



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

April 25, 2019

Re: Animal Welfare Assurance  
A3195-01 [OLAW Case 4V]

Dr. Mary Klotman  
Dean, School of Medicine and  
Vice Chancellor for Health Affairs  
Duke University Medical Center  
Duke South Clinic – 200 Trent Drive  
(b) (4) Davidson Building  
Durham, NC 27710

Dear Dr. Klotman,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 10, 2019 letter responding to my March 14, 2019 request for additional information regarding a report of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Duke University. According to the information provided, OLAW understands the following:

- 1) Animal activities have not resumed and cannot occur under the Core protocol until corrective actions are implemented. These include instituting a quality monitoring plan, standardizing data management, developing an oversight and communication plan, and notifying past Core users of the problems noted.
- 2) Improvements to recordkeeping systems are underway, Core personnel will be retrained on recordkeeping, and an online system is being created with internal auditing.
- 3) Once animal activities resume, the Core will be managed and overseen by the Division of Animal Resources under the direction of the Attending Veterinarian (AV).
- 4) After reviewing the Core records and interviewing staff, it was determined that although some records were missing, analgesics had been given and post-operative monitoring occurred.
- 5) Core personnel have been counseled by the AV and Institutional Animal Care and Use Committee chair. Additional oversight may be required to ensure compliance with the protocol.

Based on its assessment of this explanation, OLAW has a much better understanding of the corrective actions that will be initiated and the oversight that will be put into place. As you stated, any changes to the aforementioned plans will be shared with this Office. OLAW concurs with the actions taken by the institution to comply with the PHS Policy.

Page 2 – Dr. Klotman  
April 25, 2019  
OLAW Case A4195-4V

Sincerely,

(b) (6)

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

cc: IACUC Chair



Duke University  
Durham, North Carolina 27705



Office of Animal Welfare Assurance  
Campus Mail: Hock Plaza Box 2724  
US Mail: 2424 Erwin Road; Suite 606; Durham, NC 27705

Voice: 919.668.6720  
Fax: 919.668.6725  
<https://sites.duke.edu/oawa/>

April 10, 2019

Re: Duke University Animal Welfare Assurance A3195-01 [OLAW Case 4V]

Office of Laboratory Animal Welfare (OLAW)  
National Institutes of Health  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, MD 20892

Dear Dr. Wolff,

Thank you for your detailed review of OLAW Case 4V which involved a Duke Core Research Facility in which mice undergoing survival surgical procedures had inaccurate or missing records. Responses to the requested additional information is as follows:

- 1) **What were the specific corrective actions put in place?** As of January 16, 2019, new animal services cannot occur under the Core protocol until specific corrective actions are implemented. The required corrective actions include:
  - a. Implementation of a quality monitoring plan to include ongoing surgical oversight and monitoring.
  - b. Standardization of data management and reporting to include ensuring standardized recordkeeping forms are completed appropriately and periodic quality assurance reviews occur.
  - c. Development of an oversight and communication plan to include providing Core users all animal records at the time-of-service.
  - d. Notification of past Core users of the items identified.

To-date a final corrective action plan has not been approved by the Senior Response Committee and no animal activities are occurring under the Core protocol. These corrective measures will be in place prior to any resumption of animal activity under the Core protocol.

- 2) **Describe the current corrected records system.** Currently no animal activities are occurring under the Core protocol. Recordkeeping refinements are under review and include re-training of Core personnel on recordkeeping expectations and creating an on-line recordkeeping processes with internal auditing.
- 3) **Will enhanced oversight continue once new procedures are allowed to be conducted?** Currently no animal activities are occurring under the Core protocol. If the core is reinitiated, the current plan is for the Duke Animal Program, specifically, the Division of Laboratory Animal Resources (DLAR) which is under the direction of the Duke Attending Veterinarian, to manage and oversee of all animal activities performed under the Core protocol. In addition, the Duke Institutional Animal Care and Use Committee (IACUC) will review the plan to determine if additional oversight is required.
- 4) **Were any animal welfare issues identified such as not providing analgesia at all vs. providing the drugs and not maintaining documentation; not conducting post-operative monitoring vs. conducting the monitoring and not maintaining documentation?** The investigation of this item included both records review and interviews of Core personnel. Inconsistencies in recordkeeping were identified, which included inaccurate or missing records; however, laboratory personnel verbally indicated that analgesics and post-operative monitoring occurred for all survival-surgical procedures.



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Durham, North Carolina 27705



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- 5) Describe the current status of new and ongoing surgical activities in the Core and which entity is providing oversight. Currently no animal activities are occurring under the Core protocol.
- 6) Provide any additional information on how repeat noncompliance will be prevented. All Core personnel have met with the Attending Veterinarian and IACUC Chair to review this issue. Although a plan for reinitiation of this Core has not been finalized, the current plan is for DLAR to manage and oversee all animal activities provided by the Core. At the IACUC discretion, they may require additional enhanced oversight to ensure animal activities are being conducted in accordance with the approved IACUC protocol and that records are appropriately maintained.

Duke University will provide OLAW an update if Core activities are reinitiated and this is not under the management and oversight of DLAR.

Duke University is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Anna Hampton, DVM, IACUC Chair at [Anna.Hampton@Duke.edu](mailto:Anna.Hampton@Duke.edu) or (b) (6)

The PHS-funding related to this event is associated with a sub-award. The primary awardee is the University of Alabama at Birmingham. Mr. David Cannon CPIA, the Director of the University of Alabama at Birmingham Office of the IACUC is copied to the communication.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Dr. Mary E. Klotman  
Duke University  
Dean, School of Medicine  
Vice Chancellor for Health Affairs  
Institutional Official

**Wolff, Axel (NIH/OD) [E]**

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**From:** Wolff, Axel (NIH/OD) [E]  
**Sent:** Friday, April 12, 2019 6:24 AM  
**To:** Anna Hampton  
**Subject:** RE: OLAW Case A3195-4V

Thank you for this report, Dr. Hampton. I will send a response soon.  
Axel Wolff

---

**From:** Anna Hampton <anna.hampton@duke.edu>  
**Sent:** Thursday, April 11, 2019 4:26 PM  
**To:** Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>  
**Cc:** OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>  
**Subject:** OLAW Case A3195-4V

Dear Dr. Wolff,

Please see the attach response for the requested additional information for OLAW case A3195-4V.

Assurance # A3195-01 / D16-00123.

Please do not hesitate to contact me if you have any questions or need additional information.

Anna

Anna Hampton, DVM, DACLAM, DACAW, CPIA  
Director, Office of Animal Welfare Assurance  
Chair, Institutional Animal Care and Use Committee  
Duke University  
2424 Erwin Road, (b) (4)  
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March 14, 2019

Re: Animal Welfare Assurance  
A3195-01 [OLAW Case 4V]

Dr. Mary Klotman  
Dean, School of Medicine and  
Vice Chancellor for Health Affairs  
Duke University Medical Center  
Duke South Clinic – 200 Trent Drive  
(b) (4) Davidson Building  
Durham, NC 27710

Dear Dr. Klotman,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 5, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Duke University, following up on an initial telephone report on February 15, 2019. According to the information provided, OLAW understands that a Core Research Facility in which mouse survival surgeries are conducted was found to have inaccurate or missing records involving analgesia administration, post-operative monitoring, and disposition of drug waste. This area had been involved in previous noncompliance which resulted in implementation of corrective actions and enhanced oversight.

The corrective actions consisted of referring the matter to the Duke Senior Response Committee, having the compliance division and Institutional Animal Care and Use Committee (IACUC) investigate, stopping the conduct of new surgeries during the investigation, and allowing ongoing surgeries to continue under direct veterinary oversight. The Senior Response Committee determined that no new services could be provided until corrective actions were implemented and this was supported by the IACUC.

In order for OLAW to have a comprehensive understanding of the final outcome, please provide the following additional information:

- 1) What were the specific corrective actions put in place?
- 2) Describe the current corrected record system.
- 3) Will enhanced oversight continue once new procedures are allowed to be conducted?
- 4) Were any animal welfare issues identified such as not providing analgesia at all vs. providing the drugs and not maintaining documentation; not conducting post-operative monitoring vs. conducting the monitoring and not maintaining documentation?
- 5) Describe the current status of new and ongoing surgical activities in the Core and which entity is providing oversight.
- 6) Provide any additional information on how repeat noncompliance will be prevented.

*Page 2 – Dr. Klotman*  
*March 14, 2019*  
*OLAW Case A3195-41*

**Please provide the requested additional information by April 12, 2019.**

Sincerely,

(b) (6)

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

cc: IACUC Chair





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Durham, North Carolina 27705



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March 5, 2019

Duke University  
Animal Welfare Assurance # D16-00123 (A3195-01)

Office of Laboratory Animal Welfare (OLAW)  
National Institutes of Health  
6700B Rockledge Drive, Suite 2500, MSC 6910  
Bethesda, MD 20892

Duke University, in accordance with PHS Policy IV.F.3., provides this report of an incident, which involved an animal activity conducted or supported with PHS-funds or other funds with Office of Laboratory Animal Welfare oversight. This incident was reviewed and determined to be reportable by the Duke Institutional Animal Care & Use Committee (IACUC).

**Reportable requirement:** Failure to maintain appropriate animal-related records and institutional intervention limiting an animal activity.

**Preliminary report:** This incident was first reported to Dr. Neera Gopee, OLAW, on February 15, 2019 via a telephone call by Anna Hampton Anna Hampton, DVM, DACLAM, DACAW, CPIA, Director, Duke University Office of Animal Welfare Assurance.

**Grant/contract number:** 5U01HL134764-03

**Number of animals affected:** 32 mice

**Date:** March 1, 2018 – September 28, 2018

**Description, outcome, and actions taken:** In August 2018, the Duke Office of Animal Welfare Assurance found inconsistencies related to recordkeeping for mouse survival surgical procedures in a Duke Core Research Facility. This included inaccurate or missing records associated with: analgesia administration, drug waste, and postoperative monitoring. This Core Research Facility had a related non-compliance item identified in 2017, underwent IACUC required corrective measures, and enhanced Animal Program oversight until March 1, 2018.

Upon identification of this concern the following corrective measures were taken:

- The item was brought to the Duke Senior Response Committee.
- The Duke Office of Audit, Risk, and Compliance investigated the concern and the IACUC Chair and Attending Veterinarian were part of the investigation team.
- The Core Research Facility paused scheduling new survival-surgical procedures during the investigation.
- The Core continued previously scheduled and/or ongoing survival-surgical procedures under the direct oversight and continuous monitoring of Duke veterinary staff to ensure protocol compliance and appropriate recordkeeping.

**Conclusion:** The Senior Response Committee completed its review on January 16, 2019 and determined that Core could not provide any new animal services until specific corrective actions were implemented. Continuation of ongoing survival surgical activities by the Core requires direct oversight of Duke veterinary staff.





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The Duke IACUC reviewed and accepted the report issued by the Duke Senior Response Committee at the January 24, 2019 IACUC meeting. This effectively stops all animal activities under the Core; however, the animal activities remain approved under the original IACUC protocol(s). The Duke IACUC determined that the incident was reportable to regulatory, granting, and oversight bodies, where applicable. In addition, the IACUC determined that the corrective actions were appropriate and no further actions were necessary. The Duke IACUC considers this incident closed.

The Duke University is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Should you have any questions regarding this report, please contact Anna Hampton, DVM, IACUC Chair at [Anna.Hampton@Duke.edu](mailto:Anna.Hampton@Duke.edu) or (b) (6)

The PHS-funding related to this event is associated with a sub-award. The primary awardee is the University of Alabama at Birmingham. Mr. David Cannon CPIA, the Director of the University of Alabama at Birmingham Office of the IACUC is copied to the communication.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Dr. Mary E. Klotman  
Duke University  
Dean, School of Medicine  
Vice Chancellor for Health Affairs  
Institutional Official

**Gopee, Neera (NIH/OD) [E]**

---

**From:** Gopee, Neera (NIH/OD) [E]  
**Sent:** Wednesday, March 06, 2019 4:37 PM  
**To:** 'Anna Hampton'; OLAW Division of Compliance Oversight (NIH/OD)  
**Subject:** RE: Duke OLAW Report (Assurance # A3195-01)

Thank you for these three final reports Dr. Hampton. We will send official responses to each report soon.

Best Regards,  
Neera

Neera V. Gopee, DVM, PhD, DABT, DACLAM  
Acting Director, Division of Policy and Education  
Office of Laboratory Animal Welfare, NIH  
6700B Rockledge Drive  
Bethesda, MD 20892-6910  
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**From:** Anna Hampton <[anna.hampton@duke.edu](mailto:anna.hampton@duke.edu)>  
**Sent:** Wednesday, March 06, 2019 4:15 PM  
**To:** OLAW Division of Compliance Oversight (NIH/OD) <[olawdco@od.nih.gov](mailto:olawdco@od.nih.gov)>; Gopee, Neera (NIH/OD) [E] <[neera.gopee@nih.gov](mailto:neera.gopee@nih.gov)>  
**Subject:** Duke OLAW Report (Assurance # A3195-01)

Dear Dr. Gopee,

Please see the attached final reports for Duke University (Assurance # A3195-01 / D16-00123).

Please do not hesitate to contact me if you have any questions or need additional information.

Anna

Anna Hampton, DVM, DACLAM, DACAW, CPIA  
Director, Office of Animal Welfare Assurance  
Chair, Institutional Animal Care and Use Committee  
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## Initial Report of Noncompliance

By: Neera Gopal

Date: 2-15-19

Time: 1:35pm

Name of Person reporting: Anne Hampton

Telephone #: (b)(6)

Fax #:

Email:

Name of Institution: Duke UniversityAssurance number: A3195-01Did incident involve PHS funded activity? Yes

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

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

What happened?

A core facilities failed to maintain adequate records for survival  
 Surgical procedures in 32 mice

Species involved: mice

Personnel involved:

Dates and times:

Animal deaths:

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

Projected submission to OLAW of final report from Institutional Official:

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