



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

November 7, 2019

Re: Animal Welfare Assurance
A3823-01 [OLAW Case 8J]

Dr. Mary Dickinson
Vice President and Dean of Research
Baylor College of Medicine
One Baylor Plaza, BCM335
Houston, TX 77030

Dear Dr. Dickinson,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your letter dated November 5, 2019 regarding noncompliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals at Baylor College of Medicine. This letter had not been preceded by a preliminary report to OLAW.

According to the information provided, our office understands that during a semi-annual inspection, 69 rats on a PHS funded activity were found that failed to receive a secondary analgesic for tracheal surgery as described in the protocol that was approved by the Institutional Animal Care and Use Committee (IACUC). No resulting animal welfare issues were identified.

Corrective actions consisted of enhanced post-approval monitoring, and an amendment to the protocol clarifying the analgesic regimen for the procedures.

OLAW appreciates your IACUC's diligence in performing its semiannual inspection responsibilities and the institution's corrective measures as described in this report. Efforts such as this help characterize the extent and nature of programmatic issues and serve as a critical step in the development of comprehensive, institution-wide corrective actions. We look forward to a description of your progress to this end in your next report under your institution's enhanced reporting schedule. Please note that reports of noncompliance to OLAW should include dates of occurrence when describing the incident. Please include this information in future submissions. Regarding this specific instance of non-compliance, we appreciate having been informed of this matter and at this time find no cause for further action by this office.

Sincerely,

(b) (6)

Nicolette Petervary, VMD, DACAW
Animal Welfare Policy Specialist
Office of Laboratory Animal Welfare

CC: IACUC Contact



A3823-8J
no open case

OFFICE OF RESEARCH

One Baylor Plaza, BCM310
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CONFIDENTIAL

November 5, 2019

Brent Morse, DVM, DACLAM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
olawdco@mail.nih.gov

RE: Assurance #D16-00475

Dear Dr. Morse,

As Institutional Official for Baylor College of Medicine (BCM), I have the duty to inform you of our Institutional Animal Care and Use Committee's (IACUC) recent finding in animal research after an assessment of the following protocol:

Protocol: AN-5366: The Role of Gut Microbiome in Obstructive Sleep Apnea Induced Hypertension

Species: Rat

Funding Sources: National Institutes of Health (NIH) R01-HL134838 and Non-PHS funding

For this investigator's first incident of this nature, the IACUC determined that the following finding constituted *serious noncompliance*ⁱ with the federal regulations:

Experimental Process^{ii, iii, iv}

During a semi-annual inspection, it was discovered that 69 rats underwent tracheal surgery as described in the approved protocol, however, a secondary analgesic was not administered according to the approved protocol. All rats were observed daily and weighed weekly to ensure that they were healthy. There were no complications observed, and all rats recovered without incident.

Corrective Actions:

1. A Post Approval Monitoring (PAM) will be conducted within the next six months.
2. The protocol was amended to more clearly describe the analgesic regime for the various procedures indicated.

ⁱ PHS Policy IV.F.3.a: "The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to: a. any serious or continuing noncompliance with this Policy;"

ⁱⁱ The GUIDE, 8th Ed. p115: "Successful surgical outcomes require appropriate attention to presurgical planning, personnel training, anesthesia, aseptic and surgical technique, assessment of animal well-being, appropriate use of analgesics, and animal physiologic status during all phases of a protocol involving surgery and postoperative care."

ⁱⁱⁱ The GUIDE, 8th Ed. p115: "Researchers conducting surgical procedures must have appropriate training to ensure that good surgical technique is practiced – that is, asepsis, gentle tissue handling, minimal dissection of tissue, appropriate use of instruments, effective hemostasis, and correct use of suture materials and patterns."

^{iv} PHS Policy IV.B.6: "The IACUC shall with respect to PHS-conducted or supported activities "review and approve, require modifications in (to secure approval), or withhold approval of those components of PHS-conducted or supported activities related to the care and use of animals..."

This finding of non-compliance does not appear to pose any potential or actual effect on cost related to this PHS supported research.

This notification will also be sent to AAALAC International, the National Institutes of Health and the non-PHS funding source according to the terms and conditions of the award.

Please do not hesitate to contact me if you have any questions.

Sincerely,

(b) (6)

Mary Dickinson, PhD
Vice President and Dean of Research
Institutional Official
Baylor College of Medicine

cc: Principal Investigator
Department Chair
Research Compliance Services files

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, November 05, 2019 3:57 PM
To: (b) (6) OLAW Division of Compliance Oversight (NIH/OD)
Cc: (b) (6)
Subject: RE: OLAW Report - Assurance D16-0475

Thank you for providing these reports (b) (6) We will send official responses soon.

Best regards, 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: (b) (6)
Sent: Tuesday, November 05, 2019 3:04 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: OLAW Report - Assurance D16-0475

Dear Dr. Morse,
Please find attached notification of an adverse event as determined by our IACUC, and sent on behalf of Dr. Mary Dickinson, Institutional Official. Please feel free to contact me if you have any questions.

Thank you,
(b) (6)

(b) (6)