



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

August 12, 2019

Re: Animal Welfare Assurance
A3823-01 [OLAW Case 7V]

Dr. Adam Kuspa
Senior Vice President for Research
Baylor College of Medicine
One Baylor Plaza, BCM310
Houston, TX 77030

Dear Dr. Kuspa,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 1, 2019 letter reporting an instance of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals at Baylor College of Medicine. According to the information provided, OLAW understands that twelve mice were administered an expired anesthetic drug. No adverse effects were exhibited by the mice due to this action.

The corrective actions consisted of the Institutional Animal Care and Use Committee (IACUC) directing the Principal Investigator (PI) to develop a plan to ensure that all procedure drugs are accounted for and verified by another individual; the plan must be approved by the IACUC and must be discussed by the IACUC chair, PI and staff; procedures and compliance will be reviewed at laboratory meetings; and the PI will document review of surgical records and report deviations to the IACUC. The laboratory was placed under enhanced IACUC oversight which includes post-approval monitoring visits and monthly review of all records. The laboratory staff was retrained, expired controlled drugs must be labeled and discarded, and any future noncompliance will result in escalating sanctions.

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 institution to comply with the PHS Policy.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair
John Diggs, Team Leader, NHLBI



43823-7V

OFFICE OF RESEARCH

One Baylor Plaza, BCM310
Houston, Texas 77030-3411

(713) 798 - 6983
(713) 798 - 2721 FAX
akuspa@bcm.edu

CONFIDENTIAL

August 1, 2019

Brent Morse, DVM
Acting Director, Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health
olawdco@mail.nih.gov

RE: Assurance #D16-00475

Dear Dr. Morse,

As Institutional Official for Baylor College of Medicine (BCM), I have the duty to inform you of our Institutional Animal Care and Use Committee's (IACUC) recent finding in animal research after an assessment of the following protocol:

Protocol: AN-1002: Nuclear Orphan Receptor, Coup-TFII, in Development and Disease

Species: Mice

Funding Sources: National Institutes of Health (NIH) R01-HL114539 and Non-PHS Funding

For this investigator's first incident of this nature, the IACUC determined that the following finding constituted *serious noncompliance*¹ with the federal regulations:

Expired Drugs¹¹

During a post approval monitoring assessment, it was found that expired Buprenorphine sustained-release had been administered to twelve mice. None of the twelve mice had any adverse effects and recovered without incident.

Corrective Actions:

1. The IACUC requires a comprehensive plan from the PI to ensure appropriate oversight of compliance by all personnel involved in surgery.
 - The oversight plan must include a process of accounting of all surgeries conducted, substances delivered to an animal during the perioperative periods, including anesthetic and analgesic drugs (pre- & post-surgery), and a verification process that such activities were performed by the surgeon, e.g. review and sign-off by a lab manager or another lab surgeon (i.e. a "buddy system").
 - The plan will be reviewed at the next convened IACUC meeting for approval. If the plan is not approved, all surgeries will be suspended until a satisfactory plan is approved by the IACUC.
 - Once the plan is approved, the IACUC Chair will convene a mandatory meeting with the PI and laboratory personnel to review and discuss the determination, the required corrective actions, and the plans for ensuring compliance.

¹ PHS Policy IV.F.3.a: "The IACUC, through the Institutional Official, shall promptly provide OLAW with a full explanation of the circumstances and actions taken with respect to: a. any serious or continuing noncompliance with this Policy;"

¹¹ PHS Policy IV.C.1.a: "Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design."

- The Principal Investigator (PI) will review records, procedures, and compliance (e.g. any checklists, discussion at lab meetings, and description of material reviewed).
- The PI will document in writing their review of the surgical records and notify the IACUC of any deviations from approved procedures.
- 2. There will be increased oversight of the surgeries performed under supervision of the PI by the IACUC for six months after approval of the plan.
 - There will be two Post-Approval Monitoring (PAM) reviews focused on surgery within 6 months of the IACUC determination.
 - A monthly review of all surgery, anesthesia, and analgesia records and adherence to the plan will be conducted.
- 3. If compliance with the IACUC approved plan or the increased oversight is not maintained, there will be escalating punitive corrective actions including, but not limited to suspension of all surgical privileges.
- 4. All research personnel are required to complete the "Animal Work at BCM: Mice & Rat" training.
- 5. All research personnel are required to take the AALAS Learning Library Training: "Working with Controlled Substances" which includes use, documentation, and control of controlled substances.
- 6. All expired controlled substances are labelled appropriately and must be disposed of at the next DEA Controlled Substance Collection/Disposal event.

These findings of non-compliance do not appear to pose any potential or actual effect on costs related to this PHS-supported research.

This notification will also be sent to AAALAC International, the National Institutes of Health and the non-PHS funding source according to the terms and conditions of the award.

Please do not hesitate to contact me if you have any questions.

Sincerely,

(b) (6)

Adam Kuspa, PhD
Senior Vice President and Dean of Research
Institutional Official
Baylor College of Medicine

cc: Principal Investigator
Department Chair
Research Compliance Services files

Ward, Joan (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, August 5, 2019 3:07 PM
To: (b) (6)
Subject: RE: OLAW Report- Assurance D16-00475

Thank you (b) (6) for this report. Dr. Morse will respond soon.

Regards,
Joan

From: (b) (6)
Sent: Monday, August 5, 2019 11:36 AM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: OLAW Report- Assurance D16-00475

Dear Dr. Morse,

Please find the attached notifications of research non-compliance as determined by our IACUC, and sent on behalf of Dr. Adam Kuspa, Institutional Official.

Please feel free to contact me if you have any questions.

Thank you,

(b) (6)

(b) (6)



Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Wednesday, August 7, 2019 1:03 PM
To: Diggs, John W (NIH/NHLBI) [E]; OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: HL129191-04: PHS Report- Assurance D16-00475

Thank you for sending this to OLAW. We are aware of the issue and OLAW's Doctor Axel Wolff will send you a copy of our final memo to the institution when it is completed.

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: Diggs, John W (NIH/NHLBI) [E]
Sent: Wednesday, August 07, 2019 12:59 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Diggs, John W (NIH/NHLBI) [E] <diggsjw@nhlbi.nih.gov>
Subject: HL129191-04: PHS Report- Assurance D16-00475

Dear OLAW,

Please see the attached letter from the grant recipient on NHLBI award R01 HL129191-04 regarding non-compliant animal research. The letter states they sent a copy to OLAW, but I am also sending the letter to ensure it has been received.

Please let us know if any additional action on our part is needed.

Best,

*John Diggs
Team Leader
DERA, OGM
National Heart Lung and Blood Institute
6701 Rockledge Drive, Suite 7154
Bethesda, MD 20892
Express Mail: 20817
Phone # (301) 827-8028*

From: (b) (6)
Sent: Monday, August 5, 2019 12:31 PM
To: Gao, Yunling (NIH/NHLBI) [E] <gaoy2@nhlbi.nih.gov>
Cc: (b) (6)
Subject: PHS Report- Assurance D16-00475

Dear Dr. Gao,

Please find attached a notification of research non-compliance as determined by our IACUC, and sent on behalf of Dr. Adam Kuspa, Institutional Official.

Please feel free to contact me if you have any questions.

Thank you,

(b) (6)

(b) (6)





OFFICE OF RESEARCH

One Baylor Plaza, BCM310
Houston, Texas 77030-3411

(713) 798 – 6983
(713) 798 – 2721 FAX
akuspa@bcm.edu

CONFIDENTIAL

August 1, 2019

Yunling Gao, MD, PhD
Program Official
National Heart, Lung, and Blood Institute
Gaoy2@nhlbi.nih.gov

RE: Assurance #D16-00475

Dear Dr. Gao,

As Institutional Official for Baylor College of Medicine (BCM), I have the duty to inform you of our Institutional Animal Care and Use Committee's (IACUC) recent finding in animal research after an assessment of the following protocol:

Protocol: AN-1002: Nuclear Orphan Receptor, Coup-TFII, in Development and Disease

Species: Mice

Funding Sources: National Institutes of Health (NIH) R01-HL129191 and Non-PHS Funding

For this investigator's first incident of this nature, the IACUC determined that the following finding constituted *serious noncompliance*¹ with the federal regulations:

Expired Drugs²

During a post approval monitoring assessment, it was found that expired Buprenorphine sustained-release had been administered to twelve mice. None of the twelve mice had any adverse effects and recovered without incident.

Corrective Actions:

1. The IACUC requires a comprehensive plan from the PI to ensure appropriate oversight of compliance by all personnel involved in surgery.
 - The oversight plan must include a process of accounting of all surgeries conducted, substances delivered to an animal during the perioperative periods, including anesthetic and analgesic drugs (pre- & post-surgery), and a verification process that such activities were performed by the surgeon, e.g. review and sign-off by a lab manager or another lab surgeon (i.e. a "buddy system").
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² PHS Policy IV.C.1.a: "Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with sound research design."

- The PI will document in writing their review of the surgical records and notify the IACUC of any deviations from approved procedures.
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- 6. All expired controlled substances are labelled appropriately and must be disposed of at the next DEA Controlled Substance Collection/Disposal event.

This notification will also be sent to the Office of Laboratory Animal Welfare (OLAW), AAALAC International, and the non-PHS funding source according to the terms and conditions of the award.

Please do not hesitate to contact me if you have any questions.

Sincerely,
(b) (6)

Adam Kuspa, PhD
Senior Vice President and Dean of Research
Institutional Official
Baylor College of Medicine

cc: Principal Investigator
Department Chair
Research Compliance Services files