



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Bethesda, Maryland 20892-7982
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: September 30, 2022

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

FROM: Director
Division of Compliance Oversight, OLAW

SUBJECT: Animal Welfare Investigation (NIDA #34-22) - Animal Welfare Assurance
A4149-01 [Case 17M]

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 16, 2022 memo regarding an incident of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the National Institute on Drug Abuse (NIDA). According to the information provided, OLAW understands that on June 25, 2022, the ACUC Chair was informed by an investigator that they had failed to submit an amendment to add personnel to their protocol. Although all required training had been completed, the individual began the use of nonhuman primates in late January in several procedures. No issues were reported, and by all accounts the individual performed all tasks with high proficiency.

Corrective and preventive actions: The PI submitted an amendment to the protocol that was approved by the ACUC. The PI was reminded of their responsibility to ensure that personnel are added to protocols in a timely manner, and to meet in future with any new staff to explicitly counsel them that live animal work is not allowed until the individual has been confirmed to be approved on a protocol. Badge access to the vivarium will only be granted once individuals have been confirmed to be added to an active, approved protocol. The ACUC policy was modified to state "If an amendment has not been submitted prior to completing in-processing procedures, a notice will be sent to the PI stating that facility access will not be granted to personnel until the amendment is approved." A notice was sent out from the Chair to all NIDA personnel informing them of this change in access policy.

The actions taken to resolve the issues and prevent recurrence were appropriate and accepted by OLAW. The NIDA ACUC is to be commended for their attention to improving their program. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C. Morse -

S

Date: 2022.09.30 14:09:04 -04'00'

Brent C. Morse, DVM, DACLAM

Director

Division of Compliance Oversight

Office of Laboratory Animal Welfare

cc: Dr. Stephen Denny
Dr. Richard Wyatt
Dr. Hoffman, NIDA ACUC Chair



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
Bethesda, Maryland 20892

www.nih.gov

September 16, 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 34-22)

This correspondence conveys the results of an animal incident investigation by the NIH National Institute on Aging (NIA) ACUC in accordance with Assurance D16-00602 and PHS Policy IV.F.3. The incident involved the failure of an investigator to gain ACUC approval for a new research assistant to conduct nonhuman primate work prior to their performing those activities. No nonhuman primates were harmed.

The event was first reported to the NIH Office of Animal Care and Use by the NIA Animal Program Director on June 27, 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 -S	Digitally signed by Nina F. Schor -S Date: 2022.09.16 10:32:43 -04'00'
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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: 8/16/2022
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 add personnel in a protocol entitled "Determinants and long-term consequences of opioid and cocaine self-administration in squirrel monkeys" A summary of the incident, major findings, and proposed remedies are described below.

Summary of incident: On 6/25/2022, the ACUC Chair was informed by the investigator that they had failed to submit an amendment to their protocol to add personnel to their protocol. The amendment to add the individual was submitted along with the email informing the Chair. The Animal Program Director communicated this violation to the NIH Office of Animal Care and Use on 6/27/2022.

Investigation and finding: The Chair met with both the PI and the individual added to the protocol to review this case. Based on these meetings, it was determined that the individual (a new lab member) began their preliminary training offsite in mid-January 2022. The individual completed all required on-board training required for both animal and NHP use in the intramural program, including meeting with the facility veterinarian to review Bite, Scratch, Splash and Exposure procedures. The individual was cleared by OMS for NHP work. The individual then began onsite training in late January in several procedures, including basic handling of animals, chairing procedures, and catheter maintenance. The training was supervised by at least two other lab members that were fully qualified. At this point, the individual was granted full vivarium access, and continued to perform procedures. No issues were reported, and by all accounts the individual performed all tasks with high proficiency. The individual indicated that they believed they had been added to the protocol, but never confirmed this directly with the PI. In addition, a training assurance was never signed by the individual and the PI, as required when personnel are added to an ASP.

Based upon these facts, it is clear that a reportable violation of PHS policy occurred; specifically, "participation in animal-related activities by individuals who have not been determined by the IACUC to be appropriately qualified and trained as required by IV.C.1.F"

Remedy: Upon discovery of the failure to add personnel, the PI submitted an amendment to the ASP that was approved by the ACUC. The PI was reminded of their responsibility under NIH Policy 3040-2 to ensure that personnel are added to protocols in a timely manner, and to meet in future with any new staff to explicitly counsel them that live animal work is not allowed until the individual has been confirmed to be approved on an ASP. The ACUC was informed of this incident at its meeting on 7/28/2022.

Although this particular incident was confined to this lab, there was a larger concern that allowing vivarium (badge) access for individuals after on-boarding, but prior to amendment approval, could unintentionally lead to further incidents of this type. Accordingly, the ACUC voted on 7/28/2022 to amend its policy for review of significant changes to animal study proposals. Badge access to the vivarium will only be granted once all in-processing requirements have been met *and* individuals have been confirmed to be added to an active, approved protocol. The policy was modified to state "If an amendment has not been submitted prior to completing in-processing procedures, a notice will be sent to the PI stating that facility access will not be granted to personnel until the amendment is approved." A notice was sent out from the Chair to all NIDA personnel informing them of this change in access policy.

Concluding statement

Due to a self-reported oversight by the PI, an individual performed procedures on animals prior to being added to a protocol. There was no evidence that any animals were harmed by these procedures, and the individual was appropriately trained and had received all clearance appropriate for the work. The PI and staff were appropriately counseled as to the need to submit amendments sooner and the importance of knowing, rather than assuming, that personnel are fully approved prior to proceeding. Although it is felt that this represents an unusual instance of oversight by the PI, the ACUC further modified its policy to ensure that badge access to vivarium for new hires is dependent on not only completion of training, but on addition to the protocol as well. 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]

From: Denny, Stephen (NIH/OD) [E]
Sent: Friday, September 16, 2022 3:15 PM
To: OLAW Division of Compliance Oversight (NIH/OD)
Subject: D16-00602 NIH Animal Incident Report (NIDA 34-22))
Attachments: D16-00602 NIH IO Animal Incident Memo (NIDA 34-22).pdf; D16-00602 NIH ACUC Animal Incident Report (NIDA 34-22).pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Dear OLAW/DCO,

The attached documents from the NIH Institutional Official and the NIH National Institute on Drug Abuse (NIDA) ACUC address an animal incident involving the failure of the Principal Investigator to gain ACUC-approval to add a new researcher to an ACUC-approved nonhuman primate project prior to the researcher's working with the study's nonhuman primates. The incident was first reported to the NIH Office of Animal Care and Use by the NIDA Animal Program Director on June 27, 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** |

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, September 16, 2022 3:44 PM
To: Denny, Stephen (NIH/OD) [E]
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: D16-00602 NIH Animal Incident Report (NIDA 34-22))

Good afternoon 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, September 16, 2022 3:15 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: D16-00602 NIH Animal Incident Report (NIDA 34-22))

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STEPHEN DENNY, DVM, MS, DACLAM, DACVPM | Director, Office of Animal Care and Use | NIH Bethesda Campus, Building 31/Room B1C37 |
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