



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

May 12, 2023

Re: Animal Welfare Assurance  
A3317-01 [OLAW Case I]

Stacie Bloom, Ph.D.  
Vice Provost for Research  
New York University  
Office of the Provost; Bobst,  
70 Washington Square South, (b) (4)  
New York, NY 10012

Dear Dr. Bloom,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your May 5, 2023 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at New York University Washington Square Campus, following up on an initial telephone report on April 24, 2023. According to the information provided, OLAW understands that 67 mice were subjected to retro-orbital injections without the use of general anesthesia as required in the approved protocol. The student responsible had not been aware of the procedures approved in the protocol. No adverse effects were reported in the mice.

The corrective actions consisted of prohibiting continuation of the injections without anesthesia, amending the protocol to include retro-orbital injections with local ocular anesthetic application based on a scientific justification, having laboratory staff certify understanding of the contents of the protocols, and having the laboratory staff review all approved techniques in use to ensure that they are being performed as described.

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

cc: IACUC Chair

**NEW YORK UNIVERSITY***A private university in the public service*

Institutional Animal Care and Use Committee  
665 Broadway, Suite 804  
New York, NY 10012  
Phone 212-998-4256  
Fax 212-995-4029

May 5, 2023

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:

New York University Washington Square Campus (NYU-WS), in accordance with Assurance A3317-01 and PHS Policy IV.F.3., provides this report of protocol non-compliance whereby retro-orbital injections were performed on mice without the use of general anesthesia despite the IACUC-approved protocol stipulating the need for the latter. The work was conducted under IACUC-approved protocol number 2021-1139 which is funded by NIH grant NS122316 (A21-0552). Lee-Ronn Paluch, BVSc, DACLAM, Director and Attending Veterinarian, Office of Veterinary Resources (OVR) left a voice message with OLAW on Friday April 21, 2023 to report the incident, which was subsequently conveyed to Devora McCoy, MBA at OLAW, on Monday April 24, 2023 via telephone. This case was assigned number A3317-I.

This was first brought to the attention of the IACUC Director and OVR Director on March 9, 2023 by a member of a different lab who was requesting to add the technique to their own protocol based on advice they had received from a PhD student who described the technique without general anesthesia. An email was sent by the clinical veterinarian to the PI and lab manager on March 10, 2023 to verify whether injections had been performed in this manner. The lab confirmed this was the case and agreed to refrain from performing any retro-orbital injections without provision of general anesthesia until further notice.

At the IACUC's convened monthly meeting on March 16, 2023, the IACUC Director reported the non-compliance and the committee decided that a formal investigation by a sub-committee (comprised of the Chair, IACUC Director, and Attending Veterinarian) was necessary to determine the scale of non-compliance.

Over the course of the following two weeks, interviews were conducted with the lab member who first reported the issue, the PhD student who performed the injections, and the postdoctoral researcher who restrained the animals for injection.

The findings of the investigation are as follows:

- The lab manager submitted a protocol amendment to add retro-orbital injections to the

protocol in April 7, 2022 which was written by the postdoctoral researcher and did not mention the use of general anesthesia. While this justification was not provided in the amendment, the post-doc explained during the investigation that isoflurane is contraindicated as it has been shown to alter behavior and the mice were expected to perform behavioral assays immediately after injection.

- The veterinarians who pre-reviewed the amendment, required modifications to the amendment including the use of general anesthesia and conveyed this to the lab manager who made the required changes. The modified amendment was subsequently approved on May 9, 2022
- The PhD student and postdoctoral researcher did not review the modified amendment, assuming that it had been approved as originally submitted and proceeded to perform unanesthetized injections on mice on four separate occasions on a total of 67 mice as documented below:
  - June 1 2022 on 12 mice
  - August 26 2022 on 24 mice
  - November 22 2022 on 18 mice
  - March 7 2023 on 13 mice
  - All mice were euthanized per protocol between 2-24 hours post-injection. No orbital trauma, signs of pain or other adverse effects were observed in this time period.

The IACUC Director and OVR Director/AV subsequently met with the PI and lab manager on April 7, 2023 to discuss the incidents and a plan for correction. The PI and lab manager expressed remorse for the communication breakdown that led to the noncompliance, and suggested the following corrective measures:

1. Submit a protocol amendment to request the use of retro-orbital injections without general anesthesia, on the proviso that local anesthesia will be applied to the eye, providing scientific justification for withholding general anesthesia.
2. Going forward, all lab members will be required to review newly approved protocols and amendments and to document that they have read and understood them with a signature.
3. The lab will review all existing approved techniques used by the lab to ensure that all are being performed appropriately and as described.

At their meeting on April 20, 2023, the IACUC reviewed and accepted the corrective action plan as submitted by the PI and agreed that the AV should report this incident to OLAW.

New York University 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 regarding this report, please contact James Higham, PhD, IACUC Chair and Lee-Ronn Paluch, BVSc, DACLAM, Attending Veterinarian.

Thank you for your consideration of this matter.  
Sincerely,

(b) (6)

Stacie Bloom, PhD, Vice Provost for Research  
Institutional Official  
New York University

**McCoy, Devora (NIH/OD) [E]**

---

**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, May 8, 2023 1:12 PM  
**To:** leeronn.paluch@nyu.edu  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: [EXTERNAL] OLAW Final Report Case #A3317-I

Good afternoon Dr. Paluch,

Thank you for sending us this final report for case A3317-I and we will send an official response soon.

Best,  
Devora

Devora McCoy, BS, MBA ([pronunciation](#))  
Program Analyst  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

Phone: 301-435-2390  
Email: [devora.mccoy@nih.gov](mailto:devora.mccoy@nih.gov)

**From:** Lee-Ronn Paluch <lrp289@nyu.edu>  
**Sent:** Friday, May 5, 2023 11:02 AM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Cc:** (b) (6) Stacie Bloom <blooms03@nyu.edu>; James Paul Higham <jhigham@nyu.edu>  
**Subject:** [EXTERNAL] OLAW Final Report Case #A3317-I

Good morning,

Attached is the final report for NYUWS (AWA #A3317-01) Case I, reported to Devora McCoy on 4/24/23.

Sincerely,  
Lee-Ronn

Lee-Ronn Paluch, BVSc, DACLAM  
Director/Attending Veterinarian, Office of Veterinary Resources  
Co-Director, NYU-Regeneron Postdoctoral Training Program in Laboratory Animal Medicine  
Clinical Associate Professor of Neural Science  
New York University

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.



A3317-I

## Initial Report of Noncompliance

By: DCM

Date: 4/24/2023

Time: 12pm

Name of Person reporting: Leeronn Paluch

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: NYU Washington Square

Assurance number: A3317-01

Did incident involve PHS funded activity? Yes

Funding component: NIH

Was funding component contacted (if necessary):

What happened:

Protocol noncompliance. Grant NS122316; A21-0552. Retro-orbital inj. on mice without general anesthesia; post-doc submitted amendment that wasn't approved but miscommunication led to noncompliance; noncompliance incidents occurred on June 1, 2022- 12 mice, Aug 26- 4 mice, Nov 22- 8 mice, March 22- 13mice. March 10 the lab notified to suspend procedures until investigation is complete and corrective actions are established.

Species involved: mice

Personnel involved: Post-doc. & Ph.D. Student

Dates and times: March 9- IACUC became aware

Animal deaths:

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

Projected submission to OLAW of final report from Institutional Official:

~2 weeks

OFFICE USE ONLY

Case #