



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) 480-3387

July 6, 2021

Re: Animal Welfare Assurance
A4499-01 [OLAW Case 1A]

Giovanni Piedimonte, MD
Vice President for Research
Tulane University Uptown Campus
1440 Canal Street, (b) (4) TW-5
New Orleans, LA 70112-2709

Dear Dr. Piedimonte,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your June 24, 2021 letter reporting four non-compliance with the PHS Policy on the Humane Care and Use of Laboratory Animals at Tulane University. Your letter supplements the information in the preliminary telephone report of February 10, 2021. According to the information provided, OLAW understands that issues were found on the Fall 2020 IACUC semi-annual inspections involving protocols where the research was funded by the PHS:

The first issue involved 28 mice where tail snips for blood glucose monitoring were done without anesthesia although the protocol required anesthesia. The mice had also not been transferred to the PI's protocol.

Corrective measures included the PI submitting a protocol amendment to change the anesthesia required to topical lidocaine. Also, the PI submitted a transfer request.

The second issue involved 20 mice where the AVMA-approved euthanasia method was not listed in the protocols.

Corrective measures included the PI submitting protocol amendments to add the euthanasia method.

The third issue involved 18 mice where tail snips for blood collection were done without anesthesia.

Corrective measures included the PI using a topical anesthetic in accordance with the IACUC policy on Blood Collection Techniques.

The last issue involved 10 mice where expired isoflurane had been used for anesthesia.

Corrective and preventive measures included the PI discarding the expired isoflurane and being instructed to check expiration dates prior to use. New, replacement isoflurane was verified.

OLAW believes that the corrective and preventive measures put in place by Tulane University are consistent with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals. OLAW accepts the corrective and preventive measures and finds no cause for further action by this office.

Sincerely,

Brent C. Morse -S

Digitally signed by Brent C. Morse -

⁵
Date: 2021.07.06 08:49:28 -04'00'

Brent C. Morse, DVM

Director

Division of Compliance Oversight

Office of Laboratory Animal Welfare

cc: IACUC contact

A4499



Giovanni Piedimonte, MD, FAAP, FCCP
Vice President for Research and Institutional Official
Professor of Pediatrics and Biochemistry and Molecular Biology
School of Medicine

June 24, 2021

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

Final Report

Dear Dr. Morse:

Tulane University ("Tulane"), in accordance with Animal Welfare Assurance D16-00754 and PHS Policy IV.F.3, provides this final report as to the matter first reported to Dr. Brent Morse, OLAW, via telephone call on February 9, 2021, by Tulane IACUC Chair Dr. Preston Marx, (b) (6) and Tulane IACUC Director Sheila Garrison, involving four protocols where issues were found on the Fall 2020 IACUC semi-annual inspections and where the research was funded by the PHS, NSF, or VA. The Tulane New Orleans Campuses ("NOC") IACUC at its convened meeting determined that issues, which are listed as follows, constitute significant deficiencies:

Protocol No.	Approx. no. and species of animals involved	Reportable Issue(s)	Corrective Actions	Completion Status	Funding
387	28 Mice	1) Tail snips for blood glucose monitoring were done without anesthesia, and the protocol indicates the use of anesthesia. 2) Animals needed to be transferred to PI's protocol.	1) PI to submit an amendment to change the use of anesthesia for this procedure to topical lidocaine to follow the IACUC policy on Blood Collection Techniques. 2) PI to complete a transfer request.	1) The IACUC approved the amendment. 2) Transfer was completed, and cage cards updated.	NIDKK

638 and 633	20 Mice	AVMA-approved euthanasia method of conscious cervical dislocation was not listed in the protocols.	PI to submit amendments for the additional euthanasia method.	The IACUC approved the amendments.	NHLBI, NIDA
Protocol No.	Approx. no. and species of animals involved	Reportable Issue(s)	Corrective Actions	Completion Status	Funding
840	18 Mice	Blood collection was performed by snipping the tail without anesthesia.	PI instructed to follow the IACUC policy on Blood Collection Techniques or submit an amendment requesting this change.	PI will use a topical anesthetic in accordance with IACUC policy.	NIH
1020	10 Mice	Expired isoflurane used for euthanasia.	PI instructed to discard the expired isoflurane immediately and replace it with a new bottle. PI instructed to check expiration dates prior to use.	Bottle discarded and replacement of new isoflurane verified.	NIH

For the reportable events listed above, Tulane determined that the financial impact of the noncompliance is *de minimis* and not of a level necessitating reporting to the funding components or financial reconciliation.

Tulane University is committed to protecting the welfare of animals used in research and the Office of Laboratory Animal Welfare's guidance and assistance in this regard. Thank you for your consideration of this matter.

Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Giovanni Piedimonte

c Preston A. Marx, Tulane University IACUC Chair
Sheila Garrison, Tulane University IACUC Director

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, June 25, 2021 7:20 AM
To: Piedimonte, Giovanni
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Tulane Final Report to OLAW Regarding Reportable Findings From Fall 2020

Thank you for this report, Dr. Piedimonte. We will send a response soon.

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

From: Piedimonte, Giovanni <gpiedimonte@tulane.edu>
Sent: Thursday, June 24, 2021 10:49 AM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: Marx, Preston A <pmarx@tulane.edu>; Garrison, Sheila H <sgarriso@tulane.edu>; (b) (6)
Subject: Tulane Final Report to OLAW Regarding Reportable Findings From Fall 2020

Dear Dr. Morse,

Attached is Tulane University's final report to OLAW regarding reportable findings from the fall 2020 IACUC semi-annual inspections and the corresponding corrective actions, as determined by the IACUC.

Thank you,

Giovanni Piedimonte



Giovanni Piedimonte, MD, FAAP, FCCP

Vice President for Research and Institutional Official
of Tulane University

Professor of Pediatrics, Biochemistry & Molecular Biology
Tulane School of Medicine

(b) (6)

gpiedimonte@tulane.edu | <http://research.tulane.edu/>



Initial Report of Noncompliance

By: BCM

Date: 2/10/2021

Time: 4:00

Name of Person reporting: Dr. Marx, Lisa Wurtzel, Sheila Garrison, (b) (6)

Telephone #: (b) (6)

Fax #: (b) (6)

Email: (b) (6)

Name of Institution: Tulane University

Assurance number: A4499

Did incident involve PHS funded activity? yes

Funding component: (b) (6)

Was funding component contacted (if necessary): (b) (6)

What happened? Four issues found on fall 2020 SA inspection:

- 1) Investigator used cervical dislocation to euthanize 20 conscious mice.
- 2) Expired isoflurane used to euthanize 10 mice.
- 3) Tail snips w/o anesthesia used to monitor blood glucose in 28 mice. Not assigned to protocol. (protocol amended to use topical lidocaine).
- 4) Tail snips w/o anesthesia used to collect blood from 18 adult female mice.

Species involved: Mus musculus

Personnel involved: Researcher

Dates and times: Fall 2020

Animal deaths:

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

IACUC approved amendments where appropriate.

Projected submission to OLAW of final report from Institutional Official:

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Case #