



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

June 19, 2017

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

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) acknowledge receipt of your June 16, 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 March 16, 2017. According to the information provided, OLAW understands that mice were being subjected to caloric restriction although this activity had not been described in the protocol and the cage cards had not been properly completed.

The corrective actions consisted of stopping the caloric restriction until the protocol was amended. The Principal Investigator and staff were counseled on the approved protocol procedures and on record keeping, the PI and staff were retrained, the Institutional Animal Care and Use Committee re-evaluated the laboratory during the semiannual review and found it compliant, the protocol amendment was approved, and the PHS grant was reimbursed for any unauthorized animal activities.

Based on the information provided, OLAW is satisfied that appropriate actions have been taken to investigate, correct, and prevent recurrence of the noncompliance. We appreciate having been informed about this matter and find no cause for further action by this Office.

Sincerely,

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

cc: IACUC Chair



June 16, 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 nonstandard feeding in mice, an activity not reviewed and approved by the IACUC, and lack of proper protocol identification on animal cage cards. A review of the funding source for this protocol showed that federal funding is associated with the study, NIH/NIA Grant 5R01AG046835-04. The incident was first reported to OLAW on March 16, 2017, via email by [redacted] Secondary Individual, Director, Office of Animal Welfare.

On January 26, 2017 Center for Comparative Research (CCR) staff noted several cages of mice with no food. Cages had "Investigator will feed cards" that were not properly completed to indicate feeding of animals. In addition "Caloric Restriction" was indicated on the existing cards. Correct identification of the protocol was not on the animal cage cards.

Upon the identification of the cages the AV spoke with research staff to ensure timely feeding of animals. IACUC staff was informed and the PI's approved protocols were reviewed. The PI has 5 approved protocols, none of which are approved for caloric restriction.

The IACUC Chair, AV, and Director-OAW met on February 7, 2017 to discuss the potential protocol non-compliance. The subcommittee decided the Chair would contact the PI to determine if a non-compliance had occurred, identify the correct protocol number associated with the non-compliance, and discuss proper labeling of cage cards.

The Chair met with PI the same day. PI stated that caloric restriction was conducted at previous institution and failure had occurred to include it in the current protocol. PI took responsibility for the oversight and agreed to cease caloric restriction until the committee reviewed and approved a modification.

The PI submitted a modification request to add caloric restriction to the protocol on February 8, 2017.



The committee discussed the noncompliance at a convened meeting on February 21, 2017. After discussion the following corrective actions were identified by the IACUC and approved by a quorum of the membership:

1. PI and all laboratory staff meet with a member of the CCR veterinary staff, IACUC Chair, and IACUC staff to review and discuss the approved activities of all protocols and laboratory records.
2. PI and all laboratory are to retake the CITI course, "Working with the IACUC" within one week of notification.
3. Laboratory staff's access to and knowledge of protocols and laboratory records will be re-evaluated at the Spring Semi-annual laboratory visit.
4. Modification approval is contingent upon completion of retraining.
5. Failure to complete the requested training within the timeline will result in suspension of protocols and any animals in house will be placed on the CCR Holding Protocol.

On February 23, 2017 the IACUC Chair, AV, and Director-OAW met with the PI to discuss the committee's required corrective actions.

The IACUC Chair sent a letter (email) on February 24, 2017 to the PI with "Cc" copies to the Department Chair, IO, and AV that outlined the protocol noncompliance issues and the corrective actions required.

The IACUC Chair, Assistant Director-CCR, and Director-OAW met with the PI and all laboratory staff on March 3, 2016 to review the approved activities of the all protocols for the laboratory. Completion reports for CITI training from all laboratory personnel were received by the OAW on February 27, 2017.

The modification request was approved on March 3, 2017. At the IACUC meeting on March 23, 2017 the subcommittee provided a report on the completion of the corrective action plan by the PI and laboratory staff. Based on the report of the subcommittee, 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 Spring Semi-annual Program and Review and Facilities Inspection was conducted in May. The laboratory visit for the PI was conducted on May 5, 2017 by a team consisting of two voting IACUC members. The IACUC team reviewed the records and met with the PI and laboratory personnel. No deficiencies were noted by the team and the laboratory personnel demonstrated access to and knowledge of the approved protocols.

A review of the billing records found that during the dates of December 28, 2016 until February 7, 2017, all direct costs associated with procurement, care, and use of ten cages of mice



designated for "Caloric Restriction" were paid from NIH/NIA Grant 5R01AG046835-04. The Director-OAW worked with the CCR, department contact, and Director-Office of Sponsored Programs, Post Award to determine the applicable charges and facilitate removal of the charges from the grant. The IACUC notified the NIH Program Official of the reported non-compliance on June 8, 2017.

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

Secondary Individual

Phone Number
Secondary Individual

Phone Number



March 16, 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 preliminary report of noncompliance regarding nonstandard feeding in mice, an activity not reviewed and approved by the IACUC, and lack of proper protocol identification on animal cage cards. This preliminary report is submitted by secondary Individual Director, UMMC, Office of Animal Welfare (OAW).

On January 26, 2017 Center for Comparative Research (CCR) staff noted several cages of mice with no food. Cages had "Investigator will feed cards" that were not properly completed to indicate feeding of animals. In addition "Caloric Restriction" was indicated on the existing cards. Correct identification of the protocol was not on the animal cage cards.

Upon the identification of the cages the AV spoke with research staff to ensure timely feeding of animals. IACUC staff was informed and the PI's approved protocols were reviewed. The PI has 5 approved protocols, none of which are approved for caloric restriction.

The IACUC Chair, AV, and Director-OAW met on February 7, 2017 to discuss the potential protocol non-compliance. The subcommittee decided the Chair would contact the PI to determine if a non-compliance had occurred, identify the correct protocol number associated with the non-compliance, and discuss proper labeling of cage cards.

The Chair met with PI the same day. The PI stated that caloric restriction was conducted at previous institution and failure had occurred to include it in the current protocol. The PI took



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responsibility for the oversight and agreed to ~~cease~~ caloric restriction until the committee reviewed and approved a modification.

The PI submitted modification request to add caloric restriction to the protocol on February 8, 2017.

The committee discussed the noncompliance at a convened meeting on February 21, 2017. After discussion the following corrective actions were identified by the IACUC and approved by a quorum of the membership:

1. PI and all laboratory staff must meet with a member of the CCR veterinary staff, IACUC Chair, and IACUC staff to review and discuss the approved activities of all protocols and laboratory records.
2. PI and all laboratory are to retake the CITI course, "Working with the IACUC" within one week of notification.
3. Laboratory staff's access to and knowledge of protocols and laboratory records will be re-evaluated at the Spring Semi-annual laboratory visit.
4. Modification approval is contingent upon completion of retraining.
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On February 23, 2017 the IACUC Chair, AV, and Director-OAW met with the PI to discuss the committee's required corrective actions.

The IACUC Chair sent a letter (email) on February 24, 2017 to the PI with "Cc" copies to the Department Chair, IO, and AV that outlined the protocol noncompliance issues and the corrective actions required.

The IACUC Chair, Assistant Director-CCR, and Director-OAW met with the PI and all laboratory staff on March 3, 2016. Completion reports for CITI training from all laboratory personnel were received by the OAW on February 27, 2017.

A review of the funding source for this protocol showed that federal funding is associated with the study, NIH/NIA Grant R01AG046835. The Office of Animal Welfare will work with the



departmental office to ensure that any charges to the account during the time of noncompliance are removed and will notify the NIH funding component.

After the committee has completed review of the corrective actions completed by the PI and laboratory staff and review of billing records are completed, 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](#)
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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: Friday, March 17, 2017 8:01 AM
To: 'IACUC'
Subject: RE: Preliminary report of protocol noncompliance

Thank you for this preliminary report, [redacted]. 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: Thursday, March 16, 2017 1:55 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Richard L. Summers <rsummers@umc.edu>
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:

[redacted]
Director - Office of Animal Welfare
University of Mississippi Medical Center
2500 North State Street
Jackson, MS 39216
T: [redacted] | F: [redacted]
[redacted]@umc.edu
umc.edu

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