

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 B 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

May 6, 2019

Re: Animal Welfare Assurance A3094-01 [OLAW Case E]

Joseph M. Moerschbaecher, III, Ph.D. Vice Chancellor for Academic Affairs Louisiana State University Health Sciences Center 433 Bolivar Street New Orleans, LA 70112-2223

Dear Dr. Moerschbaecher,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 30, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at the Louisiana State University HSC – New Orleans. We received the initial report via an email on April 17, 2019. According to the information provided, OLAW understands that on March 7, 2017 your institution became aware that mice on a surgical study were not being given buprenorphine SR preoperatively as required by the protocol. The study team gave assurance that this unfortunate mistake would not occur again. The involved animals were supported by PHS funding.

Corrective actions included the IACUC sending the PI a letter requiring a meeting between the study team and the veterinarians during which the laboratory personnel were able to demonstrate satisfactory use of buprenorphine SR to the veterinarians.

The prompt consideration of this matter by the Louisiana State University HSC – New Orleans was consistent with the philosophy of institutional self-regulation. Similarly, the actions taken to resolve the issue and prevent recurrence were appropriate. We appreciate being informed of this matter and find no cause for further action by this office.

Sincerely.

(b) (6)

Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

cc: IACUC contact



School of Medicine
School of Dentistry
School of Nursing
School of Allied Health Professions
School of Graduate Studies
School of Public Health

April 30, 2019

Brent Morse, DVM, DACLAM
Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
Rockledge 1, Suite 360
6705 Rockledge Drive
Bethesda, MD 20892

RE:

Protocol Deviation in an NIH-Funded Study Assurance number: #D16-00058

Dear Dr. Morse,

On March 7th 2019, during its semiannual inspections, the LSUHSC-NO IACUC discovered that analgesic buprenorphine SR was not being administered to the study animals (mice) as specified in the approved protocol for the approved procedures. In a letter to the IACUC, the PI explained that the reason they were not administering the buprenorphine SR to the mice was due to the fact that the mice did not show any signs associated with pain or distress. The exclusion of the analgesic was an unfortunate mistake that the study team assured will not occur again. All members of the laboratory have been informed that buprenorphine SR must be administered before every surgery as indicated in protocol 3561. Additionally, all personnel will carefully review and uphold compliance to the protocol.

Because this protocol deviation had a potential impact on animal welfare, it was classified as a major non-compliance incident. The following corrective actions have been taken or are planned in response to this protocol deviation: A letter was sent to the PI on protocol 3561 outlining the incident and requesting a meeting between the study team and the Division of Animal Care veterinarians to review the protocol and evaluate the ability of appropriate team members to administer buprenorphine SR to mice. This meeting occurred on April 9th at 2:00pm. The laboratory personnel were conducting an experiment at that time, and thus were able to demonstrate satisfactory use of buprenorphine SR to the veterinarians. The veterinarians explained the importance and necessity of not only adhering to protocol, but also of giving an analgesic before a potentially painful procedure. The laboratory personnel will administer buprenorphine SR at a dose of 1 mg/kg before every surgical procedure as stated in the protocol. The study team is committed to protecting the welfare of the animals, and they appreciate the guidance and assistance provided by the veterinarians.

Follow-up discussions and demonstrations are tentatively scheduled for approximately two weeks and eight weeks from this initial meeting.

Louisiana State University Health Sciences Center is committed to protecting the welfare of animals used in research. This study is funded by the NIH National Eye Institute, and it was recommended by the Office of Laboratory Animal Welfare that the funding agency did not need to be contacted. The guidance and assistance that OLAW provided in this matter is much appreciated. Should you have any questions regarding this report, please contact Jennifer Pepping, DVM, IACUC Chair.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Joseph Moerschbaecher, Ph.D. Vice Chancellor for Academic Affairs Institutional Official Louisiana State University Health Sciences Center

Morse, Brent (NIH/OD) [E]

From:

OLAW Division of Compliance Oversight (NIH/OD)

Sent:

Wednesday, May 01, 2019 7:20 AM

To:

Pepping, Jennifer K.; OLAW Division of Compliance Oversight (NIH/OD)

Subject:

RE: noncompliance incident

* Thank you for providing this report Dr. Pepping. 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

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From: Pepping, Jennifer K. [mailto:jpeppi@lsuhsc.edu]

Sent: Tuesday, April 30, 2019 5:26 PM

To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Subject: RE: noncompliance incident

Attached is the finalized report of this noncompliance. Thank you for your assistance in this matter. Please let me know if anything else needs to be done.

Thank you

Jennifer Pepping, DVM, MS

IACUC/IBC Coordinator

LSU Health Sciences Center, Office of Research Services

433 Bolivar St (b) (4) New Orleans, LA 70112

jpeppi@lsuhsc.edu

From: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>

Sent: Thursday, April 18, 2019 6:52 AM

To: Pepping, Jennifer K. cjpeppi@lsuhsc.edu; OLAW Division of Compliance Oversight (NIH/OD) <<pre>clawdco@od.nih.gov

Subject: RE: noncompliance incident

EXTERNAL EMAIL: EVALUATE

Thank you for this preliminary report. We will open a case file and await the final report. Please contact me this afternoon at 301-594-2921 regarding the funding agency.

Best regards, Brent Morse 301-594-2921

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

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From: Pepping, Jennifer K. [mailto:jpeppi@lsuhsc.edu]

Sent: Wednesday, April 17, 2019 7:53 PM

To: OLAW Division of Compliance Oversight (NIH/OD) < olawdco@od.nih.gov>

Subject: RE: noncompliance incident

Dr. Morse,

Attached is the preliminary report for the noncompliance incident. I still need to discuss with you as to what needs to be done about contacting the funding agency.

Thank you

Jennifer Pepping, DVM, MS
IACUC/IBC Coordinator
LSU Health Sciences Center, Office of Research Services
433 Bolivar St^(b) (4) New Orleans, LA 70112
(b) (6) jpeppi@Isuhsc.edu

From: Pepping, Jennifer K.

Sent: Wednesday, April 10, 2019 4:56 PM

To: <u>olawdco@mail.nih.gov</u>
Subject: noncompliance incident

I am currently in the process of drafting a report of a noncompliance incident that occurred at my institution, and I was wondering what the process/procedure is when contacting the funding agency. Is it the PI's responsibility to do so? This project is funded by a grant through the NIH National Eye Institute.

Thank you

Jennifer Pepping, DVM, MS
IACUC/IBC Coordinator
LSU Health Sciences Center, Office of Research Services
433 Bolivar St (b) (4) New Orleans, LA 70112
(b) (6)
ipeppi@lsuhsc.edu

ABOGA-E

National Institutes of Health Office of Laboratory Animal Welfare Division of Compliance Oversight (301) 594-2921 olawdco@mail.nih.gov

RE:

Protocol Deviation in an NIH-Funded Study

Assurance number: #D16-00058

Funding: NIH- NEI: R01EY019465 (has not been contacted)

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Follow-up discussions and demonstrations are tentatively scheduled for approximately two weeks and eight weeks from this initial meeting.

A final report from the Institutional Official will most likely be sent before the end of the month.

Thank you for your consideration of this matter.

Jennifer Pepping, DVM, MS
Chair, IACUC
LSU Health Sciences Center, Office of Research Services
433 Bolivar St (b) (4)
New Orleans, LA 70112
(b) (6)
jpeppi@lsuhsc.edu

Morse, Brent (NIH/OD) [E]

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

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