



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTHFOR 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

July 20, 2020

Re: Animal Welfare Assurance
#A3002-01 [OLAW Case 1T]

Dr. Steven E. Braverman
Medical Center Director
VA Greater Los Angeles Healthcare System
Department of Veterans Affairs
11301 Wilshire Boulevard
Los Angeles, CA 90073

Dear Dr. Braverman,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your July 7, 2020 letters reporting two instances of protocol deviation resulting in noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Greater Los Angeles Healthcare System. We also acknowledge the letter from your IACUC Chair explaining the circumstances surrounding the reporting delay. According to the information provided, OLAW understands that on January 15, 2020 it was determined that two felines had received microinjection volumes and drug dosages that were higher than approved in the protocol. In one animal, an unapproved alternative technical method for inducing short-term hypoxia was used. There were no detrimental clinical effects. This activity was funded by NINDS.

Corrective actions included the lab immediately stopping unapproved procedures and submitting protocol modifications that were subsequently approved by the IACUC.

The second incident involved the Attending Veterinarian finding that a post-operative feline had undergone a minor skin repair surgery. Although the incision had healed without complication, the research team was not approved by the IACUC to perform this specific surgery, and the Attending Veterinarian was not consulted in advance. This activity was also funded by NINDS.

Corrective actions included the lab agreeing to always contact the VMO in the future before any steps are taken to anesthetize or perform surgery when the procedure is not described in the approved protocol. The research team submitted an addendum to perform such minor surgeries as part of their protocol, which the IACUC approved

The prompt consideration of these matters by the Greater Los Angeles Healthcare System was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to resolve the issues and prevent recurrence were appropriate. We appreciate being informed of these matters and find no cause for further action by this office at this time.

Sincerely,

Brent C. Morse -S Digitally signed by Brent C. Morse -S
Date: 2020.07.20 10:37:58 -04'00'

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact

(b)(6) (b)(6) VA

(b)(6) NINDS

A3002-IT



DEPARTMENT OF VETERANS AFFAIRS
Greater Los Angeles Healthcare System
11301 Wilshire Boulevard
Los Angeles, CA 90073

7/7/20

In Reply Refer To: 691/MC

Axel Wolff, DVM, MS
 Deputy Director, Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health
 RKL1, Suite 360, MSC 7982
 6705 Rockledge Drive
 Bethesda, MD 20892-7982

Dear Dr. Wolff,

In accordance with our PHS Assurance # D16-00002 and consistent with VA agency policies, we report a case of non-compliance with PHS Policy. This research was funded by NINDS.

We completed a post-approval monitoring of one of our research protocols on 1/15/20 involving felines, and found the following deviations from the approved protocol, none of which had any detrimental clinical effects on the animals:

- a. In two animals, microinjection volumes were higher than approved by the IACUC and the dose of several drugs was higher than approved by the IACUC.
 - b. In one animal, an alternative technical method of inducing short-term hypoxia was used but not approved by the IACUC.
2. The lab agreed to immediately stop all non-approved work and only do work that was on the approved protocol. They also submitted a modification to incorporate the changes noted above. The modification to make the changes was reviewed and approved at our IACUC meeting on 2/5/20.

Should you have further questions regarding this matter, please contact the IACUC Chair at (b)(6) or the Animal Program Compliance Officer at (b)(6)

Steven E. Braverman, M.D.
 Medical Center Director

Bakersfield Community
 Based Outpatient Clinic
 1801 Westwind Drive
 Bakersfield, CA 93301
 (661) 632-1800

Los Angeles Ambulatory
 Care Center
 351 E. Temple Street
 Los Angeles, CA 90012
 (213) 253-2677

Santa Barbara
 Community
 Based Outpatient Clinic
 4440 Calle Real
 Santa Barbara, CA
 93110
 (805) 683-1491

Sepulveda Ambulatory
 Care
 Center and Nursing
 Home
 16111 Plummer Street
 North Hills, CA 91343
 (818) 891-7711

West Los Angeles
 Healthcare Center
 11301 Wilshire
 Boulevard
 Los Angeles, CA 90073
 (310) 478-3711

cc: Chief of Staff (691/11)
Associate Chief of Staff/R&D (691/151)
Research Compliance Officer (691/00EI)
Research Compliance Analyst (691/00EI)
IACUC Chair (691/151)
Research and Development Committee Chair (691/151)
Animal Program Compliance Officer (691/151)
Chief Veterinary-Medical Officer (508/151V)
AAALAC International
Director of NINDS



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Greater Los Angeles Healthcare System
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7/7/20

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Axel Wolff, DVM, MS
 Deputy Director, Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health
 RKL1, Suite 360, MSC 7982
 6705 Rockledge Drive
 Bethesda, MD 20892-7982

Dear Dr. Wolff,

In accordance with our PHS Assurance # D16-00002 and consistent with VA agency policies, we report a case of non-compliance with PHS Policy. This research was funded by NINDS.

Our Attending Veterinarian found that a minor skin repair surgery had been performed under anesthesia on a post-operative feline in March 2019 without her knowledge. Although the incision had healed without complication, the research team was not approved by the IACUC to perform this specific surgery, and the Attending Veterinarian should have been consulted in advance.

The lab agreed to always contact the VMO in the future before any steps are taken to anesthetize or perform surgery when the procedure is not described in the approved protocol. The research team submitted an addendum to perform such minor surgeries as part of their protocol, which the IACUC approved in June 2019.

Should you have further questions regarding this matter, please contact the IACUC Chair at (b)(6) or the Animal Program Compliance Officer at (b)(6)

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AAALAC International
Director of NINDS



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Los Angeles, CA 90073

7/8/20

In Reply Refer To: 691/MC

Axel Wolff, DVM, MS
 Deputy Director, Division of Compliance Oversight
 Office of Laboratory Animal Welfare
 National Institutes of Health
 RKL1, Suite 360, MSC 7982
 6705 Rockledge Drive
 Bethesda, MD 20892-7982

Dear Dr. Wolff,

This is a cover letter to explain our delay in reporting two protocol deviations, one a drug dose deviation and one an unapproved procedure. The research was funded by NINDS and our PHS Assurance number is D16-00002.

- a. One was originally reported to the IACUC in March 2019 and the other in February 2020. Both protocol deviations were reviewed by our IACUC at the time of reporting, and the IACUC voted that neither case was reportable. In the case of the drug dose deviation, the IACUC's decision was based in part on guidance from the VA Central Office.
- b. The VA Office of Research Oversight (ORO) recently reviewed our program and informed us that these actually were reportable.
- c. The IACUC obtained additional guidance and did a fresh review of both episodes of noncompliance at their July 2020 meeting. The IACUC voted that both episodes were reportable, and the reports are included.

The IACUC is taking additional training on when instances of noncompliance are reportable, including taking the PRIM&R Webinar "Advanced Noncompliance Scenarios for IACUCs - Laboratory Animals and Wildlife Recording".

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Should you have further questions regarding this matter, please contact the IACUC

Chair at (b)(6) or the Animal Program Compliance Officer at (b)(6)

(b)(6)

(b)(6)

(b)(6)

(b)(6)

cc: Medical Center Director
Chief of Staff (691/11)
Associate Chief of Staff/R&D (691/151)
Research Compliance Officer (691/00EI)
Research Compliance Analyst (691/00EI)
IACUC Chair (691/151)
Research and Development Committee Chair (691/151)
Animal Program Compliance Officer (691/151)
Chief Veterinary Medical Officer (508/151V)
AAALAC International
Director of NINDS

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Friday, July 10, 2020 7:25 AM
To: (b)(6)
Subject: RE: Reports on protocol deviations

Thank you for these reports, (b)(6). We will send responses soon.

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

From: (b)(6) (b)(6)@va.gov>
Sent: Thursday, July 9, 2020 1:44 PM
To: Wolff, Axel (NIH/OD) [E] (b)(6)@od.nih.gov>
Cc: accredit@aaalac.org; Koroshetz, Walter (NIH/NINDS) [E] (b)(6)@ninds.nih.gov>
Subject: Reports on protocol deviations

Dear Dr. Wolff,

Attached are three documents concerning research on a project that was funded by NINDS:

- 1) A letter signed by our Institutional Official about deviations in drug doses.
- 2) A letter signed by our Institutional Official about an unapproved procedure.
- 3) A letter signed by the Chair of our IACUC explaining why these were not reported to you sooner.

These reports are being copied to AAALAC and to the Director of NINDS and will be forwarded to various VA authorities.

Please let me know if you have any questions.

Sincerely,

(b)(6)

**Department of Veterans Affairs
 Greater Los Angeles Healthcare System**

(b)(6)

Los Angeles, CA 90073

(b)(6)

(b)(6)@va.gov