



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE  
NATIONAL INSTITUTES OF HEALTH

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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

March 26, 2020

Re: Animal Welfare Assurance  
#A3283-01 (OLAW Case 2S)

Dr. Milan Mrksich  
Interim Vice President for Research  
Northwestern University  
750 N. Shore Drive  
Rubloff Bldg. 7<sup>th</sup> Floor  
Evanston, IL 60208

Dear Dr. Mrksich,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your letter dated March 24, 2020 reporting two administrative instances of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Northwestern University. According to the information provided, OLAW understands that the membership appointments of two IACUC members expired on December 31, 2019 and January 23, 2020, respectively. While expired, the members participated in Designated Member Review (DMR) and approval of five Animal Study Protocols (ASPs). To rectify the issue, both appointments were renewed on February 20, 2020. The protocols were re-reviewed by a qualified DMR. The ASP changes had not yet been implemented other than the use of a new mouse strain. To prevent such a future error the incident was reviewed with team members and a new tracking system with automatic reminders was implemented for upcoming membership expirations.

The second issue involved the Center for Comparative Medicine's (CCM) accounting for pups at the time of weaning which was properly identified as not consistent with OLAW guidance. To address this error, the IACUC Office and CCM will modify the CCM census and procurement system to allow for accounting of pre-weanling animals by PIs and laboratory staff. An IACUC policy will be developed and implemented regarding the requirements for accounting of pre-weanling animals.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken by Northwestern University to investigate these issues, provide corrective measures, and prevent recurrences. OLAW concurs that the incidents warranted reporting. We commend your program for identifying these internal issues and making proper corrections. We appreciate being informed of these matters and find no cause for further action by this office.

Sincerely,

(b) (6)

Brent C. Morse, DVM  
Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact

March 24, 2020

Brent Morse, DVM, DACLAM, Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
OLAW Division of Assurance  
National Institutes of Health  
Suite 360 MSC 7982  
6700B Rockledge Dr., Suite 2500, MSC 6910  
Bethesda, MD 20817

Dear Dr. Morse:

The Northwestern University Institutional Animal Care and Use Committee (NU IACUC; Assurance # A3283-01) self-reported two administrative issues inconsistent with 1) NU's Assurance on use of designated member reviewers (DMRs) and 2) OLAW guidance on accounting of pre-weanling animals.

1. IACUC Membership Appointment

Due to administrative error, two IACUC membership appointments inadvertently expired on December 31, 2019 and January 23, 2020, respectively. While expired, the Committee members participated in the review and approval of five Animal Study Protocols (ASPs) submissions. NU's Assurance with OLAW requires each ASP to be reviewed by two qualified DMRs. As a result of the lapsed membership, however, all five ASP submissions were not reviewed by two properly appointed DMR.

The IACUC Office Director implemented the following corrective action:

- As soon as the lapsed appointments were discovered, both members were reappointed effective February 20, 2020.
- The protocols were re-reviewed by a qualified DMR.
- Confirmed that the proposed ASP changes had not implemented prior to re-review with the exception of the use of a new mouse strain.
- To prevent future errors:
  - Review the incident with team members and stress the importance of monitoring Committee membership expiration dates and a review of PHS Policy requirements and NU's Assurance.
  - Develop and implement a new tracking system that automatically sends reminders to IACUC Office staff of upcoming membership expirations at 2 months, 1 month, 2 weeks and 1 week. If the membership is not renewed at 1 week, the system will notify the Director. Revise the NU Assurance to align with the PHS Policy requirements of one DMR.

## 2. Animal Accounting

The approximate number of rodents needed to complete experiments proposed in the Animal Study Protocol (ASP) is described and justified in the approved ASP. Upon *de novo* review, PIs are asked to provide a summary of the research completed and adjust animal numbers based on the number of animals used during the previous three years. The Center for Comparative Medicine (CCM) accounts for pups at the time of weaning; however, the CCM census process for accounting of pre-weaning pups is not consistent with OLAW guidance on accounting for animal use.

To address this error, the IACUC Office and CCM are taking the following actions:

- Modify the CCM census and procurement system to allow for accounting of pre-weanling animals by PIs and laboratory staff.
- Develop and implement an IACUC policy on requirements for accounting of pre-weaning animals.

These matters were discussed at the March 19, 2020 IACUC meeting and the Committee approved the action plans to prevent recurrence.

Please let me know if you need any further information.

Sincerely,

(b) (6)

Milan Mrksich, Ph.D.  
Interim Vice President for Research  
Institutional Official

cc: (b) (6)  
C. Heckman, Ph.D., Chair-IACUC  
M. Kozlowski, MSL, CPIA, Director IACUC Office  
(b) (6)

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Wednesday, March 25, 2020 9:11 AM  
**To:** VP Research  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Correspondence from Northwestern University

Thank you for this report, (b) (6) We will send a response soon.

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

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**From:** VP Research <VP-Research@northwestern.edu>  
**Sent:** Tuesday, March 24, 2020 3:51 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6) CJ Heckman <c-heckman@northwestern.edu>; Mandy J Kozlowski <m-kozlowski@northwestern.edu>; (b) (6)  
**Subject:** Correspondence from Northwestern University

Dear Dr. Morse.

Attached please find correspondence from Northwestern University.



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