



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

April 17, 2023

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

Giovanni Piedimonte, MD, FAAR, FCCP
Vice President for Research
Tulane University Uptown Campus
1440 Canal Street, (b) (4)
New Orleans, LA 70112

Dear Dr. Piedimonte,

The Office of Laboratory Animal Welfare (OLAW) acknowledges receipt of your April 14, 2023 letter reporting a 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 December 14, 2022. According to the information provided, OLAW understands that five rhesus macaques assigned to a specific group in a protocol did not receive placebo treatment as per the IACUC-approved protocol due to unforeseen COVID- related unavailability of placebo. In addition, six rhesus macaques were allocated to a separate group before official IACUC approval was granted. The related protocol was suspended by the IACUC. The NIH funding component and the Program Official has been notified regarding applicable grant reconciliation and allowance of expenditure of grant funds for maintenance and care of the animals.

Corrective and preventive actions:

- Training in animal welfare, responsible use of animals, and IACUC compliance for the PI and members of the PI's laboratory (completed).
- Modification of the scheduling processes to require a second member of the lab team to check the planned experimental procedures against the approved IACUC protocols and amendments (completed).
- IACUC PAM staff to be included on all scheduling requests with a certification by the PI as to the request's compliance with the IACUC-approved protocols and amendments (completed).
- Monthly compliance report by the PI to the IACUC (completed).
- Amendment submissions to obtain approval for proposed changes prospectively with requisite justification (completed).

The IACUC reinstated IACUC approval and determined that focused PAM of the PI would occur over the next three to six months with reporting back to the IACUC as to any issues identified (ongoing; no additional issues identified to date).

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. OLAW accepts the corrective and preventive measures and finds no cause for further action by this office.

Page 2 – Dr. Piedimonte
April 17, 2023
OLAW Case A4499-1C

Sincerely,
Jacquelyn
T. Tubbs -S
Brent C. Morse, DVM
Director
Division of Compliance Oversight
Office of Laboratory Animal Welfare

Digitally signed by
Jacquelyn T. Tubbs -S
Date: 2023.04.17
11:52:21 -04'00'

cc: IACUC contact
Dr. Robert M. Gibbens, USDA, APHIS, AC



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

April 14, 2023

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 Assurance D16-00754 and PHS Policy IV.F.3, provides this final report. Tulane's preliminary report was via telephone call by (b) (6) to Dr. Brent Morse, OLAW, on December 14, 2022, reporting the Tulane IACUC's suspension of IACUC approval as to a Principal Investigator's ("PI's") protocol. Two separate incidents occurred in this research study that were identified through the IACUC's Post Approval Monitoring ("PAM") program:

- Five rhesus macaques assigned to a specific group in the protocol did not receive placebo treatment as per the IACUC-approved protocol due to unforeseen COVID-related unavailability of placebo. As part of the investigation, the PI provided justification that removing the placebo treatment would not result in any animal health or welfare issues and would not impede the usability of the data from these animals. However, IACUC approval should have been obtained prior to the PI implementing this change.
- Six rhesus macaques were allocated to a separate group, which is permitted pursuant to the protocol pending IACUC approval, but was finalized before official IACUC approval was granted.

Tulane University #8401, 1440 Canal Street, Suite 949, New Orleans, LA 70112-2709 tel 504.988.3291 fax 988.1238
gpiedimonte@tulane.edu <https://research.tulane.edu>

An IACUC-directed review of incidents related to the PI resulted in IACUC-mandated corrective actions:

- Training in animal welfare, responsible use of animals, and IACUC compliance for the PI and members of the PI's laboratory (completed).
- Modification of the scheduling processes to require a second member of the lab team to check the planned experimental procedures against the approved IACUC protocols and amendments (completed).
- IACUC PAM staff to be included on all scheduling requests with a certification by the PI as to the request's compliance with the IACUC-approved protocols and amendments (completed).
- Monthly compliance report by the PI to the IACUC (completed).
- Amendment submissions to obtain approval for proposed changes prospectively with requisite justification (completed).

The IACUC reinstated IACUC approval on January 5, 2023 and determined that focused PAM of the PI would occur over the next three to six months with reporting back to the IACUC as to any issues identified (ongoing; no additional issues identified to date). The enhanced monitoring serves to further support PHS-supported activities at Tulane.

The federal funding component is NINDS/NIH, and the Program Official has been notified regarding applicable grant reconciliation and allowance of expenditure of grant funds for maintenance and care of the animals.

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. Thank you for your consideration of this matter.

Sincerely,

(b) (6)

Giovanni Piedimonte

c Preston Marx, Ph.D., Tulane University IACUC Chair

(b) (6)

McCoy, Devora (NIH/OD) [E]

From: OLAW Division of Compliance Oversight (NIH/OD)
Sent: Friday, April 14, 2023 10:42 AM
To: Piedimonte, Giovanni
Cc: OLAW Division of Compliance Oversight (NIH/OD)
Subject: RE: Tulane Final Report

Good morning Dr. Piedimonte,

Thank you for sending us this final report for case A4499-1C and we will send an official response soon.

Best,
Devora

Devora McCoy, BS, MBA ([pronunciation](#))
Program Analyst
Division of Compliance Oversight
Office of Laboratory Animal Welfare
National Institutes of Health

Phone: 301-435-2390
Email: devora.mccoy@nih.gov

From: Piedimonte, Giovanni <gpiedimonte@tulane.edu>
Sent: Friday, April 14, 2023 10:05 AM
To: Morse, Brent (NIH/OD) [E] <morseb@mail.nih.gov>; OLAW Division of Compliance Oversight (NIH/OD) <olawdco@od.nih.gov>
Cc: [REDACTED] (b) (6) Marx, Preston A <pmarx@tulane.edu>
Subject: [EXTERNAL] Tulane Final Report

Dear Dr. Morse,

Attached is Tulane's final report on the matter first reported to OLAW on December 14, 2022, regarding the IACUC's suspension of [REDACTED] (b) (6) protocol.

Thank you,

[REDACTED] (b) (6)



Initial Report of Noncompliance

By: [REDACTED] (b) (6)

Date: 12/14/2022

Time: 11:30

Name of Person reporting [REDACTED] (b) (6)

Telephone #: [REDACTED] (b) (6)

Fax #: [REDACTED]

Email: [REDACTED]

Name of Institution: Tulane U.

Assurance number: A4499

Did incident involve PHS funded activity? Yes

Funding component: [REDACTED]

Was funding component contacted (if necessary): No?

What happened? IACUC suspended protocol in Nov 2022 due to concerns about PI's understanding of status of animals dating back to Spring of 2020.

Species involved: Rhesus

Personnel involved: PI

Dates and times: [REDACTED]

Animal deaths: No

Animals moved to holding protocol.

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

PI has been retrained and counseled by AV.
PAM will continue and monthly reports required by IACUC.

Projected submission to OLAW of final report from Institutional Official:

OFFICE USE ONLY

Case # [REDACTED]