



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) 480-3387

July 16, 2020

Re: Animal Welfare Assurance
A3472-01 [OLAW Case 5J]

Dr. David Russell
Vice President and Dean of Basic Research
University of Texas Southwestern Medical Center
5323 Harry Hines Boulevard
Dallas, TX 75390-9002

Dear Dr. Russell,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 29, 2020 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the University of Texas – Southwestern Medical Center. Your letter supplements the information in the prompt telephone report to our office on February 24, 2020 and interim reports dated March 23, 2020 and April 23, 2020. According to the information supplied OLAW understands that on February 20, 2020, your institution received an anonymous report that included several allegations of non-compliance, spanning the period of January 2017 to February 20, 2020. Additional allegations were received on February 27, 2020. Based on these allegations and information obtained during the investigation, the IACUC suspended all research animal activities associated with the PI. This suspension was effective on March 2, 2020. An additional three separate allegations of non-compliance were subsequently received by the IACUC. It is further understood that these allegations and suspension were reported to the NIH funding components on April 16, 2020.

The substantiated instances of non-compliance, spanning the entire time period of the allegations, were:

1. Aseptic technique was not required of laboratory members except when they were being observed by representatives of the IACUC or veterinary staff. This breach included not autoclaving surgical instruments and implants, not maintaining a sterile field during surgery, inappropriately disinfecting instruments between animals, and not sterilizing implants.
2. Provision of post-operative analgesia for rodent surgeries was not required of laboratory members until November 2019. From January 2017 to November 2019, laboratory staff inconsistently administered post-operative analgesics according to their own criteria not based on the IACUC approved protocols. When not administered, required documentation for post-operative analgesics was either missing or falsified.
3. Provision of inaccurate summaries of IACUC policies and approved protocols as well as directions for procedures to laboratory staff, resulting in the performance of procedures inconsistent with policies and protocols (e.g., incorrect administration schedules for doxycycline, the drilling of multiple burr holes when only one was approved).
4. Lack of action on behalf of the PI when informed about unanticipated pain and distress in animals undergoing doxycycline administration.

5. Unapproved housing of mice in the laboratory for more than 24 hours.
6. Lack of training and oversight for the correct preparation and maintenance of tribromoethanol used for anesthesia, resulting in the administration of solutions that were of inadequate strength and/or had visible precipitate.
7. Failure to provide appropriate surgical supplies to laboratory staff on a consistent basis.
8. Failure to train laboratory staff on how to access IACUC approved protocols.

During a full committee meeting on April 17, 2020, your IACUC determined the below corrective actions:

1. The laboratory is not allowed to conduct any live animal work, other than euthanasia, outside of the animal facility, permanently.
2. The required mentor was appointed by the PI's Department Chair for the PI to provide guidance for animal research. The IACUC met with the mentor on April 24, 2020.
3. The current Laboratory Manager was no longer allowed to be involved in animal research activities at UT Southwestern and the PI identified another individual to provide an appropriate level of oversight for the animal activities in the laboratory. The IACUC met with this new person on May 1, 2020.
4. The laboratory members completed hands-on rodent aseptic surgical technique training and isoflurane anesthesia training. They will no longer be able to use tribromoethanol as an anesthetic.
5. The PI's rat protocol was closed by the IACUC on April 21, 2020.
6. As of June 26, 2020, the PI's protocols had been amended, re-reviewed and approved by the IACUC thus lifting the suspensions. Once animal work is resumed, the laboratory will be subject to at least one year of heightened post- approval monitoring, including unannounced visits.
7. The corrective action plan may be modified in the future, as warranted, by the IACUC.

It was stated that this animal activity was supported by grants 1R01NS104828 and 1R15MH120144-01.

The prompt consideration of this matter by the University of Texas – Southwestern Medical Center was consistent with the philosophy of institutional self-regulation and self-correction. Similarly, the actions taken to resolve the issues and prevent recurrence were appropriate. We find no cause for further action by this office.

Sincerely,

Brent C. Morse –S

Digitally signed by Brent C.

Morse –S

Date: 2020.07.16 15:45:17 -04'00'

Brent C. Morse, DVM

Director

Division of Compliance Oversight

Office of Laboratory Animal Welfare

cc: IACUC contact

Anna R. Taylor, Ph.D., Acting Chief Grants Management Officer, NINDS

Rebecca Claycamp, Chief Grants Management Officer, NIMH

UT Southwestern Medical Center

David W. Russell, Ph.D.
Vice Provost and Dean of Research
UT Southwestern Medical School
Department of Molecular Genetics
Eugene McDermott Distinguished Chair
June 29, 2020

Brent Morse, DVM
Director, Division of Compliance Oversight
National Institutes of Health, Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

RE UT Southwestern Medical Center Animal Welfare Assurance Statement # D16-00296
Grants 1R01NS104828 and 1R01MH120144-01

Dear Dr. Morse,

I write to provide a final report of non-compliance with the *PHS Policy on Humane Care and Use of Laboratory Animals*. The IACUC determined that multiple serious and continued instances of non-compliance with IACUC requirements and *PHS Policy* guidelines were undertaken by the PI that resulted in the IACUC being deceived based on previous post-approval monitoring observations. A preliminary report was provided to you via a voicemail message by the Assistant Vice President of Conflict of Interest & IACUC on February 20, 2020 and written interim reports were provided to you on March 24, 2020 and April 28, 2020. This letter represents the final report as previously promised.

A timeline for completion of the IACUC required corrective actions is as follows:

1. The PI's Department Chair appointed the required mentor to provide guidance to the PI regarding animal research. The requisite meeting between the mentor and the IACUC Chair and other IACUC representatives was held on April 24, 2020.
2. The PI identified another individual, as required by the IACUC, to provide oversight of animal activities in the laboratory. The requisite meeting between this individual and the IACUC Chair and other IACUC representatives was held on May 1, 2020.
3. The IACUC determined during a convened meeting on May 8, 2020, with a majority vote of more than a quorum of members present, that the PI would be allowed to bring animals to his laboratory for euthanasia purposes only upon protocol re-review and approval due to the unique nature of the equipment in the laboratory. All other procedures involving live animals must occur inside one of the centrally managed UT Southwestern animal facilities.
4. On May 27, 2020, all laboratory members completed hands-on retraining in rodent aseptic surgical technique with veterinary staff.
5. As of June 26, 2020, all four of the PI's mouse protocols have been amended, re-reviewed, and approved by the IACUC, thus lifting the suspension as per the IACUC's previous decision. The laboratory will no longer use tribromoethanol as an anesthetic.
6. On June 29, 2020, all laboratory members completed hands-on training in the use of isoflurane anesthesia with veterinary staff.
7. The laboratory is now subject to at least one year of heightened post-approval monitoring, including unannounced visits.

We believe the actions taken by the IACUC are appropriate for this situation.

Yours sincerely,

(b) (6)

David W. Russell, Ph.D.
Vice Provost, Dean of Basic Research, and Institutional Official

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, July 1, 2020 7:15 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Report to OLAW

Thank you for this report. We will respond soon.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: (b) (6)
Sent: Tuesday, June 30, 2020 4:13 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) David Russell <David.Russell@UTSouthwestern.edu>
Subject: Report to OLAW

To the Division of Compliance Oversight,

Attached is a final report of non-compliance. Please let me know if you have any questions regarding this report.

(b) (6)

(b) (6)

UT Southwestern

Medical Center

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2nd interim rec'd 4/28/20

A3472

UT Southwestern
Medical Center

David W. Russell, Ph.D.
Vice Provost and Dean of Research
UT Southwestern Medical School
Department of Molecular Genetics
Eugene McDermott Distinguished Chair
April 23, 2020

Brent Morse, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

RE: UT Southwestern Medical Center Animal Welfare Assurance Statement # D16-00296
Grants: 1R01NS104828 and 1RF1MH120144-01

Dear Dr. Morse,

I write to provide a second interim report of non-compliance with the *PHS Policy on Humane Care and Use of Laboratory Animals*. On February 20, 2020, the Assistant Vice President of Conflict of Interest (COI) & IACUC received a report that included several allegations of non-compliance, spanning the period of January 2017 to February 20, 2020, with IACUC policies that had been provided to the university's anonymous Compliance Hotline. The IACUC immediately began an investigation. On February 27, 2020, the IACUC Chair received a separate set of allegations of non-compliance with IACUC policies. Based on these allegations and information obtained during the investigation, the IACUC suspended all research animal activities associated with the PI with a majority vote of more than a quorum of members present at a convened meeting. This suspension was effective on March 2, 2020. An additional three separate allegations of non-compliance were subsequently received by the IACUC. A written interim report regarding this situation was provided to you on March 24, 2020.

These allegations and suspension were reported to the funding components on April 16, 2020. On April 17, 2020, the IACUC concluded its investigation and determined that multiple serious and continued instances of non-compliance with IACUC requirements and *PHS Policy* guidelines were committed by the PI, which resulted in the inability of the IACUC to fully understand laboratory practices during previous post-approval monitoring visits.

The substantiated instances of non-compliance, spanning the entire time period of the allegations, were:

1. Aseptic technique was not required of laboratory members except when they were being observed by representatives of the IACUC or veterinary staff. This breach included not autoclaving surgical instruments and implants, not maintaining a sterile field during surgery, inappropriately disinfecting instruments between animals, and not sterilizing implants.
2. Provision of post-operative analgesia for rodent surgeries was not required of laboratory members until November 2019. From January 2017 to November 2019, laboratory staff inconsistently administered post-operative analgesics according to their own criteria not based on the IACUC approved protocols.

5323 Harry Hines Blvd., Dallas, Texas 75390-9046 Phone: 214-648-2007 Fax: 214-648-8955 david.russell@utsouthwestern.edu
utsouthwestern.edu

When not administered, required documentation for post-operative analgesics was either missing or falsified.

3. Provision of inaccurate summaries of IACUC policies and approved protocols as well as directions for procedures to laboratory staff, resulting in the performance of procedures inconsistent with policies and protocols (e.g., incorrect administration schedules for doxycycline, the drilling of multiple burr holes when only one was approved).
4. Lack of action on behalf of the PI when informed about unanticipated pain and distress in animals undergoing doxycycline administration.
5. Unapproved housing of mice in the laboratory for more than 24 hours.
6. Lack of training and oversight for the correct preparation and maintenance of tribromoethanol used for anesthesia, resulting in the administration of solutions that were of inadequate strength and/or had visible precipitate.
7. Failure to provide appropriate surgical supplies to laboratory staff on a consistent basis.
8. Failure to train laboratory staff on how to access IACUC approved protocols.

During a full committee meeting on April 17, 2020, the IACUC determined the below corrective actions:

1. The laboratory is not allowed to conduct any live animal work outside of the animal facility, permanently.
2. In order to re-initiate animal work, the PI's Department Chair must appoint a mentor for the PI to provide guidance for animal research. Without appointment of a mentor, the PI is unable to conduct animal research at UT Southwestern. The IACUC must meet with the mentor before the mentorship begins, the IACUC may request periodic updates from the PI and/or the mentor, and the mentorship relationship will continue for as long as the IACUC deems necessary.
3. The current Laboratory Manager can no longer be involved in animal research activities at UT Southwestern and the PI must identify another individual to provide an appropriate level of oversight for the animal activities in the laboratory. The IACUC must meet with this new person before they can assume their oversight responsibility and, should this person leave the laboratory, the IACUC must be notified within 14 days regarding who the replacement will be. The IACUC must meet with the replacement prior to their authorization to take on oversight.
4. The PI's four mouse protocols must be re-reviewed by the IACUC prior to work resuming. The laboratory will no longer be able to use tribromoethanol as an anesthetic and additional training will be required as identified during the re-review process.
5. The PI's rat protocol was closed by the IACUC on April 21, 2020.
6. Once animal work is resumed, the laboratory will be subject to at least one year of heightened post-approval monitoring, including unannounced visits.
7. The corrective action plan may be modified in the future, as warranted, by the IACUC.

The PI was notified of these required corrective actions on April 17, 2020 and agreed to them. We expect to provide a final report by July 1, 2020.

Respectfully,

(b) (6)

David W. Russell, Ph.D.
Vice Provost, Dean of Research, and Institutional Official

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, April 29, 2020 7:16 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Interim Report to OLAW

Thank you for this interim report, (b) (6) We will add it to the case file.
Axel Wolff

From: (b) (6)
Sent: Tuesday, April 28, 2020 6:06 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) David
Russell <David.Russell@UTSouthwestern.edu>
Subject: Interim Report to OLAW

To the Division of Compliance Oversight,

Attached is a second interim report of non-compliance. Please let me know if you have any questions regarding this report.

(b) (6)

(b) (6)

UT Southwestern

Medical Center

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A3472

UT Southwestern
Medical Center

David W. Russell, Ph.D.
Vice Provost and Dean of Research
UT Southwestern Medical School
Department of Molecular Genetics
Eugene McDermott Distinguished Chair

March 23, 2020

Brent Morse, DVM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC 6910
Bethesda, MD 20892

RE: UT Southwestern Medical Center Animal Welfare Assurance Statement # D16-00296

Dear Dr. Morse,

I write to provide an interim report of non-compliance with the *PHS Policy on Humane Care and Use of Laboratory Animals*. On February 20, 2020, the Assistant Vice President of Conflict of Interest (COI) & IACUC received a report including several allegations of noncompliance with IACUC policies that had been provided to the university's anonymous Compliance Hotline. This incident was initially reported to you via voicemail message by the Assistant Vice President of COI & IACUC on February 20, 2020.

The IACUC immediately began an investigation. On February 27, 2020, the IACUC Chair received a separate set of allegations of noncompliance with IACUC policies. Based on the allegations and information revealed during the investigation, the IACUC suspended all research animal activities for the PI with a majority vote of more than a quorum of members present at a convened meeting. This suspension became effective at 5 p.m. on March 2, 2020. Subsequent visits to the laboratory and discussions with the PI by the Sr. IACUC Liaison, Assistant Vice President of COI & IACUC, and IACUC Chair have confirmed that all animal work has ceased. An additional three separate allegations have been subsequently received by the IACUC. The investigation is currently ongoing.

We expect to provide a final report by May 1, 2020.

Yours sincerely,

(b) (6)

David W. Russell, Ph.D.
Vice Provost, Dean of Research, and Institutional Official

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, March 25, 2020 9:06 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Interim Report to OLAW

Thanks for this interim report, (b) (6) If the study in question is PHS/NSF supported, please notify the funding component about the suspension.

Axel Wolff, M.S., D.V.M.
Deputy Director, OLAW

From: (b) (6)
Sent: Tuesday, March 24, 2020 12:51 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6) David Russell <David.Russell@UTSouthwestern.edu>
Subject: Interim Report to OLAW

To the Division of Compliance Oversight,

Attached is an interim report of non-compliance. Please let me know if you have any questions regarding this report.

(b) (6)

(b) (6)

UT Southwestern

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Initial Report of Noncompliance

By: (b) (6)

Date: 2/24/20

Time: Voicemail from 2/20/20

Name of Person reporting: (b) (6)

Telephone #: (b) (6)

Fax #: (b) (6)

Email: (b) (6)

Name of Institution: Southwestern Med. Ctr. - Dallas

Assurance number: A3472

Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): _____

What happened? Whistle blower complaint.

Surgery, analgesia, hazardous waste disposal issues. Covers 3 yr. period.

Species involved: _____

Personnel involved: PI

Dates and times: _____

Animal deaths: _____

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

Early in investigation

Projected submission to OLAW of final report from Institutional Official: _____

Late March

OFFICE USE ONLY

Case # _____