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Purchase Order

Purchase Order Date	Purchase Order Number	Revision No.
Nov 17, 2020	**1399775**	**0**

Contact Information

Requestor Name	Jerrold Ellner
Requestor Phone	973-868-0185
Requestor e-mail	ellnerjj@njms.rutgers.edu

Supplier Information

Fundacao de Apoio Cassiano Antonio Moraes

Avenida Marechal Campos 1355
Santa Cecilia - ES 29043-260
Vitoria, ES CEP: 29043-260 BR

Phone	+55 27 3335-7448
Net Terms	0, Net 45
Quote number	
Contract	*no value*

Delivery Information

Delivery Address
Rutgers University

Attn:	Jerrold Ellner
Bldg/Room:	NJMS - c/o Audrey Mioli

Medical Science Bldg
185 South Orange Ave
NEWARK, NJ 07101-1709

F.O.B. Destination

Billing Information

Email invoices to:
accountspayable@finance.rutgers.edu

INVOICES SUBMITTED WITHOUT A P.O. NUMBER WILL NOT BE PROCESSED.

THIS P.O. # MUST APPEAR ON INVOICES, PACKING SLIPS AND ANY CORRESPONDENCE RELATED TO THIS PURCHASE.

Line No.	Product Description	Catalog No.	Unit Price	Quantity	Ext. Price
1 of 1	Sub Award Form - Sub Award Detail - PID#828384 SUB#1629		1.00 USD	47,747 EA	47,747.00 USD

ADDITIONAL INFO

Sponsor	NIH/NIAID
Principal Investigator	Jerrold Ellner
RAPPS Reference Number	PID#828384 SUB#1629

Subtotal	**47,747.00**
Shipping	0.00
Handling	0.00
Total	**47,747.00 USD**

Supplier Terms and Conditions

By accepting this Purchase Order, the supplier agrees to Rutgers' Terms and Conditions of the procurement of goods and services, available at http://procurementservices.rutgers.edu. The Rutgers' Terms and Conditions are hereby incorporated by reference, and shall not be modified without the express written consent of Rutgers, The State University of New Jersey.

FDP Cost Reimbursement Foreign Research Subaward Agreement

Federal Awarding Agency: National Institutes of Health (NIH) NIAID

Pass-Through Entity (PTE):	**Subrecipient:**
Rutgers, The State University	Universidade Federal do Espirito Santo
PTE PI: Jerrold Ellner	Sub PI: Reynaldo Dietze
PTE Federal Award No: 5U19AI111276-08	Subaward No: 1629

Project Title: Biomarkers and Mechanisms of Paucibacillary and Latent Tuberculosis

Subaward Period of Performance (Budget Period): Start: 08/01/2020 End: 07/31/2021	Amount Funded This Action (USD): $ 47,747.00
Estimated Project Period (if incrementally funded): Start: End:	Incrementally Estimated Total (USD): $

Terms and Conditions

1. PTE hereby awards a cost reimbursable Subaward, as described above, to Subrecipient. The Statement of Work and budget for this Subaward are as shown in Attachment 5. In its performance of Subaward work, Subrecipient shall be an independent entity and not an employee or agent of PTE. No Party has the authority to bind any other Party in contract or to incur any debts or obligations on behalf of any other Party, and no Party (including an employee or other representative of such Party) shall take any action that attempts or purports to bind any other Party in contract or to incur any debt or obligations on behalf of any other Party, without the affected party's prior written approval.

2. Subrecipient shall submit invoices Quarterly for allowable costs incurred. All invoices shall be submitted using PTE's standard invoice shown in Attachment 6, and shall include current and cumulative costs (including cost sharing information if applicable), Subaward number, and certification, as required in 2 CFR 200.415 (a). Invoices that do not reference PTE Subaward number shall be returned to Subrecipient. Invoices and questions concerning invoice receipt or payments shall be directed to the party's Authorized Official Contact, shown in Attachment 3A. Expenditures of Subrecipient shall conform to budget in Attachment 5. All payments will be in U.S. Dollars.

3. A final statement of cumulative costs incurred, including cost sharing, marked "FINAL" must be submitted to PTE's Financial Contact, as shown in Attachment 3A, NO LATER THAN 30 Days after Subaward end date. The final statement of costs shall constitute Subrecipient's final financial report.

4. All payments shall be considered provisional and subject to adjustment within the total estimated cost, in the event such adjustment is necessary as a result of an adverse audit finding against the Subrecipient. Upon the receipt of proper invoices, the PTE agrees to process payments in accordance with this Subaward and 2 CFR 200.305.

5. Matters concerning the technical performance of this Subaward Agreement shall be directed to the appropriate party's Principal Investigator as shown in Attachments 3A and 3B. Technical reports are required as shown in Attachment 4:"Reporting Requirements"

6. Matters concerning the request or negotiation of any changes in the terms, conditions, or amounts cited in this Subaward Agreement and any changes requiring prior approval, shall be directed to the appropriate party's Authorized Official Contact, as shown in Attachments 3A and 3B. Any su change made to this Subaward requires the written approval of each party's Authorized Official, as shown in Attachments 3A and 3B.

7. The PTE may issue non-substantive changes (defined as: documentation of prior approvals, addition of non-competing continuation budget periods / funds and no cost extensions) to the Period of Performance and budget Unilaterally . Unilateral modifications shall be considered valid 14 days after receipt, unless otherwise indicated by Subrecipient. Requests for No Cost Extensions are as shown in Attachment 2.

8. Each Party shall be responsible for its negligent acts or omissions, and the negligent acts or omissions of its employees, officers, or directors, to the extent allowed by law.

9. Either Party may terminate this Subaward Agreement with 30 days written notice to the appropriate Party's Authorized Official Contact, as shown in Attachments 3A and 3B. PTE shall pay Subrecipient for termination costs as allowable under Uniform Guidance, 2 CFR 200, or 45 CFR Part 75 Appendix IX, "Principles for Determining Costs Applicable to Research & Development under Grants and Contracts with Hospitals" as applicable.

10. No Party shall be in default by reason of any failure in performance of this Subaward if such failure arises, directly or indirectly, out of causes reasonably beyond the direct control or foreseeability of such Party, including but not limited to, acts of God or of the public enemy, U.S. or foreign governmental acts in either a sovereign or contractual capacity, labor, fire, flood, epidemic and strikes.

11. By signing this Subaward, including the attachments hereto which are hereby incorporated by reference, Subrecipient certifies that it will perform the Statement of Work in accordance with the terms and conditions of this Subaward and the applicable terms of the Federal Award, including the appropriate Research Terms and Conditions ("RTCs") of the Federal Awarding Agency, as referenced in Attachment 2. The parties further agree that they intend this Subaward to comply with all applicable laws, regulations and requirements.

By an Authorized Official of Pass-through Entity:	By an Authorized Official of Subrecipient:
Chrissa Papaioannou, PE, CRA Digitally signed by Chrissa Papaioannou, PE, CRA Date: 2020.11.16 13:20:31 -05'00'	
Name: Chrissa Papaioannou, PE, CRA Date: 11/16/2020	Name: Date: 10/30/2020
Title: Assistant Director, RSP	Title: Director of Health Sciences

Notice of Award

RESEARCH PROJECT COOPERATIVE AGREEMENT **Federal Award Date:** 07/22/2020

Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Grant Number: 5U19AI111276-08
FAIN: U19AI111276

Principal Investigator(s):
David Alland, MD
Jerrold J. Ellner (contact), MD
Padmini Salgame, PHD

Project Title: Biomarkers and Mechanisms of Paucibacillary and Latent Tuberculosis

Jessie McNabb
Stanley S. Bergen Building
65 Bergen Street, Suite 538
Newark, NJ 07103

Award e-mailed to: rbhsnewark-orsp@grants.rutgers.edu

Period Of Performance:
Budget Period: 08/01/2020 – 07/31/2021
Project Period: 08/01/2014 – 07/31/2021

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $3,457,326 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to RBHS-NEW JERSEY MEDICAL SCHOOL in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 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 National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number U19AI111276. 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,

Ann W. Devine
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

SECTION I – AWARD DATA – 5U19AI111276-08

Award Calculation (U.S. Dollars)

Salaries and Wages	$884,527
Fringe Benefits	$396,639
Personnel Costs (Subtotal)	$1,281,166
Materials & Supplies	$75,746
Travel	$128,754
Other	$31,274
Subawards/Consortium/Contractual Costs	$1,088,365
Tuition Remission	$2,535
Federal Direct Costs	$2,607,840
Federal F&A Costs	$849,486
Approved Budget	$3,457,326
Total Amount of Federal Funds Obligated (Federal Share)	$3,457,326
TOTAL FEDERAL AWARD AMOUNT	$3,457,326
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$3,457,326

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
8	$3,457,326	$3,457,326

Fiscal Information:

CFDA Name:	Allergy and Infectious Diseases Research
CFDA Number:	93.855
EIN:	1462354111A1
Document Number:	UAI111276B
PMS Account Type:	P (Subaccount)
Fiscal Year:	2020

IC	CAN	2020
AI	8011074	$3,457,326

NIH Administrative Data:
PCC: M33D B / **OC**: 41029 / **Released**: ADEVINE 07/21/2020
Award Processed: 07/22/2020 12:01:53 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5U19AI111276-08

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 – 5U19AI111276-08

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:

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 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).

Carry over of an unobligated balance into the next budget period requires Grants Management Officer prior approval.

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) U19AI111276. 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 represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

A final expenditure Federal Financial Report (FFR) (SF 425) must be submitted through the eRA Commons (Commons) within 120 days of the period of performance end date; see the NIH Grants Policy Statement Section 8.6.1 Financial Reports, http://grants.nih.gov/grants/policy/policy.htm#gps, for additional information on this submission requirement. The final FFR must indicate the exact balance of unobligated funds and may not reflect any unliquidated obligations. There must be no discrepancies between the final FFR expenditure data and the Payment Management System's (PMS) quarterly cash transaction data. A final quarterly federal cash transaction report is not required for awards in PMS B subaccounts (i.e., awards to foreign entities and to Federal agencies). NIH will close the awards using the last recorded cash drawdown level in PMS for awards that do not require a final FFR on expenditures or quarterly federal cash transaction reporting. It is important to note that for financial closeout, if a grantee fails to submit a required final expenditure FFR, NIH will close the grant using the last recorded cash drawdown level. If the grantee submits a final expenditure FFR but does not reconcile any discrepancies between expenditures reported on the final expenditure FFR and the last cash report to PMS, NIH will close the award at the lower amount. This could be considered a debt or result in disallowed costs.

A Final Invention Statement and Certification form (HHS 568), (not applicable to training, construction, conference or cancer education grants) must be submitted within 120 days of the expiration date. The HHS 568 form may be downloaded at: http://grants.nih.gov/grants/forms.htm. This paragraph does not apply to Training grants, Fellowships, and certain other programs—i.e., activity codes C06, D42, D43, D71, DP7, G07, G08, G11, K12, K16, K30, P09, P40, P41, P51, R13, R25, R28, R30, R90, RL5, RL9, S10, S14, S15, U13, U14, U41, U42, U45, UC6, UC7, UR2, X01, X02.

Unless an application for competitive renewal is submitted, a Final Research Performance Progress Report (Final RPPR) must also be submitted within 120 days of the period of performance end date. If a competitive renewal application is submitted prior to that date, then an Interim RPPR must be submitted by that date as well. Instructions for preparing an Interim or Final RPPR are at: https://grants.nih.gov/grants/rppr/rppr_instruction_guide.pdf. Any other specific requirements set forth in the terms and conditions of the award must also be addressed in the Interim or Final RPPR. *Note that data reported within Section I of the Interim and Final RPPR forms will be made public and should be written for a lay person audience*.

NIH strongly encourages electronic submission of the final invention statement through the Closeout feature in the Commons, but will accept an email or hard copy submission as indicated below.

Email: The final invention statement may be e-mailed as PDF attachments to: NIHCloseoutCenter@mail.nih.gov.

Hard copy: Paper submissions of the final invention statement may be faxed to the NIH Division of Central Grants Processing, Grants Closeout Center, at 301-480-2304, or mailed to:

National Institutes of Health
Office of Extramural Research
Division of Central Grants Processing
Grants Closeout Center
6705 Rockledge Drive
Suite 5016, MSC 7986
Bethesda, MD 20892-7986 (for regular or U.S. Postal Service Express mail)
Bethesda, MD 20817 (for other courier/express deliveries only)

NOTE: If this is the final year of a competitive segment due to the transfer of the grant to another institution, then a Final RPPR is not required. However, a final expenditure FFR is required and should be submitted electronically as noted above. If not already submitted, the Final Invention Statement is required and should be sent directly to the assigned Grants Management Specialist.

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 (FAPIIS)). 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 – AI Special Terms and Conditions – 5U19AI111276-08

Clinical Trial Indicator: No
This award does not support any NIH-defined Clinical Trials. See the NIH Grants Policy Statement Section 1.2 for NIH definition of Clinical Trial.

The Research Performance Progress Report (RPPR), Section G.9 (Foreign component), includes reporting requirements for all research performed outside of the United States. Research conducted at the following site(s) must be reported in your RPPR:

Hospital Universitario Cassiano Antonio de Moraes/Nucleo de Doencas Infecciosas/Universidade Federal do Espirito Santo - UFES - BRAZIL
University of Cape Town - SOUTH AFRICA
Max-Planck-Institut fur infectionsbiologie, Germany
Gheskio Center, Haiti
International Tuberculosis Research Center, Republic of South Korea
MRC National Institute for Medical Research, United Kingdom

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This Notice of Award (NoA) includes funds for activity with **HMH Hospitals Corporation** in the amount of **$59,741** (**$33,733** direct costs + **$26,008** F&A costs).

This Notice of Award (NoA) includes funds for activity with **Albert Einstein College of Medicine** in the amount of **$106,421** (**$63,725** direct costs + **$42,696** F&A costs).

This Notice of Award (NoA) includes funds for activity with **Massachusetts Institute of Technology** in the amount of **$103,481** (**$66,762** direct costs + **$36,719** F&A costs).

This Notice of Award (NoA) includes funds for activity with **University of Washington** in the amount of **$222,978** (**$126,333** direct costs + **$96,645** F&A costs).

This Notice of Award (NoA) includes funds for activity with **Universidade Federal do Espirito Santo** in the amount of **$47,747**(**$44,210** direct costs + **$3,537** F&A costs).

This Notice of Award (NoA) includes funds for activity with **University of Cape Town** in the amount of **$48,740** (**$45,130** direct costs + **$3,610** F&A costs).

This Notice of Award (NoA) includes funds for activity with **Boston Medical Center** in the amount of **$21,791** (**$12,242** direct costs + **$9,549** F&A costs).

This Notice of Award (NoA) includes funds for activity with **Boston University Medical Campus** in the amount of **$90,314** (**$54,736** direct costs + **$35,578** F&A costs).

This Notice of Award (NoA) includes funds for activity with **Boston University Medical Campus** in the amount of **$90,316** (**$54,737** direct costs + **$35,579** F&A costs).

This Notice of Award (NoA) includes funds for activity with **Boston Medical Center** in the amount of **$21,789** (**$12,241** direct costs + **$9,548** F&A costs).

This Notice of Award (NoA) includes funds for activity with **Albert Einstein College of Medicine** in the amount of **$142,244** (**$85,176** direct costs + **$57,068** F&A costs).

This Notice of Award (NoA) includes funds for activity with **HMH Hospitals Corporation** in the amount of **$132,803** (**$75,030** direct costs + **$57,773** F&A costs).

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This award may include collaborations with and/or between foreign organizations. Please be advised that short term travel visa expenses are an allowable expense on this grant, if justified as critical and necessary for the conduct of the project.

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Select Agents:
Awardee of a project that at any time involves a restricted experiment with a select agent, is responsible for notifying and receiving prior approval from the NIAID. Please be advised that changes in the use of a Select Agent will be considered a change in scope and require NIH awarding office prior approval. The approval is necessary for new select agent experiments as well as changes in on-going experiments that would require change in the biosafety plan and/or

biosafety containment level. An approval to conduct a restricted experiment granted to an individual cannot be assumed an approval to other individuals who conduct the same restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html).

Highly Pathogenic Agent:
NIAID defines a Highly Pathogenic Agent as an infectious Agent or Toxin that may warrant a biocontainment safety level of BSL3 or higher according to the current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) (http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm). Research funded under this grant must adhere to the BMBL, including using the BMBL-recommended biocontainment level at a minimum. If your Institutional Biosafety Committee (or equivalent body) or designated institutional biosafety official recommend a higher biocontainment level, the highest recommended containment level must be used.
When submitting future Progress Reports indicate at the beginning of the report:

If no research with a Highly Pathogenic Agent or Select Agent has been performed or is planned to be performed under this grant.

If your IBC or equivalent body or official has determined, for example, by conducting a risk assessment, that the work being planned or performed under this grant may be conducted at a biocontainment safety level that is lower than BSL3.

If the work involves Select Agents and/or Highly Pathogenic Agents, also address the following points:

Any changes in the use of the Agent(s) or Toxin(s) including its restricted experiments that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by your IBC or equivalent body or official.

If work with a new or additional Agent(s)/Toxin(s) is proposed in the upcoming project period, provide:

o A list of the new and/or additional Agent(s) that will be studied;
o A description of the work that will be done with the Agent(s), and whether or not the work is a restricted experiment;
o The title and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or official. It is important to note if the work is being done in a new location.

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This award is subject to the Clinical Terms of Award referenced in the NIH Guide for Grants and Contracts, July 8, 2002, NOT AI-02-032. These terms and conditions are hereby incorporated by reference, and can be accessed via the following World Wide Web address: https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award All submissions required by the NIAID Clinical Terms of Award must be forwarded electronically or by mail to the responsible NIAID Program Official identified on this Notice of Award.

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This award is issued as a Cooperative Agreement, a financial assistance mechanism in which substantial NIH scientific and/or programmatic involvement is anticipated in the performance of the activity. This award is subject to the Terms and Conditions of Award as set forth in Section VI: Award Administrative Information of **RFA AI-12-045**, "**Tuberculosis Research Units (U19)**," posted date **11/06/12**, which are hereby incorporated by reference as special terms and conditions of this award.

This RFA may be accessed at: http://grants.nih.gov/grants/guide/index.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: Annie Noel Grimes
Email: annie.grimes@nih.gov **Phone**: 301-761-7315 **Fax**: 301-493-0597

Program Official: Susana Mendez
Email: mendezs@niaid.nih.gov **Phone**: (240) 669-5077

SPREADSHEET SUMMARY
GRANT NUMBER: 5U19AI111276-08

INSTITUTION: RBHS-NEW JERSEY MEDICAL SCHOOL

Budget	Year 8
Salaries and Wages	$884,527
Fringe Benefits	$396,639
Personnel Costs (Subtotal)	$1,281,166
Materials & Supplies	$75,746
Travel	$128,754
Other	$31,274
Subawards/Consortium/Contractual Costs	$1,088,365
Tuition Remission	$2,535
TOTAL FEDERAL DC	$2,607,840
TOTAL FEDERAL F&A	$849,486
TOTAL COST	$3,457,326

Facilities and Administrative Costs	Year 8
F&A Cost Rate 1	56%
F&A Cost Base 1	$1,516,940
F&A Costs 1	$849,486

Scope of Work

This document describes the scope of work for the NIAID Tuberculosis Research Unit (TBRU) activities to be undertaken by the ***Núcleo de Doenças Infecciosas of the Universidade Federal do Espírito Santo***, Vitoria, Brazil during Year Two.

1. Maintain capacity for conduct of the approved protocols in the following ways: maintenance of relationships with local TB programs in order to facilitate future recruitment into the proposed clinical study; maintain knowledge with respect to local TB epidemiology in order to guide suitability of the site for the proposed study; maintain laboratory infrastructure for conduct of conventional mycobacteriology tests; maintain a relationship with an FWA-assured IRB/ethics committee that will oversee the TBRU study.

2. Participate in periodic TBRU telephone conference calls

3. Facilitate site visits for the purpose of TBRU-related protocol training and site monitoring. Facilitation will include identifying an appropriate site/venue for activities, assisting with organization of activities, providing access to necessary documents, interacting collaboratively with trainers and monitors, and related activities.

4. The site PI will participate in the TBRU Executive Committee, including periodic telephone calls.

5. Implement agreed-upon TBRU clinical studies in accordance with the approved protocols and with the approval and oversight of relevant regulatory groups.

REPORTS

1. Provide financial expenditure as required by the contractor (Boston Medical Center) and the sponsor (National Institutes of Health).
2. Provide scientific progress reports as required by the contractor (Boston Medical Center) and the sponsor (National Institutes of Health).

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY	FROM 8/01/20	THROUGH 07/31/21

List PERSONNEL *(Applicant organization only)*
Use Cal, Acad, or Summer to Enter Months Devoted to Project
Enter Dollar Amounts Requested *(omit cents)* for Salary Requested and Fringe Benefits

NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	INST.BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
Dietze, Reynaldo	Co Investigator	1.11			80,000	7,375	0	7,375
Palaci, Moses	Co Investigator	1.11			60,000	5,531	0	5,531
Rodriguez, Rodrigo	Co Investigator	1.11			65,000	5,992	0	5,992
Vinhas, Solange	Lab Tech	3.65			9,000	2,738	0	2,738
TBN	Admin Asst.	3.65			8,000	1,427	0	1,427
Stringari, Lorenzo	Lab Tech	3.65			9,000	2,738	0	2,738
Molina, Lucilia	Med Officer	2.88			12,000	2,876	0	2,876
SUBTOTALS →						Cont		Cont

CONSULTANT COSTS	
EQUIPMENT *(Itemize)*	
SUPPLIES *(Itemize by category)* Lab Supplies AFB Cultures Smears Programmatic Supplies	667
TRAVEL International Travel	1,350
INPATIENT CARE COSTS	
OUTPATIENT CARE COSTS	
ALTERATIONS AND RENOVATIONS *(Itemize by category)*	
OTHER EXPENSES *(Itemize by category)* Vehicle Maintenance/Fuel Laboratory Equipment Maintenance Contract	2,195
CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7a, Face Page)*	$ See next pg
CONSORTIUM/CONTRACTUAL COSTS	FACILITIES AND ADMINISTRATIVE COSTS
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD	$ See next pg.

DETAILED BUDGET FOR INITIAL BUDGET PERIOD DIRECT COSTS ONLY	FROM 8/01/20	THROUGH 07/31/21

List PERSONNEL *(Applicant organization only)*
Use Cal, Acad, or Summer to Enter Months Devoted to Project
Enter Dollar Amounts Requested *(omit cents)* for Salary Requested and Fringe Benefits

NAME	ROLE ON PROJECT	Cal. Mnths	Acad. Mnths	Summer Mnths	INST.BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
From page 1 of 2						50,313	0	50,313
Cazarini, Bruna	Data Manager	2.63			10,000	2,194	0	2,194
Borges, Andressa	Nurse	1.43			12,000	1,427	0	1,427
Marques, Patricia	Study Coordinator	6.08			7,210	3,651	0	3,651
TBN	Driver	6.08			6,000	3,042	0	3,042
SUBTOTALS →						39,998	0	39,998

CONSULTANT COSTS	
EQUIPMENT *(Itemize)*	
SUPPLIES *(Itemize by category)* From Page 1 of 2	667
From Page 1 of 2	1,350
INPATIENT CARE COSTS	
OUTPATIENT CARE COSTS	
ALTERATIONS AND RENOVATIONS *(Itemize by category)*	
OTHER EXPENSES *(Itemize by category)* From Page 1 of 2	2,195

CONSORTIUM/CONTRACTUAL COSTS	DIRECT COSTS	
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7a, Face Page)*		$ 44,210
CONSORTIUM/CONTRACTUAL COSTS	FACILITIES AND ADMINISTRATIVE COSTS	3,537
TOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD		$ 47,747

BUDGET JUSTIFICATION – Núcleo de Doenças Infecciosas (NDI), Vitória, Brazil: (Dietze, R-Project 1) Yr 7

PERSONNEL

Reynaldo Dietze, M.D., M.T.M.H., Ph.D., Subcontract Principal Investigator, (1.11 Calendar Months requested), Dr. Dietze is Associate Professor of Medicine and Director of the Núcleo de Doenças Infecciosas (NDI) at the Federal University of Espírito Santo (UFES), Vitória, ES, Brazil. Dr. Dietze is the former President of the Brazilian Society of Tropical Medicine, and is the Clinical Trial Coordinator of the Brazilian TB Research Network and member of the TB committee of the TB National Program at the Ministry of Health. Dr. Dietze completed his Master Degree in Tropical Medicine at the University of Brasilia under the tutorship of the late Prof. Philip Davis Marsden from the London School of Hygiene & Tropical Medicine. During this time Dr. Dietze gained experience in the field of schistosomiasis, malaria, leishmaniasis and Chagas' disease. After completing doctoral studies in Infectious Diseases at the University of São Paulo, Dr. Dietze returned to his home town Vitória in the Espírito Santo state. He joined the UFES and founded the NDI in 1990. He started then to recruit a multi-disciplinary research team for the study of epidemiology, microbiology, molecular biology, and immunology of infectious diseases. The initial two research lines created were in leishmaniasis with WRAIR and TB initially with Duke University, then Case Western Reserve University, University of Medicine & Dentistry of New Jersey (UMDNJ), and now Boston University/Boston Medical Center. In collaboration with Duke University and Becton-Dickinson, Inc., a state of the art TB laboratory was created at the NDI and initially supervised by Dr. Mark Perkins currently at FIND. In 1994, Dr. Dietze started his collaboration with Dr. Ellner and the TB Research Unit which continues to this day. Dr. Dietze has participated in phase I/II clinical trials in TB, schistosomiasis, leishmaniasis, sporotrichosis, and candidiasis in immunosuppressed patients. Dr. Dietze is therefore highly experienced in clinical trial design and logistical and regulatory issues related to IND trials as well as leading multidisciplinary international collaborations. Dr. Dietze is the primary Brazilian investigator for the study and is responsible for facilitating the field work and coordinating with the Brazilian authorities.

Moises Palaci, Ph.D,, Co-Investigator, (1.11 Calendar Months), Dr. Palaci is the director of the Mycobacteriology Lab at the NDI and the former director of the TB laboratory at the Adolfo Lutz Institute in São Paulo, a national TB reference laboratory. He oversees mycobacteriology laboratory staff including one biologist, one pharmacist/biochemist, three technicians, and a secretary. He insure TB case diagnosis and work with TB isolate collection.

Rodrigo Rodrigues, Ph.D., Co-Investigator, (1.11 Calendar Months), Dr. Rodrigues is Head of the Department of Pathology and Adjunct Professor of Immunology, Federal University of Espirito Santo. He has extensive experience in immunology, infectious diseases and parasitology, with an emphasis on immunology and cellular immunology. Dr. Rodrigues directs the research immunology and coordinate activities with Dr. Salgame at Rutgers University.

Solange Vinhas, Laboratory Technician, (3.65 Calendar Months). Laboratory technician who will work under the direction of Drs. Dietze, Rodrigues and Palaci. She conducts research protocol assays as per standard operating procedures for the protocol – microbiologic or immunologic. She will work with Dr. Palaci in preparing AFB smears/cultures and liquid media for MGIT analysis.

Lucilia Molina, Medical Officer, (2.88 Calendar Months), is a medical officer for the project responsible for clinical evaluation/screening of all household contacts, completes clinical case report forms, dispenses treatment as per standard of care and serves as the primary medical officer for all medical activities.

Patricia Margues, Study Coordinator, (6.08 Calendar Months), Ms. Margues is the study coordinator, and team leader working with the investigators on all aspects of study conduct, quality assurance and control. She leads the regulatory communications, including submitting the IRB application, progress reports and any protocol reports – local and national IRBs. She coordinates work with the BMC Study Coordinator in coordinating study activity, providing regular reports on progress, identifying obstacles and insuring quality data collection and validity assurance.

Lorenzo Stringari, Laboratory Technician, (3.65 Calendar Months). Laboratory technician works under the direction of Drs. Dietze, Rodrigues and Palaci. He conducts research protocol assays as per standard operating procedures for the protocol – microbiologic or immunologic. He works with Palaci in preparing AFB smears/cultures and liquid media for MGIT analysis.

Andressa Silva Borges, Research Nurse, (1.43 Calendar Months), Responsible for recruitment and follow-up of Index Cases and Household Contacts. This will involve screening participants, obtaining informed consent, administering questionnaires, placing and reading TSTs/QFTs, drawing blood samples, reviewing medical records, and scheduling follow-up visits.

Bruna Cazarini, Data Manager, (2.63 Calendar Months), Ms Cazarini is trained in Excel, Access and TeleForm data management software. She is currently responsible for providing quality assurance/quality control of the case report forms, scanning and uploading to the Data Center in Boston, and working with staff to resolve queries. She will also be responsible for coordinating regulatory activities at the site and with BMC.

TBN, Driver, (6.08 Calendar Months). Mr. Canal will work with the research nurses to track and follow-up on study participants, bring participants in to NDI for study visits, and bring participant samples to the NDI laboratories.

TBN, Administrative Assistant, (3.65 Calendar Months). The Project Administrative Assistant deals with staffing, supply procurement, equipment maintenance, processing and monitoring regulatory and institutional approvals and subcontract/fiscal management.

No fringe benefits are requested for NDI Research Staff.

EQUIPMENT

None

SUPPLIES

Office Supplies ($157). Funds requested to defray the cost of office supplies – paper, toner, envelopes for regulatory submissions, contractual communications/invoices.

Laboratory/Clinical Supplies ($255). Funds requested to partially defray the cost of typical laboratory supplies – disposable plasticware (e.g. plates, pipettes), replacement of glassware,

personal protective gear (e.g. lab gloves, N9 masks), reagents, cleaning supplies and other consumables used in all proposed laboratory activities. Clinical supplies for index case and household contact participant exams and samples collection include gloves, vacutainers, needles, swabs, bandaids for phlebotomy, Quantiferon Gold in Tube tests.

AFB Cultures/Smears ($255). Funds are requested to defray the expense of setting up/storing and reading acid fast bacilli (AFB) cultures (LJ slants and liquid MGIT) and smears on all study participants at baseline and required follow-up time points to establish growth or no growth (clearance) of MTB. Combination of culture and smear are the presumptive diagnosis of TB.

TRAVEL

International Travel ($1350) – Partially defray travel for Co-Investigator trip to Boston to work on protocol activities, implementation/evaluation of quality assurance/control measures, review study progress and work with investigators at improving study conduct.

OTHER EXPENSES

Laboratory Equipment Maintenance ($695) requested to support routine laboratory equipment maintenance and service contracts. Immunologic and Microbiologic equipment includes biosafety hoods, refrigerator for reagents/materials, -80 freezers storing protocol samples, BACTEC MGIT system for liquid culture.

Vehicle Maintenance/Fuel ($1,500). Funds requested to defray the cost of typical project vehicle maintenance and fuel usage. Project vehicle is used for home-visiting to visit with study participants, households, track participants who defaulted on scheduled clinic visits, run participant blood samples back to the laboratory for immediate processing, hand-deliver IRB submissions to local and federal government IRBs, and pick up laboratory and clinical supplies as needed.

Indirect Costs:

Indirect costs are calculated at 8% of total direct costs per NIH guidelines for foreign institutions.

Insert Name of Subcontractor
Insert Address of Subcontractor

Exhibit D Sample Invoice

Send Invoices To:
accountspayable@finance.rutgers.edu

Invoice#:
Rutgers Account#:
Organizational ID#:
Grant Period:
Reporting Period:
Rutgers Subcontract #:
Rutgers Purchase Order #:

FINAL ☐ **INTERIM** ☐ *Check Appropriate Box*

Total Amount of Award **$0.00**

Total Amount Received to Date **$0.00** **Required Cost Sharing *** **$** _____

EXPENDITURES	APPROVED BUDGET	PREVIOUSLY REPORTED	CURRENT EXPENSE	CUMULATIVE EXPENSES	CURRENT Cost Sharing*	CUMULATIVE Cost Sharing*
Salaries & Wages	0.00	0.00	0.00	0.00	0.00	0.00
Fringe Benefits	0.00	0.00	0.00	0.00	0.00	0.00
Supplies	0.00	0.00	0.00	0.00	0.00	0.00
Travel	0.00	0.00	0.00	0.00	0.00	0.00
Other Services	0.00	0.00	0.00	0.00	0.00	0.00
	0.00	0.00	0.00	0.00	0.00	0.00
MTDC	0.00	0.00	0.00	0.00	0.00	0.00
Equipment	0.00	0.00	0.00	0.00	0.00	0.00
Other Expenses	0.00	0.00	0.00	0.00	0.00	0.00
TOTAL DIRECT EXPENDITURES	0.00	0.00	0.00	0.00	0.00	0.00
Facilities and Administrative Cost %=_____ of MTDC	0.00	0.00	0.00	0.00	0.00	0.00
TOTAL COSTS	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00

PAYMENT REQUESTED THIS INVOICE **$0.00**

***NOTE:** Cost Sharing information must be provided if cost sharing is required.

Required for All Invoices :
"I certify that the above charges accurately represent actual expenditures incurred during the period reported under the terms and conditions of the subaward, that any prior approvals required have been obtained and that all expenses are allowable for this project."

_____
Signature of Authorized Certifying Fiscal Official ***Date***

Please Provide:

Name of Financial Contact **Telephone** **Email Address**

Required For FINAL Invoices Only:
"I certify that the above charges accurately represent actual expenditures incurred and personnel effort provided during the period reported in accordance with the terms and conditions of the award agreement."

_____
Signature of Subcontractor's Project Investigator ***Date***

Subaward Amendment

Pass-through Entity ("PTE")	Subawardee
Name: Rutgers, The State University Address: Office of Research & Sponsored Programs 33 Knightsbridge Road, 2nd Floor East Wing Piscataway, NJ 08854-3925 DUNS: 078795851 Project ID: 828384	**Institution / Organization ("COLLABORATOR")** Name: Fundacao Espirito Santense De Tecnologia FEST Address: Av. Fernando Ferrari 845 Campus Universitario Vitoria (Goiaberas) 29075-010 Brazil
Prime Sponsor: NIH Prime Award: 5U19AI111276-08 FAIN: U19AI111276	Subaward No. 1629 R & D ☒ Yes ☐ No Modification No. 1
Rutgers Principal Investigator: Jerrold Ellner	Subawardee Principal Investigator: Reynaldo Dietze

CFDA Number: 93.855 CFDA Title: Allergy and Infectious Diseases Research

Project Title: Biomarkers and Mechanisms of Paucibacillary and Latent Tuberculosis

The following amends the original Subaward Agreement Terms and Conditions:

1. Change the Subawardee's legal name and payment address from Fundacao de Apoio Cassiano Antonio Moraes- FUCAM Av. Marechal Campos, 1468 Maruipe Vitoria – ES CEP 29040-091 to Fundacao Espirito Santese de Tecnologia FEST Av. Fernando Ferrari 845 Campus Universitario Vitoria (Goiabeiras) 29075-010 BRAZIL

(NOTE: A new purchase order will be issued with this name and address and will include the balance of closed purchase order number 1399775. Please use the new purchase order number on invoices)

2. All other terms and conditions of this Subaward Agreement remain in full force and effect.

Revisions to Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (Uniform Guidance) are effective November 12, 2020, except for the amendments to Sections 200.216 and 200.340, which are effective as of August 13, 2020.

By an Authorized Official of Pass-through Entity:	By an Authorized Official of SUBAWARDEE:
Chrissa Papaioannou, PE, CRA Digitally signed by Chrissa Papaioannou, PE, CRA Date: 2020.11.16 13:20:31 -05'00'	ARMANDO BIONDO FILHO:37671740730 Assinado de forma digital por ARMANDO BIONDO FILHO:37671740730 Dados: 2021.05.10 11:39:09 -03'00'
Name: Chrissa Papaioannou, PE, CRA	Name: Armando Biondo Filho
Title: Assistant Director, RSP	Title: Superintendente/Dirigente FEST
11/16/2020 Date	may 10, 2021 Date