



DEPARTMENT OF HEALTH & HUMAN SERVICES

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Office of Laboratory Animal Welfare
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Home Page: <http://grants.nih.gov/grants/olaw/olaw.htm>

FOR EXPRESS MAIL:

Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

January 8, 2019

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

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 January 2, 2019 letter reporting several instances of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the State University of New York Downstate Medical Center, following up on an initial telephone report on April 5, 2018. According to the information provided, OLAW understands that on a pilot study involving six pigs, several significant changes were made without prior Institutional Animal Care and Use Committee approval. The specific changes included not weighing animals at the frequency stated in the protocol, not conducting sling training at the frequency described in the protocol, using a sling that was constructed differently than the one described in the protocol, changing the physiological monitoring techniques from what was described in the protocol, and not adding veterinarian prescribed drugs to the protocol for use in subsequent procedures. Some of the unapproved significant changes were made to enhance animal welfare and none of the changes impacted the pigs negatively.

The corrective actions consisted of amending the protocol to modify the frequency of weighing and assessing of body condition, discontinuing sling acclimation due to conducting a single terminal procedure, using the modified sling, modifying the physiological monitoring, and amending the list of approved medications. Additional procedures were conducted which incorporated the changes and the study was completed. The noncompliance was reported to the primary grantee institution and the PHS funding component (FDA).

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of these incidents. OLAW concurs with the actions taken by the institution to comply with the PHS Policy. Thank you for keeping OLAW apprised on this matter.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair
Julie Sharp, D.V.M., Director, Office of Animal Welfare
Robert Gibbens, D.V.M., USDA-APHIS-AC



**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

January 2, 2019

Deputy Director
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. Wolff,

I'm writing to update you on the previously reported non-compliances associated with an FDA-funded project (FDA - 1U01FD005862). During 2017-2018, six swine underwent non-surgical and surgical procedures as part of a pilot study.

An IACUC subcommittee reviewed the details of the protocol, records, and associated procedures and identified the following non-compliances. There were no animal welfare concerns associated with any of these items.

1. Animals were periodically weighed, but not at the frequency described in the protocol. The animals remained in good body condition for the entire study.
2. Animals that underwent non-surgical procedures were acclimated to the sling prior to the procedure, but sling training did not occur at the frequency described in the protocol.
3. The protocol described the use of a cloth mesh-type sling. As the animals grew, the sling required modification to adequately support their weight. To do this, a solid sling was manufactured and included pressure-relieving polyfoam cushion to provide full-body contouring support and distribute the body weight more evenly along the entire ventral aspect to relieve the "hammocking" compressive forces that the fabric sling would create. The sling refinement was not approved by the IACUC prior to use.
4. The physiologic monitoring during the procedure described in the protocol included use of EKG leads during jugular catheter instrumentation and for the duration of the study. Appropriate physiologic monitoring occurred for the entire procedure, but the leads were removed after successful instrumentation and transition of the animal from ventral to dorsal positioning within the sling. This was appropriate to prevent development of pressure sores at the placement sites but not captured within the protocol description.

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

5. Animals appropriately received medically necessary drugs associated with the procedure (i.e., enrofloxacin, furosemide, carprofen) at the discretion of the veterinarian. These agents were not incorporated into the IACUC protocol before use during subsequent procedures.

To correct the non-compliances, protocol amendments were submitted and approved to:

1. modify the frequency of weighing/assessing body condition scoring;
2. transition to a single terminal procedure, no longer requiring acclimation to the sling;
3. incorporate the refined sling;
4. remove EKG monitoring after jugular catheter instrumentation; and
5. modify the list of approved medications.

The remaining animals underwent the approved protocol procedures to complete the study, which is now closed. The non-compliances were reported to Long Island University, the primary grant recipient, and the FDA.

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

Best,

(b) (6)

Heidi Aronin
Institutional Official

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

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

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Gopee, Neera (NIH/OD) [E]

From: Julie Sharp <Julie.Sharp@downstate.edu>
Sent: Friday, July 27, 2018 11:14 AM
To: Gopee, Neera (NIH/OD) [E]
Cc: Wolff, Axel (NIH/OD) [E]
Subject: RE: [EXTERNAL] OLAW Request for update on preliminary noncompliance report for A3260-S

Dear Dr. Gopee,

Thank you for getting back to me so quickly. We will be in touch with the final report. Please let me know if you need anything else in the meantime.

Best,
Julie

Julie M. Sharp, DVM, CPIA, DACLAM
Director

Office of Animal Welfare, BSB 8-59, MSC 112
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450 Clarkson Ave.
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From: Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>
Sent: Friday, July 27, 2018 9:02 AM
To: Julie Sharp <Julie.Sharp@downstate.edu>
Cc: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Subject: RE: [EXTERNAL] OLAW Request for update on preliminary noncompliance report for A3260S

Dear Dr. Sharp,

Thank you for your prompt response. Dr Wolff briefed me on the case and this serves as an interim report. We look forward to receiving the final report in the near future.

Best Regards,
Neera

From: Julie Sharp [mailto:Julie.Sharp@downstate.edu]
Sent: Thursday, July 26, 2018 3:57 PM
To: Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>
Subject: RE: [EXTERNAL] OLAW Request for update on preliminary noncompliance report for A3260-S

Dear Dr. Gopee,

Thank you for the reminder. I've been in touch with Dr. Wolff by phone a few times since then to provide updates, and his suggestion was to include the April 5th and subsequent items discussed by phone into a single report. I was planning to submit the written report after the one remaining animal undergoes study (within the next 1-2 months). Would that be acceptable? Please feel free to contact me by phone or email if you'd like to discuss further.

Best,
Julie

Julie M. Sharp, DVM, CPIA, DACLAM
Director

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

From: Gopee, Neera (NIH/OD) [E] <neera.gopee@nih.gov>
Sent: Thursday, July 26, 2018 2:50 PM
To: Julie Sharp <Julie.Sharp@downstate.edu>
Subject: [EXTERNAL] OLAW Request for update on preliminary noncompliance report for A3260-S

Do not click links, open attachments or provide your User ID or Password if the sender is unknown.

Dear Dr. Sharp,

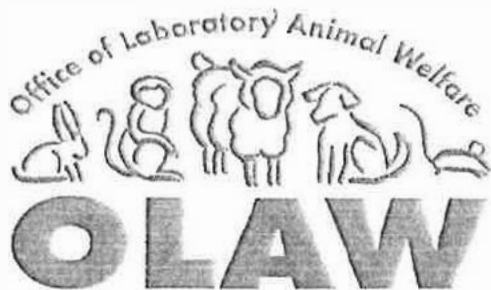
I am writing with regards to the non-compliance case which was reported by via telephone on April 5, 2018 involving significant changes without prior IACUC approval in pigs at SUNY, Downstate Medical Center. To date we do not have a record of receiving further information regarding this preliminary report. OLAW requests that submission of a final or interim report to the OLAW Division of Compliance Oversight (NIH/OD) olawdco@od.nih.gov 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: 4/5/18

Time: 11:30

Name of Person reporting: Julie Sharp, DVM Novotny, I don't chair

Telephone #: (b)(6)

Fax #:

Email:

Name of Institution: SUNY DOWNSTATE Medical Ctr

Assurance number: A3260

Did incident involve PHS funded activity? Yes

Funding component: FDA

Was funding component contacted (if necessary): _____

What happened?

Pigs on skin absorption study, had significant protocol changes - change sling, no acclimation to sling, no EKG throughout study, drugs changed

Species involved: PIGS

Personnel involved:

Dates and times:

Animal deaths:

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

Amend protocol

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # _____

Send cc to USDA