2017 meeting and then completed its discussion on December 13, 2017.

All researchers at the College, who use animals, including the PI involved with this incident, are informed through IACUC documents and email notifications of the procedures associated with annual reviews and renewal of protocols. All PIs (faculty and professional staff) have experience with submission of new protocols, annual renewals and amendments through our IACUC. When a new protocol is approved or when one is renewed on an annual basis the communication to the PI includes the anniversary date, the requirement to renew annually and the consequences if a protocol is allowed to lapse. The PIs are also reminded in that same communication about the expiration date of the protocol; i.e., the 3-year anniversary as per PHS requirements. Nonetheless, this PI, who noted that ultimately it was his responsibility to have completed this renewal in a timely manner, contended that he received insufficient information or reminders about due dates for this protocol. Given the PI's assertions the IACUC acknowledges that matters of communication with the PI may have contributed to the lapse of this protocol.

The following corrective actions, which have been discussed by the IACUC, have been completed or are in progress:

- 1) Immediate resolution of the problematic situation for this PI who wished to continue research with this protocol was handled by submission of a *de novo* protocol which was subsequently approved using standard procedures of the IACUC. The *de novo* protocol was approved on October 23, 2017.
- 2) Because this research was not federally funded the IACUC concluded that the PI could use the data from the 24 mice used after the lapse of the protocol. In part this decision was made to be consistent with the "Three Rs" approach to the use of animals in research. The PI has been informed that he may use the data with a reminder that conducting research without an active protocol is a violation of our assurance on file with OLAW that such violations could have repercussions for the institution. Also, the communication from IACUC noted

that future noncompliance incidents by the PI could result in a much different response by IACUC.

- 3) In order to address general issues related to possible deficiencies in communications with PIs the language in the approval notifications for new protocols and renewals will be amended to more clearly highlight the 1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup> anniversary dates. The email communication will include "hot links" so that a PI can readily incorporate the dates on their own Google calendar, which is a standard online application at the College.
- 4) A courtesy reminder system for PIs is being initiated using a dedicated Google calendar account so that a PI will receive reminders 30 day and 60 days in advance of an anniversary date.
- 5) The IACUC will communicate to the PI involved with this incident and all other PIs who use animals in their research or teaching about these changes in the method for communication regarding anniversary dates, reminders and renewals.
- 6) The PI involved has been asked to consider changes he might make to avoid future incidents and communicate them to the IACUC.

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 and Dr. Morris 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](mailto:marcus.thomsen@fandm.edu) or [Phone Number]).

Sincerely,

Signature

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

cc: M. Thomsen

**Gopee, Neera (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, December 15, 2017 4:43 PM  
**To:** Marcus W. Thomsen; OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Reporting Noncompliance Incident

Thank you for this final report Dr. Thomsen. We will send an official response soon.

Best Regards,  
Neera

Neera V. Gopee, DVM, PhD, DACLAM, DABT  
Veterinary Medical Officer  
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:** Marcus W. Thomsen [mailto:marcus.thomsen@fandm.edu]  
**Sent:** Friday, December 15, 2017 4:32 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** Reporting Noncompliance Incident

Dear Dr. Wolff,

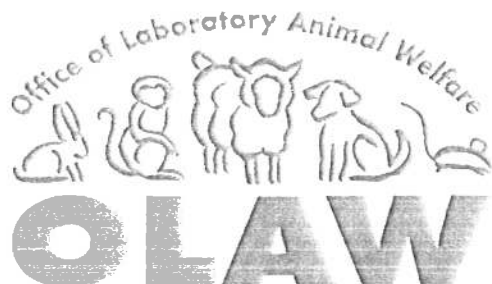
A report of noncompliance from Franklin & Marshall College is attached.

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

Sincerely,  
Marcus W. Thomsen

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



## Initial Report of Noncompliance

By: *aw*Date: *10/24/17*Time: *10:00*Name of Person reporting: *MARKUS THOMPSON*

Telephone #:

Phone Number

Fax #:

Email:

Name of Institution: *Franklin + Marshall College*Assurance number: *A4309*Did incident involve PHS funded activity? *Yes*

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

*Annual continuing review not completed, work done  
w/ out approval*

Species involved: *Mice*

Personnel involved:

Dates and times:

Animal deaths:

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

*Send reminders to PI's, use holding protocol,  
maybe change assurance to 3 year approval not annual*

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # \_\_\_\_\_