



DEPARTMENT OF HEALTH & HUMAN SERVICES

PUBLIC HEALTH SERVICE
NATIONAL INSTITUTES OF HEALTH

FOR US POSTAL SERVICE DELIVERY:
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August 7, 2017

Re: Animal Welfare Assurance
A4499-01 [OLAW Case S]

Laura Levy, Ph.D.
Vice President for Research
Tulane University Uptown Campus
1440 Canal Street, Room # TW-5
New Orleans, LA 70112-2709

Dear Dr. Levy,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your August 2, 2017 letter reporting non-compliances with the PHS Policy on the Humane Care and Use of Laboratory Animals at Tulane University documented in the IACUC's February 2016 semi-annual inspection. According to the information provided, OLAW understands that:

- 1) for protocol 4050R2 diluted Inactin was not discarded after 30 days as per Tulane Policy and was used in research utilizing mice. Corrective actions included disposal of the drug, instruction to PI and laboratory staff and Post-Approval Monitoring (PAM).
- 2) for protocol 4142R2 sterilization of surgical instruments not consistently practiced for all mice surgeries. Corrective actions included re-training, mandatory attendance at Aseptic Technique Wet-Lab course and Post-Approval Monitoring (PAM).
- 3) for protocol 4142R2 mice were euthanized using a method not approved on the protocol. Corrective actions included re-training of personnel and Post-Approval Monitoring (PAM).

OLAW believes that the corrective measures put in place by Tulane University are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. It is understood that, although the animal activities were funded by NIH, the non-compliances did not result in financial impacts that required reporting to the funding components or financial reconciliation. Subsequent PAM showed compliance with the IACUC-approved protocols. OLAW accepts the corrective and preventive measures and finds no cause for further action by this office.

Sincerely,

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

cc: IACUC contact



Laura S. Levy, Ph.D.
Professor of Microbiology and Immunology
Vice President for Research

August 2, 2017

Brent Morse, DVM
 Animal Welfare Program Specialist
 Division of Compliance Oversight
 Office of Laboratory Animal Welfare ("OLAW")
 Via email: morseb@mail.nih.gov

Initial and Final Report re. Noncompliance; Semi-annual Inspections Conducted in Calendar Year 2016

Dear Dr. Morse:

Tulane University, in accordance with Animal Welfare Assurance and PHS Policy IV.F.3, provides this initial and final report of noncompliance regarding the following reportable issues identified during the IACUC's semi-annual inspections conducted in February 2016 and where the research was funded by the PHS or the NSF:

1. Failure to follow the Tulane Policy for the Use of Nonpharmaceutical Grade Anesthetics and/or Analgesics and discard diluted Inactin after 30 days in research utilizing mice:
 - a. **Protocol 4050R2.** Corrective action: Disposal of the drug, instruction to PI and laboratory staff and Post Approval Monitoring ("PAM"). Date Corrective actions completed: July 15, 2016. Funding component: PHS (NIH).
2. Sterilization of surgical instruments not consistently practiced for all mice surgeries:
 - a. **Protocol 4142R2.** Corrective action: Re-training, mandatory attendance at Aseptic Technique Wet-Lab course and PAM. Date Corrective actions completed: August 1, 2016. Funding Component: PHS (NIH).
3. Use of euthanasia method on mice not approved in the protocol:
 - a. **Protocol 4142R2.** Re-training and PAM. Date Corrective actions completed: August 23, 2016. Funding Component: PHS (NIH).

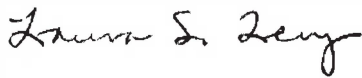
For each of the reportable events listed above:

1. Subsequent PAM showed compliance with the IACUC-approved protocol; and
2. Tulane determined that the financial impact of the noncompliance is *de minimis* and not of a level necessitating financial reconciling and reporting to the respective sponsoring entities.

Tulane University is committed to protecting the welfare of animals used in research and appreciates the guidance and assistance provided by OLAW in this regard. Those individuals courtesy copied on this report worked most closely on the matter and can be contacted if you have any questions.

Thank you for your consideration of this matter.

Yours sincerely,



Laura S. Levy, PhD
Professor of Microbiology and Immunology
Vice President for Research and Institutional Official
Tulane University

cc: Sheila Garrison, Tulane IACUC Chair and Director (via email)
Secondary Individual University Research Compliance Officer (via email)

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