



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

February 7, 2022

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

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 February 1, 2022 final report letter, as well as interim reports on August 14 and November 12, 2021, in response to my July 12, 2021 request for an investigation into a retracted publication involving nonhuman primate studies at Tulane University. According to the information provided, OLAW understands that the matter was thoroughly investigated and that the following determinations were made by the Institutional Animal Care and Use Committee (IACUC):

- The protocol covering the published work was closed at Tulane and the Principal Investigator (PI) left the institution on December 31, 2018.
- In July 2015, one cohort of five rhesus monkeys did not undergo the one-month rest period described in the protocol between the end of treatment and the infectious agent inoculation and the matter had not been reported to the IACUC. This information was shared with the Principal Investigator's new institution. No corrective actions were taken at Tulane as the PI had left.
- The authors support the retraction because there were differences in the performance of the study and because the published article did not accurately reflect how the animals were infected and treated.
- Grant costs will be reconciled as appropriate.

Based on its assessment of the IACUC's determination, OLAW has a better understanding of the matter and will not pursue it further. It is evident that the Tulane IACUC and other staff members carefully evaluated and researched the matter and OLAW will inform SAEN, the complainant organization, of the determination and that no further actions will be taken. OLAW is obligated to investigate animal welfare concerns from any source and we thank you and your team for taking the matter seriously and providing the detailed response.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair
Robert Gibbens, D.V.M., USDA-APHIS-AC

Obtained by Rise for Animals.
Uploaded to Animal Research Laboratory Overview (ARLO) on 08/22/2022



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Office of Laboratory Animal Welfare
6700B Rockledge Drive, Suite 2500
Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 402-7065

February 7, 2022

(b) (6)

In response to your July 6, 2021 letter requesting an investigation into a retracted journal article involving nonhuman primates studies conducted at Tulane University, the following was determined:

- In July 2015, one cohort of five rhesus monkeys did not undergo the one-month rest period described in the protocol between the end of treatment and the infectious agent inoculation and the matter had not been reported to the IACUC.
- The protocol covering the published work was closed at Tulane and the Principal Investigator left the institution on December 31, 2018.
- The authors support the retraction because there were differences in the performance of the study and because the published article did not accurately reflect how the animals were infected and treated.
- Grant costs were reconciled as appropriate.

OLAW has closed the investigation and will take no further action. Thank you for your interest in animal welfare.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare



Giovanni Piedimonte, MD, FAAP, FCCP

*Vice President for Research and Institutional Official
Tulane University*

*Professor of Pediatrics and Biochemistry and Molecular Biology
Tulane School of Medicine*

February 1, 2022

Axel Wolff, M.S., D.V.M.

Deputy Director

Office of Laboratory Animal Welfare ("OLAW")

Via email: wolffa@od.nih.gov

Report, OLAW Case A4499-1B

Dear Dr. Wolff:

Tulane University ("Tulane"), in accordance with Assurance A4499-01 and PHS Policy IV.F.3, provides an additional report regarding OLAW Case A4499-1B. I, in the capacity of Tulane's Institutional Official ("IO"), submitted interim reports to OLAW dated August 14, 2021, and November 12, 2021.

The relevant IACUC protocol and corresponding study are closed at Tulane. The Principal Investigator ("PI") on the study protocol ceased affiliation with Tulane effective December 31, 2018, at which time the PI became affiliated with Southwest National Primate Research Center, which is affiliated with Texas Biomedical Research Institute ("Texas Biomedical").

The group that Tulane convened to investigate this matter reviewed and compared the available animal treatment records for the study, the available laboratory records, and the IACUC-approved protocols and amendments. The findings of this review indicate that in one cohort involving five rhesus macaques in July 2015, the one-month rest period described in the protocol between the end of treatment and the infectious agent inoculation did not occur. Tulane has provided this information to the IO and Vice President for Research at the PI's current institution, Texas Biomedical. The IO at Texas Biomedical is prepared to be contacted by OLAW about this matter. Tulane understands that the PI, under the purview of Texas Biomedical, plans to repeat the research, or has already repeated the research.

The TNPRC IACUC made the following determinations at its convened meeting of January 6, 2022, following review of the matter:

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>

1. The protocol deviation described above represents noncompliance with the IACUC-approved protocol, and the deviation should have been reported to the Tulane IACUC at the time of its occurrence. The PI would have been the party responsible for reporting the deviation to the IACUC.
2. There was no noncompliance found on the part of individuals who – unlike the PI – remain affiliated with Tulane, and no institutional noncompliance. Therefore, no corresponding corrective actions appear to be required at Tulane.
3. The PI is no longer affiliated with Tulane and the study, and the affiliated grant funding was transferred to Texas Biomedical as part of the PI's departure from Tulane and subsequent affiliation with Texas Biomedical. The Tulane IACUC, therefore, is not in a position to impose corrective actions to prevent recurrence by this PI.
4. Tulane would defer to the IO at Texas Biomedical and its IACUC regarding:
 - a. review and determinations as to noncompliance that led to the retraction and if noncompliance is identified, providing a reasonable and specific plan and schedule for correction of each deficiency, and required reporting to OLAW, as to the PI's continued research activities involving animals; and
 - b. specifically addressing the reasons for the journal retraction of the study in question.

In its letter to OLAW dated "7-21" (see <https://saenonline.org/news-media-news-2021/Tulane-University-OLAW-Federal-Complaint-7-21.pdf>), SAEN provides that the reason for the retraction is "Error in Methods" and "Unreliable Results." Tulane notes that neither "Error in Methods" nor "Unreliable Results" are words listed in the published retraction, which is available at <https://www.atsjournals.org/doi/full/10.1164/rccm.v203retraction1?af=R>. The published retraction instead states as follows:

"The authors of the article (1), published in the February 15, 2020, issue of the Journal, have discovered that infection and 3HP treatment of a cohort of the animals did not conform to the stated experimental protocol. Since analysis of the other cohort of animals that did not experience protocol deviation generated similar results, the conclusions of the article may be correct. However, the authors believe that retraction is appropriate because of the differences in performance of the study, and because the published article does not accurately reflect how all of the animals were infected and treated with 3HP."

As noted previously, Tulane would respectfully suggest that OLAW contact the IO at Texas Biomedical (the institution of the PI and corresponding author) to determine the exact reason for the retraction.

Tulane and Texas Biomedical have agreed to work together with the Pass-through Entity ("PTE") on any required grant reconciliation as appropriate following Texas Biomedical's completion of review of the matter. The following has been identified as the potentially relevant funding component:

- PTE: Emory University ("Emory"); Subrecipient: Tulane. Funding component: NIH/NIAID. PTE award No.: U19AI111211. The subaward's end date at Tulane was December 31, 2018, and the subaward was transferred to Texas Biomedical.

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

Sincerely,

(b) (6)

Giovanni Piedimonte

c Joanne Turner, PhD, Texas Biomedical Research Institute IO and VPR
Preston A. Marx, PhD, Tulane IACUC Chair

(b) (6)

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Wednesday, February 2, 2022 7:31 AM
To: (b) (6)
Subject: RE: Tulane Report to OLAW, Case A4499-1B

Thank you, the letter was attached this time.
Axel Wolff

From: (b) (6)
Sent: Tuesday, February 1, 2022 3:52 PM
To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Subject: [EXTERNAL] RE: Tulane Report to OLAW, Case A4499-1B

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dr. Wolff,

I apologize. Here is the letter.

Thank you,

(b) (6)

From: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Sent: Tuesday, February 1, 2022 2:30 PM
To: (b) (6)
Subject: RE: Tulane Report to OLAW, Case A4499-1B

External Sender. Be aware of links, attachments and requests.

Please resend the letter, (b) (6) as it was not attached.

Axel Wolff

From: (b) (6)
Sent: Tuesday, February 1, 2022 11:34 AM
To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Cc: joanneturner@txbiomed.org; Marx, Preston A <pmarx@tulane.edu>; (b) (6)

(b) (6)

Subject: [EXTERNAL] Tulane Report to OLAW, Case A4499-1B

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and are confident the content is safe.

Dear Dr. Wolff,

Please find attached a letter from Giovanni Piedimonte, Vice President for Research and Institutional Official at Tulane University, regarding OLAW Case A4499-1B.

Thank you,

(b) (6)



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

November 12, 2021

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare ("OLAW")
Via email: wolffa@od.nih.gov and keri.walker@nih.gov

Interim Report, OLAW Case A4499-1B

Dear Dr. Wolff:

Tulane University ("Tulane"), in accordance with Assurance A4499-01 and PHS Policy IV.F.3, provides this interim report regarding OLAW Case A4499-1B. The relevant IACUC protocol and corresponding study are closed. The Principal Investigator ("PI") on the protocol is no longer affiliated with Tulane.

The group that Tulane has convened to review and investigate this matter has reviewed and compared the animal treatment records for the study, the available laboratory records, and the IACUC-approved protocols and amendments. The result of this review is that for one cohort involving five rhesus macaques, the one-month rest period described in the protocol between the end of treatment and the infectious agent inoculation did not occur. The rest period should have occurred pursuant to the protocol. Tulane will provide this information to the Institutional Official of the PI's current institution.

These findings will be presented to the convened IACUC for review and appropriate determinations including any corrective actions to prevent re-occurrence and reportability.

Tulane seeks to timely submit to OLAW its final report (or an interim report if that matter is not ready for final report) within three months of this correspondence. Tulane seeks to include in its final reporting to OLAW the relevant grant(s) or contract number(s) (for situations related to PHS-supported activities), any potential or actual effect on PHS-supported activities, and compliance with terms and conditions.

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

Sincerely,

Tulane University #8401,1440 Canal Street, Suite 2400, New Orleans, LA 70112-2709; phone 504.988.3291 fax 504.988.1238

gpiedimonte@tulane.edu

<https://research.tulane.edu>

(b) (6)

A large rectangular area of the document is redacted with a solid grey fill.

Giovanni Piedimonte, M.D., F.A.A.P., F.C.C.P.
Vice President for Research and Institutional Official
of Tulane University

c Preston A. Marx, PhD, Tulane IACUC Chair

(b) (6)

A rectangular area of the document is redacted with a solid grey fill.

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Monday, November 15, 2021 6:58 AM
To: Piedimonte, Giovanni
Subject: RE: Interim Report, OLAW Case A4499-1B

Thank you for this interim report, Dr. Piedimonte. I will place it in the case file. In the final report, please specifically address the reasons for the journal retraction of the study in question.

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

From: Piedimonte, Giovanni <gpiedimonte@tulane.edu>
Sent: Friday, November 12, 2021 2:50 PM
To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>; Walker, Keri (NIH/OD) [E] <keri.walker@nih.gov>
Cc: Marx, Preston A <pmarx@tulane.edu>; (b) (6)
Subject: Interim Report, OLAW Case A4499-1B

Please, find attached Interim Report, OLAW Case A4499-1B.

Thanks, GP



Giovanni Piedimonte, MD, FAAP, FCCP

Vice President for Research
& Institutional Official of Tulane University
Professor of Pediatrics, Biochemistry & Molecular Biology
Tulane School of Medicine

📍 Location: Tidewater Bldg., #8401
1440 Canal Street, (b) (4)
New Orleans, LA 70112-2709
(b) (6)

✉ Email: gpiedimonte@tulane.edu
🌐 Web: <http://research.tulane.edu/>



Giovanni Piedimonte, MD, FAAP, FCCP

Vice President for Research and Institutional Official

Tulane University

Professor of Pediatrics and Biochemistry and Molecular Biology

Tulane School of Medicine

August 14, 2021

Axel Wolff, M.S., D.V.M.

Deputy Director

Office of Laboratory Animal Welfare ("OLAW")

Via email: wolffa@od.nih.gov and keri.walker@nih.gov

Interim Report, OLAW Case A4499-1B

Dear Dr. Wolff,

Tulane University ("Tulane"), in accordance with Assurance A4499-01 and PHS Policy IV.F.3, provides this interim report regarding OLAW Case A4499-1B. The relevant IACUC protocol and corresponding study are closed. The Principal Investigator ("PI") on the protocol is no longer affiliated with Tulane. Tulane has advised the Institutional Official of the PI's current institution of the inquiry from Stop Animal Exploitation Now ("SAEN") and of OLAW's directive to Tulane to investigate this allegation and report to OLAW accordingly.

Tulane has convened a group to review and investigate this matter. Currently, Tulane's investigation is centered upon a detailed review of the animal treatment records and laboratory records in order to compare the procedures approved in the IACUC protocol and amendments with the procedures performed. The findings will be presented for review to the TNPRC IACUC for appropriate determinations. If there were any instances of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals and/or noncompliance with the IACUC-approved protocol and amendments, the committee would require a reasonable and specific plan and schedule for correction of each deficiency and make determinations as to reportability of any such noncompliant items.

Tulane seeks to timely submit to OLAW its final report (or an interim report if that matter is not ready for final report) within three months of this correspondence. Tulane seeks to include in its final reporting to OLAW the relevant grant(s) or contract number(s) (for situations related to PHS-supported activities), any potential or actual effect on PHS-supported activities, and compliance with terms and conditions.

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

Sincerely,

(b) (6)

Giovanni Piedimonte

c Preston A. Marx, PhD, Tulane IACUC Chair

(b) (6)

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>

Wolff, Axel (NIH/OD) [E]

From: Wolff, Axel (NIH/OD) [E]
Sent: Monday, August 16, 2021 7:03 AM
To: Piedimonte, Giovanni
Cc: Walker, Keri (NIH/OD) [E]
Subject: RE: Interim Report, OLAW Case A4499-1B

Thank you for this interim report, Dr. Piedimonte. I will add this to the file and look forward to receiving either a final or interim report by November 15, 2021. Thank you for keeping OLAW apprised on this matter.
Axel Wolff

From: Piedimonte, Giovanni <gpiedimonte@tulane.edu>
Sent: Saturday, August 14, 2021 7:30 PM
To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>; Walker, Keri (NIH/OD) [E] <keri.walker@nih.gov>
Cc: Marx, Preston A <pmarx@tulane.edu>; (b) (6)
(b) (6)
Subject: Interim Report, OLAW Case A4499-1B

Dear Dr. Wolff and Ms. Walker,

Please find attached an interim report from Tulane University regarding OLAW Case A4499-1B.

Thank you,



GIOVANNI PIEDIMONTE, MD, FAAP, FCCP

Vice President for Research & Institutional Official
of Tulane University
Professor of Pediatrics, Biochemistry & Molecular Biology

📍 location: Tidewater Bldg., (b) (4)
(b) (6)

✉ email: gpiedimonte@tulane.edu

🌐 web: <http://research.tulane.edu/>



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Bethesda, Maryland 20817
Telephone: (301) 496-7163
Facsimile: (301) 480-3387

July 12, 2021

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

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) has received from the organization Stop Animal Exploitation Now (SAEN), an inquiry about a study using nonhuman primates at Tulane University. Specifically, SAEN has identified a retracted publication entitled *Isoniazid and Rifapentine Treatment Eradicates Persistent Mycobacterium tuberculosis in Macaques*, published in the *American Journal of Respiratory Critical Care Medicine*, 2020 Feb 15; 201(4): 469-477. The reason given for retraction states that there was an error in methods and that the results were unreliable which may point to a potential problem with following the protocol or in the conduct of the procedures. The study was supported by the following NIH grants: U19AI111211, R01AI111943, R01AI123047, R01AI134240, P51OD011104, P51OD011133, K24AI058609, and K24AI114444.

Please direct the Institutional Animal Care and Use Committee (IACUC), avoiding any conflicts of interest, to investigate this allegation and determine if there were any instances of noncompliance with the PHS Policy on Humane Care and Use of Laboratory Animals, specifically as related to the conduct of the protocol which led to the retraction. If noncompliance is identified, provide a reasonable and specific plan and schedule for correction of each deficiency. Also, provide comment on whether any noncompliant items should have been reported to OLAW. Please provide a final or interim report by **August 15, 2021**.

Sincerely,

(b) (6)

Axel Wolff, M.S., D.V.M.
Deputy Director
Office of Laboratory Animal Welfare

cc: IACUC Chair

Wolff, Axel (NIH/OD) [E]

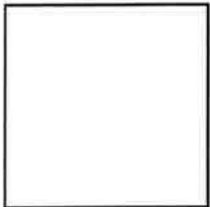
A 4499 - 1B

From: Wolff, Axel (NIH/OD) [E]
Sent: Friday, July 9, 2021 7:38 AM
To: (b) (6)
Subject: RE: OLAW Complaint

Thank you for this report. OLAW will investigate and provide a response upon completion.

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

From: (b) (6)
Sent: Tuesday, July 6, 2021 5:04 PM
To: Wolff, Axel (NIH/OD) [E] <wolffa@od.nih.gov>
Subject: OLAW Complaint



Axel Wolff, M.S., D.V.M., Deputy Director,
Office of Laboratory Animal Welfare
National Institutes of Health (NIH),
9000 Rockville Pike,
Bethesda, Maryland 20892
Via Email: wolffa@od.nih.gov

Dr. Wolff,

I am writing to you today to request an investigation of an incident which took place regarding a federally funded project at Tulane University.

According to the PubMed website this article: *Isoniazid and Rifapentine Treatment Eradicates Persistent Mycobacterium tuberculosis in Macaques* (Am J Respir Crit Care Med 2020 Feb 15;201(4):469-477.) has been retracted (see attached PubMed screenshot).

The Retraction Watch website (see attached screen shot) lists the reason for retraction as "Error in Methods" and "Unreliable Results." This website defines "Error in Methods" as "A mistake made in the experimental protocol, either in following the wrong protocol, or in erring during the performance of the protocol." This project involved 16 macaques, who were apparently necropsied at the end of the project. If a mistake was made in the protocol, or the wrong protocol was followed, this would clearly violate the NIH Policy on the Humane Care & Use of Laboratory Animals.

Regarding funding, the article states: "Supported by a Tuberculosis Research Unit grant from NIH and National Institutes of Allergy and Infectious Diseases (U19AI111211) and support from other NIH grants (R01AI111943; R01AI123047; R01AI134240; P51OD011104; P51OD011133; K24AI058609; and K24AI114444)." Clearly, this project received funding under multiple federal grants.

As you know, we receive all reports filed with OLAW, and have seen nothing regarding this project. Therefore, I believe that your office must investigate this matter.

I will look forward to seeing the results of your investigation.

Sincerely,

(b) (6)

(b) (6)

1081-B State Route 28 #280 Milford, OH 45150 513-575-5517 www.SAENonline.org