



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
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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

October 25, 2021

Re: Animal Welfare Assurance  
A3612-01 [OLAW Case 10]

Dr. Oliver Garden  
Dean, School of Veterinary Medicine  
Louisiana State University  
Skip Bertman Drive  
Baton Rouge, LA 70803-3103

Dear Dr. Garden,

The Office of Laboratory Animal Welfare (OLAW) acknowledges your October 13, 2021 letter reporting three instances of noncompliance with the Public Health Policy on Humane Care and Use of Laboratory Animals (Policy) at Louisiana State University. According to the information provided, it is understood that for the first incident the Principal Investigator (PI) was notified via email in April and May 2021 that the approved animal care and use protocol would expire June 26, 2021. The PI had ample time to submit a new protocol for review and approval prior to protocol expiration. The PI responded to the May email, stating that the animals would be euthanized before the expiration date. On July 22, 2021, the vivarium manager notified the IACUC that there were six (6) mice left on the project upon protocol expiration. The mice were transferred to the approved DLAM holding protocol while the matter was investigated. On July 26, 2021, the PI was instructed to discontinue all animal use effective immediately. The PI was also instructed to provide a written explanation explaining why she allowed the protocol to expire with remaining animals, and to include assurance that an incident of this nature would not reoccur. The PI responded on Monday, July 26, 2021, stating that the project was no longer active, so a new protocol was not needed. The PI did not expect to have any animals remaining on the protocol and confirmed that she understood animals must be on a protocol at all times. The PI consented to euthanasia of the remaining mice, as described in the expired protocol. The IACUC met on August 11, 2021 and discussed this issue. The IACUC accepted the PI's explanation and decided no further action was required at this time.

Non-compliant incident 2:

The PI was notified on May 14, 2021 that his protocol would expire on June 26, 2021. Eighty-one (81) mice remained on the project upon protocol expiration. The animals were transferred to the approved DLAM holding protocol while the matter was investigated. On August 5, 2021, the PI was instructed to discontinue all animal use effective the expiration date. The PI was also instructed to provide a written explanation of why he allowed this protocol to expire with animals remaining in the vivarium, and to include a written assurance that an incident of this nature would not reoccur.

On Monday, August 9, 2021, the PI responded, and stated that he was aware of the protocol expiration date and did submit a protocol to replace the expiring one. This protocol was reviewed during the June 17, 2021, IACUC meeting. The PI addressed the modifications required for approval by the IACUC, and believed that in doing so, the revised protocol had been submitted for final review through the new online protocol submission system implemented in February 2021. That is, the PI did not realize that the protocol did not submit to the IACUC.

He also did not follow-up with the protocol participants to ensure they completed the mandatory requirement of enrolling in the university's Occupational Health & Safety Program (OHSP) and understood protocol approval was dependent on this requirement being met. The PI indicated he assumed responsibility and would make sure to learn how to use the new online system, he would follow up with the IACUC office to confirm his submission was received, follow-up with protocol participants to ensure they complete the mandatory OHSP enrollment requirement timely, and he would mark the protocol expiration dates on his calendar. The IACUC met on August 11, 2021 and discussed this issue. The IACUC accepted the PI's explanation and decided no further action was required at this time.

Non-compliant incident 3:

On August 5, 2021, the vivarium manager notified the DLAM Associate Director and Chief Clinical Veterinarian that the approved number of mice on a particular protocol was exceeded by 32, due to the number of pups born the month prior. The PI was immediately notified, and the mice were transferred to the approved DLAM holding protocol while the matter was investigated. The PI was instructed to provide a written explanation of why the number of mice approved on the protocol had been exceeded, along with a plan to rectify, and assurance that this non-compliance would not reoccur. The IACUC also instructed the PI to discontinue mouse breeding until the approved protocol was amended or replaced. The PI promptly responded on August 6, 2021, and indicated he was aware of potential overuse of the animals, and to avoid non-compliance he had submitted a new animal care and use protocol in June. This protocol had been reviewed during the June 17, 2021, IACUC meeting. The PI addressed the IACUC's required modifications for approval and was under the impression that the revised protocol had been submitted to the IACUC for final review via the new online protocol submission system. The PI stated he did not realize the protocol did not properly submit. He also did not follow-up with the protocol participants to ensure they completed the mandatory requirement of enrolling in the OHSP, and understood protocol approval was dependent on fulfillment of this requirement. The PI assumed responsibility and assured the IACUC that he would learn how to use the new online system, follow up with the IACUC office to confirm his submission was received, ensure that protocol participants completed the mandatory OHSP enrollment requirement timely, would record protocol expiration dates on his calendar, and would review his animal use on a monthly basis. The IACUC met on August 11, 2021 and discussed this issue. The IACUC accepted the PI's explanation and decided no further action was required at this time.

OLAW appreciates the prompt consideration of this matter by Louisiana State University, which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate this incident, correct the noncompliance, and prevent recurrence. OLAW concurs that the incident warranted reporting. Although this activity was not PHS funded, the application of the expectations of the PHS Policy across the animal care and use program reduces any potential appearance of a double standard. OLAW advises that the process and training that provides for PI submission of protocols be reviewed for effectiveness. 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: 2021.10.25 16:20:54 -04'00'

Brent C. Morse, DVM

Director

Division of Compliance Oversight

Office of Laboratory Animal Welfare

cc: IACUC contact



**School of Veterinary Medicine**  
Office of the Dean

10/13/2021

**To:** Brent Morse, DVM  
Director: Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
BG 6700B Rm 2504  
6705 Rockledge Drive  
Bethesda, MD 20892-7982  
Email: olawdco@mail.nih.gov

**From:** Dr. Oliver Garden  
Institutional Official for Animal Care and Use, and  
Dean, School of Veterinary Medicine  
Through the Institutional Animal Care and Use Committee  
Louisiana State University  
Baton Rouge, LA 70803

**Re:** Non-compliance- Assurance number D16-00372 (A3612-01)

The Louisiana State University (LSU) IACUC, through the Institutional Official, herein report three deviations from the provisions of the *Public Health Service Policy on Humane Care and Use of Laboratory Animals* and the *Animal Welfare Act* (AWA). The IACUC determined that U.S. Government Principle I was violated in that an approved protocol expired with no provision being made to transfer the remaining animals to a currently active or new approved protocol. While the covered research was not funded by the PHS, our Assurance Statement indicates that we will equally apply all federal laws governing the use of animals in research, teaching, and testing, regardless of PI, vertebrate animal species, experimental use, funding source or animal housing location. Hence, we make the following report.

1) Non-compliant incident 1:

The Principal Investigator (PI) was notified via email in April and May 2021 that her approved animal care and use protocol would expire June 26, 2021. The PI had ample time to submit a new protocol for review and approval prior to protocol expiration. The PI responded to the May email, stating that the animals would be euthanized before the expiration date. On July 22, 2021, the vivarium manager notified the IACUC that there were six (6) mice left on the project upon protocol expiration. The mice were transferred to the approved DLAM holding protocol while the matter was investigated. On July 26, 2021, the PI was instructed to discontinue all animal use effective immediately. The PI was also instructed to provide a written explanation explaining why she allowed the protocol to expire with remaining animals, and to include assurance that an incident of this nature would not reoccur. The PI responded on Monday, July 26, 2021, stating that the project was no longer active so a new protocol was not needed. The PI did not expect to have any animals remaining on the protocol, and confirmed that she understood animals must be on a



protocol at all times. The PI consented to euthanasia of the remaining mice, as described in the expired protocol. The IACUC met on August 11, 2021, and discussed this issue. The IACUC accepted the PI's explanation and decided no further action was required at this time.

## 2) Non-compliant incident 2:

The PI was notified on May 14, 2021 that his protocol would expire on June 26, 2021. Eighty-one (81) mice remained on the project upon protocol expiration. The animals were transferred to the approved DLAM holding protocol while the matter was investigated. On August 5, 2021, the PI was instructed to discontinue all animal use effective the expiration date. The PI was also instructed to provide a written explanation of why he allowed this protocol to expire with animals remaining in the vivarium, and to include a written assurance that an incident of this nature would not reoccur.

On Monday, August 9, 2021, the PI responded, and stated that he was aware of the protocol expiration date and did submit a protocol to replace the expiring one. This protocol was reviewed during the June 17, 2021, IACUC meeting. The PI addressed the modifications required for approval by the IACUC, and believed that in doing so, the revised protocol had been submitted for final review through the new online protocol submission system implemented in February, 2021. That is, the PI did not realize that the protocol did not submit to the IACUC. He also did not follow-up with the protocol participants to ensure they completed the mandatory requirement of enrolling in the university's Occupational Health & Safety Program (OHSP), and understood protocol approval was dependent on this requirement being met. The PI indicated he assumed responsibility and would make sure to learn how to use the new online system, he would follow up with the IACUC office to confirm his submission was received, follow-up with protocol participants to ensure they complete the mandatory OHSP enrollment requirement timely, and he would mark the protocol expiration dates on his calendar. The IACUC met on August 11, 2021, and discussed this issue. The IACUC accepted the PI's explanation and decided no further action was required at this time.

## 3) Non-compliant incident 3:

On August 5, 2021, the vivarium manager notified the DLAM Associate Director and Chief Clinical Veterinarian that the approved number of mice on a particular protocol was exceeded by 32, due to the number of pups born the month prior. The PI was immediately notified and the mice were transferred to the approved DLAM holding protocol while the matter was investigated. The PI was instructed to provide a written explanation of why the number of mice approved on the protocol had been exceeded, along with a plan to rectify, and assurance that this non-compliance would not reoccur. The IACUC also instructed the PI to discontinue mouse breeding until the approved protocol was amended or replaced. The PI promptly responded on August 6, 2021, and indicated he was aware of potential overuse of the animals, and to avoid non-compliance he had submitted a new animal care and use protocol in June. This protocol had been reviewed during the June 17, 2021, IACUC meeting. The PI addressed the IACUC's required modifications for approval, and was under the impression that the revised protocol had been submitted to the IACUC for final review via the new online protocol submission system. The PI stated he did not realize the protocol did not properly submit. He also did not follow-up with the protocol participants to

ensure they completed the mandatory requirement of enrolling in the OHSP, and understood protocol approval was dependent on fulfillment of this requirement. The PI assumed responsibility and assured the IACUC that he would learn how to use the new online system, follow up with the IACUC office to confirm his submission was received, ensure that protocol participants completed the mandatory OHSP enrollment requirement timely, would record protocol expiration dates on his calendar, and would review his animal use on a monthly basis. The IACUC met on August 11, 2021, and discussed this issue. The IACUC accepted the PI's explanation and decided no further action was required at this time.

The LSU-IACUC and the University regret the occurrence of this incidents and will make every effort to ensure they do not reoccur in the future.

Sincerely,

(b) (6)

Dr. Oliver Gardén, BVetMed, PhD, FHEA, FCPP, FRCVS, DACVIM, DECVIM-CA  
Dean, School of Veterinary Medicine  
Institutional Official for Animal Care  
Louisiana State University  
Baton Rouge, LA

**Wolff, Axel (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Friday, October 15, 2021 8:38 AM  
**To:** (b) (6)  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Non-compliance letter from LSU School of Veterinary Medicine

Thank you for this report. We will send a response soon.

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

**From:** (b) (6)  
**Sent:** Thursday, October 14, 2021 3:44 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6)  
**Subject:** Non-compliance letter from LSU School of Veterinary Medicine

Dear Dr. Morse,  
Please find the attached non-compliance letter, Assurance Number D16-00372 (A3612-01).

Best Regards,

(b) (6)