



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) 402-7065

May 26, 2021

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

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 May 18, 2021 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the State University of New York Downstate Medical Center - Brooklyn. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, this Office understands that the SUNY Downstate Animal Care and Use Committee (ACUC) determined that instances of noncompliance occurred with respect to: the conduct of animal-related activities without prior IACUC review and approval. The final report states between March 28, 2019 – November 5, 2020, protocol personnel administered human chorionic gonadotropin (hCG) to at least 35 rats without prior IACUC approval. It is stated no animal welfare issues or adverse events developed due to the noncompliance.

The IACUC chairperson and the principal investigator (PI) discussed the findings on December 8, 2020. The PI was instructed to immediately cease administration of hCG to rats and submit an amendment to the protocol to add the agent. At the December 14, 2020 IACUC meeting, the committee reviewed and approved the following corrective action plan:

- The use of hCG in rats by the PI's lab is to be suspended until an amendment to add this agent to the associated protocol is approved by the IACUC.
 - The amendment was approved by the IACUC on January 21, 2021.
- The lab areas listed in the associated protocol will be visited quarterly by the Sr. Research Support Specialist to conduct post-approval monitoring (PAM) sessions beginning in April 2021 and ending in January 2022. The PAM sessions will include review of the hCG drug administration log.

It is noted that this research is supported by PHS funds. Based on its assessment of this explanation, OLAW understands that the State University of New York Downstate Medical Center - Brooklyn has implemented appropriate measures to correct and prevent recurrences of these problems and is now compliant with provisions of the PHS Policy. We appreciate being informed of these matters and find no cause for further action by this Office.

Sincerely,

Jacquelyn T.
Tubbs -S

Digitally signed by Jacquelyn T.
Tubbs -S
Date: 2021.05.26 15:07:49 -0400

Jacquelyn Tubbs, DVM, DACLAM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

No prelim.



**SUNY
DOWNSTATE**
Health Sciences University

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

Heidi J. Aronin, MPA
Senior Vice President and Chief Administrative Officer

May 18, 2021

Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892
Animal Welfare Assurance Number: D16-00167(A3260-01)

Dear Dr. Morse:

I'm writing to inform you of a protocol non-compliance regarding the use of hCG (human chorionic gonadotropin) in rats associated with NIH grants NIH-R44CA188154, 2 R44 OD026184-02. Between 03/28/2019 and 11/05/2020, protocol personnel administered hCG, which is a New York State controlled substance, to at least 35 rats without prior IACUC approval. No animal welfare issues or adverse events were found to have occurred due to the non-compliance.

On 12/8/2020, the IACUC Chair and the PI met to discuss the nature of the findings and the need for a corrective action plan. At that time, the PI was instructed to immediately halt administration of hCG to rats and submit an amendment to add this agent to the protocol. The following corrective plan was discussed and approved by the IACUC during the committee's 12/14/2020 meeting:

- a. The use of hCG in rats by the PI's lab is to be suspended until an amendment to add this agent to the associated protocol is approved by the IACUC. The amendment was received by the IACUC and approved on January 21, 2021.
- b. The lab areas listed in the associated protocol will be visited quarterly by the Sr. Research Support Specialist to conduct post approval monitoring (PAM) sessions beginning in April 2021 and ending in January 2022. The PAM sessions will include review of the hCG drug administration log.

Please let us know if you need additional information on this matter.

Best,

DocuSigned by:
(b) (6)
6758E984DE884DE...

Heidi J. Aronin
Institutional Official

State University of New York Downstate Health Sciences University
450 Clarkson Avenue, Brooklyn, New York 11203-2098 ★ Phone: 718.270.1000

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Wednesday, May 19, 2021 8:29 AM
To: Amy Fish
Cc: Heidi Aronin
Subject: RE: Non-compliance Report (D16-00167/A3260-01)

Hello Ms. Fish, and congratulations on your new position. I remember you as a dedicated, knowledgeable, and efficient member of the research community. We will send an official response to the report soon. Yes, we do prefer a preliminary report. Email or phone are fine. If you ever want to discuss an incident before making a report, please don't hesitate to contact me, Dr. Jai Tubbs, or Dr. Axel Wolff here at OLAW.

Best regards, Brent Morse

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

From: Amy Fish <Amy.Fish@downstate.edu>
Sent: Tuesday, May 18, 2021 5:27 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Cc: Heidi Aronin <Heidi.Aronin@downstate.edu>
Subject: Non-compliance Report (D16-00167/A3260-01)

Hi Dr. Morse,

I hope you are doing well and that everyone at OLAW remains safe and healthy. I recently joined SUNY Downstate in Brooklyn this past January and prior to that I was the IACUC manager at Rutgers University in Newark.

We have a non-compliance incident to report to OLAW. Please see the attached letter. No initial report was done however, the incident has been resolved. Please let me know if there are any comments or questions. Also, does OLAW still prefer preliminary non-compliance reports by phone or email?

Thanks again,
Amy

Amy Fish, BS, CPIA
IACUC Director
Institutional Animal Care and Use Committee (IACUC)
SUNY Downstate Health Sciences University
450 Clarkson Ave, MSC 112
Brooklyn, NY 11203-2098
amy.fish@downstate.edu

(b) (6)



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