



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

October 16, 2019

Re: Animal Welfare Assurance
A3823-01 [OLAW Case 8B]

Dr. Mary Dickinson
Vice President and Dean of Research
Baylor College of Medicine
One Baylor Plaza, BCM335
Houston, TX 77030

Dear Dr. Dickinson,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your October 4, 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 eight mice received recently expired sustained release analgesic. No adverse events were reported with the animals due to use of the expired agent.

The corrective actions consisted of the Institutional Animal Care and Use Committee (IACUC) requiring the Principal Investigator to submit a surgical oversight plan requiring the following:

- Accounting for all surgeries, substances given to animals, anesthetics/analgesics, and certifying that all procedures were performed as described in the protocol
- The plan must be approved by the IACUC or surgeries will be suspended
- Once the plan is approved, the IACUC chair will counsel the Principal Investigator (PI) and staff
- The PI will be responsible for reviewing records, procedures, and compliance
- The PI will document review of surgical records and will notify the IACUC of any deviations

In addition, the laboratory was placed under enhanced post-approval monitoring, continuing noncompliance will result in escalating sanctions, the PI must review the expired drug policy with laboratory staff, and the staff must undergo retraining in controlled substances. A monthly drug inventory monitoring system was developed by the PI.

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.

Sincerely,

(b) (6)

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

cc: IACUC Chair
Dr. Susan Taymans, NICHD Program Official



A3823-8B

OFFICE OF RESEARCH

One Baylor Plaza, BCM310
Houston, Texas 77030-3411

(713) 798 - 6966
(713) 798 - 2721 FAX
mdickins@bcm.edu

CONFIDENTIAL

October 4, 2019

Brent Morse, DVM, DACLAM
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-699: LH Action in Ovarian Cell Differentiation

Species: Mice

Funding Sources: National Institutes of Health (NIH) RO1-HD097321 & National Cancer Institute (NCI) R01-CA181808

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

Expired Drugsⁱⁱ

During a post approval monitoring assessment, it was discovered that a recently expired sustained-release analgesic was administered to eight mice following a subcutaneous pellet implantation. None of the animals experienced any adverse effects.

Corrective Actions:

1. The IACUC requires a comprehensive plan from the PI to ensure appropriate oversight of compliance by all personnel involved in surgery.
 - o 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").
 - o 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.

ⁱ 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;"

ⁱⁱ 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."

- 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.
 - 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. The PI is required to review: "Use Guidelines for Expired Drugs and Medical Materials" with all laboratory members.
 5. All research personnel are required to complete Controlled Substance training with a clinical veterinarian.
 6. The PI has developed a monthly drug inventory monitoring system to prevent using expired drugs in the future.

This finding of non-compliance does not appear to pose any potential or actual effect on cost related to this PHS supported research.

This notification will also be sent to AAALAC International, the National Institutes of Health and the National Cancer Institute according to the terms and conditions of the awards.

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

Sincerely,

(b) (6)

Mary Dickinson, PhD
Vice President and Dean of Research
Institutional Official
Baylor College of Medicine

cc: Principal Investigator
Department Chair
Research Compliance Services files

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Monday, October 7, 2019 6:53 AM
To: (b) (6)
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: OLAW Report - Assurance D16-0475

Thanks for these reports, (b) (6) We will send responses soon.

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

From: (b) (6)
Sent: Friday, October 4, 2019 2:34 PM
To: OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: (b) (6)
Subject: OLAW Report - Assurance D16-0475

Dear Dr. Morse,
Please find attached notification of an adverse event as determined by our IACUC, and sent on behalf of Dr. Mary Dickinson, Institutional Official. Please feel free to contact me if you have any questions.

Thank you,

(b) (6)

(b) (6)



A3823

OFFICE OF RESEARCH

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CONFIDENTIAL

October 4, 2019

Susan Taymans, PhD
Program Official
National Institutes of Health
taymanss@mail.nih.gov

RE: Assurance #D16-00475

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This notification will also be sent to The Office of Laboratory Animal Welfare (OLAW), AAALAC International and the National Cancer Institute according to the terms and conditions of the award.

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

Sincerely,

(b) (6)

Mary Dickinson, PhD
Vice President and Dean of Research
Institutional Official
Baylor College of Medicine

cc: Principal Investigator
Department Chair
Research Compliance Services files

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Thursday, October 10, 2019 3:03 PM
To: Copeland, Melissa (NIH/NICHD) [E]
Subject: RE: Non- Compliance: 1RO1-HD097321 Notice of IACUC non-compliance

Hello Ms. Copeland,

Baylor College of Medicine has notified OLAW under separate cover. We will review their corrective and preventive measures and send them an official response soon. There is no further action required by NICHD at this time. Thank you for notifying OLAW.

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: Copeland, Melissa (NIH/NICHD) [E] <melissa.copeland@nih.gov>
Sent: Thursday, October 10, 2019 7:38 AM
To: OLAW Division of Assurances (NIH/OD) <assurances.olaw@od.nih.gov>
Subject: FW: 1RO1-HD097321 Notice of IACUC non-compliance

Dear OLAW Representative,

The attached letter regarding an IACUC non-compliance issue was recently submitted to the Program Official.

Please let me know if the SO is required to submit this notification directly to OLAW with a cc to the IC, and whether any additional requirements and/or documents are needed to resolve.

Thank you for your assistance in resolving this matter.

Best regards,

Melissa R. Copeland, MBA | Senior Grants Management Specialist
Grants Management Branch
Eunice Kennedy Shriver National Institute of Child Health & Human Development
National Institutes of Health
6710B Rockledge Drive, Bethesda, MD 20817
Phone: 240.401.3847 | Email: melissa.copeland@nih.gov



From: Taymans, Susan (NIH/NICHD) [E] <taymanss@cc1.nichd.nih.gov>

Sent: Friday, October 4, 2019 2:45 PM

To: Copeland, Melissa (NIH/NICHD) [E] <melissa.copeland@nih.gov>; Young, Margaret (NIH/NICHD) [E] <margaret.young@nih.gov>

Cc: De Paolo, Louis (NIH/NICHD) [E] <depaolol@exchange.nih.gov>

Subject: 1RO1-HD097321 Notice of IACUC non-compliance

Dear Melissa,

Please see the attached for the official grant file, and let me know if there is any action that I need to take. I'm satisfied that Baylor has taken appropriate steps to ensure that a similar incident won't happen in the future.

Susan

From: [REDACTED] (b) (6)

Sent: Friday, October 04, 2019 2:37 PM

To: Taymans, Susan (NIH/NICHD) [E] <taymanss@cc1.nichd.nih.gov>

Cc: [REDACTED] (b) (6)

Subject: PHS Report_Assurance D16-00475

Dear Dr. Taymans,

Please find attached a notification of research non-compliance as determined by our IACUC, and sent on behalf of Dr. Mary Dickinson, Institutional Official. Please feel free to contact me if you have any questions.

Thank you,

[REDACTED] (b) (6)

[REDACTED] (b) (6)

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Assurances (NIH/OD)
Sent: Thursday, October 10, 2019 7:51 AM
To: Morse, Brent (NIH/OD) [E]
Cc: OLAW Division of Assurances (NIH/OD)
Subject: Non- Compliance: 1RO1-HD097321 Notice of IACUC non-compliance
Attachments: NIH Notification D16-00475 AN-699.pdf

Good Morning Dr. Morse,

Please find enclosed a Notice of IACUC Non-Compliance regarding Baylor College of Medicine.

Kind Regards,

Tiffani T. Mills

Program Assistant (*Contractor*)
Office of Laboratory Animal Welfare (OLAW)
National Institutes of Health
6700 B Rockledge Drive
Suite 2500, MSC 6910
Bethesda, Maryland 20892
Phone: 301-496-7163 (Main)
Phone: (301) 451-4211 (Direct)
Email: tiffani.soto@nih.gov

Division of Assurances

E-Fax (301) 451-5672
Email: OLAWdoa@mail.nih.gov

Disclaimer: 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.

Quote:

Tell me and I forget, Teach me and I remember, Involve me and I learn.
Benjamin Franklin

From: Copeland, Melissa (NIH/NICHD) [E] <melissa.copeland@nih.gov>
Sent: Thursday, October 10, 2019 7:38 AM

To: OLAW Division of Assurances (NIH/OD) <assurances.olaw@od.nih.gov>
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Best regards,

Melissa R. Copeland, MBA | Senior Grants Management Specialist
Grants Management Branch
Eunice Kennedy Shriver National Institute of Child Health & Human Development
National Institutes of Health
6710B Rockledge Drive, Bethesda, MD 20817
Phone: 240.401.3847 | Email: melissa.copeland@nih.gov



Eunice Kennedy Shriver National Institute
of Child Health and Human Development



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