



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

December 12, 2018

Re: Animal Welfare Assurance
A3397-01 [OLAW Case V]

Dr. Lawrence Dreyfus
Vice Chancellor for Research
and Economic Development
University of Missouri – Kansas City
5211 Rockhill Road
Kansas City, Missouri 64110

Dear Dr. Dreyfus,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your December 6, 2018 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Missouri- Kansas City, following up on an initial October 15, 2018. According to the information provided, OLAW understands that animal activities had been conducted without prior approval from the Institutional Animal Care and Use Committee (IACUC) and one individual conducting animal procedures had not been approved on the protocol. Specifically, animals were given alcohol by gavage and were subjected to behavior testing at time points not listed in the protocol.

The corrective actions consisted of the IACUC counseling the Principal Investigator (PI) about the noncompliance, having laboratory staff ensure that all procedures are approved on the protocol, and ensuring that all participating staff is listed on the protocol. The IACUC required monthly updates and placed the laboratory under enhanced post-approval monitoring. The PI accepted responsibility and implemented additional corrective actions including keeping the laboratory door locked, keeping a protocol binder, submitting monthly reports to the IACUC, ensuring all animal activities are covered on a protocol, and having only the PI correspond with the IACUC. The NIH grant was not charged for any unauthorized animal activities and the funding component was notified about this matter.

Based on its assessment of this explanation, OLAW understands that measures have been implemented to correct and prevent recurrence of this problem. OLAW concurs with the actions taken by the IACUC to comply with the PHS Policy. Please remember to state the species involved in the noncompliance. 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



Office of Research Services

December 6, 2018

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
Phone: 301-594-2061
FAX: 301-402-2803
E-mail: olawdco@mail.nih.gov

The University of Missouri at Kansas City (UMKC), in accordance with Assurance A3397-01 and PHS Policy IV.F.3., provides this final report regarding a noncompliance issue with the PHS Policy pertaining to the conduct of animal-related activities. This incident was first reported by Chris Winders, UMKC Director of Research Compliance, to the Division of Compliance Oversight, Office of Laboratory Animal Welfare, on October 15, 2018 via an email to olawdco@od.nih.gov.

On September 6, 2018 the UMKC Office of Research Compliance received information that experiments may have been performed without prior IACUC approval. On September 27, 2018, an IACUC subcommittee reviewed all pertinent documents and interviewed the principal investigator (PI) and a member of the PI's research staff. Based on the results of the investigation, the IACUC subcommittee concluded that the Investigator violated the policies and procedures of the IACUC by conducting procedures and experiments that were unapproved by the IACUC. It was also determined that one member of the research team conducting procedures and experiments was not approved to conduct research activities under the protocol.

A review of billing records showed that direct costs associated with the procurement, care, and use of the animals were initially paid from NIH Grant 1 R01 AA020806-01A1. These costs are being removed from this account and invoiced to and paid from a nonfederal source. The NIH funding component will be notified of the situation.

The findings of the sub-committee were presented to the convened IACUC on October 31, 2018. The convened IACUC voted to recognize the following non-compliance activities:

1. Administration of alcohol by gavage and administration of alcohol and behavioral testing at time points (4, 8, and 12 weeks) not listed in the protocol.
2. In addition there is no record of a member of the research team, responsible for conducting procedures and experiments, having been approved by the IACUC.

Due to these non-compliance issues, the convened IACUC voted and approved the following corrective actions:

1. Require the PI to submit a formal response to the IACUC:

UNIVERSITY OF MISSOURI-KANSAS CITY

Office of Research Services • 5211 Rockhill Road • Kansas City, MO 64110

www.umkc.edu/research

an equal opportunity/affirmative action institution

Obtained by Rise for Animals.

Uploaded to Animal Research Laboratory Overview (ARLO) on 08/05/2021

- a. Addressing the non-compliance findings to include your recognition of the items, your understanding of why each is an issue of non-compliance, and a plan to implement avoidance of such instances of non-compliance in the future.
 - b. That you, as the PI, and your laboratory members, have carefully reviewed your animal protocols and affirm that:
 - i. All research procedures being conducted are approved under respective IACUC protocols, and
 - ii. All research personnel conducting research under your approved protocols are listed on the respective IACUC protocols.
2. Post-approval monitoring:
- a. As the PI, complete and submit, to umkciacuc@umkc.edu, a monthly report on your animal research to the UMKC IACUC. The report will need to be signed by you as the PI, responsible for the overall conduct of the research, and research personnel approved on protocol 1215-03. These post-approval monitoring reports will be required monthly for a minimum of 6 months.
 - i. Unannounced inspections of your laboratory space may occur over the next 6 months.
3. An assurance statement signed by all approved research personnel listed on your current IACUC protocols stating that they have read the protocols and the work conducted in the laboratory matches what is described in the protocol.

The PI expressed in a letter to the IACUC that this was an unfortunate incident and took responsibility for the noncompliance. The PI assured the IACUC that an incident of such nature would not occur again. The IACUC determined that this was an isolated incident and not a programmatic failure.

The following corrective action plan was implemented by the PI and research team after the incident:

1. The PI submitted correspondence to the IACUC, dated November 16, 2018, accepting responsibility for the non-compliance.
2. The PI described corrective action measures that have been implemented to prevent a reoccurrence of an incident of this nature. The measures included:
 - a. The lab door is always locked so that no unauthorized person can enter in the lab.
 - b. We have made one binder for each protocol and every paper will be filed in the binder.
 - c. I have set up six monthly calendar invites compilation of the first draft of the monthly report required by the IACUC. I will then finalize the report and submit to IACUC.
 - d. I will ensure that any animal related experiment is approved by the IACUC before students start the experiment.
 - e. The future correspondence with IACUC will be done only by PI so that any mistakes can be avoided in future.

UMKC is committed to the protection of animals used in research and the prevention of Investigator violations. Should you have any questions regarding this report, please contact Chris Winders, Director of Research Compliance at windersc@umkc.edu or (b) (6). Please accept this letter as a final report of incidents and corrective action plan.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Lawrence Dreyfus, PhD
Vice Chancellor for Research and Economic Development
Institutional Official
University of Missouri-Kansas City

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Thursday, December 06, 2018 12:13 PM
To: Winders, Christopher; OLAW Division of Compliance Oversight (NIH/OD)
Cc: UMKC-IACUC; (b) (6)
Subject: RE: Preliminary report of non-compliance

Thank you for submitting this final report. We will send an official response soon.

Best regards, Brent Morse

Brent C. Morse, DVM, DACLAM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Please note that this message and any of its attachments are intended for the named recipient(s) only and may contain confidential, protected or privileged information that should not be distributed to unauthorized individuals. If you have received this message in error, please contact the sender.

From: Winders, Christopher [mailto:windersc@umkc.edu]
Sent: Thursday, December 06, 2018 11:48 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) UMKC-IACUC <umkciacuc@umkc.edu>; (b) (6)
(b) (6)
Subject: RE: Preliminary report of non-compliance

Dr. Morse,

Please find the attached final report regarding this non-compliance incident. Please let me know if you have any questions.

Thank you.

Chris

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Sent: Monday, October 15, 2018 1:06 PM
To: Winders, Christopher <windersc@umkc.edu>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: RE: Preliminary report of non-compliance

Thank you for this preliminary report. We will open a case file and await further information.

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: Winders, Christopher [<mailto:windersc@umkc.edu>]
Sent: Monday, October 15, 2018 2:01 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Subject: Preliminary report of non-compliance

Division of Compliance Oversight,

Please find the preliminary report information below pertaining to a non-compliance issue at our university. If there are any questions in advance of the final report please let us know.

- Name and contact information of person reporting

Chris Winders
Director of Research Compliance
University of Missouri - Kansas City
5319 Rockhill Road
Kansas City, Missouri 64110-2499
(b) (6) (Office)
windersc@umkc.edu

- Name of institution
 - University of Missouri - Kansas City
- Assurance number (see list of domestic and foreign Assured institutions)
 - A3397-01
- Funding component and if contacted (for situations related to PHS-supported activities)
 - Potentially NIH funded studies. NIH has not been contacted
- Brief description of incident (e.g., species, category of personnel involved, dates, times, animal deaths)
 - conduct of animal-related activities without appropriate IACUC review and approval
- Plan and schedule for correction and prevention (if known)

- A sub-committee was assembled and met on September 27, 2018 to review pertinent documents and interview the PI and study staff. A presentation was made to the convened IACUC on October 11, 2018 with the following corrective action plan approved:
 - Revise and update protocol 1215-03 with an accurate description of all procedures and experiments. We request that you carefully review the document to make sure information is correct and consistent throughout the whole protocol. In addition, you are requested to state in an email, along with your resubmitted materials, that you have carefully reviewed the protocol.
 - Post approval monitoring:
 - As the PI, complete and submit, to umkciacuc@umkc.edu, a monthly report on your animal research to the UMKC IACUC. Please use the Annual Continuation form for this report. The report will need to be signed by you as the PI, responsible for the overall conduct of the research, and research personnel approved on protocol 1215. The first monthly report will be due 1 month after protocol 1215-03 is approved and will be required monthly for 6 months.
 - Unannounced inspections of your laboratory space may occur over the next 6 months.
 - An assurance statement signed by all approved research personnel listed on each protocol stating that they have read the protocols and the work conducted in the laboratory matches what is described in the protocol. This includes protocols 1201-03, 1215-03, 1508-02, 1702, and 1703.
 - The IACUC requests a written response from you addressing the non-compliance findings here to include your recognition of the items, your understanding of why each is an issue of non-compliance, and to address a plan you intend to implement to avoid such instances of non-compliance in the future.
- Timeframe for final report from the Institutional Official
 - October 31, 2018

Chris Winders

Director of Research Compliance

<http://ors.umkc.edu/research-compliance>

University of Missouri - Kansas City

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(b) (6) (Office)

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