



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

March 12, 2020

Re: Animal Welfare Assurance
#A3095-01 (OLAW Case J)

Chris Kevil, Ph.D.
Vice Chancellor for Research and Director
Center for Cardiovascular Diseases and Sciences
Louisiana State University Health Sciences Center Shreveport
1501 Kings Highway
Shreveport, LA 71103

Dear Dr. Kevil,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your March 9, 2020 letter responding to OLAW's January 16, 2020 request for additional information regarding an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Louisiana State University Health Science Center Shreveport.

According to the information provided, OLAW understands retraining for the entire lab was conducted on February 20, 2020 and the individual responsible for the non-compliance event participated in hands-on training conducted by the Assistant Director, Animal Resources on February 27, 2020. Furthermore, the Assistant Director, Animal Resources will be monitoring all surgeries conducted by the responsible individual until compliance with institutional policy and standard operating procedures for surgical procedures is considered satisfactory.

OLAW appreciates the prompt consideration of this matter by the Louisiana State University Health Science Center Shreveport which is consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW is satisfied that appropriate steps have been taken to investigate this incident. We appreciate being informed of this matter and please contact us with any further questions or concerns.

Sincerely, 

(b) (6)

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact



SHREVEPORT

Health Sciences Center

Office of the Vice Chancellor
for Research

Chris Kevil, PhD

1501 Kings Highway
P.O. Box 33932
Shreveport, LA 71130-3932

O 318-675-4101
F 318-675-5244
www.lsuhsccshreveport.edu

March 9, 2020

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Division of Oversight Compliance
Office of Laboratory Animal Welfare
National Institutes of Health
6700 Rockledge Suite 2500, MSC 6910
Bethesda, MD 20892

Dear Dr. Lukovsky-Akhsanov,

The LSU Health Sciences Center Shreveport (LSUHSC Shreveport) wishes to provide the following response to your letter of January 16, 2020 regarding case number A3095-01 (OLAW Case J).

The responsible individual at the center of this noncompliance returned to the institution on or about February 20, 2020. Retraining for the entire lab was conducted on February 25, 2020, and hands-on training for the responsible individual was conducted on February 27, 2020. All training was conducted by the Assistant Director, Animal Resources. The Assistant Director, Animal Resources will also monitor all surgeries conducted by the responsible individual until she (the Assistant Director) is satisfied that the surgeries are being conducted in compliance with institutional policy and standard operating procedures.

If additional information is needed, please do not hesitate to contact me.

Sincerely,

(b) (6)

Chris Kevil, PhD
Vice Chancellor for Research
Dean, School of Graduate Studies
Institutional Official



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

January 16, 2020

Re: Animal Welfare Assurance
#A3095-01 (OLAW Case J)

Chris Kevil, Ph.D.
Vice Chancellor for Research and Director
Center for Cardiovascular Diseases and Sciences
Louisiana State University Health Sciences Center Shreveport
1501 Kings Highway
Shreveport, LA 71103

Dear Dr. Kevil,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your January 7, 2020 letter responding to OLAW's December 17, 2019 request for additional information regarding an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Louisiana State University Health Science Center Shreveport.

According to the information provided, OLAW understands that surgeries were stopped immediately and the responsible individual's access to the animal facility was revoked at the time of the non-compliance report and remains revoked as he is not working with animals currently. The institution expects the principal investigator (PI) to have complete oversight of personnel in their lab. Retraining of the entire lab group including the PI has not taken place as the individual responsible for the noncompliance has been out of the country and no surgeries have been performed hence the delay in retraining. Until all retraining is completed by all individuals, no surgical procedures will be performed by anyone in the lab group. After completion of online training, the responsible individual and the entire lab will receive training from the Associate Director-Animal Resources (AD), on all aspects of survival surgery technique, sterile technique, proper anesthesia and analgesia administration and proper post-operative monitoring. After completion of training, the AD will supervise the responsible individual in all surgeries until the AD is satisfied surgery can be conducted properly. Of the ten animals impacted, one was euthanized immediately and the remaining nine were monitored and treated by Veterinary Services until euthanasia approximately two weeks later.

OLAW appreciates the prompt consideration of this matter by the Louisiana State University Health Science Center Shreveport which is consistent with the philosophy of institutional self-regulation. OLAW expects that all active laboratory members including the PI receive training without delay before further work with animals occurs as it is OLAW's understanding that analgesia was not provided to animals based on information from previous individuals working on this project. Based on the information provided, OLAW requests being informed of when training for all active laboratory members is completed to ensure appropriate animal welfare. We appreciate being informed of this matter and look forward to your responses referencing **Case A3095-J** to the additional information request by **March 6, 2020**.

Page 2 – Dr. Kevil
January 16, 2020
OLAW Case A3095-J

Sincerely

(b) (6)

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

Health Sciences Center

Office of the Vice Chancellor
for Research

Chris Kevill, PhD

1501 Kings Highway
P.O. Box 33932
Shreveport, LA 71130-3932

O 318-675-4101
F 318-675-5244
www.lsuhs.shreveport.edu

January 7, 2020

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
6700B Rockledge Drive, Suite 2500, MSC-6910
Bethesda, MD 20892-6910

Re: Animal Welfare Assurance #A3095-01 (OLAW Case J)

Dear Dr. Akhsanov,

Thank you for the opportunity to offer clarification on the issue of non-compliance reported to you on November 19, 2019.

In response to your questions in your letter of December 17, 2019, I am providing the following additional information:

1. *Does the individual responsible have access to the animal facility and/or is still currently working with animals?*

Surgeries on this particular protocol were stopped immediately. Within the week after the non-compliance, the individual responsible had left the country due to visa issues and has only recently returned. That individual's access to the animal facility was revoked at the time the non-compliance was reported, and remains revoked at this time. He is not currently working with animals and has not since the incident occurred.

2. *Describe the institution's expectations for PI oversight of research personnel. Did the PI and entire lab group have retraining on IACUC procedures and requirements for maintaining appropriate animal welfare (i.e., analgesia administration, post-operative monitoring)?*

The institution expects the PI to have complete oversight of the personnel in his/her lab. Since the individual responsible for the non-compliance issue has been out of the country since the incident, retraining of the entire lab group (including the PI) has not taken place. In addition, no one in that lab group has been performing any surgery on animals. Hence, the delay in the initiation of retraining. Until retraining has been completed by all individuals in the lab, no surgical procedures will be performed by anyone in this lab group.

After completion of the on-line training, the responsible individual and the entire lab will receive personal training from the Associate Director, Animal Resources on all aspects of survival surgical techniques, sterile technique, proper anesthesia and analgesia administration, and proper post-operative monitoring. At the completion of that training, the Associate Director will supervise the responsible individual in all surgeries until the Associate Director



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 17, 2019

Re: Animal Welfare Assurance
#A3095-01 (OLAW Case J)

Chris Kevil, Ph.D.
Vice Chancellor for Research and Director
Center for Cardiovascular Diseases and Sciences
Louisiana State University Health Sciences Center Shreveport
1501 Kings Highway
Shreveport, LA 71103

Dear Dr. Kevil,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your November 19, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Louisiana State University-Shreveport. Your letter supplements the information provided in a preliminary telephone report made on October 28, 2019. The study is not supported by PHS funding.

According to the information provided, OLAW understands that on October 9, 2019 the Assistant Director, Animal Resources, notified a principal investigator (PI) that the prior evening an individual from his lab had left a procedure room in an unacceptable condition. The next morning on October 10, 2019, a veterinary technician found ten mice belonging to the same PI with open surgical wounds on hindlimbs as the animals had bone graft surgery the day before which was performed by an individual from the PI's lab. The sutures at the surgical sites dehiscd, leaving deep defects with apparent contamination from bedding and the technician reported this to the clinical veterinarian. The veterinarian met with the PI and the following facts were ascertained:

- The individual performing surgeries had performed nine in a row and some mice had surgery on both hindlimbs.
- The individual began surgery late afternoon and rushed to finish the surgery. The automatic light timer had turned the lights off and the individual did not know how to override the automatic timer and turn the lights back on. The last four surgeries were performed by the light of his cell phone.
- The individual did not use any analgesics because previous individuals working on this project told him analgesics were not necessary however the protocol states analgesics will be used post-surgically.
- The individual performed surgery on both hind limbs even though the protocol indicates one hind limb surgery in the allograft procedure with the other hind limb used as a control.

Several specific issues were identified including the individual should have stopped performing surgery when lights turned off, a disregard for animal welfare and humane treatment due to lack of analgesia and interest in speed of completing surgery and protocol non-compliance as performing surgery on both hindlimbs were not approved due to potential for mice to have difficult accessing food and/or water.

As a corrective measure, these are the recommendations of the veterinary staff:

- The individual's access to the procedure room has been revoked until vet services feels the individual can follow guidelines for survival surgery,
- The individual will need to receive retraining in proper surgical technique.
- Surgeries and invasive procedures performed by the individual will be observed by veterinary services until veterinary services has confidence that the individual will adhere to approved protocol and is cognizant of animal welfare.
- The individual is limited to performing a maximum of five surgeries in a single day and limited to Monday-Thursday morning- no surgery on to start after 1pm and no surgery Friday or weekends.
- The individual will give veterinary services 24 hours advance notice of any plans to perform surgery or other invasive procedures.

The ACUC approved the recommendations and since the that time, there has been no contact with the responsible individual regarding completion of training or other recommendations.

OLAW appreciates the prompt consideration of this matter by the Louisiana State University-Shreveport which is consistent with the philosophy of institutional self-regulation. Based on the information provided, OLAW requests further information as follows:

- Does the individual responsible have access to the animal facility and/or is still currently working with animals?
- Describe the institution's expectations for PI oversight of research personnel. Did the PI and entire lab group have retraining on IACUC procedures and requirements for maintain appropriate animal welfare (i.e. analgesia administration, post-operative monitoring)?
- What is the disposition of the ten animals impacted by the non-compliance?

We appreciate being informed of this matter and look forward to your responses referencing **Case A3095-J** to the additional information request by **January 31, 2020**.

Sincerely,



(b) (6)

Nicole Lukovsky-Akhsanov, DVM, MPH, DACLAM
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC Contact

LSU Health

SHREVEPORT

Health Sciences Center

Office of the Vice Chancellor
for Research

Chris Kevil, PhD

1501 Kings Highway
P.O. Box 33932
Shreveport, LA 71130-3392

O 318-675-4101
F 318-675-5244
www.lsuhseshreveport.edu

November 5, 2019

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

Dear Dr. Morse,

The LSU Health Sciences Center Shreveport (LSUHSC Shreveport), in accordance with Assurance D16-00059 (A3095-01) and PHS Policy IV.F.3., provides this report of a noncompliance issue.

The noncompliance issue is a result of an event involving one animal use protocol. A preliminary report was provided to you on October 30, 2019, via telephone call by Dr. V. Hugh Price, DVM, Director, Animal Resources and Attending Veterinarian. This report consists of the details of the non-compliance issue that was considered by the Animal Care and Use Committee (ACUC) of the LSUHSC Shreveport at its regularly scheduled monthly meeting on October 22, 2019.

The project and the animals covered by the protocol are not on a PHS funded grant.

The issue began on October 9, 2019, when the Assistant Director, Animal Resources notified a principal investigator (PI) that on the evening before, an individual from his lab had left a procedure room in an unacceptable condition.

During her clinical rounds the next morning (October 10, 2019), the veterinary technician found 10 mice belonging to this same PI with opened surgical wounds on the hind limbs. These mice had bone graft surgery the day before, performed by an individual from the PI's lab. The sutures at the surgical sites had dehisced leaving deep defects with apparent contamination from bedding. The veterinary technician reported this to the clinical veterinarian. The clinical veterinarian met with the PI concerning these findings. From this conversation, the following facts were ascertained:

1. The individual performing the surgeries (responsible individual) had performed nine surgeries in a row. Some of the mice had had surgery on both rear legs.
2. The responsible individual had begun the surgeries late in the afternoon, and was rushing to finish them. The automatic light timer had turned the lights

off, and the responsible individual did not know how to override the automatic timer and turn the lights back on. (Note: The procedure room was a converted animal housing room that had been converted into a procedure room some five years earlier.) Therefore, the last four mouse surgeries were performed by the light of his cell phone.

3. The responsible individual did not use any analgesic because the previous individuals working on this same project told him that analgesic was not necessary. The animal use protocol describing this work clearly states that analgesics will be used post-surgically.

4) The responsible individual was performing surgery on both hind limbs, but the protocol clearly states that surgery will only be conducted on one hind limb in the allograft procedure as the other hind limb was to serve as control.

Specific issues:

1. Performing nine mouse surgeries at one time by one individual indicates there was very little thought to proper surgical technique in the interest of speed.

2. Surgery by phone light? The responsible individual should have stopped performing the surgeries when the lights were cut off and finished the next day.

3. There is a complete disregard for animal welfare and humane treatment in evidence here: the mice are crippled, some can't bend their legs at all and drag them, yet no analgesics given.

4. Surgery on both rear limbs means the potential for mice not to be able to obtain food or water. Surgery on both hind legs simultaneously was not described in the animal use protocol, and is a specific non-compliance.

Recommendations:

1. The responsible individual's access to the procedure room has been revoked until vet services feels that he can follow guidelines for survival surgery.

2. The responsible individual will receive retraining in proper surgical technique.

3. In the future, surgeries and invasive procedures done by the responsible individual will be observed by veterinary services until veterinary services has confidence that he will be compliant with his protocol and be cognizant of animal welfare.

4. The responsible individual will be limited as to the number of surgeries he may perform in one day - five, and surgeries will be limited to Monday – Thursday mornings. No surgery will be allowed to begin after 1 pm. There will be weekend or Friday surgeries allowed.

5) The responsible individual will provide veterinary services 24 hours of advance notice of any plans to perform surgeries or other invasive procedures

Since the ACUC meeting, there has been no contact with the responsible individual concerning the training required or any other recommendation.

If additional information is required, please do not hesitate to contact me.

Sincerely,

(b) (6)

Chris Kevil, PhD
Vice Chancellor for Research
Dean, School of Graduate Studies
Institutional Official

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Wednesday, November 06, 2019 2:03 PM
To: Price, Hugh
Cc: (b) (6)
Subject: RE: Report of Non-Compliance

Thank you for these reports Dr. Price. 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

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: Price, Hugh [mailto:HPrice@lsuhsc.edu]
Sent: Wednesday, November 06, 2019 1:59 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Cc: (b) (6)
Subject: Report of Non-Compliance

Dr. Morse,

Attached are two reports of non-compliance. Both reports were received by the Animal Care and Use Committee (ACUC) of the LSU Health Sciences Center at its regularly scheduled monthly meeting on October 22, 2019, and the recommendations listed in the reports from the veterinary staff were approved.

The responsible individual in report #1 has completed all requirements. The responsible individual in report #2 has not contacted the veterinary staff to begin re-training.

The ACUC considers both issues closed and has only requested it be notified when all individuals have completed the requirements listed in the recommendations.

If I need to provide additional details or information, please let me know.

Thank you.

Chip Price, DVM
Director, Animal Resources and Attending Veterinarian



Initial Report of Noncompliance

By: [REDACTED] (b) (6)

Date: 10/28/19

Time: 4:20

Name of Person reporting: Chip Price DVM, A/V
Telephone #: [REDACTED] (b) (6)
Fax #: [REDACTED]
Email: [REDACTED]

Name of Institution: LSU-HSC-Shreveport
Assurance number: A3095

Did incident involve PHS funded activity? No
Funding component: _____
Was funding component contacted (if necessary): _____

What happened? Resident performing surgery on both legs. Only approved for one leg. Dehiscence of surgery site.

Species involved: Mice
Personnel involved: Resident
Dates and times: 10/9/19
Animal deaths: _____

Projected plan and schedule for correction/prevention (if known):
Retrain lab + surgeon

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY
Case # _____