



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

June 19, 2018

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

Dr. John 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 June 5, 2018 letter reporting noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) which was preceded by a preliminary report via telephone on February 21, 2018. The letter indicated that it was discovered that official IACUC business requiring a quorum (full committee review of an activity in accord with PHS Policy IV.C.2) occurred in the absence of a quorum at the University of Wisconsin-Oshkosh on August 29, 2017. It was determined that this incident occurred due to an oversight where the total number of IACUC members had not been recalculated upon the Chair's return from sabbatical in conjunction with review of a protocol renewal and a protocol modification with one recused IACUC member. The associated work was not PHS funded.

Corrective actions included the review and approval, in a manner consistent with PHS Policy, of the animal activities that had previously been approved with the lack of a quorum. Preventive measures include a plan to list committee member names at the top of the meeting agenda with the number required for quorum to ensure that quorum can be confirmed in a quick and easy manner for all future full committee meetings. This incident and plan was discussed and accepted by the IACUC on May 24, 2018.

Although the associated animal activity was not PHS funded, there was the potential for this incident to have affected animal activity with any funding source. The reporting of this incident reinforces the underlying foundation of the PHS Policy which is that of institutional self-evaluation, self-monitoring, and self-reporting. OLAW commends the vigilance of the University of Wisconsin-Oshkosh IACUC and appreciates your institution's commitment to protecting the welfare of animals used in research. OLAW concurs with the corrective and preventive actions and finds no cause for further action by this Office. Thank you for informing OLAW of this matter.

Sincerely,

(b) (6)

Jane Na, DVM
Veterinary Medical Officer, OLAW
Office of Laboratory Animal Welfare

cc: IACUC Chair
IACUC Contact



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

Date: June 5, 2018

Re: Final Report of Noncompliance

INSTITUTION: University of Wisconsin Oshkosh

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

FUNDING COMPONENT: N/A

UW Oshkosh, in accordance with Assurance D16-00342 and PHS Policy IV.F.3., provides this final report of noncompliance regarding an incident in which quorum was not maintained for parts of the August 29, 2017 IACUC meeting. A preliminary report was submitted on February 21, 2018 via telephone to Dr. Na in the OLAW Division of Compliance Oversight by (b) (6)

Incident Description:

During an IACUC record review in preparation for the AAALAC site visit, (b) (6) noticed a discrepancy in the number of IACUC members recorded in the minutes (August 29, 2017 & December 7, 2017) and the number on the current IACUC roster. Looking into it further, it was realized that the Chair had not been recalculated into the total number of members following her return from sabbatical and we had a total of 10 members. A quorum was maintained for the December 7, 2017 meeting with 7/10 members but quorum was not maintained for parts of the August 29, 2017 meeting.

A quorum was not maintained for voting on three items during the August 29, 2017 meeting:

- 1) Minutes from May 1, 2017 meeting,
- 2) 3 year renewal of Protocol 250-R2 in which PI/IACUC member Kurtz recused herself, and
- 3) Modification to Protocol 233-R2 to change the euthanasia method in which PI/IACUC member Kurtz recused herself

(b) (6) called OLAW on February 21, 2018 when the quorum issue was discovered and spoke to Dr. Na to see if the event was reportable given that the protocols were not PHS or NSF funded. No work had been conducted under Protocol 250-R2. In addition, the modification to euthanasia method requested in Protocol 233-R2 had not been implemented yet. Dr. Na indicated that the incident should be reported to OLAW since it falls under a program wide concern and took the preliminary report over the phone.

IACUC Recommendation/Preventive Plan:

A copy of the incident was shared with the IACUC via email on February 21, 2018. A subset of the IACUC met on April 5, 2018 and discussed the incident. It was determined that the minutes from the August 29, 2017 and December 7, 2017 meeting will be revised to reflect the correct number of IACUC members and be placed on the next convened meeting agenda for approval by the committee. Protocol 250-R2, Protocol 233-R2 modification request, and the May 1, 2017 minutes would be re-reviewed by the IACUC. In the future, the committee member names will be listed at the top of the

meeting agenda along with the number required for quorum to ensure that quorum can be confirmed in a quick and easy manner. All items that needed IACUC review were sent back to the IACUC and approved as indicated below:

Item for Re-Review	Status
Minutes of May 1, 2017 IACUC Meeting	Reviewed and Approved at Convened Meeting on May 24, 2018
Protocol 250-R2 Renewal	Reviewed and Approved via DMR on April 8, 2018
Protocol 233-R2 Modification	Reviewed and Approved at Convened Meeting on May 24, 2018
Revised Minutes from IACUC Meetings held on August 29, 2017 and December 7, 2017	Reviewed and Approved at Convened Meeting on May 24, 2018

The IACUC discussed the incident at the May 24, 2018 convened meeting and was satisfied with the correction plan. 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 (b) (6)@uwosh.edu.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

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

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, June 12, 2018 1:44 PM
To: Animal Care and Use Committee
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW Final Report: Loss of Quorum

Thank you for this report. Dr. Na will send a response soon.

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

From: Animal Care and Use Committee [mailto:iacuc@uwosh.edu]
Sent: Tuesday, June 12, 2018 10:10 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: John Koker <koker@uwosh.edu>; (b) (6)@uwosh.edu
Subject: OLAW Final Report: Loss of Quorum

Good morning,

Please find attached the final report regarding an incident involving loss of quorum at the August 29, 2017 IACUC meeting. This incident was identified on February 21, 2018 and a preliminary report was taken by Dr. Na over the phone.

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

Sincerely,

(b) (6)





Initial Report of Noncompliance

By: Jane Na

Date: 2/21/18

Time: 11:40AM

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #:

Email: (b) (6)@uwosh.edu

Name of Institution: University of Wisconsin – Oshkosh

Assurance number: D16-00342 (Legacy A3564-01)

Did incident involve PHS funded activity? *No*

Funding component: *n/a*

Was funding component contacted (if necessary): *n/a*

What happened?

Upon records review, it was just noted that an appropriate quorum was not in place when a member of the IACUC recused herself for a protocol modification and another protocol review during a full committee IACUC meeting. There was an oversight where the number of members on the committee was thought to be 9 when it was actually 10.

Species involved:

Personnel involved: *IACUC*

Dates and times: *8/29/2017*

Animal deaths: *None*

Projected plan and schedule for correction/prevention (if known): *The protocol mod was a change in approved AVMA method of euthanasia and can go to VVC and the other approval will potentially go for DMR if there are no calls to FCR.*

Projected submission to OLAW of final report from Institutional Official: *After the next IACUC meeting in April 2018*

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Case # _____