



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 R]

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 three manually restrained rats died following oral gavage. Necropsy revealed the cause of death to have been due to regurgitation and aspiration.

The corrective actions consisted of retraining the laboratory staff on the appropriate performance of gavage procedures. The rats will be acclimated to handling, a veterinarian will monitor the gavage procedure and certify competency, and the rats will be observed following the procedure. The protocol was amended to include humane endpoints associated with aspiration pneumonia and the standard operating procedures will now include acclimation to restraint. The laboratory was placed under enhanced post-approval monitoring.

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



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.

On February 1, 2022, 8 rats were given study-approved material via oral gavage by a fully trained lab staff member. These animals were not sedated during the gavaging, and the lab staff had difficulty restraining them manually. Of those 8 rats, 3 died due to regurgitation and aspiration of the material administered via oral gavage. The cause of death was confirmed via necropsy.

The following corrective action plan was implemented after the incident:

The lab has been assigned required retraining of oral gavage and must repeat the training twice, at minimum. The animals on the study will be acclimated to intentional handling for at least 5 days prior to starting any experiments. For the first 5 days of the study, the lab coordinated to have a representative from the Veterinary Technical Team present for each gavaging episode. The Clinical Veterinarian has reported to the IACUC that this is now complete along with signed documentation and that no adverse events were witnessed as well as proper technique. The lab is required to monitor all animals for at least 30 minutes following an oral gavage procedure, and their IACUC protocol will be amended to include humane endpoints associated with aspiration pneumonia. The IACUC will continue to follow up with this protocol with additional Post-Approval Monitoring and review our restraint SOPs to include acclimation to restraint as a standard policy.

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)



A3544-R



Initial Report of Noncompliance

By: (b) (6)

Date: 3/28/22

Time: 1000

Name of Person reporting: Dennis DUBBIN, 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? No

Funding component: _____

Was funding component contacted (if necessary): _____

What happened?

3 rats died after gavage. Necropsy revealed aspiration pneumonia

Species involved: Rat

Personnel involved: _____

Dates and times: _____

Animal deaths: 3

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

Retrain staff

Projected submission to OLAW of final report from Institutional Official: _____

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Case # _____