



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

January 4, 2022

Re: Animal Welfare Assurance
A3612-01 [OLAW Case 1P]

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 December 13, 2021 letter reporting several 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 these non-compliance issues were identified starting February 2021. The Principal Investigator (PI) was sent repeated notices from the DLAM supervisor, and the issues persisted. The reported non-compliance issues included breeding mice in a non-breeding cage; housing multiple male mice with females in a breeder box, resulting in male-male aggression and severe wounding; overcrowding of mouse boxes; housing of weaned male/female mice together with the intent to genotype. Due to the failure to genotype and separate mice promptly, breeding occurred; housing pups past due for weaning; breeding of pups on an experimental protocol rather than on a breeding protocol; displaying cage cards with some required information missing or failing to display cage card appropriately among other things. The associated activity is PHS-supported.

The IACUC sent a letter to the investigator giving him the option to either stop his work voluntarily on his protocols or have the IACUC shut down his protocols and notify the appropriate funding agencies. The PI elected to stop the work himself and rectify the problems with IACUC oversight. Immediate corrective action was provided by the IACUC that included the PI developing a comprehensive plan to correct the deficiencies and establish a system to prevent further non-compliance. The PI was requested to contact the Attending Veterinarian to schedule re-training on all aspects of animal care related to the PI's protocols and review the standard operating procedures to be followed. The PI was also told to provide a detailed plan to the IACUC including the steps he and his staff would implement to ensure compliance with *The Guide for the Care and Use of Laboratory Animals*, DLAM SOP (mouse breeding), and DLAM veterinary staff instructions. The IACUC also recommended the PI consider hiring a laboratory manager or assign oversight of animal care to some other responsible person. It was also reiterated that the PI is ultimately responsible for all animal care and use originating from his laboratory.

The Attending Veterinarian held training for the PI and his staff. The following topics were covered:

- I. Federal Rules and Regulations: How they apply to what the IACUC and DLAM are charged to comply with. The emphasis was that the university must follow the guidelines required to maintain accreditation and remain in good standing with the Office of Laboratory Animal Welfare (OLAW).

2. Cage cards: What information is required by the regulations and the importance of the information being noted correctly.
3. Harem Breeding: How this should be done with the emphasis on the fact that only one male should be used in the harem breeding and why.
4. Mouse space requirements: The group was shown the regulations regarding the housing of mice which is generally based on the animal's weight. Using the size of the cage, it was then demonstrated how DLAM arrives at five (5) adults per cage.

The IACUC agreed to send the PI a letter requesting an amendment be submitted for the breeding protocol where his harem breeding practices would be modified. The IACUC also discussed several suggestions to the summary plan provided by the PI and comments were added to the document regarding changes and/or suggestions.

The IACUC received the revised summary plan from the PI and after IACUC review, correspondence was sent to the PI notifying him that the plan was approved as of December 1, 2021, and the matter was considered closed. It was reiterated to the PI that it was his responsibility to ensure that his animal care and use protocols remained compliant. It was also noted that should another non-compliance incident happen, the PI risked suspension of his research by the IACUC.

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 the issues, correct the noncompliance, and prevent recurrence. OLAW concurs that the issues warranted reporting. Please be sure that any associated grants are not charged for the unapproved activities. 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: 2022.01.04 13:37:13 -05'00'

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

12/13/2021

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 a deviation 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 VII was violated in that the living conditions for the animals should promote their health and comfort. This research work was and is covered 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.

Several non-compliance issues were identified since February 2021. The Principal Investigator (PI) was sent repeated notices from the DLAM supervisor, and the issues persisted. The reported non-compliance issues included breeding mice in a non-breeding cage; housing multiple male mice with females in a breeder box, resulting in male-male aggression and severe wounding; overcrowding of mouse boxes; housing of weaned male/female mice together with the intent to genotype. Due to the failure to genotype and separate mice promptly, breeding occurred; housing pups past due for weaning; breeding of pups on an experimental protocol rather than on a breeding protocol; displaying cage cards with some required information missing or failing to display cage card appropriately among other things. Each of the items was discussed during the IACUC meeting, including the PI having similar non-compliance issues reported in 2015 and 2017.

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Skip Bertman Drive at River Road
Baton Rouge, LA 70803

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The IACUC discussed this non-compliance during the October 12, 2021 meeting. The IACUC sent a letter to the investigator giving him the option to either stop his work voluntarily on his protocols or have the IACUC shut down his protocols and notify the appropriate funding agencies. The PI elected to stop the work himself and rectify the problems with IACUC oversight. Immediate corrective action was provided by the IACUC that included the PI developing a comprehensive plan to correct the deficiencies and establish a system to prevent further non-compliance. The PI was requested to contact the Attending Veterinarian to schedule re-training on all aspects of animal care related to the PI's protocols and review the standard operating procedures to be followed. The PI was also told to provide a detailed plan to the IACUC by Wednesday, October 20, 2021, including the steps he and his staff would implement to ensure compliance with *The Guide for the Care and Use of Laboratory Animals*, DLAM SOP 3.2 (mouse breeding), and DLAM veterinary staff instructions. The IACUC also recommended the PI consider hiring a laboratory manager or assign oversight of animal care to some other responsible person. It was also reiterated that the PI is ultimately responsible for all animal care use originating from his laboratory. Upon notice of the training being completed and receipt of the PI's plan, the IACUC would reconvene to discuss the information and determine the next course of action.

The PI emailed the IACUC on October 13, 2021, acknowledging receipt of the letter from the IACUC and noted responsibility. He indicated he would prepare a detailed plan and submit it to the IACUC. The PI submitted an initial plan to the IACUC on October 16, 2021. The plan, after revision, was received via email by the PI on Wednesday, October 27, 2021. A special meeting of the IACUC was scheduled for November 3, 2021, to review and discuss the plan.

The Attending Veterinarian held training for the PI and his staff on Friday, October 22, 2021. The following topics were covered:

1. Federal Rules and Regulations: How they apply to what the IACUC and DLAM are charged to comply with. The emphasis was that the university must follow the guidelines required to maintain accreditation and remain in good standing with the Office of Laboratory Animal Welfare (OLAW).
2. Cage Cards: What information is required by the regulations and the importance of the information being noted correctly.
3. Harem Breeding: How this should be done with the emphasis on the fact that only one male should be used in harem breeding and why.
4. Mouse space requirements: The group was shown the regulations regarding the housing of mice which is generally based on the animal's weight. Using the size of the cage, it was then demonstrated how DLAM arrives at five (5) adults per cage.

The IACUC met on November 3, 2021, and discussed the PI's plan. It was agreed to send the PI a letter requesting an amendment be submitted for the breeding protocol where his harem breeding practices would be modified. The IACUC also discussed several suggestions to the summary plan provided by the PI and comments were added to the document regarding changes and/or

suggestions. Correspondence was sent to the PI on November 5, 2021, requesting the amendment and revisions to the plan. The PI immediately responded by submitting an amendment to the breeding protocol on November 5, 2021.

The IACUC received the revised summary plan from the PI and after IACUC review, correspondence was sent to the PI notifying him that the plan was approved as of December 1, 2021, and the matter was considered closed. It was reiterated to the PI that it was his responsibility to ensure that his animal care and use protocols remained compliant. It was also noted that should another non-compliance incident happen, the PI risked suspension of his research by the IACUC.

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

Sincerely,

(b) (6)

Dr. Oliver Garden, 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]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, December 15, 2021 8:24 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: LSU School of Veterinary Medicine OLAW Letter

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, December 14, 2021 9:46 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: [EXTERNAL] LSU School of Veterinary Medicine OLAW Letter

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dear Dr. Morse,
Please see the attached non-compliance letter, Assurance number D16-00372. If we can be of further assistance please let me know.

Best Regards,

(b) (6)

(b) (6)