



DEPARTMENT OF HEALTH & HUMAN SERVICES

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NATIONAL INSTITUTES OF HEALTH

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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) 402-7065

January 7, 2019

Re: Animal Welfare Assurance
#A3260-01 (OLAW Case U)

Dr. Heidi Aronin
Senior Vice President and
Chief Administrative Officer
SUNY Downstate Medical Center
450 Clarkson Avenue, MSC#112
Brooklyn, NY 11203

Dear Ms. Aronin,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 31, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the SUNY Downstate Medical Center. Your letter supplements the information provided to this office on September 28, 2018. According to the information provided, OLAW understands that fifteen rats on a PHS-funded study did not receive the post-surgical analgesic during the subsequent two days as required by protocol. They did receive morphine, the experimental agent, on each of these two days.

Corrective actions included counseling of the PI including review of the noncompliance. The PI submitted, and the IACUC approved, a protocol amendment to modify the post-operative analgesia plan for specific surgeries. The PI will follow the analgesia plan for all surgeries as approved in the protocol.

OLAW appreciates the prompt consideration of this matter by the SUNY Downstate Medical Center, which was consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate actions have been taken regarding this incident. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely,

(b) (6)

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

cc: IACUC Contact



SUNY
DOWNSTATE
Medical Center

University Hospital of Brooklyn
College of Medicine
School of Graduate Studies
School of Public Health
College of Nursing
College of Health Related Professions

Institutional Animal Care and Use Committee

December 31, 2018

Acting Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982

Animal Welfare Assurance Number: D16-00167(A3260-01)

Dear Dr. Morse,

I'm writing to advise you of a protocol non-compliance associated with a PHS-funded project. Between January – June 2018, fifteen rats underwent survival surgery and received pre-emptive systemic analgesia as described in the protocol. However, animals did not receive post-operative analgesia during the subsequent two days according to the protocol. They did receive systemic morphine, the experimental agent, on each of these two days. The PI submitted and the IACUC approved a protocol amendment to modify the post-operative analgesia plan for specific surgeries. The IACUC Chair and Director, Office of Animal Welfare met with the PI to review the non-compliance, and the PI will follow the analgesia plan for all surgeries as approved in the protocol. During the preliminary report of the non-compliance to OLAW, we were advised that the amount of animal-related cost is below the threshold for reimbursement to the NIH. Please let us know if you need additional information on this matter.

Best,

(b) (6)

Heidi Aronin
Institutional Official

State University of New York Downstate Medical Center
450 Clarkson Avenue, MSC 112; Brooklyn, NY 11203-2098 • Phone 718-270-4645

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, January 03, 2019 2:25 PM
To: Julie Sharp; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: D16-00167 (A3260-01) Reporting Non-compliance

Thank you for these two final reports Dr. Sharp. We will send official responses soon.

Best regards and a Happy New Year to you , too! Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

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From: Julie Sharp [mailto:Julie.Sharp@downstate.edu]
Sent: Thursday, January 03, 2019 12:42 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: D16-00167 (A3260-01) Reporting Non-compliance

Dear OLAW,

Happy New Year! Attached are two close out letters for non-compliances that were previously reported verbally to Dr. Morse (letter dated 12-31-2018) and Dr. Wolff (letter dated 01-02-2019). Please let me know if you need additional information for either casefile.

Best,
Julie

Julie M. Sharp, DVM, CPIA, DACLAM
Director, Office of Animal Welfare
Office of Research Administration – IACUC

SUNY - Downstate Medical Center
450 Clarkson Ave., MSC 112
Brooklyn, NY 11203-2098
Office: [REDACTED]
Fax: [REDACTED]
<http://research.downstate.edu/iacuc/iacuc.html>

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A3260 - U
Prelim.

PI: Dr. Alan Ginzler

Grant: NIH R01 DA043774

Species: Rats

Number of Animals: 15

Time Frame: January – June 2018

Direct Animal Costs: 30 days (\$0.35) = \$10.50

All animals received pre-operative systemic NSAID but did not receive the subsequent two doses per the IACUC protocol. They received systemic morphine (experimental agent) on subsequent days.

Corrective Action: An amendment to modify the post-operative analgesia plan for specific surgeries is under review by the IACUC, and any procedures performed prior to approval of the amendment will follow the currently approved protocol.

SUNY Downstate

Submitted by Julie Sharp, DVM on 9/28/18