



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) 480-3387

November 16, 2021

Re: Animal Welfare Assurance
A3196-01 [OLAW Case 6N]

Dr. Roger M. Wakimoto
Vice Chancellor for Research
University of California, Los Angeles
(b) (4) Murphy Hall - 104501
Los Angeles, CA 90024-1405

Dear Dr. Wakimoto,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 9, 2021 letter reporting an adverse event that occurred within the animal care and use program at the University of California - Los Angeles. A preliminary report was provided via phone call to this office on September 9, 2021. According to the information provided, OLAW understands that on September 1, 2021, your Animal Research Committee (ARC) was notified that survival surgical procedures were performed on rats that day. Upon review of the ARC protocol database, it was noted that the protocol under which the surgeries were performed was closed by the Principal Investigator (PI) on August 7, 2020. The lab members were instructed to cease conducting further surgeries. In addition, a failure to administer post-operative analgesia as described in the protocol was also noted and one of the surgeons was not listed as personnel on the protocol. A data transfer problem between the ARC and DLAM online systems failed to close the protocol in the DLAM system after the early closure (i.e., prior to the triennial review date) in the ARC system. This allowed rats to be ordered. This data transfer problem has since been corrected and, as a safeguard, a separate communication is sent to DLAM by the ARC administrative staff when early closure of a protocol is requested. The activity was PHS-funded.

The PI had inadvertently closed the wrong protocol in August 2020; consequently, the lab team continued performing experiments described in the protocol in question for 13 months before the mistake was identified. The PI reported performing surgeries (lung and artery incision) on a total of nine rats, subcutaneous implantation on approximately ten rats, and liver bleeding experiments on nine rats since the August 7, 2020 closure. These experiments were related to two NIH grants. The PI did not have ARC approval for these experiments under another protocol. Regarding the departure from the approved post-operative analgesic regimen, the PI assured the ARC that all research personnel will read and follow procedures written in the approved protocol going forward. The lab will maintain printed copies of protocols for easy access and review. Finally, the PI provided assurance that she would monitor every experiment performed in the animal facility to avoid any issues in the future. The PI was required to submit a new protocol to cover work described in her NIH grants. That protocol was approved on October 25, 2021.

Based on the information provided, OLAW is satisfied that the proposed corrective and preventive actions to be taken by the University of California - Los Angeles would be expected to prevent a recurrence of this incident. OLAW concurs that this issue warranted reporting. **Please be advised** that it is your institution's responsibility to report this incident to the Chief Grants Management Officer of the funding component(s) to make sure that no expenses related to these noncompliant activities are charged to the grant(s). We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C.
Morse -S

Date: 2021.11.16 10:06:41 -05'00'

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact

November 9, 2021

Brent Morse, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

RE: Final Report of an Incident of Noncompliance
Animal Welfare Assurance A3196-01

Dear Dr. Morse:

I am writing to provide you with a final report of an incident of noncompliance that involved non-USDA covered species (rats) and was initially called in to OLAW on September 9, 2021. The grants associated with this noncompliance are HL140618 and EB023052.

On September 1, 2021, a Division of Laboratory Animal Medicine (DLAM) veterinarian contacted the Chancellor's Animal Research Committee (ARC) administrative staff about survival surgical procedures performed on rats that day. The veterinarian had questions about the surgeons and post-operative analgesic regimen. Upon review of the ARC protocol database, it was noted that the protocol under which the surgeries were performed was closed by the Principal Investigator (PI) on August 7, 2020. With this information, DLAM instructed the lab members to cease conducting further surgeries and submitted their concerns to the ARC. In addition to noting performance of surgeries without ARC approval, the veterinarian identified a failure to administer post-operative analgesia as described in the protocol, and reported that one of the surgeons was not listed as personnel on the protocol.

In initial communications with the PI, it was unclear how personnel were able to order rats under the closed protocol. Subsequent inquiry identified a data transfer problem between the ARC and DLAM online systems that failed to close the protocol in the DLAM system after the early closure (i.e., prior to the triennial review date) in the ARC system. This data transfer problem has since been corrected and, as a safeguard, a separate communication is sent to DLAM by the ARC administrative staff when early closure of a protocol is requested.

When questioned about the closure, the PI identified that she had inadvertently closed the wrong protocol in August 2020; consequently, her team continued performing experiments described in the protocol in question for 13 months before the mistake was identified. The data transfer problem noted above prevented earlier identification of the error. The PI reported performing surgeries (lung and artery incision) on a total of nine rats, subcutaneous implantation on approximately ten rats, and liver bleeding experiments on nine rats since the August 7, 2020 closure. These experiments were related to the two grants identified above. The PI did not have ARC approval for these experiments under another protocol.

The ARC discussed this incident, along with the PI's initial response, at a meeting on September 13, 2021; on October 11, 2021, the ARC discussed additional information provided by the PI in response to an inquiry sent after the September 13, 2021 meeting. The ARC had requested information regarding the involvement of the unapproved surgeon and the failure to follow the approved post-operative analgesic regimen. The PI had been traveling in September 2021 and reported that the surgeries on September 1 were to have been conducted by an individual listed on the protocol; that individual had an emergency related to clinical duties and asked his fellow, who had completed all ARC-required training to perform survival surgeries with rats, to conduct the procedure on his behalf. The PI has since counseled research personnel that only personnel approved by the ARC can work on any given ARC protocol. She further created a form that personnel are required to complete prior to conducting any in vivo experiments in order to ensure all steps and policies are followed correctly. Regarding the departure from the approved post-operative analgesic regimen, the PI assured the ARC that all research personnel will read and follow procedures written in the approved protocol going forward. The lab will maintain printed copies of protocols for easy access and review. Finally, the PI provided her assurance that she would monitor every experiment performed in the animal facility to avoid any issues in the future.

The action plans the PI proposed to prevent recurrence of both issues were found by the ARC to be detailed and appropriate. Due to the lengthy closure and constraints of the ARC online system, the PI was required to submit a new protocol to cover work described in her NIH grants; that protocol was approved on October 25, 2021. With no further questions, the ARC determined that the noncompliance had been addressed and considers the matter closed.

At UCLA, the ARC is responsible for overseeing an animal program involving approximately 950 protocols for over 400 different PIs. Despite the complex nature of this program, we are proud to report that incidents of noncompliance are infrequent. When such incidents do transpire, they are investigated promptly and corrective actions are implemented, including education and retraining as appropriate.

If you have any questions or concerns, please contact the Director – Research Safety & Animal Welfare at (b) (6)

Report to OLAW: A3196-01

Sincerely,

(b) (6)

Roger M. Wakimoto
Vice Chancellor for Research and Creative Activities

cc: AAALAC
ARC Chair
Associate Vice Chancellor for Research
Director – Office of Contract and Grant Administration
Director – Research Safety & Animal Welfare
DLAM Executive Director and Attending Veterinarian
Interim Executive Vice Chancellor and Provost

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, November 12, 2021 8:13 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final Report of an Incident of Noncompliance (A3196-01)

Thank you for this report, (b) (6). We will send a response soon.

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

From: (b) (6)
Sent: Tuesday, November 9, 2021 7:32 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: AAALAC International <accredit@AAALAC.org>; (b) (6)
(b) (6)

Subject: Final Report of an Incident of Noncompliance (A3196-01)

Dear Dr. Morse,

Please see the attached final report of noncompliance regarding an incident initially called in to OLAW on September 9, 2021. Please do not hesitate to contact me if you have any questions.

Best, (b) (6)



Initial Report of Noncompliance

By: BCM

Date: 9/9/2021

Time: 11:19

Name of Person reporting: (b) (6)
Telephone #: (b) (6)
Fax #:
Email:

Name of Institution: UCLA
Assurance number: A3196

Did incident involve PHS funded activity? maybe
Funding component:
Was funding component contacted (if necessary):

What happened?

PI may have conducted surgeries on rats on a NIH funded protocol that had been closed in August 2020.

Species involved: rats
Personnel involved: PI
Dates and times: ??
Animal deaths: ??

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

IACUC is investigating if surgeries were indeed related to the NIH-funded, closed protocol.

Projected submission to OLAW of final report from Institutional Official:

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Case #