



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

September 10, 2018

Re: Animal Welfare Assurance  
#A3260-01 (OLAW Case T]

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

Dear Dr. Aronin,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 5, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at SUNY Downstate Medical Center, following up on an initial May 7, 2018 telephone notification. According to the information provided, OLAW understands that the Designated Member Review (DMR) process for a protocol amendment on an FDA-funded protocol was inappropriately executed and processed by a new staff member. Apparently, the amendment was not electronically distributed to all IACUC members and failed to provide the opportunity to call for Full Committee Review (FCR) in accordance with the PHS Policy on Humane Care and Use of Laboratory Animals and IACUC policy. Fortunately, the oversight was identified and the amendment reviewed and approved by FCR corrected prior to the performance of any animal activity on the aforementioned protocol.

The corrective actions consisted of retraining the responsible member and processing all current and subsequent amendments using FCR per IACUC policy.

The establishment and application of policies and practices that are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals at SUNY Downstate Medical Center are commendable and avoid the perception of a double standard. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

(b) (6)

Neera V. Gopee, DVM, PhD, DACLAM, DABT  
Animal Welfare Program Specialist  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare

cc: IACUC Contact



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**

September 5, 2018

Dr. Brent Morse, DVM, DACLAM  
Acting Director, Division of Compliance Oversight  
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 program non-compliance concerning review and approval of a protocol amendment for an FDA-supported activity, previously reported by phone on May 7, 2018. The amendment was not properly processed by the approved Designated Member Review (DMR) procedures, which detail email distribution of amendments to all members for the opportunity to call for Full Committee Review (FCR). A new staff member processed the amendment by DMR, emailing it to [IACUC@Downstate.edu](mailto:IACUC@Downstate.edu) (the email distribution list used for submission of documents to the IACUC administrative staff) with the misunderstanding that all IACUC members were the recipients of the distribution list. The amendment was approved on April 13, 2018. Once identified on May 4, 2018, the amendment was called for FCR and subsequently reviewed and approved on May 7, 2018. The staff member was retrained, no animal work was performed prior to FCR and approval, no other amendments were approved in this manner, and all current and subsequent amendments under DMR review were distributed to the full committee for processing according to IACUC policy. Please let us know if you need additional information on this matter.

Sincerely,

(b) (6)

Heidi J. Aronin  
Institutional Official  
Senior Vice President and Chief Administrative Officer

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

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

**To:** Julie Sharp <Julie.Sharp@downstate.edu>

**Subject:** RE: [EXTERNAL] OLAW Request for update on preliminary noncompliance report for A3260-T

Sure, not a problem.

Neera

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**From:** Julie Sharp <Julie.Sharp@downstate.edu>

**Sent:** Monday, August 20, 2018 12:12 PM

**To:** Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>

**Subject:** RE: [EXTERNAL] OLAW Request for update on preliminary noncompliance report for A3260-T

Dear Neera,

The final letter is with the IO for signature, but she is out of town until the end of the month. Is it ok if I get it to you upon her return the first week of September?

Best,

Julie

Julie M. Sharp, DVM, CPIA, DACLAM  
Director

Office of Animal Welfare, BSB 8-59, MSC 112  
SUNY - Downstate Medical Center  
450 Clarkson Ave.  
Brooklyn, NY 11203-2098

Office: (b) (6)

Fax: (b) (6)

<http://research.downstate.edu/iacuc/iacuc.html>

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**From:** Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>

**Sent:** Wednesday, August 08, 2018 9:51 AM

**To:** Julie Sharp <Julie.Sharp@downstate.edu>

**Subject:** RE: [EXTERNAL] OLAW Request for update on preliminary noncompliance report for A3260-T

Thank you Dr. Sharp for your prompt response and I look forward to receiving the final report in the near future.

Neera

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**From:** Julie Sharp [mailto:Julie.Sharp@downstate.edu]

**Sent:** Wednesday, August 08, 2018 9:31 AM

**To:** Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>

**Subject:** RE: [EXTERNAL] OLAW Request for update on preliminary noncompliance report for A3260-T

Dear Dr. Gopee,

Thank you for the follow-up. We will provide the final signed report by next week. Please let me know if there are any concerns with this plan.

Best,  
Julie

Julie M. Sharp, DVM, CPIA, DACLAM  
Director

Office of Animal Welfare, BSB 8-59, MSC 112  
SUNY - Downstate Medical Center  
450 Clarkson Ave.  
Brooklyn, NY 11203-2098

Office: (b) (6)  
Fax: (b) (6)  
<http://research.downstate.edu/iacuc/iacuc.html>

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**From:** Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>  
**Sent:** Tuesday, August 07, 2018 2:24 PM  
**To:** Julie Sharp <Julie.Sharp@downstate.edu>  
**Subject:** [EXTERNAL] OLAW Request for update on preliminary noncompliance report for A3260-T  
**Importance:** High

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Dear Dr. Sharp,

I am writing with regards to the non-compliance case which was reported by via telephone on May 7, 2018 involving the failure to provide all IACUC members an opportunity to call for Designated Member Review of an amendment to an approved protocol at SUNY, Downstate Medical Center. To date we do not have a record of receiving further information regarding this preliminary report. OLAW requests that submission of a final or interim report to the OLAW Division of Compliance Oversight (NIH/OD) [olawdco@od.nih.gov](mailto:olawdco@od.nih.gov) at your earliest convenience.

If you have any questions or concerns regarding this matter, please do not hesitate to contact me.

Regards,  
Neera

Neera V. Gopee, DVM, PhD, DACLAM, DABT  
Animal Welfare Program Specialist  
Division of Compliance Oversight  
Office of Laboratory Animal Welfare  
National Institutes of Health

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## Initial Report of Noncompliance

By: aw

Date: 5/7/18

Time: 9:30

Name of Person reporting: Julie Sharp

Telephone #: (b) (6)

Fax #:

Email:

Name of Institution: SUNY Downstate

Assurance number: A3260

Did incident involve PHS funded activity? Yes

Funding component: \_\_\_\_\_

Was funding component contacted (if necessary): \_\_\_\_\_

What happened?

Protocol needed to be amended but not all IACUC members got the request to use DMR & protocol was approved

Species involved: Pig

Personnel involved:

Dates and times:

Animal deaths:

Projected plan and schedule for correction/prevention (if known): \_\_\_\_\_

Change policies to have all IACUC members get notice

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # \_\_\_\_\_