



DEPARTMENT OF HEALTH & HUMAN SERVICES

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FOR US POSTAL SERVICE DELIVERY:

Office of Laboratory Animal Welfare  
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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

DATE: December 16, 2022

TO: Nina F. Schor, M.D., Ph.D.  
Deputy Director for Intramural Research, NIH

FROM: Deputy Director, Office of Laboratory Animal Welfare

SUBJECT: Animal Welfare Investigation (NIDA 46-22) - Animal Welfare Assurance  
A4149-01 [Case 17V]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 7, 2022 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the National Institute on Drug Abuse, NIH. According to the information provided, OLAW understands that the post-operative cage cards on some rat cages were incomplete and did not list the date of surgery or the treatments given. The laboratory staff was not providing adequate information on the cage cards and this had occurred on several occasions.

The corrective actions consisted of counseling the Principal Investigator and retraining the laboratory staff on how to appropriately fill out the cage cards and stressing the requirement for maintaining adequate animal procedure records.

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: Dr. Richard Wyatt  
Dr. Stephen Denny  
Dr. Alex Hoffman



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health  
Bethesda, Maryland 20892

[www.nih.gov](http://www.nih.gov)

December 7, 2022

TO: Brent C. Morse, D.V.M.  
Director, Division of Compliance Oversight  
Office of Laboratory Animal Welfare

FROM: Deputy Director for Intramural Research, NIH

SUBJECT: Animal Welfare Investigations - Assurance D16-00602 (NIDA 46-22)

This correspondence conveys the results of an animal incident investigation by the NIH National Institute on Drug Abuse (NIDA) ACUC in accordance with Assurance D16-00602 and PHS Policy IV.F.3. The incident involved a research team's failure to maintain appropriate post-operative records following several rat surgeries.

The event was first reported to the NIH Office of Animal Care and Use by the NIDA ACUC Chairman on November 9, 2022.

Please contact me or Dr. Stephen Denny, Director, Office of Animal Care and Use, if additional information or clarifications are required.

Nina F. Schor -	Digitally signed by Nina F. Schor - S
S	Date: 2022.12.07 13:30:53 -0500

Nina F. Schor, M.D., Ph.D.

Attachment

cc: Dr. Wyatt  
Dr. Denny  
Dr. Hoffman



**TO:** Dr. Nina Schor, Deputy Director for Intramural Research  
**FROM:** Alexander F. Hoffman, Chair, NIDA Animal Care and Use Committee  
**DATE:** 12/7/2022  
**SUBJECT:** Reportable incident on protocol non-compliance

The National Institute on Drug Abuse Intramural Research Program, in accordance with Assurance A4149-01 and PHS Policy IV.F.3., reports the following incident of protocol non-compliance involving failure to maintain appropriate animal-related records in a protocol entitled "Evaluation of the therapeutic effects of transcranial magnetic stimulation in rodent models of cocaine dependence." A summary of the incident, major findings, and proposed remedies are described below.

**Summary of incident:** On 11/9/2022, a single, post-operative rat required minor treatment by animal care staff. Upon review of the animal's medical history, the facility veterinarian reported to the ACUC Chair that laboratory staff were insufficiently documenting post-operative records. Specifically, the post-operative cage card maintained with the animal was incomplete, with no information about the date of surgery or treatments given. The veterinarian further reported to the Chair that this had occurred on at least 3 previous occasions over the last few months. The ACUC Chair communicated this violation to the NIH Office of Animal Care and Use on 11/9/2022, and to the ACUC at its regular meeting on 11/17/2022.

Based upon these facts, it is clear that a reportable violation of PHS policy occurred; specifically, "failure to maintain appropriate animal-related records (e.g., identification, medical, husbandry)."

**Remedy:** The facility veterinarian met with lab personnel on 11/9/2022 to review the importance of documenting all post-operative records on the cage card, and to demonstrate how to complete the cards properly. In addition, the Chair contacted both the PI and responsible personnel directly to stress the need to thoroughly document all animal health records in order to facilitate treatment by animal care staff when necessary. The Chair further reminded the PI and personnel that failure to do so is a reportable violation of PHS policy, and that additional incidents could result in suspension of animal activities. The PI met with the veterinarian, all lab personnel, as well as the Branch Chief, to ensure that appropriate record-keeping practices would be maintained in the future.

### **Concluding statement**

Although no major issues with the health and welfare of the animals were noted, the failure to appropriately maintain medical records on multiple occasions is clearly a reportable issue. The PI and staff were appropriately retrained by the facility veterinarian and discussed with the ACUC Chair the need to maintain appropriate and complete medical records of all animals. The ACUC feels that these steps will sufficiently mitigate against recurrence of such issues in the future.

The NIDA IRP ACUC is committed to the highest animal welfare standards, and appreciates the support of OLAW in this regard. Should you have any additional questions or concerns regarding this report, please do not hesitate to contact me.

Sincerely,

(b) (6)

Alex Hoffman, Ph.D.

***Chair***

***NIDA IRP Animal Care and Use Committee***

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

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**From:** OLAW Division of Compliance Oversight (NIH/OD)  
**Sent:** Monday, December 12, 2022 8:06 AM  
**To:** Denny, Stephen (NIH/OD) [E]  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: D16-00602 NIH Animal Incident Report (NIDA 46-22)

Good morning Dr. Denny,

Thank you for sending us this report and we will send an official response soon.

Best,  
Devora

Devora McCoy, BS, MBA  
Program Analyst  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health  
301-435-2390

**From:** Denny, Stephen (NIH/OD) [E] <stephen.denny@nih.gov>  
**Sent:** Friday, December 9, 2022 2:18 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** D16-00602 NIH Animal Incident Report (NIDA 46-22)

Dear OLAW/DCO,

The attached documents from the NIH Institutional Official and the NIH National Institute on Drug Abuse (NIDA) ACUC address a research team's failure to maintain appropriate post-operative records following several rat surgeries.

The incident was first reported to the NIH Office of Animal Care and Use by the NIDA ACUC Chair on November 9, 2022.

If you have any questions please contact me via email or at the phone number listed below. Thank you, Steve

STEPHEN DENNY, DVM, MS, DACLAM, DACVPM | Director, Office of Animal Care and Use | NIH Bethesda Campus, Building 31/Room B1C37 |  
Phone: (301) 435-2188 | *NIH . . . Turning Discovery Into Health* |