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

May 26, 2020

Re: Animal Welfare Assurance
A3564-01 [OLAW Case H]

Dr. Joh Koker
Interim Provost and Vice Chancellor
University of Wisconsin-Oshkosh
800 Algoma Boulevard
Oshkosh, WI 54901-8622

Dear Dr. Koker,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 20, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Wisconsin Oshkosh following up on an initial April 20, 2020 notification by email.

According to the information provided, this Office understands that the University of Wisconsin Oshkosh Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: failure to adhere to IACUC-approved protocol. The final report states on March 30, 2020, a gerbil was anesthetized by the Principal Investigator (PI) to perform IP infection of *Brugia malayi* and ear punching as approved per IACUC protocol. The gerbil was anesthetized using a tabletop laboratory animal anesthesia system with a rodent induction box. Following the ear punch and prior to the IP infection procedure, the PI noticed that the gerbil was not breathing. Thermal support and chest compressions were provided by the PI, but the animal did not revive. Next, the PI notified the Laboratory Animal Manager of the incident and voiced difficulty using the anesthesia machine. The investigator was instructed to complete an unexpected event form and was provided refresher training on March 31, 2020 via videoconference on how to properly use the anesthesia equipment. The Laboratory Manager reviewed the anesthesia monitoring log and the record keeping requirements in the surgery room. They determined the anesthesia monitoring log was not completed for the procedure on March 30, 2020. Per the final report, the study protocol refers to following SOP#11 for anesthesia procedures and record-keeping. Therefore, it was determined that the PI failed to adhere to the IACUC-approved protocol.

On April 15, 2020, a subcommittee of the IACUC met to discuss the event, and confirmed the PI was up to date for training for surgery and anesthesia procedures. The subcommittee discussed that it is a best practice to have at least two people present when doing procedures involving anesthesia. After discussion, the subcommittee recommended modifying SOP #11 to state "An assistant must be present" as opposed to "should". The revised SOP #11 was presented to the IACUC at the May 14, 2020 meeting and approved as presented. The unexpected event was discussed by the full committee as well. In addition to the refresher training that has been provided, the updated SOP#11 was shared with the PI and lab for review. It is noted that additional training on the SomnoSuite anesthesia system will be scheduled with the PI prior to the next procedure. A recommendation was made for the lab to wait to perform procedures involving anesthesia until the campus returns to normal operations (post COVID-19 reduced operations) or until a minimum of two lab members can be present to assist with anesthesia, animal monitoring, and record keeping. The report states the lab plans to voluntarily pause animal procedures during the COVID-19 reduced operations campus closure.

It is noted that this research is supported by PHS funds. Based on its assessment of this explanation, OLAW understands that the University of Wisconsin Oshkosh has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

Jacquelyn T. Tubbs -S

Digitally signed by Jacquelyn T. Tubbs -S
Date: 2020.05.27 08:28:12 -04'00'

Jacquelyn T. Tubbs, DVM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact
Robert M. Gibbens, DVM, Director, Animal Welfare Operations

UNIVERSITY OF WISCONSIN OSHKOSH

To: Office of Laboratory Animal Welfare
Division of Compliance Oversight
Rockledge One, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Date: May 20, 2020

Re: Final Report of Noncompliance

INSTITUTION: University of Wisconsin Oshkosh

ASSURANCE NUMBER: D16-00342 (Legacy: A3564-01)

FUNDING COMPONENT: NIH-NIAIDS Subcontract with University of Georgia, HHSN272201700035: C09

UW Oshkosh, in accordance with Assurance D16-00342 and PHS Policy IV.F.3., provides this preliminary report of noncompliance regarding a protocol deviation involving anesthesia procedures.

INCIDENT: On March 30, 2020, a gerbil was anesthetized by the Principal Investigator of the study in order to perform the following IACUC-approved procedures: IP infection of Brugia malayi and ear punching. The gerbil was anesthetized by the Principal Investigator using a tabletop laboratory animal anesthesia system with a rodent induction box. The gerbil was ear punched for identification purposes. Following the ear punch and prior to the IP infection procedure, the Principal Investigator noticed that the gerbil was not breathing. Thermal support was provided and chest compressions, but the gerbil did not revive. The Principal Investigator placed the gerbil in the freezer and notified the Laboratory Animal Manager of the incident and expressed difficulty using the anesthesia machine. The Laboratory Manager asked the Principal Investigator to complete an unexpected event form for the IACUC and provided refresher training on March 31, 2020 via videoconference on how to properly use the anesthesia equipment. The Laboratory Animal Manager also reviewed where in the surgery room *SOP #11: Anesthesia Monitoring for Small Animals* and the anesthesia monitoring log are stored and the record keeping requirements. An anesthesia monitoring log was not completed for the procedure on March 30, 2020. Since the study protocol refers to following SOP#11 for anesthesia procedures and record-keeping, it was determined that the Principal Investigator failed to adhere to the IACUC-approved protocol.

IACUC FOLLOW UP AND CORRECTION PLAN: A subcommittee of the IACUC met to discuss the incident on 4/15/20. The subcommittee reviewed the Principal Investigator's protocol and training records and confirmed that the Principal Investigator was up to date for training for surgery and anesthesia procedures. It was noted that a technician in the laboratory typically assists with anesthesia and monitoring of the animal. The subcommittee discussed that it is a best practice to have at least two people present when doing procedures involving anesthesia. SOP #11: Anesthesia Monitoring for Small Animals states the following: "An assistant should be present to assist with anesthesia and animal monitoring." After discussion, the subcommittee recommended modifying SOP #11 to state "An assistant **must** be present" as opposed to "should". The revised SOP #11 was presented to the IACUC at the May 14, 2020 and approved as presented. The unexpected event report and a copy of this report was also discussed by the full committee. Refresher training on the tabletop anesthesia system and SOP #11 was provided on 3/31/20. The updated SOP #11 was shared with the PI and laboratory for review. An additional training in the SomnoSuite anesthesia system will be scheduled with the Principal Investigator as well prior to the next procedure. A recommendation was made for the lab to wait to perform procedures involving anesthesia until the campus returns to normal operations (post COVID-19 reduced operations) or until a minimum of two lab members are able to be present so that one individual can assist with anesthesia, animal monitoring, and record keeping. The lab manager for the research lab indicated that the lab plans to voluntarily pause animal procedures during the COVID-19 reduced operations campus closure.

UWO is committed to protecting the welfare of animals used in research and appreciates the guidance provided by OLAW. Should you have any questions or need additional information regarding this report, please contact (b) (6) (b) (6)

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Dr. John Koker
Provost and Vice Chancellor for Academic Affairs
Institutional Official for Research

IACUC ADMINISTRATION • OFFICE OF SPONSORED PROGRAMS
UNIVERSITY OF WISCONSIN OSHKOSH • 800 ALGOMA BLVD • OSHKOSH WI 54901-8460
(920) 424-3375 • IACUC@UWOSH.EDU

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, May 22, 2020 8:10 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Final Report Assurance D16-00342

Thank you for this report (b) (6). We will respond soon.

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

From: (b) (6)
Sent: Wednesday, May 20, 2020 4:14 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: John Koker <koker@uwosh.edu> (b) (6) Animal Care and Use Committee <iacuc@uwosh.edu>
Subject: Final Report Assurance D16-00342

Good afternoon,

Attached is the final report from the University of Wisconsin Oshkosh regarding a March 30, 2020 incident involving a deviation from the IACUC-approved anesthesia procedure. A preliminary report was submitted on April 20, 2020. Our OLAW Assurance number is D16-00342.

Please let me know if you have any questions or require additional information.

Sincerely,

(b) (6)

*Attention: OSP staff are currently working remotely. For OSP COVID-19 updates related to external funding agencies and research activities, please visit our website: https://uwosh.edu/sponsoredprograms/

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(b) (6)

A3564-H

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Prelim Report

To: Office of Laboratory Animal Welfare
Division of Compliance Oversight
Rockledge One, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Date: April 20, 2020

Re: Preliminary Report of Noncompliance

INSTITUTION: University of Wisconsin Oshkosh

ASSURANCE NUMBER: D16-00342 (Legacy: A3564-01)

FUNDING COMPONENT: NIH-NIAIDS Subcontract with University of Georgia, HHSN272201700035: C09

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INCIDENT: On March 30, 2020, a gerbil was anesthetized by the Principal Investigator of the study in order to perform the following IACUC-approved procedures: IP infection of Brugia malayi and ear punching. The gerbil was anesthetized by the Principal Investigator using a tabletop laboratory animal anesthesia system with a rodent induction box. The gerbil was ear punched for identification purposes. Following the ear punch and prior to the IP infection procedure, the Principal Investigator noticed that the gerbil was not breathing. Thermal support was provided and chest compressions, but the gerbil did not revive. The Principal Investigator placed the gerbil in the freezer and notified the Laboratory Animal Manager of the incident and expressed difficulty using the anesthesia machine. The Laboratory Manager asked the Principal Investigator to complete an unexpected event form for the IACUC and provided refresher training on March 31, 2020 via videoconference on how to properly use the anesthesia equipment. The Laboratory Animal Manager also reviewed where in the surgery room *SOP #11: Anesthesia Monitoring for Small Animals* and the anesthesia monitoring log are stored. An anesthesia monitoring log was not completed for the procedure on March 30, 2020. Since the study protocol refers to following SOP#11 for anesthesia procedures and record-keeping, it was determined that the Principal Investigator failed to adhere to the IACUC approved protocol.

PLAN AND SCHEDULE FOR CORRECTION: A subcommittee of the IACUC met to discuss the incident on 4/15/20. The subcommittee reviewed the Principal Investigator's protocol and training records and confirmed that the Principal Investigator was up to date for training. It was noted that a technician in the laboratory typically assists with anesthesia and monitoring of the animal. The subcommittee discussed that it is a best practice to have at least two people present when doing procedures involving anesthesia. SOP #11: Anesthesia Monitoring for Small Animals states the following: "An assistant should be present to assist with anesthesia and animal monitoring." After discussion, the subcommittee recommended modifying SOP #11 to state "An assistant **must** be present" as opposed to "should". This change will be presented to the IACUC at the upcoming meeting on May 14, 2020. The unexpected event report and a copy of this report will also be discussed by the full committee. Refresher training on the tabletop anesthesia system and SOP #11 was provided on 3/31/20. An additional training in the SomnoSuite anesthesia system will be scheduled with the Principal Investigator as well. A recommendation was made to the lab to wait to perform procedures involving anesthesia until the campus returns to normal operations (post COVID-19 reduced operations) or until two lab members are able to be present so that one individual can assist with anesthesia, animal monitoring, and record keeping. The lab

manager for the research lab indicated that the lab plans to voluntarily pause animal procedures during the COVID-19 reduced operations campus closure.

TIMEFRAME FOR FINAL INCIDENT REPORT FROM I.O.: The IACUC will discuss the incident at the May 14, 2020 meeting. A final report will be prepared and submitted by May 31, 2020. Should you have any questions or need additional information regarding this report, please contact (b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, April 22, 2020 7:23 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Preliminary Report to OLAW

Thank you for this report, (b) (6). We will start a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation.

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

From: (b) (6)
Sent: Monday, April 20, 2020 9:39 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: John Koker <koker@uwosh.edu>, (b) (6)
Subject: Preliminary Report to OLAW

Greetings,

I spoke to Dr. Brent Morse on Friday, April 17, 2020 about an incident involving a gerbil death involving anesthesia procedures. Attached is a preliminary report of noncompliance with the details of the incident required under PHS policy section IV.F.3.

Please feel free to contact me with any questions.

Sincerely,

(b) (6)

*Attention: OSP staff are currently working remotely. For OSP COVID-19 updates related to external funding agencies and research activities, please visit our website: https://uwosh.edu/sponsoredprograms/

UW UNIVERSITY OF WISCONSIN OSHKOSH

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A3564-H

THE UNIVERSITY OF WISCONSIN OSHKOSH

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