



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
Office of Laboratory Animal Welfare
Rockledge One, Suite 360
6705 Rockledge Drive – MSC 7982
Bethesda, Maryland 20892-7982
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

April 14, 2017

Re: Animal Welfare Assurance
A3275-01 [OLAW Case K]

Dr. Richard L. Summers
Associate Vice Chancellor for Research
University of Mississippi – Jackson
Medical Center
Office of Research
2500 North State Street
Jackson, MS 39216-4505

Dear Dr. Summers,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 10, 2017 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Mississippi Medical Center, following up on an initial report on December 30, 2016. According to the information provided, OLAW understands that rats were subjected to cecum removal surgery although this activity had not been described in the approved protocol. Also, the analgesic regimen was not followed as described.

The corrective action consisted of the veterinarian directing the Principal Investigator to stop further surgeries. The PI received counseling, and retraining on working with the Institutional Animal Care and Use Committee (IACUC) and submitted an amended protocol. The amendment was reviewed and approved and a veterinarian will oversee the next surgery once animal activities resume.

OLAW understands that the protocol involved was not PHS-supported, but concurs that the incidents were serious and supports the actions taken by the IACUC. The establishment and application of policies and practices that are consistent with the provisions of the PHS Policy at the University of Mississippi Medical Center are commendable and avoid the perception of a double standard. Thank you for keeping OLAW apprised on this matter.

Sincerely,

Axel Wolff, M.S., D.V.M.

Director

Division of Compliance Oversight

cc: IACUC Chair



April 10, 2017

Axel Wolff, DVM
Director, 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

Dear Dr. Wolff:

The University of Mississippi Medical Center (UMMC), in accordance with Assurance D16-00174 (A3275-01) and PHS Policy IV.F.3., provides this report of noncompliance regarding a procedure to remove the cecum from Sprague Dawley rats, an activity not reviewed and approved by the IACUC, and failure to adhere to analgesic plan as outlined in a Principal Investigator's (PI) animal study protocol. The protocol was approved as a pilot study and receives no federal funding, as all direct cost associated with the procurement, care, and use of the rats are paid for by the department. The incident was first reported to OLAW on December 30, 2016, via email by **secondary Individual** Director, Office of Animal Welfare.

On December 13, 2016, during a routine check on post-surgical animals, one of the veterinarians noted the animals were not in the housing room. Upon contacting the PI in the laboratory, the veterinarian discovered the PI had conducted a surgical procedure that was not approved on the protocol. While the protocol was approved for a second abdominal procedure, the procedure performed, cecum removal, had not been reviewed and approved. The veterinarian advised the PI to cease activities and contact the IACUC Chair. The PI contacted the Chair on the afternoon of December 13th and the Chair instructed the PI to cease all activities until further notice.

The PI submitted a modification request to add the cecum removal surgery to the protocol on the afternoon of December 13, 2016.

The veterinarian spoke with the PI again and the PI acknowledged that all animals approved by the IACUC for the pilot study had been used in the experiments. The PI was asked to submit a summary report of the pilot study to the IACUC.

On December 19, 2016, the UMMC, Office of Animal Welfare received a report from the PI on results of the pilot study. The report detailed six animals underwent cecum removal surgery, a procedure that was not reviewed and approved by the committee. Additionally the report identified that analgesics were not administered as outlined in the approved protocol.



The committee reviewed the report at a convened meeting on December 20, 2016. After discussion of the pilot study report, the following corrective actions were identified by the IACUC and approved by a quorum of the membership:

1. The modification request was tabled due to protocol non-compliance.
2. The PI is to meet with an assigned IACUC subcommittee to review and discuss the approved activities, including pain management, for the protocol.
3. The PI is to receive retraining on working with the IACUC and procedures for modification of an approved protocol.
4. The PI is to submit a revised modification for a second pilot study for the protocol, outlining all procedures to be conducted, including a timeline of events and a plan for pain management.
5. The PI is to communicate with the veterinary staff in advance of initiation of the second pilot study activity when the surgical events are scheduled to begin and arrange for a member of the veterinary staff to be present during surgical activities.

At the time the committee reviewed the report no rats were on inventory for this protocol or available for procurement. The committee required that corrective actions #2, #3, and #4 be completed by the PI before any additional animals would be considered by the IACUC for the study.

The IACUC Chair sent a letter (email) December 29th to the PI with "Cc" copies to the Department Chair, IO, and AV that outlined the protocol noncompliance issues and the corrective actions required.

On January 4, 2017, the PI met with the IACUC Chair, the AV, and the Director-OAW and reviewed the approved protocol. During the meeting the PI received re-education on appropriate procedures for modification of protocols and regulations governing the use of animals in research. The PI took full account of the actions and recognized the importance of following the IACUC-approved protocol. After discussion of the surgical procedure and analgesic plan, the PI requested additional consultation with the veterinary staff on drafting the revised protocol modification request.

A modification was submitted to the IACUC for consideration on February 10th. At the IACUC meeting on February 21, 2017, the committee reviewed and approved the modification. Based on the report from the subcommittee and the modification request, the committee felt as though this oversight was an isolated incident and the PI has a full understanding of the importance of adhering to the written, approved protocol.

The PI notified the veterinarians on April 4th of initiation of the pilot study. Members of the veterinary staff were involved throughout the surgical procedure and post-operative period.



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MEDICAL CENTER
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The University of Mississippi Medical Center 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 the Office of Animal Welfare.

Thank you for consideration of this matter.

Sincerely,

Richard Summers, MD
Associate Vice Chancellor for Research
And Institutional Official

RLS/AMK

Secondary Individual

Secondary Individual:

Phone Number	Phone Number
Secondary Individual	



December 30, 2016

Axel Wolff, DVM
Director, 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

Dear Dr. Wolff:

The University of Mississippi Medical Center (UMMC), in accordance with Assurance D16-00174 (A3275-01) and PHS Policy IV.F.3., provides this preliminary report of noncompliance regarding a procedure to remove the cecum from Sprague Dawley rats, an activity not reviewed and approved by the IACUC, and failure to adhere to analgesic plan as outlined in a Principal Investigator's (PI) animal study protocol. The protocol receives no federal funding, as all direct cost associated with the procurement, care, and use of the rats are paid for financial information. This preliminary report is submitted by econdary Individu, Manager, UMMC, Office of Animal Welfare.

On December 13, 2016 during a routine check on post-surgical animals one of the veterinarians noted the animals were not in the housing room. Upon contacting the PI in the laboratory, the veterinarian discovered the PI had conducted a surgical procedure that was not approved on the protocol. While the protocol was approved for a second abdominal procedure, the procedure performed, cecum removal, had not been reviewed and approved. The veterinarian advised the PI to cease activities and contact the IACUC Chair. The PI contacted the Chair on the afternoon of December 13th and the Chair instructed the PI to cease all activities until further notice.

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4. The PI is to submit a revised modification for a second pilot study for the protocol, outlining all procedures to be conducted, including a timeline of events and a plan for pain management.
5. The PI is to communicate with the veterinary staff in advance of initiation of the second pilot study activity when the surgical events are scheduled to begin and arrange for a member of the veterinary staff to be present during surgical activities.

Currently no rats are on inventory for this protocol or available for procurement. Corrective actions #2, #3, and #4 must be completed by the PI before any additional animals will be considered by the IACUC for the study.

The IACUC Chair sent a letter (email) December 29th to the PI with "Cc" copies to the Department Chair, IO, and AV that outlined the protocol noncompliance issues and the corrective actions required.



After the PI meets with the assigned subcommittee and submits a revised modification, our Institutional Official will send a final report.

The University of Mississippi Medical Center 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 the Office of Animal Welfare.

Thank you for consideration of this matter.

Sincerely,

Secondary Individual

Manager - Office of Animal Welfare
University of Mississippi Medical Center
2500 North State Street
Jackson, MS 39216
T: Phone Number | F: Phone Number
Secondary Individual@umc.edu
umc.edu

Institutional Animal Care and Use Committee
2500 North State Street • Jackson, Mississippi 39216
Phone: 601.815.5000 • Fax: 601.815.5010 • umc.edu

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, January 03, 2017 8:08 AM
To: 'IACUC'
Subject: RE: Preliminary report of protocol noncompliance

Thank you for this preliminary report, **Secondary Individual**. We will open a new case file and look forward to receiving the final report from the IO after the IACUC has completed its investigation.

Axel Wolff, M.S., D.V.M.
Director, Division of Compliance Oversight
OLAW

From: IACUC [mailto:iacuc@umc.edu]
Sent: Friday, December 30, 2016 6:04 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Preliminary report of protocol noncompliance

The University of Mississippi Medical Center (UMMC), in accordance with Assurance D16-00174 (A3275-01) and PHS Policy IV.F.3., provides this preliminary report of protocol noncompliance.

Submitted by:

Secondary Individual
Manager - Office of Animal Welfare
University of Mississippi Medical Center
2500 North State Street
Jackson, MS 39216
T: **Phone Number** | F: **Phone Number**
Secondary Individual@umc.edu
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