



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 16, 2020

Re: Animal Welfare Assurance  
A3544-01 [OLAW Case N]

Dr. Dennis Durbin  
Chief Scientific Officer  
Nationwide Children's Hospital  
700 Children's Drive – W177  
Columbus, Ohio 43205-2696

Dear Dr. Durbin,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 10, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Research Institute at Nationwide Children's Hospital, following up on an initial telephone report on December 13, 2019. According to the information provided, OLAW understands that two mice were subjected to footpad injection which led to tissue swelling. The procedure had not been approved by the Institutional Animal Care and Use Committee (IACUC) but had been previously conducted on four additional mice.

The corrective actions consisted of euthanizing the mice, contacting the Principal Investigator (PI), having the PI and staff undertake retraining, and amending the protocol to include injections into the hock, not the footpad. The IACUC approved the corrective actions and amendment. The NIH grant was not charged for any unauthorized animal activities and the funding component was notified.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

Axel V. Wolff, M.S., D.V.M.  
Deputy Director  
Office of Laboratory Animal Welfare

cc: IACUC Chair



**NATIONWIDE CHILDREN'S**  
*"When your child needs a hospital, everything matters."*

3544-N

**Abigail Wexner Research Institute at Nationwide Children's Hospital**

January 10, 2020

Axel Wolff, DVM  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
Rockledge 1, Suite 360  
6705 Rockledge Drive  
Bethesda, MD 20892

Dear Dr. Wolff:

The Research Institute at Nationwide Children's Hospital, in accordance with Assurance A3544-01 and PHS Policy IV.F.3., provides this report of noncompliance. I first reported this incident to you on December 13, 2019 via a telephone call.

On October 23, 2019, a vivarium staff member found two male mice with swollen hind footpads. Footpad injections were noted on the cage card. Both mice were euthanized by the laboratory staff on Oct. 23, 2019 per direction from the Attending Veterinarian for clinical condition and because the procedure was not approved by the IACUC. An IACUC investigation found that footpad injections were also undertaken at two earlier dates in August and September, 2019. Two mice were used on each occasion. The staff member who performed the footpad injections was unaware that the procedure was not approved by the IACUC. The PI mistakenly thought footpad injections had been added to an approved protocol by amendment, but this was not the case. The PI took responsibility for the error.

The following corrective action plan was implemented after the incident:

1. PI and all lab staff will undergo retraining on January 15, 2020 to reinforce their shared responsibility to review the approved protocol and confirm that procedures are described before proceeding. Training will be conducted by the Office of Research Compliance and Integrity and the IACUC Coordinator.
2. An amendment to carry out injections by another route (hock instead of footpad as recommended by the NIH) has been submitted for IACUC review and approved.

At the IACUC meeting on December 2, 2019 the Committee accepted the corrective action plan. The IACUC committee determined that this was an isolated incident and not a programmatic failure.

The footpad injections on October 23, 2019 were charged to NIH grant U01CA232488-01. (Ruoning Wang, PI). Federal funds were not used for footpad injections in August and September, 2019. The charges for the Oct. 23 incident will be removed from the NIH grant and the funding agency will be notified.

Please do not hesitate to contact me if you require further information.

With regards,

(b) (6)

Dennis Durbin, MD, MSCE  
Chief Scientific Officer  
Institutional Official  
Abigail Wexner Research Institute at Nationwide Children's Hospital

cc: IACUC Chair

700 Children's Drive | Columbus, Ohio 43205 | [www.NationwideChildrens.org](http://www.NationwideChildrens.org)

**Morse, Brent (NIH/OD) [E]**

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Thursday, January 16, 2020 8:35 AM  
**To:** (b) (6) OLAW Division of Compliance Oversight (NIH/OD)  
**Cc:** Durbin, Dennis; (b) (6)  
**Subject:** RE: Final report from D16-00331

Thank you for providing this report (b) (6) We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM  
Director  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

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**From:** (b) (6)  
**Sent:** Wednesday, January 15, 2020 3:54 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** Durbin, Dennis <Dennis.Durbin@nationwidechildrens.org>; (b) (6)  
(b) (6)  
**Subject:** Final report from D16-00331

Good afternoon,

Please see the attached Final Report for D16-00331. If you need any additional information, please let me know.

(b) (6)



**NATIONWIDE CHILDREN'S**  
*"When your child needs a hospital, everything matters."*



## Initial Report of Noncompliance

By: *aw*

Date: *12/13/19*

Time: *11:30*

Name of Person reporting: *Dennis Duggan*

Telephone #: *(b)(6)*

Fax #:

Email:

Name of Institution: *Research Institute at Nationwide Children's Hospital - Ohio*

Assurance number: *A3544*

Did incident involve PHS funded activity? *yes*

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

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

What happened?

*2 mice got post op infections, not approved*

Species involved: *Mice*

Personnel involved:

Dates and times:

Animal deaths: *2*

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

*Euthanize 2 mice, amend protocol, retrain*

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

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