



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

September 6, 2018

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

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

Dear Dr. Levy,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your September 4, 2018 letter reporting a non-compliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at Tulane University documented in the IACUC's August 2018 semi-annual inspection. According to the information provided, OLAW understands that:

For protocol 0317R4 – an unapproved procedure of use of a fiber optic cannula on five mice was found. The PI was instructed to not conduct this procedure until IACUC approval is obtained. The IACUC approved an amendment to add the procedure. This protocol was funded by the NIH.

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 activity was funded by NIH, the non-compliance did not result in a financial impact that required reporting to the funding component or financial reconciliation. OLAW accepts the corrective and preventive measures and finds 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



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

September 4, 2018

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

Initial and Final Report re. Noncompliance: Semi-annual Inspections Conducted in August of Calendar Year 2018

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 issue identified during the IACUC's semi-annual inspections and determined by the Tulane University New Orleans Campuses ("NOC") IACUC at its convened meeting of August 15, 2018 to be a significant deficiency where the research was funded by the PHS, NSF, or VA:

Protocol No.	Approx. no. of animals involved and Species	Reportable Issue	Corrective Actions	Completion Status	Funding
0317R4	5 Mice	Procedure (use of fiber optic cannula) conducted on anesthetized mice not included in the IACUC-approved protocol.	PI instructed to submit an amendment to the protocol. The PI was instructed not to conduct this procedure until IACUC approval is obtained and was notified that this could be a reportable issue.	The IACUC has approved the amendment to add the procedure.	NIH

For the reportable event listed above, 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 entity.

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,

(b) (6)

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)
Georgina Dobek, DVM, DACLAM, Tulane University Director of Comparative Medicine
(via email)

(b) (6)

Morse, Brent (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Tuesday, September 04, 2018 1:46 PM
To: Levy, Laura S; OLAW Division of Compliance Oversight (NIH/OD)
Cc: Dobek, Georgina L; Garrison, Sheila H; (b) (6)
Subject: RE: Tulane report to OLAW 9.4.18

Thank you for providing this report Dr. Levy. 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: Levy, Laura S [mailto:llevy@tulane.edu]
Sent: Tuesday, September 04, 2018 1:12 PM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Dobek, Georgina L <gdobek@tulane.edu>; Garrison, Sheila H <sgarriso@tulane.edu>; (b) (6)
(b) (6)
Subject: Tulane report to OLAW 9.4.18

Dear Dr. Morse,

Attached please find the Tulane University Institutional Official's initial and final report of an issue identified as part of the Tulane IACUC's semi-annual inspections.

Thank you for your consideration.

Best regards,

Laura Levy

Laura S. Levy, Ph.D.

Professor of Microbiology & Immunology

Vice President for Research and Institutional Official

Tulane University #8401

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