



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
Rockledge One, Suite 360  
6705 Rockledge Drive - MSC 7982  
Bethesda, Maryland 20892-7982  
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

March 22, 2017

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

Dr. Lane R. Earns  
Provost and Vice Chancellor  
Academic Affairs  
University of Wisconsin-Oshkosh  
800 Algoma Boulevard  
Oshkosh, WI 54901-8622

Dear Dr. Earns,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 14, 2017 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 January 12, 2017 telephone notification. According to the information provided, OLAW understands that a two day lapse in IACUC approval occurred on two expired protocols involving gerbils. Federal funds were not used to support the relevant protocols nor was any animal activity performed during the two day lapse.

The corrective actions consisted of improving communication between the IACUC and Principal Investigators specifically regarding deadlines for protocol submissions and revisions, approving an animal holding protocol and updating the applicable Standard Operating Procedures to include a description of the procedures for transfer of animals to the animal holding protocol.

The establishment and application of policies and practices that are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Wisconsin Oshkosh are commendable and avoid the perception of a double standard. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

Neera V. Gopee, DVM, PhD, DACLAM, DABT  
Animal Welfare Program Specialist  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Chair

Dr. Elizabeth Goldentyer, Director Eastern Sector, USDA, APHIS, AC



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

Date: March 14, 2017

Re: Final Report of Noncompliance

**INSTITUTION:** University of Wisconsin Oshkosh

**ASSURANCE NUMBER:** A3564-01

**FUNDING COMPONENT:** This research is supported by NIH-NIAID Subaward No. RR211-508/4787376

UW Oshkosh, in accordance with Assurance A3564-01 and PHS Policy IV.F.3., provides this final report of noncompliance regarding an incident in which a protocol had a 2 day lapse in IACUC approval. A preliminary report was submitted on January 12, 2017 via telephone to Dr. Nera Golpe in the OLAW Division of Compliance Oversight by IACUC Administrator, secondary individual.

**Incident Description:**

A lapse in IACUC approval was realized by IACUC Administration while they were processing protocol approval paperwork for the following studies:

- *Molecular Basis of Infectivity-microfilariae and maintenance of contingency life cycle for Filariasis Research*
- *Reagent Resource Center (FR3) and Feeding of Laboratory-Reared Mosquitoes on Anesthetized Mongolian Gerbils*

The approval for the above referenced studies had expired on January 9, 2017. The IACUC had reviewed the renewals for the protocols on January 3, 2017 at a convened meeting and had requested revisions in order to secure approval. The revisions were received by the IACUC on January 11, 2017 and approval for the renewal protocol was secured on January 12, 2017. Given that there was a two day lapse in IACUC approval, OLAW requested that a noncompliance report be submitted.

IACUC Administration notified the Principal Investigator regarding the lapse in IACUC approval. The Principal Investigator confirmed that no animals were used during the lapse in IACUC approval and no federal funds that support the above projects were disbursed during the lapse in IACUC approval.

**IACUC Recommendation/Preventive Plan:**

An IACUC subcommittee consisting of three IACUC members: the Attending Veterinarian, IACUC chair, and IACUC Compliance member met on January 24, 2017. The subcommittee discussed the incident and what preventive measures could be used in the future to avoid a potential gap in IACUC approval. The subcommittee discussed ways to avoid a similar situation in the future and provided the following recommendations for a preventive plan:

- 1) Improved communication between IACUC and Principal Investigator. While the IACUC office does send out expiration notices to Principal Investigators, it was suggested that a specific deadline for submitting revisions to

protocols be included following review of new or renewal protocols. The template used by the IACUC office has been updated and now includes boilerplate language with a due date for submitting the revisions. In addition, the template includes the protocol expiration date for protocols that are pending renewal.


- 2) Protocol #302: *Temporary Holding of Animals* was approved by the IACUC on February 27. This protocol allows animals to be held in one of the Animal Care Facilities for the following circumstances: PI unexpectedly leaves his/her position at UW Oshkosh, PI's protocol expires and there are animals assigned to that protocol, or the IACUC suspends a protocol in which animals are assigned. Care for the animals will follow husbandry procedures outlined in the species care SOP.
- 3) SOP#39: Holding Procedure for Temporary Animal Holds was updated to describe the procedure for transferring animals to Protocol #302: *Temporary Holding of Animals*. The following language has also been added to the SOP:
  - In the event that a PI's protocol expires or the protocol is suspended by the IACUC, the PI will also be notified that no animal work may be conducted under that protocol. In addition, no federal funds may be used for that project during a lapse in IACUC approval.

A draft of this report and subcommittee suggestions for preventive actions was shared with the full IACUC at the February 27, 2017 convened meeting. The full committee voted to accept the recommendations and suggested preventative plan prepared by the IACUC subcommittee.

UW Oshkosh is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions or need additional information regarding this report, please contact [ondary indivi](#) IACUC Administrator, at [dary ind](#) [duwosh.edu](mailto:duwosh.edu).

Thank you for your consideration of this matter.

Sincerely,



Lane R. Earns  
Provost and Vice Chancellor  
Institutional Official

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

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, March 15, 2017 10:44 AM  
**To:** 'Animal Care and Use Committee'  
**Subject:** RE: OLAW Final Report of Noncompliance A3564-01

Thank you for this report [redacted] We will respond soon.

Axel Wolff, M.S., D.V.M.  
Director, Division of Compliance Oversight  
OLAW

**From:** Animal Care and Use Committee [mailto:iacuc@uwosh.edu]  
**Sent:** Wednesday, March 15, 2017 9:49 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** [redacted]@uwosh.edu  
**Subject:** OLAW Final Report of Noncompliance A3564-01

Good morning,

Please find attached a final report of noncompliance for the University of Wisconsin Oshkosh, Assurance number A3564-01, related to an incident in which a lapse in IACUC approval occurred.

Please let me know if you have any questions or need any further information.

Best,

[redacted] IACUC Administrator

--  
University of Wisconsin Oshkosh  
Office of Sponsored Programs & Faculty Development  
IACUC Administration

[redacted] Secondary individual

Dempsey Hall [redacted] Room #  
800 Algoma Boulevard  
Oshkosh, WI 54901

[redacted] telephone #

IACUC Website

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## Initial Report of Noncompliance

By: Neora

Date: 1-12-17

Time: 3:50 pm  
4:08 pm

Name of Person reporting:

Secondary individual

Telephone #:

telephone #

telephone #

Fax #:

Email:

Name of Institution:

University of Wisconsin-Oshkosh

Assurance number:

A3564-01

Did incident involve PHS funded activity? Yes

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

Protocol expired for 3 days before de novo approval. "Holding policy"  
did not address many issues

Species involved: Geckos

Personnel involved:

Dates and times:

Animal deaths:

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

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # \_\_\_\_\_