



DEPARTMENT OF HEALTH & HUMAN SERVICES
HEALTH

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare
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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

October 10, 2017

Re: Animal Welfare Assurance
#A4300-01 [OLAW Case E]

Dr. Peter Marks
Director, Center for Biologics and Research
FDA - Center for Biologics Evaluation & Research
10903 New Hampshire Avenue, Bldg. 71
Silver Spring, MD 20993

Dear Dr. Marks,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 27, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the FDA White Oak Consolidated Animal Program. According to the information provided, OLAW understands that 28 mice were subjected to blood draws after the approved protocol had expired. Work continued for ten days following expiration. The Principal Investigator (PI) on the protocol was unaware of the animal activity and the investigator responsible was not notified about the expiration.

The corrective actions consisted of stopping the animal activities and transferring the mice to a holding protocol. At the three year renewal, a new PI was designated who is more directly involved in the work. Notifications to PIs regarding protocol expiration will now include the number of animals remaining, the Institutional Animal Care and Use Committee (IACUC) chair and vice chair will be copied on these notifications, and if PIs do not respond the IACUC administrator will contact them by telephone.

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.

Sincerely,

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

cc: IACUC Chair



**White Oak Consolidated
Animal Program**

Food and Drug Administration
10903 New Hampshire Ave. Bldg 71
Silver Spring, MD 20993

Date: September 27, 2017

From: (b) (6) DVM, Ph.D., Chairperson
White Oak Consolidated IACUC

(b) (6)

Through: Peter Marks, MD, Ph.D., Institutional Official

Peter W. Marks -S

Digitally signed by Peter W. Marks -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA,
ou=People, cn=Peter W. Marks -S,
0.9.2342.19200300.100.1.1=2000932716
Date: 2017.09.28 10:45:01 -04'00'

Subject: Incident Report

To: Axel V. Wolff, MS, DVM, Director, Division of Compliance Oversight, OLAW, NIH

Incident Details:

A protocol expired on Sept 9, 2017 with active experimental animals and studies ongoing. Work continued until Sept 19, at which time all animals were transferred to the facility animal holding protocol and experimental work was halted. The work that occurred from the time of expiration to transfer consisted of small blood draws of 20ul from 28 mice on Sept 11, 13, 15 and 18.

Corrective and Follow-up actions:

1. As soon as it was recognized that the protocol expired, all animals were transferred to the facility holding protocol and work was halted.
2. An investigation occurred to determine how the protocol could expire with experimental animals present and studies ongoing. It was determined that the PI listed in the protocol was not directly involved with the studies and was unaware there were studies ongoing. The lead investigator did not receive communications related to the impending expiration.
3. As part of the three-year renewal that was submitted, the PI has been changed to someone more directly involved in the research. This renewal is being processed via designated member review to expedite the approval process and return all animals to an active protocol.
4. Procedures for notification of PI's regarding protocol expiration have been revised to provide investigators with information on the number of animals on the protocol with the three-year renewal reminder. In addition, the committee Chair and Vice-Chair will be copied on notifications sent to PIs for protocols close to expiring and with animals present if a renewal had not been submitted at the last IACUC meeting prior to expiration. The IACUC Administrator will also contact PI's via phone if they have not responded to email correspondence.

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, September 28, 2017 3:05 PM
To: WO AP IACUC; OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6) FDA/CDER); Dennis, John (FDA/CBER); Marks, Peter (FDA/CBER)
Subject: RE: Incident Report for FDA White Oak Consolidated Animal Program Assurance A4300-01

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

Regards, Brent Morse

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

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From: WO AP IACUC [mailto:WOAPIACUC@fda.hhs.gov]
Sent: Thursday, September 28, 2017 11:11 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) (FDA/CDER) (b) (6) @fda.hhs.gov; Dennis, John (FDA/CBER) <John.Dennis@fda.hhs.gov>; Marks, Peter (FDA/CBER) <Peter.Marks@fda.hhs.gov>
Subject: Incident Report for FDA White Oak Consolidated Animal Program Assurance A4300-01

The White Oak Consolidated (WOC) Animal Program and IACUC, is self-reporting a non-compliance incident and corrective action plan for Animal Welfare Assurance A4300-01. Please review the attached Incident Report.

Please contact Dr. John Dennis, (b) (6) or Dr. (b) (6), if you have any questions.

Thank you,

(b) (6)

WOC IACUC Administrator
 Division of Veterinary Services

(b) (6)