

Room #

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

June 29, 2017

Brent Morse, DVM
Animal Welfare Program Specialist
Division of Compliance Oversight
Office of Laboratory Animal Welfare ("OLAW")

Via email: morseb@mail.nih.gov

Re: Final Report – Noncompliance

Dear Dr. Morse:

Tulane University, in accordance with Animal Welfare Assurance and PHS Policy IV.F.3, provides this final report of noncompliance. Tulane's Research Compliance Officer made an initial report to OLAW on this matter on September 16, 2016 regarding the following reportable issues identified during the IACUC's semiannual inspections conducted in August 2015 and where the research was funded by PHS or NSF:

1. Use of euthanasia method on mice not approved in the protocol:
 - a. **Protocol 2806R3**. Corrective action: re-training and Post Approval Monitoring ("PAM"). Funding component: PHS (NIH).
 - b. **Protocol 0461**. Corrective action: re-training and PAM. Funding component: PHS (NIH).
2. Use of analgesics/anesthetics on mice not approved in the protocol but that would have been appropriate had an amendment been submitted and approved:
 - a. **Protocol 0426R**. Corrective action: Re-training, submission and subsequent approval by the IACUC of an amendment to approve a change to the analgesic/anesthetic, and PAM. Funding Component: PHS (NIH).
3. Use of analgesics/anesthetics on rats not approved in the protocol but that would have been appropriate had an amendment been submitted and approved:
 - a. **Protocol 2806R3**. Corrective action: Re-training, submission and subsequent approval by the IACUC of an amendment to approve a change to the analgesic/anesthetic, and PAM. Funding Component: PHS (NIH).

For each of the reportable events listed above:

1. Subsequent PAM showed compliance with the IACUC-approved protocol.
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)

Morse, Brent (NIH/OD) [E]

From: Morse, Brent (NIH/OD) [E]
Sent: Friday, June 30, 2017 11:31 AM
To: Secondary Individual
Cc: Levy, Laura S; Garrison, Sheila H
Subject: RE: Final Report - Noncompliance

Thank you for this final report Secondary Individual. We will send an official response soon.

Regards, Brent Morse

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

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From: Secondary Individual [mailto:Secondary Individual@tulane.edu]
Sent: Friday, June 30, 2017 11:09 AM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>
Cc: Levy, Laura S <llevy@tulane.edu>; Garrison, Sheila H <sgarriso@tulane.edu>
Subject: Final Report - Noncompliance

Dear Dr. Morse,

Attached, please find the Tulane University Institutional Official's final report on noncompliance initially reported by telephone on September 16, 2016.

Many thanks, and please do not hesitate to contact us if you have questions or need further information.

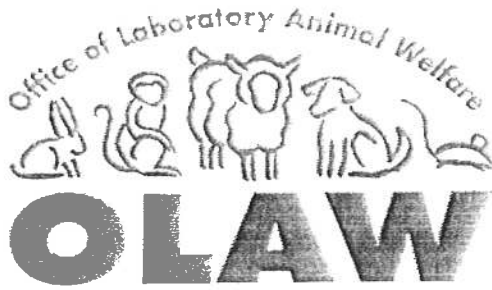
Sincerely,

Secondary Individual

University Research Compliance Officer
 Tulane University #8401
 1440 Canal Street, Suite 2425
 New Orleans, LA 70112
 office phone: Phone Number
 mobile phone: Phone Number
 fax: ACUC Member
 email: Secondary Individual@tulane.edu
 web: <http://www2.tulane.edu/asvpr/research-compliance.cfm>

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Initial Report of Noncompliance

By: mgmDate: 9/16/16Time: VoicemailName of Person reporting: Secondary IndividualTelephone #: Phone Number

Fax #:

Email:

Name of Institution: Tulane U.Assurance number: A4499Did incident involve PHS funded activity? Yes

Funding component: _____

Was funding component contacted (if necessary): Will be noted in final report.What happened? Protocol noncompliance involving euthanasia of mice on 4 protocols + analgesia/anesthesia of mice + rats on 3 protocols.Species involved: Mice + ratsPersonnel involved: InvestigatorsDates and times: Aug 2015 semiannual inspec.

Animal deaths:

Projected plan and schedule for correction/prevention (if known): _____

Done. This is a late report in response to OLAW June 2016 site visit.

Projected submission to OLAW of final report from Institutional Official:

< 30 d.

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Case # _____



Division of Compliance Oversight

Record of Call for Case # A4499-1R

Date & Time	Message	Initials
10/6/16	Voicemail from [Secondary Individual] requesting more time for final report. I authorized until 11/18/16	Bmm
3/1/17 10:20	Spoke w/ [Secondary Individual]. He will get final info. on funding + send report in 3 weeks.	Bmm