



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

April 8, 2022

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

Dr. Dennis Durbin
Chief Scientific Officer
Nationwide Children's Hospital
700 Children's Drive — (b) (4)
Columbus, Ohio 43205-2696

Dear Dr. Durbin,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 4, 2022 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 March 28, 2022. According to the information provided, OLAW understands that twelve mice received an expired anesthetic. No adverse effects were reported with the mice.

The corrective actions consisted of the Principal Investigator retraining the laboratory staff on the appropriate handling and expiration information regarding the anesthetic drug. An information sheet is now kept in the controlled substance drawer and a color coded sticker system will be used on the vials to track expiration dates.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Sincerely,

(b) (6)

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

cc: IACUC Chair

A3544



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

Abigail Wexner Research Institute at Nationwide Children's Hospital

April 4, 2022

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 D16-00331 and PHS Policy IV.F.3., provides this report of an adverse event. We first reported this incident to you on March 28, 2022, via a telephone call.

Between the dates of January 15, 2022, through February 9, 2022, expired Telazol was administered to 12 mice. The drug expires after 7 days following reconstitution when stored at room temperature, which the lab was unaware of. The lab did not observe any negative effects on mice that received the expired drug. This was an isolated event found during the Hospital Pharmacy's annual inspection.

The following corrective action plan was implemented after the incident:

The Principal Investigator has reviewed all handling and expiration information for Telazol with laboratory personnel, and an information sheet containing all of the details is now provided and stored in the controlled substance drawer. The lab is now also utilizing a system with color-coded stickers to track expiration dates, which each lab member will be required to validate prior to using.

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

With regards,

(b) (6)

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

cc: IACUC Chair

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, April 6, 2022 10:20 AM
To: IACUC
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: D16-00331 Final Reports

Thank you for these reports. We will send responses soon.

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

From: IACUC <IACUC@nationwidechildrens.org>
Sent: Wednesday, April 6, 2022 10:05 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Durbin, Dennis <Dennis.Durbin@nationwidechildrens.org>; (b) (6)

Subject: [EXTERNAL] D16-00331 Final Reports

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Good morning,

Attached are the three final reports requested by Dr. Wolff on March 28, 2022. Please let us know if you have any questions.

Thank you,

The Institutional Animal Care and Use Committee (IACUC) Office
Abigail Wexner Research Institute at Nationwide Children's Hospital

(b) (6)





Initial Report of Noncompliance

By: (b) (6)

Date: 3 / 28 / 22

Time: 10:00

Name of Person reporting: DENNIS DURBIN, MD
Telephone #: (b) (6)
Fax #:
Email:

Name of Institution: Research Institute at Nationwide Children's Hospital
Assurance number: A3544

Did incident involve PHS funded activity? PHS
Funding component: NHLBI
Was funding component contacted (if necessary):

What happened?
12 mice received spinal analgesic; no adverse effects

Species involved: Mice
Personnel involved:
Dates and times:
Animal deaths: 0

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

Projected submission to OLAW of final report from Institutional Official:

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Case #