



EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN DEVELOPMENT

Grant Number: 5R01HD095857-02
FAIN: R01HD095857

Principal Investigator(s):
PIERRE BUEKENS (contact), MD
María Luisa Cafferata

Project Title: Short-course Benznidazole Treatment to Reduce Trypanosoma cruzi Parasitic Load in Women of Reproductive Age: A Non-inferiority Randomized Controlled Trial

Ms. KOZAR, KATHLEEN M.
DIRECTOR, SPONSORED PROJECTS ADMINISTRATION
1430 TULANE AVENUE, MB CODE 8915
NEW ORLEANS, LA 701122632

Award e-mailed to: elecnotf@tulane.edu

Period Of Performance:
Budget Period: 06/01/2019 – 05/31/2020
Project Period: 09/01/2018 – 05/31/2023

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of \$511,095 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to TULANE UNIVERSITY OF LOUISIANA in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award including the "Terms and Conditions" is acknowledged by the grantee when funds are drawn down or otherwise obtained from the grant payment system.

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the Eunice Kennedy Shriver National Institute Of Child Health & Human Development of the National Institutes of Health under Award Number R01HD095857. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

Award recipients must promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct and reporting of research funded under NIH awards will be free from bias resulting from an Investigator's Financial Conflict of Interest (FCOI), in accordance with the 2011 revised regulation at 42 CFR Part 50 Subpart F. The Institution shall submit all FCOI reports to the NIH through the eRA Commons FCOI Module. The regulation does not apply to Phase I Small Business Innovative Research (SBIR) and Small Business Technology Transfer (STTR) awards. Consult the NIH website <http://grants.nih.gov/grants/policy/coi/> for a link to the regulation and additional important information.

If you have any questions about this award, please contact the individual(s) referenced in Section IV.

Sincerely yours,

Rehana A. Chowdhury
Grants Management Officer
EUNICE KENNEDY SHRIVER NATIONAL INSTITUTE OF CHILD HEALTH & HUMAN
DEVELOPMENT

Additional information follows

SECTION I – AWARD DATA – 5R01HD095857-02**Award Calculation (U.S. Dollars)**

Salaries and Wages	\$108,753
Fringe Benefits	\$20,540
Personnel Costs (Subtotal)	\$129,293
Materials & Supplies	\$22,638
Travel	\$13,702
Other	\$415
Subawards/Consortium/Contractual Costs	\$261,193

Federal Direct Costs	\$427,241
Federal F&A Costs	\$83,854
Approved Budget	\$511,095
Total Amount of Federal Funds Obligated (Federal Share)	\$511,095
TOTAL FEDERAL AWARD AMOUNT	\$511,095

AMOUNT OF THIS ACTION (FEDERAL SHARE) \$511,095

SUMMARY TOTALS FOR ALL YEARS			
YR	THIS AWARD		CUMULATIVE TOTALS
2		\$511,095	\$511,095
3		\$500,948	\$500,948
4		\$493,844	\$493,844
5		\$579,897	\$579,897

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

Fiscal Information:

CFDA Name: Child Health and Human Development Extramural Research
CFDA Number: 93.865
EIN: 1720423889A2
Document Number: RHD095857A
PMS Account Type: P (Subaccount)
Fiscal Year: 2019

IC	CAN	2019	2020	2021	2022
HD	8014702	\$511,095	\$500,948	\$493,844	\$579,897

Recommended future year total cost support, subject to the availability of funds and satisfactory progress of the project

NIH Administrative Data:

PCC: MPIDB-NC / **OC:** 414E / **Released:** CHOWDHURYR 05/20/2019
Award Processed: 05/21/2019 12:10:55 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5R01HD095857-02

For payment and HHS Office of Inspector General Hotline information, see the NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm>

SECTION III – TERMS AND CONDITIONS – 5R01HD095857-02

This award is based on the application submitted to, and as approved by, NIH on the above-titled project and is subject to the terms and conditions incorporated either directly or by reference in the following:

- The grant program legislation and program regulation cited in this Notice of Award.
- Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
- 45 CFR Part 75.

- d. National Policy Requirements and all other requirements described in the NIH Grants Policy Statement, including addenda in effect as of the beginning date of the budget period.
- e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
- f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

(See NIH Home Page at <http://grants.nih.gov/grants/policy/awardconditions.htm> for certain references cited above.)

Research and Development (R&D): All awards issued by the National Institutes of Health (NIH) meet the definition of “Research and Development” at 45 CFR Part§ 75.2. As such, auditees should identify NIH awards as part of the R&D cluster on the Schedule of Expenditures of Federal Awards (SEFA). The auditor should test NIH awards for compliance as instructed in Part V, Clusters of Programs. NIH recognizes that some awards may have another classification for purposes of indirect costs. The auditor is not required to report the disconnect (i.e., the award is classified as R&D for Federal Audit Requirement purposes but non-research for indirect cost rate purposes), unless the auditee is charging indirect costs at a rate other than the rate(s) specified in the award document(s).

An unobligated balance may be carried over into the next budget period without Grants Management Officer prior approval.

This grant is subject to Streamlined Noncompeting Award Procedures (SNAP).

This award is subject to the requirements of 2 CFR Part 25 for institutions to receive a Dun & Bradstreet Universal Numbering System (DUNS) number and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a DUNS requirement must be included. See <http://grants.nih.gov/grants/policy/awardconditions.htm> for the full NIH award term implementing this requirement and other additional information.

This award has been assigned the Federal Award Identification Number (FAIN) R01HD095857. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

Based on the project period start date of this project, this award is likely subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170. There are conditions that may exclude this award; see <http://grants.nih.gov/grants/policy/awardconditions.htm> for additional award applicability information.

In accordance with P.L. 110-161, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: <http://publicaccess.nih.gov/>.

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of [Public Law 110-85](#)), the “responsible party” must register “applicable clinical trials” on the [ClinicalTrials.gov Protocol Registration System Information Website](#). NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than \$10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal

Awardee Performance and Integrity Information System (FAPIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:

Additional Costs

SECTION IV – HD Special Terms and Conditions – 5R01HD095857-02

Clinical Trial Indicator: Yes

This award supports one or more NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

This award is subject to the requirements indicated in PA16-032, which are hereby incorporated by reference. Copies of this Funding Opportunity Announcement are available at <http://grants.nih.gov/grants/guide/index.html>.

This award includes funding **in the amount of \$216,193 total costs** for the following sites: Instituto De Defectividad Clinicay, Buenos Aires, Argentina.

This award includes funds awarded for consortium activity with University of California at San Diego. Consortia are to be established and administered as described in the NIH Grants Policy Statement (rev. 10/17) (<http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf>).

The recipient is required to follow the Multiple Principal Investigator Leadership Plan included in the application dated 9/28/2017 and may not implement any changes in the plan without the written prior approval of NICHD.

Although the signatures of all PIs are not required on prior approval requests submitted to NICHD, the recipient institution must secure and retain the signatures of all of PIs within their own internal processes. See NIH Guide Notice NOT-OD-06-054 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-06-054.html>).

Total direct costs (salary, fringe benefits and tuition remission) for graduate students are provided at the NIH maximum allowable amount (zero level of the Ruth L. Kirschstein-NRSA stipend in effect at the time of the competing award.) See NIH Guide Notice NOT-OD-02-017 (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-02-017.html>).

STAFF CONTACTS

The Grants Management Specialist is responsible for the negotiation, award and administration of this project and for interpretation of Grants Administration policies and provisions. The Program Official is responsible for the scientific, programmatic and technical aspects of this project. These individuals work together in overall project administration. Prior approval requests (signed by an Authorized Organizational Representative) should be submitted in writing to the Grants Management Specialist. Requests may be made via e-mail.

Grants Management Specialist: Rehana A. Chowdhury
Email: rc29a@nih.gov **Phone:** 301-435-7007

Program Official: Nahida Abdo Chakhtoura
Email: nahida.chakhtoura@nih.gov **Phone:** (301) 435-6872

SPREADSHEET SUMMARY

GRANT NUMBER: 5R01HD095857-02

INSTITUTION: TULANE UNIVERSITY OF LOUISIANA

Budget	Year 2	Year 3	Year 4	Year 5
Salaries and Wages	\$108,753	\$106,111	\$110,521	\$100,792
Fringe Benefits	\$20,540	\$19,761	\$20,607	\$20,286

Personnel Costs (Subtotal)	\$129,293	\$125,872	\$131,128	\$121,078
Consultant Services			\$7,470	
Materials & Supplies	\$22,638	\$14,205	\$14,205	\$14,205
Travel	\$13,702	\$17,058	\$25,200	\$20,415
Other	\$415	\$415	\$415	\$415
Subawards/Consortium/Contractual Costs	\$261,193	\$263,835	\$225,325	\$287,809
TOTAL FEDERAL DC	\$427,241	\$421,385	\$403,743	\$443,922
TOTAL FEDERAL F&A	\$83,854	\$79,563	\$90,101	\$135,975
TOTAL COST	\$511,095	\$500,948	\$493,844	\$579,897

Facilities and Administrative Costs	Year 2	Year 3	Year 4	Year 5
F&A Cost Rate 1	50.5%	50.5%	50.5%	50.5%
F&A Cost Base 1	\$166,048	\$157,550	\$178,418	\$269,258
F&A Costs 1	\$83,854	\$79,563	\$90,101	\$135,975