FDP Foreign Cost Reimbursement Subaward

Run Template

Federal Awarding Agency: National Institutes of Health (NIH)

Pass-Through Entity (PTE):	**Subrecipient:**
Vanderbilt University Medical Center	Universidade Federal de Sao Paulo - UNIFESP
PTE PI: Catherine McGowan	Sub PI: Regina Succi and Daisy Machado
PTE Federal Award No: 2U01AI069923-17	Subaward No: VUMC98406

Project Title: Caribbean, Central, and South America Network for HIV Epidemiology (CCASAnet)

Subaward Period of Performance (Budget Period): Start: 07/01/2021 ? End: 04/30/2022 ?	Amount Funded This Action (USD): $ 52,864.00
Estimated Project Period (if incrementally funded): Start: 06/15/2006 End: 04/30/2026	Incrementally Estimated Total (USD): $ 52,864.00

Terms and Conditions

1. PTE hereby awards a cost reimbursable Subaward, (as determined by 2 CFR 200.330), 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), breakdown by major cost category, 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 Administrative Contact, as shown in Attachment 3A, NO LATER THAN 30 Days after Subaward end date. The final statement of costs shall constitue 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 PTE's Authorized Official Contact, and the Subrecipient's Authorized Official Contact as shown in Attachments 3A and 3B. Any such 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 Bilaterally Unilateral modifications shall be consdered 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 PTE's Authorized Official Contact, and the Subrecipient'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.

KB

By an Authorized Official of Pass-through Entity:	By an Authorized Official of Subrecipient:
_____ Date	DocuSigned by: Maria José da Silva Fernandes 215CE61E6F0349D... 20/4/2023
Name: John Plummer	Name: Maria José da Silva Fernandes Date
Title: Interim Director, Office of Contracts Management	Title: Diretora Presidente

Read and Acknowledged: _____ Catherine McGowan Date

_____ FUNDAÇÃO DE APOIO À UNIVERSIDADE FEDERAL DE SÃO PAULO

Attachment 1
Certifications and Assurances

Subaward Number: VUMC98406

By signing the Subaward, the Authorized Official of Subrecipient certifies, to the best of his/her knowledge and belief, that:

Certification Regarding Lobbying (2 CFR 200.450)
No U.S. Federal appropriated funds have been paid or will be paid, by or on behalf of the Subrecipient, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any U.S. Federal contract, the making of any U.S. Federal grant, the making of any U.S. Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any U.S. Federal contract, grant, loan, or cooperative agreement.

If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or intending to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the Subrecipient shall complete and submit Standard Form -LLL, "Disclosure Form to Report Lobbying," to the PTE.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by 31 U.S.C. 1352. Any person who fails to file the required certification shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each such failure.

Debarment, Suspension, and Other Responsibility Matters (2 CFR 200.213 and 2 CFR 180)
All foreign institutions and international organizations, except for foreign governments or governmental entities, public international organizations, or foreign-government-owned or -controlled entities (in whole or in part) are subject to the Debarment, Suspension and Other Responsibility Matters.

○ Subrecipient certifies by signing this Subaward that neither it, nor its principals, are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from participation in this transaction by any U.S. Federal Department or Agency.

Or

◉ Subrecipient is either a foreign government or governmental entity, public international organization, or foreign-government-owned or -controlled entity (in whole or in part); and it IS NOT subject to the debarment or suspension certification requirement or to debarment or suspension under 45 CFR Part 75.

Audit and Access to Records
Subrecipient certifies by signing this Subaward that it complies with the Uniform Guidance, will provide notice of the completion of required audits and any adverse findings which impact this Subaward Agreement as required by parts 200.501- 200.521, and will provide access to records as required by parts 200.336, 200.337, and 200.201 as applicable.

All financial and related documentation, including but not limited to financial reports, invoices, financial audits, or receipts, shall be provided to PTE in English at Subrecipient's expense.

Protecting Life in Global Health Assistance (Mexico City Policy)
Subrecipient certifies that no funds granted under this Subaward will be used to fund organizations or programs that support or participate in the management of a program of coercive abortion or involuntary sterilization. See the NOA, Attachment 2 of this Subaward and/or Federal Awarding Agency's terms and conditions for further details.

☒ This regulation applies to the Federal Award and is flowed down to Subrecipient.

Use of Name
Neither party shall use the other party’s name, trademarks, or other logos in any publicity, advertising, or news release without the prior written approval of an authorized representative of that party. The parties agree that each party may use factual information regarding the existence and purpose of the relationship that is the subject of this Subaward for legitimate business purposes, to satisfy any reporting and funding obligations, or as required by applicable law or regulation without written permission from the other party. In any such statement, the relationship of the parties shall be accurately and appropriately described.

Foreign Corrupt Practices
Subrecipient agrees to use funds in compliance with (1) the U.S. Foreign Corrupt Practices Act; (2) Subrecipient agrees that, under this Subaward, it will not offer, promise, or provide (or authorize the offer, promise, or provision of), directly or indirectly, anything of value to any government official, political party official, political candidate, or employee thereof, or to any other third party, for the purpose of obtaining or retaining business or obtaining any illegal benefit or advantage.

Export Controls
Each Party is responsible for determining whether its performance is subject to, and in compliance with, U.S. export control laws and regulations ("U.S. Export Controls"), including but not limited to the Export Administration Regulations - EAR (Department of Commerce), the International Traffic in Arms Regulations - ITAR (Department of State), the sanctions programs embodied in regulations administered by the Department of the Treasury's Office of Foreign Assets Control (OFAC), the U.S. anti-boycott laws and regulations (EAA) and U.S. anti-terrorism financing laws and regulations.

☒ Attachment 8 of this Subaward includes additional applicable terms related to Export Controls.

The Subrecipient shall require that the language of the certifications above in this Attachment 1 be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

Attachment 2
Federal Award Terms and Conditions

Subaward Number: VUMC98406

Required Data Elements

The data elements required by Uniform Guidance are incorporated in the attached Federal Award. ?

Awarding Agency Institute (If Applicable): National institute of Allergy and Infectious Diseases

Federal Award Issue Date	FAIN	CFDA No.
06/01/21	U01AI069923	93.855

CFDA Title: Allergy and Infectious Diseases Research

Key Personnel Per NOA: ?

This Subaward Is:

■ Research & Development ■ Subject to FFATA

General Terms and Conditions

By signing this Subaward, Subrecipient agrees to the following:

1. To abide by the conditions on activities and restrictions on expenditure of federal funds in appropriations acts that are applicable to this Subaward to the extent those restrictions are pertinent. This includes any recent legislation noted on the Federal Awarding Agency's website:
   https://grants.nih.gov/policy/notices.htm
2. 2 CFR 200
3. The Federal Awarding Agency's grants policy guidance, including addenda in effect as of the beginning date of the period of performance or as amended found at:
   http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf
4. Research Terms and Conditions, including any Federal Awarding Agency's Specific Requirements found at:
   https://www.nsf.gov/awards/managing/rte.jsp except for the following :
   a. No-cost extensions require the written approval of the PTE. Any requests for a no-cost extension shall be directed to the Administrative Contact shown in Attachment 3A, not less than 30 days prior to the desired effective date of the requested change.
   b. Any payment mechanisms and financial reporting requirements described in the applicable Federal Awarding Agency Terms and Conditions and Agency-Specific Requirements are replaced with Terms and Conditions (1) through (4) of this Subaward; and
   c. Any prior approvals are to be sought from the PTE and not the Federal Awarding Agency.
   d. Title to equipment as defined in 2 CFR 200.33 that is purchased or fabricated with research funds or Subrecipient cost sharing funds, as direct costs of the project or program, shall vest in the Subrecipient subject to the conditions specified in 2 CFR 200.313.
   e. Prior approval must be sought for a change in Subrecipient PI or change in Key Personnel (defined as listed on the NOA).
5. Treatment of program income: Additive

Special Terms and Conditions:

Data Sharing and Access:
Subrecipient agrees to comply with the Federal Awarding Agency's data sharing and/or access requirements as reflected in the NOA or the Federal Awarding Agency's standard terms and conditions as referenced in General Terms and Conditions 1-4 above.

No additional requirements

Data Rights:
Subrecipient grants to PTE the right to use data created in the performance of this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Copyrights:

Subrecipient Grants to PTE an irrevocable, royalty-free, non-transferable, non-exclusive right and license to use, reproduce, make derivative works, display, and perform publicly any copyrights or copyrighted material (including any computer software and its documentation and/or databases) first developed and delivered under this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its PTE Federal Award.

Subrecipient grants to PTE the right to use any written progress reports and deliverables created under this Subaward solely for the purpose of and only to the extent required to meet PTE's obligations to the Federal Government under its Federal Award.

Promoting Objectivity in Research (COI):
Subrecipient must designate herein which entity's Financial Conflicts of Interest policy (COI) will apply: Subrecipient

If applying its own COI policy, by execution of this Subaward, Subrecipient certifies that its policy complies with the requirements of the relevant Federal Awarding Agency as identified herein: NIH - 42 CFR Part 50 Subpart F

Subrecipient shall report any financial conflict of interest to PTE's Administrative Representative or COI contact, as designated on Attachment 3A. Any financial conflicts of interest identified shall, when applicable, subsequently be reported to Federal Awarding Agency. Such report shall be made before expenditure of funds authorized in this Subaward and within 45 days of any subsequently identified COI.

Governing Language:
In the event that a translation of this Subaward is prepared and signed by the parties, and a conflict arises between the English version and other language version, this English language version shall be the official version and shall govern and control.

Governing Law:
The Parties acknowledge that PTE is subject to the laws of the United States. The parties hereby agree that nothing in this Subaward or any of its attachments or references shall be deemed to require either Party to breach any mandatory statutory law under which each Party is operating.

Patents:
Pursuant to Public Law 96-517, as amended by Public law 98-620, title to any invention or discovery made or conceived under this Subaward shall vest in the Subrecipient. Subrecipient shall promptly notify PTE as shown in Attachment 4 hereto.

Subrecipient hereby grants to PTE a royalty-free, non-exclusive license for research purposes to any Subrecipient invention or discovery under this Subaward.

Second Tier Subawards:
Subrecipient may not issue any subawards under this Subaward without the express prior written consent of PTE. In the event that such consent is granted, all assurances, certifications, and terms included in this Subaward shall be flowed down to the second tier subaward.

Disputes:
The Parties shall attempt to resolve disputes through good faith negotiations. Any dispute arising under, or related to, this Subaward shall be resolved to the maximum possible extent through informal dispute resolution. Unresolved issues shall be arbitrated in accordance with the International Arbitration Rules of the American Arbitration Association.
Arbitration Association.

Additional Terms ?

The FUNDAÇÃO DE APOIO À UNIVERSIDADE FEDERAL DE SÃO PAULO is responsible for the administrative management of the financial resources of the international contracts, including research contracts, of the UNIVERSIDADE FEDERAL DE SÃO PAULO, and is headquartered at Rua Dr. Diogo de Faria, 1087, sets 801-804, São Paulo – SP, Brazil, 04037 -003, under CNPJ/MF 07.437.996/0001-46 (hereinafter “FUSP” or “Collaborating Organization”). Further, Subrecipient will not subcontract any work under this Subaward to a third party without PTE's written consent.

See Attachment 7

Work Involving Human or Vertebrate Animals (Select Applicable Options)

☐ No Human or Vertebrate Animals

☒ Human Subjects

IRB Upon Request

☐ Vertebrate Animals

The PTE requires verification of IRB and/or IACUC approval be sent to the *Administrative Contact* *as required above:*

Subrecipient agrees that any non-exempt human and/or vertebrate animal research protocol conducted under this Subaward shall be reviewed and approved by the appropriate Institutional Review Board (IRB) and/or its Institutional Animal Care and Use Committee (IACUC), as applicable and that it will follow current and duly approved research protocols for all periods of the Subaward involving human and/or vertebrate animal research. If Subrecipient is using its own IRB and/or IACUC, Subrecipient certifies that its IRB and/or IACUC are in full compliance with applicable state and federal laws and regulations. The Subrecipient certifies that any submitted IRB/IACUC approval represents a valid, approved protocol that is entirely consistent with the Project associated with this Subaward. In no event shall Subrecipient invoice or be reimbursed for any human or vertebrate animals related expenses incurred in a period where any applicable IRB/IACUC approval is not properly in place.

Human Subjects Data (Select One) Applicable

Human Subjects Data will be exchanged under this Subaward (check all that apply):

☒ From Subrecipient to PTE

☐ From PTE to Subrecipient

The PTE will set forth the terms of the exchange of Human Subjects Data (Select One):

In Attachment 7.

This section left intentionally blank

Attachment 3A
Pass-Through Entity (PTE) Contacts

Subaward Number: VUMC98406

PTE Information

Entity UEI/DUNS Name: Vanderbilt University Medical Center

Legal Address:
1161 21st Avenue South
Medical Center North, Suite D3300
Nashville, TN 37232-0011

Website: www.vumc.org

PTE Contacts

Central Email: research.contracts@vumc.org

Principal Investigator Name: Catherine McGowan

Email: c.mcgowan@vumc.org Telephone Number: 615 936-1174

Administrative Contact Name: Hilary Vansell

Email: hilary.vansell@vumc.org Telephone Number: 615 875-3991

COI Contact email (if different to above):

Financial Contact Name: Paula Yarbrough

Email: vumc.finance.invoices@vumc.org Telephone Number: 615 322-2974

Email invoices? (●) Yes ( ) No Invoice email (if different): Same as above

Authorized Official Name: John Plummer

Email: research.contracts@vumc.org Telephone Number: 615 322-2281

PI Address:

Infectious Disease - Medicine
One Hundred Oaks, Suite 37189
719 Thompson Lane
Nashville, TN 37204

Administrative Address:

Office of Contracts Management
3319 West End Ave., Suite 100
Nashville, TN 37203
w/copy to: PI Address

Invoice Address:

PI Address w/copy to: Department of Finance
3319 West End Ave., Suite 800
Nashville, TN 37203

Attachment 3B

Subrecipient Contacts

Subaward Number: VUMC98406

Subrecipient Information for FFATA reporting

Entity UEI/DUNS Name:

EIN No.:

Institution Type: Non-Domestic (non-US) Entity

UEI/DUNS:

Currently registered in SAM.gov: ◯ Yes ◯ No

Exempt from reporting executive compensation: ◯ Yes ◯ No *(if no, complete 3Bpg2)*

Parent UEI/DUNS:

This section for U.S. Entities:

Zip Code Look-up

Congressional District:

Zip Code+4:

Place of Performance Address ?

Subrecipient Contacts

Central Email:

Website:

Principal Investigator Name: Regina Succi and Daisy Machado

Email: Telephone Number:

Administrative Contact Name:

Email: Telephone Number:

Financial Contact Name:

Email: Telephone Number:

Invoice Email:

Authorized Official Name:

Email: Telephone Number:

Legal Address:

Administrative Address:

Payment Address:

Attachment 3B-2

Highest Compensated Officers

Subaward Number: VUMC98406

Subrecipient:

Institution Name: Universidade Federal de Sao Paulo - UNIFESP

PI Name: Regina Succi and Daisy Machado

Highest Compensated Officers

The names and total compensation of the five most highly compensated officers of the entity(ies) must be listed if the entity in the preceding fiscal year received 80 percent or more of its annual gross revenues in Federal awards; and $25,000,000 or more in annual gross revenues from Federal awards; and the public does not have access to this information about the compensation of the senior executives of the entity through periodic reports filed under section 13(a) or 15(d) of the Securities Exchange Act of 1934 (15 U.S.C. §§ 78m(a), 78o(d)) or section 6104 of the Internal Revenue Code of 1986. See FFATA § 2(b)(1) Internal Revenue Code of 1986.

Officer 1 Name:

Officer 1 Compensation:

Officer 2 Name:

Officer 2 Compensation:

Officer 3 Name:

Officer 3 Compensation:

Officer 4 Name:

Officer 4 Compensation:

Officer 5 Name:

Officer 5 Compensation:

Attachment 4
Reporting and Prior Approval Terms

Subaward Number: VUMC98406

Subrecipient agrees to submit the following reports (PTE contacts are identified in Attachment 3A):

Technical Reports:

☐ Monthly technical/progress reports will be submitted to the PTE's Administrative Contact within 15 days of of the end of the month.

☐ Quarterly technical/progress reports will be submitted within 30 days after the end of each project quarter to the PTE's Administrative Contact .

☒ Annual technical / progress reports will be submitted 60 days prior to the end of each budget period to the PTE's Administrative Contact . Such report shall also include a detailed budget for the next Budget Period, updated other support for key personnel, certification of appropriate education in the conduct of human subject research of any new key personnel, and annual IRB or IACUC approval, if applicable.

☒ A Final technical/progress report will be submitted to the PTE's Administrative Contact within 60 days of the end of the Project Period or after termination of this award, whichever comes first.

☒ Technical/progress reports on the project as may be required by PTE's Administrative Contact in order for the PTE to satisfy its reporting obligations to the Federal Awarding Agency.

Prior Approvals:

Carryover:

Carryover is restricted for this subaward by the: Federal Awarding Agency

Carryover instructions and requirements are as stated by the Federal Awarding Agency guidance or as shown below.

Submit carryover requests to the Administrative Contact .

Other Reports:

☒ In accordance with 37 CFR 401.14, Subrecipient agrees to notify both the Federal Awarding Agency via iEdison and PTE's Administrative Contact within 60 days after Subrecipient's inventor discloses invention(s) in writing to Subrecipient's personnel responsible for patent matters. The Subrecipient will submit a final invention report using Federal Awarding Agency specific forms to the PTE's Administrative Contact within 60 days of the end of the Project Period to be included as part of the PTE's final invention report to the Federal Awarding Agency.

A negative report is required: Upon Request

☐ Property Inventory Report (only when required by Federal Awarding Agency), specific requirements below.

☐ Each invoice must be accompanied by a brief technical report, and: (i) be sequentially numbered; (ii) indicate the date(s) of performance by the Subrecipient; (iii) state the Purchase Order number, the title of the project and the name of the PTE Principal Investigator; (iv) itemize costs in detail, in accordance with the Subaward budget; (v) include both current costs and cumulative costs; (vi) include the Subrecipient certification, with authorized official's signature, that costs are appropriate and accurate and that payment has not yet been received; and (vii)) be supported by a general ledger report originating directly from the Subrecipient's financial record keeping system. PTE may request supporting documentation in certain categories prior to or subsequent to approving the invoice. Supporting documentation includes, but is not limited to, travel receipts, purchase orders, invoices for services or supplies, or time records, Property Inventory Report; frequency, type, and submission instructions listed here and only to be used when required by PTE Federal Award.

Other Special Reporting Requirements: ?

Subaward Number: VUMC98406

Attachment 5
Statement of Work, Cost Sharing, Indirects & Budget

Statement of Work

○ Below ◉ Attached, 3 pages

If award is FFATA eligible and SOW exceeds 4000 characters, include a *Subrecipient Federal Award Project Description*

Scope of Work

Universidade Federal de São Paulo (UNIFESP), São Paulo, Brazil
The Brazil UNIFESP site will participate in the Adolescent and Young Adult Network of IeDEA (AYANI), in addition to the CCASAnet retrospective cohort. The site will work to enroll 30 participants into the AYANI cohort per protocol and provide, at a minimum, annual database transfers of the CCASAnet retrospective cohort. Drs. Succi and Machado, along with the co-investigators, will be actively involved in the implementation of the CCASAnet activities, studies, and scientific agenda, enhancing the site participation in its development and implementation. Drs. Succi and Machado will ensure site targets and goals are met and will have overall responsibility for the site.

Budget Information

Indirect Information Indirect Cost Rate (IDC) Applied: 8 %

Rate Type: Modified Total Direct Costs

Cost Sharing ? No

If Yes, include Amount: $

Budget Details

○ Below ◉ Attached, 3 pages

Budget and Budget Justification are attached.

Budget Totals

Direct Costs	$ 48,949.00
Indirect Costs	$ 3,916.00
Total Costs	$ 52,864.00

All amounts are in United States Dollars

Principal Investigator/Program Director *(Last, first, middle)*: McGowan, Catherine — Brazil UNIFESP

DETAILED BUDGET FOR INITIAL BUDGET PERIOD — FROM 7/1/2021 THROUGH 4/30/2022

List PERSONNEL *(applicant organization only)* — PROJECTS: Parent, AYANI

Use Cal, Acad, or Summer to Enter Months Devoted to Project — *cells in grey are calculated cells, adjust cells in

Enter Dollar Amounts Requested (omit cents) for Salary Requested and Fringe Benefits

NAME	ROLE ON PROJECT	Cal. Mnths	Effort %	Sum. Mnths	INST.BASE SALARY	SALARY REQUESTED	FRINGE BENEFITS	TOTAL
Regina Succi	PI	6.00	50.0%			8,750	-	8,750
Daisy Machado	PI	6.00	50.0%			8,750	-	8,750
Aída Gouvea	Co-investigator	6.00	50.0%			7,500	-	7,500
Fabiana do Carmo	Co-investigator	3.00	25.0%			4,958	-	4,958
		0.00	0.0%			-	-	-
		0.00	0.0%			-	-	-
		0.00	0.0%			-	-	-
		0.00	0%			-	-	-
	SUBTOTALS					**29,958**	**-**	**29,958**

CONSULTANT COSTS				0
EQUIPMENT *(Itemize)*				0
SUPPLIES *(Itemize by category)*				
Office Supplies and Software	$ 480			
Study Supplies	$ 2,000			2,480
TRAVEL		#	Cost	
Annual CCASAnet Meeting	$ 6,600	3	2,200	6,600
PATIENT CARE COSTS		INPATIENT		
		OUTPATIENT		
ALTERATIONS AND RENOVATIONS *(Itemize by category)*				0
OTHER EXPENSES *(Itemize by category)*				
AYANI Participant Costs	$ 8,910			
Telecommunications	$ 1,000			9,910
SUBTOTAL DIRECT COSTS FOR INITIAL BUDGET PERIOD *(Item 7a, Face Page)*				**48,948**
CONSORTIUM/CONTRACTUAL COSTS			FACILITIES AND ADMINISTRATIVE COSTS	3,916
TOTAL COSTS FOR INITIAL BUDGET PERIOD				**52,864**

SBIR/STTR Only: FEE REQUESTED

Budget Justification

Universidade Federal de São Paulo (UNIFESP), São Paulo, Brazil

The Brazil UNIFESP site will participate in the Adolescent and Young Adult Network of IeDEA (**AYANI**) in addition to the CCASAnet retrospective core cohort.

Personnel

Regina Succi, MD, Site Co-Principal Investigator (6.0 calendar months, 50% effort)
Dr. Succi will be the Co-Principal Investigator at the UNIFESP Brazilian site. She will manage the administrative responsibilities of the site and supervise the work of co-Investigator, Dr. Gouvea. Dr. Succi will provide scientific input together with the rest of local investigators during the duration of the project, with a particular focus on pediatric antiretroviral therapies and the pediatric continuum of care. She will be part of writing committees for several papers and will provide input and comments for all other manuscripts written by the network. For the AYANI cohort, Dr. Succi will provide scientific input for the duration of the project, and will participate in writing committees for concept sheets, abstracts, and manuscripts.

Daisy Machado, MD, Site Co-Principal Investigator (6.0 calendar months, 50% effort)
Dr. Machado will be the Co-Principal Investigator at the UNIFESP Brazilian site. She will be responsible for the supervision of accurate data collections and timely data submissions. She will provide scientific input together with the rest of local investigators for the duration of the project, with a particular focus on pediatric opportunistic infections and non-communicable diseases. She will work with the CCASAnet Data Coordinating Center on the expansion of the CCASAnet pediatric data transfer protocol and associated coding lists for pediatric conditions. She will be part of writing committees for several papers and will provide input and comments for all other papers written by the network.

Aída F. Barbosa Gouvêa, MD, Co-Investigator (6.0 calendar months, 50% effort)
Dr. Gouvêa is a clinical researcher. She will verify the quality of medical data in all the projects, including validation of pediatric clinical endpoints, and will work closely with the data manager for the prompt generation of comprehensive data. She will have progressive responsibilities on specific projects in order to enhance her skills to be able to carry out her own projects. She will be supervised directly by the site PIs, Dr. Succi and Dr. Machado.

Fabiana do Carmo, MD, Co-Investigator (3.0 calendar months, 25% effort)
Dr. do Carmo is a clinical researcher with specific adolescent expertise. She will assist with all project-related activities of the AYANI cohort and will work closely with Drs. Succi and Machado to meet milestones and ensure data completeness.

Travel (Foreign)
We request $6,600 per year to cover travel, lodging, and per diem for three members of the UNIFESP site to attend the CCASAnet Investigators meetings held annually at one of the CCASAnet sites. If the meeting is held in Sao Paulo in a given year, no travel will be charged to the project. Flight costs will depend on the meeting location.

	Airfare	Trips/yr	Meals, Hotel/day	Days per trip	Total
CCASAnet Investigators Meeting	$1,200	3	250	4	$6,600

Materials and Supplies
$480 is requested to cover the costs of **general office and study supplies** for the project. This includes any general office supplies required for the project, such as binders, paper, pens, and small computer equipment. Printing costs are also included for printing of regulatory documents, data collection case report forms, data audit forms, quality control reports, and study folders.

$2,000 is requested to cover the costs of **laboratory supplies** required to process patient specimens for the AYANI cohort. Laboratory supplies will include gloves, phlebotomy supplies, needles, specimen cups, vacutainers, and lancets.

Other Direct Costs

Laboratory and enrollment costs are detailed below for the AYANI cohort. It is estimated that 30 participants will be enrolled in the previous CCASAnet funding cycle, and then followed once per year until Year 5 of the new funding cycle. $8,910 is requested annually to complete the study visits and required laboratory testing specified in the AYANI protocol.

Annual costs:

Laboratory Tests/Enrollment costs	Cost per test	# Patients	Total Cost
Dried blood spot (DBS) collection and storage	$ 2.00	30	$ 60.00
Viral load testing	$ 100.00	30	$ 3,000.00
CD4 testing	$ 30.00	30	$ 900.00
Urine testing	$ 50.00	30	$ 1,500.00
Questionnaire administration	$ 100.00	30	$ 3,000.00
Patient transportation reimbursement	$ 15.00	30	$ 450.00
		TOTAL	$ 8,910.00

$1,000 is requested annually for **telecommunications costs**. The site will attempt to use free methods of communication when possible, but some international and local phone charges may be needed to contact VUMC, other co-investigators, and study participants.

Facilities and Administrative Costs

Per NIH policy, 8% F&A costs have been added to the budget to provide funds to foreign institutions and international organizations to support the costs of compliance with DHHS and NIH requirements including, but not limited to, protection of human subjects, animal welfare, invention reporting, financial conflict of interest and research misconduct.

Attachment 5
STATEMENT OF WORK ("SOW")
Universidade Federal de Sao Paulo (UNIFESP)

I. Definitions. Capitalized terms that are not defined in this SOW will have the meaning given in the "Additional Terms" Section of the Subaward.

II. Purpose. (1) To participate in the Adolescent and Young Adult Network of IeDEA (AYANI) by working to enroll 30 adolescents living with HIV (ALWH) into the AYANI cohort and prospectively collecting in-depth Data (defined in the Additional terms to this Subaward) to answer critical questions around HIV care and public health policies for ALWH; and (2) to participate in the CCASAnet retrospective core cohort by contributing to the shared Data repository in order to answer questions about the characteristics of the regional HIV epidemic. The AYANI study and the CCASAnet retrospective core cohort will each be referred to individually as a "Study" and collectively the AYANI and CCASAnet retrospective core cohort will be referred to as the "Studies" herein.

III. General Obligations of Subrecipient. In consideration of the funding under the Subaward, Subrecipient will perform and/or will cause CO-PIs to perform the activities described in this SOW as further detailed by the Grant Application, the Notice of Award, and the applicable Protocol (defined in the Additional Terms of this Subaward). Subrecipient will be responsible for overseeing daily activities associated with implementing and conducting the Studies at Subrecipient's site.

IV. Staffing. In support of the SOW, Subrecipient commits the services of its employees and agents as set forth in the Budget Justification attached to the Subaward and any other employees and agents necessary to perform the Study in accordance with the Subaward.

V. General obligations of Co-PIs. Co-PIs shall:

1. Administratively supervise and fiscally manage the Subaward, which obligations shall include, but are not limited to:
   a. Review and payment of invoices, and financial reporting in accordance with NIH and PTE policies; and
   b. Tracking all costs and submitting invoices to PTE

2. Assume responsibility for the performance and oversight of the activities for the Studies at Subrecipient's site.

3. Ensure human subjects training compliance for all personnel engaged with human subjects, including provision of certification and recertification in human subjects and good clinical practice and maintaining active documentation of all certificates.

4. Maintain active communication with the team at Vanderbilt University Medical Center which shall at a minimum meet and communicate with ("PTE PI") regularly regarding SOW activities, but no less than once per month.

5. Prepare and submit reports in accordance with the Subaward, Grant Application, and applicable Protocol.

6. Collect, organize, process, and share Data and Biospecimens in accordance with the Subaward, Grant Application applicable Protocol and applicable laws, rules and regulations.

7. Cooperate and participate in preparing publications regarding the Studies.
8. Other obligations as set forth in the Grant Application and applicable Protocol.

VI. Regulatory and IRB Approval and Review. Subrecipient shall be responsible for obtaining and maintaining IRB approvals from all relevant institutional, state, and other entities as needed, including, without limitation, CEP and CONEP. Without limiting the generality of the foregoing, Subrecipient shall:

1. Be responsible for ensuring that any regulatory documents required by Brazilian law or regulation (including the Brazilian Resolution No. 196/1996, the Brazilian Resolution No. 340/2004 and the Brazilian Resolution No. 466/2012 of the CNS as well as the Brazilian Privacy Laws, including BGDPA) are properly filed. If applicable, Subrecipient shall be listed as and shall serve as the sponsor of the Study in Brazil in accordance with all applicable laws, rules, and regulations.
2. Maintain an active registration with the relevant authorities (such as the CNS and the Brazilian Health Surveillance Agency ("Anvisa")) throughout the conduct of the Studies for all facilities in which the Studies are conducted, if and to extent required by applicable law.
3. Ensure that the IRB responsible for oversight of the Studies at Subrecipient maintains an active registration with the relevant regulatory authorities as applicable.
4. Obtain initial IRB approval and ongoing IRB review and approval of the Studies at Subrecipient and ensure that the IRB provides oversight for the conduct of the Studies at Subrecipient. Provide copies of all required IRB approvals to PTE, upon request.
5. Obtain either IRB approval from of informed consent form(s) and authorizations to be used for the conduct of the Studies at Subrecipient or a waiver from the IRB (including, without limitation, CEP and CONEP) for such consent and authorization requirements. The informed consent and authorization or waiver must comply with applicable U.S. law including, but not limited to, 21 CFR Parts 50 and 56, 45 CFR Part 46,and HIPPA and must also comply with any other laws and regulations applicable in Brazil.

VII. Study Performance. Subrecipient shall:

1. Collect or otherwise ensure that all necessary consents and authorizations required under applicable law, rules and regulations have been obtained from all patients in the Studies to allow for his/her inclusion in the applicable Study and for the collection, use, processing and transfer of his/her Personal Data and Biospecimens to conduct the applicable Study in accordance with the Grant Application, applicable Protocol, and Federal Award.
2. As further detailed in the applicable Protocol and the Grant Application: timely and accurately enroll patients, carry out the Study and/or submit Data Biospecimens as applicable for each; supervise the transfer of accurate Data by the Data Manager; supervise

and discuss Study findings with the CO-PIs and PTE PI, contribute intellectual input in collaboration with the local and main Study investigators; participate in writing committees and provide input an documents for all other manuscripts written by the network; represent CCASAnet in the IAS CIPHER pediatric network and in the IeDEA Pediatric Working Group.

3. Subrecipient shall submit all Data, Biospecimens and information to PTE and/or the applicable repository as required by the Grant Application and applicable Protocol and in accordance with the terms of the Subaward. Subrecipient will collect all of the Data and Biospecimens in compliance with all applicable federal, state and local laws, rules, and regulations in carrying out its activities related to this Agreement and the Protocol including but not limited to the General Personal Data Protection Law (Brazil) 13709/2018 ("LGPD"). Prior to entering the Data into the Database or transferring any Biospecimens to the appropriate repository as directed by the Protocol, Subrecipient shall ensure that it has obtained all necessary consents and authorizations from research subjects as well as approvals and authorizations from any applicable governmental or regulatory authorities to permit the sharing of the Data and biospecimens with the PTE and/or applicable repository, consistent with the Protocol, this Subaward and applicable laws, rules and regulations.
4. Subrecipient shall perform Data and Biospecimen collection, processing, storage, maintenance, transfer and destruction per the Grant Agreement, applicable Protocol and applicable laws, rules and regulations.
5. Subrecipient will provide other services as required by the Grant Application and/or applicable Protocol and as agreed in writing by PTE, PTE PI, and Co-PIs.

Subaward Number:
VUMC98406

Attachment 6

Notice of Award (NOA) and any additional documents

◉ The following pages include the NOA and the attached Attachment 7, Additional Terms

○ Not incorporating the NOA or any additional documentation to this Subaward.

Recipient Information

1. Recipient Name
VANDERBILT UNIVERSITY MEDICAL CENTER
1161 21ST AVE S STE D3300 MCN

NASHVILLE, TN 37232

2. Congressional District of Recipient
05

3. Payment System Identifier (ID)
1352528741A1

4. Employer Identification Number (EIN)
352528741

5. Data Universal Numbering System (DUNS)
079917897

6. Recipient's Unique Entity Identifier

7. Project Director or Principal Investigator
CATHERINE C MCGOWAN, MD (Contact)

c.mcgowan@vumc.org
615-875-5111

8. Authorized Official
Donald Clinton Brown
sponsoredprograms@vumc.org
615-875-6070

Federal Agency Information

9. Awarding Agency Contact Information
MARY GRACE BROOKS Pazmany

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
mary.pazmany@nih.gov
301.761.7589

10. Program Official Contact Information
Lori B. Zimand
Health Specialist
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
lzimand@niaid.nih.gov
240-627-3212

Federal Award Information

11. Award Number
2U01AI069923-17

12. Unique Federal Award Identification Number (FAIN)
U01AI069923

13. Statutory Authority
42 USC 241 31 USC 6305 42 CFR 52

14. Federal Award Project Title
Caribbean, Central, and South America network for HIV Epidemiology (CCASAnet)

15. Assistance Listing Number
93.855

16. Assistance Listing Program Title
Allergy and Infectious Diseases Research

17. Award Action Type
Competing Continuation

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information

19. Budget Period Start Date 07/01/2021 **– End Date** 04/30/2022	
20. Total Amount of Federal Funds Obligated by this Action	$3,250,000
20 a. Direct Cost Amount	$2,463,901
20 b. Indirect Cost Amount	$786,099
21. Authorized Carryover	$0
22. Offset	$0
23. Total Amount of Federal Funds Obligated this budget period	$3,250,000
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$3,250,000
26. Project Period Start Date 06/15/2006 **– End Date** 04/30/2026	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$3,250,000

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Michael W. Fato

30. Remarks

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

RESEARCH PROJECT COOPERATIVE AGREEMENT
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

SECTION I – AWARD DATA – 2U01AI069923-17

Principal Investigator(s):
Pedro Enrique Cahn, MD
Stephany Norah Duda, PHD
CATHERINE C MCGOWAN (contact), MD

Award e-mailed to: sponsoredprograms@vumc.org

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $3,250,000 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to VANDERBILT UNIVERSITY MEDICAL CENTER 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 recipient when funds are drawn down or otherwise requested 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 U01AI069923. 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 direct questions to the Federal Agency contacts.

Sincerely yours,

Michael W. Fato
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

Cumulative Award Calculations for this Budget Period (U.S. Dollars)

Salaries and Wages	$540,104
Fringe Benefits	$117,288
Personnel Costs (Subtotal)	$657,392
Materials & Supplies	$6,002
Travel	$85,390
Other	$28,203
Subawards/Consortium/Contractual Costs	$1,675,440
Publication Costs	$11,474
Federal Direct Costs	$2,463,901
Federal F&A Costs	$786,099
Approved Budget	$3,250,000
Total Amount of Federal Funds Authorized (Federal Share)	$3,250,000
TOTAL FEDERAL AWARD AMOUNT	$3,250,000
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$3,250,000

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
17	$3,250,000	$3,250,000
18	$3,135,682	$3,135,682
19	$3,159,329	$3,159,329
20	$3,088,719	$3,088,719
21	$2,877,225	$2,877,225

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

Fiscal Information:

Payment System Identifier: 1352528741A1
Document Number: UAI069923E
PMS Account Type: P (Subaccount)
Fiscal Year: 2021

IC	CAN	2021	2022	2023	2024	2025
HD	8014710	$750,000	$750,000	$750,000	$750,000	$750,000
AI	8017492	$184,354	$70,036	$93,683	$23,073	
HL	8028951	$153,628	$153,628	$153,628	$153,628	$153,628
DK	8472279	$76,813	$76,813	$76,813	$76,813	$76,813
AI	8472297	$1,509,494	$1,509,494	$1,509,494	$1,509,494	$1,321,073
DA	8472628	$131,352	$131,352	$131,352	$131,352	$131,352
AA	8475642	$76,814	$76,814	$76,814	$76,814	$76,814
TW	8476359	$83,333	$83,333	$83,333	$83,333	$83,333
CA	8479567	$284,212	$284,212	$284,212	$284,212	$284,212

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

NIH Administrative Data:
PCC: A27I / **OC**: 41027 / **Released**: Fato, Michael 05/17/2021
Award Processed: 06/01/2021 12:11:00 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 2U01AI069923-17

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 – STANDARD TERMS AND CONDITIONS – 2U01AI069923-17

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 grant is excluded from 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) U01AI069923. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

This award is not subject to the Transparency Act subaward and executive compensation reporting requirement of 2 CFR Part 170.

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 is funded by the following list of institutes. Any papers published under the auspices of this award must cite the funding support of all institutes.

Eunice Kennedy Shriver National Institute Of Child Health & Human Development (NICHD)
National Institute Of Allergy And Infectious Diseases (NIAID)
National Heart, Lung, And Blood Institute (NHLBI)
National Institute Of Diabetes And Digestive And Kidney Diseases (NIDDK)
National Institute On Drug Abuse (NIDA)
National Institute On Alcohol Abuse And Alcoholism (NIAAA)
Fogarty International Center (FIC)
National Cancer Institute (NCI)

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 SPECIFIC AWARD CONDITIONS – 2U01AI069923-17

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.

RESTRICTION: The grantee must notify the NIAID to add or change research protocols in Brazil. No funds for new protocols may be expended until all NIH administrative requirements have been met. The NIAID will notify the grantee via revised Notice of Award (NoA) when the NIH administrative requirements have been met.

This award is funded at the recommended level adjusted to a 10-month initial budget period. To reduce the fiscal impact of the budget start date change, only personnel costs are adjusted.

Future year anniversary dates for this grant will be April 1 and the Research Performance Progress Report (RPPR) will be due on February 1.

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This Notice of Award (NoA) includes funds for activity with **Fundacion Huesped, ARGENTINA** in the amount of **$112,008** (**$103,711** direct costs + **$8,297** F&A costs).

This Notice of Award (NoA) includes funds for activity with **Vanderbilt University** in the amount of **$13,387** (**$8,446** direct costs + **$4,491** F&A costs).

This Notice of Award (NoA) includes funds for activity with **Fundacao de Densenvolvimento da Pesquisa, BRAZIL** in the amount of **$52,640** (**$48,741** direct costs + **$3,899** F&A costs).

This Notice of Award (NoA) includes funds for activity with **Universidade Federal de Sao Paulo, BRAZIL** in the amount of **$52,864** (**$48,948** direct costs + **$3,916** F&A costs).

This Notice of Award (NoA) includes funds for activity with **Universidad de Chile, CHILE** in the amount of **$83,971** (**$77,751** direct costs + **$6,220** F&A costs).

This Notice of Award (NoA) includes funds for activity with **Weill Medical College of Cornell University** in the amount of **$33,842** (**$26,859** direct costs + **$6,983** F&A costs).

This Notice of Award (NoA) includes funds for activity with **Les Centres GHESKIO, HAITI** in the amount of **$120,122** (**$111,224** direct costs + **$8,898** F&A costs).

This Notice of Award (NoA) includes funds for activity with **Horwath Central America S. de R.L. de C.V., HONDURAS** in the amount of **$83,846** (**$77,635** direct costs + **$6,211** F&A costs).

This Notice of Award (NoA) includes funds for activity with **Instituto Nacional de Ciencias Medicas y Nutricion, MEXICO** in the amount of **$261,300** (**$242,337** direct costs + **$18,963** F&A costs).

This Notice of Award (NoA) includes funds for activity with **Universidad Peruana Cayetano Heredia, PERU** in the amount of **$88,501** (**$81,945** direct costs + **$6,556** F&A costs).

This Notice of Award (NoA) includes funds for activity with **Fiotec Fundacao Para o Desenvolvimento Cientifico e Tecnol, BRAZIL** in the amount of **$243,410** (**$225,380** direct costs + **$18,030** F&A costs).

This Notice of Award (NoA) includes funds for activity with **Fiotec Fundacao Para o Desenvolvimento Cientifico e Tecnol, BRAZIL** in the amount of **$529,550** (**$492,285** direct costs + **$37,265** F&A costs).

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:

Fundacion Huesped, ARGENTINA
Instituto Nacional de Infectologia Evandro Chagas, BRAZIL
Federal University of Sao Paolo, BRAZIL
Universidade Federal de Minas Gerais, BRAZIL
Fundacao Oswaldo Cruz, BRAZIL
Universidade Federal Do Rio de Janerio, BRAZIL
Instituto Brasiliero para Investigacao da Tuberculose, BRAZIL
Fundacao de Medicina Tropical Doutor Heitor Viera Dourado, BRAZIL
Fiotec, BRAZIL
Fundación Arriarán, CHILE
Gheskio Center, HAITI
Universidad National Autonoma de Honduras-Hospital Escuela Universitario, HONDURAS
Horwath Central America, HONDURAS
Instituto Hondureño de Seguro Social, HONDURAS
National Intitute of Medical Sciences and Nutrition Salvador Zubiran, MEXICO
Instituto de Medicina Tropical 'Alexander von Humboldt' (IMTAvH) - Universidad Peruana Cayetano Heredia, PERU
Hospital National Cayetano Heredia, PERU

This award is co-funded by **National Institute on Drug Abuse, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Heart, Lung, and Blood Institute, National Institute on Alcohol Abuse and Alcoholism, National Institute of Diabetes and Digestive and Kidney Diseases, National Cancer Institute, Fogarty International Center, and the National Institute of Allergy and Infectious Diseases**. All publications, posters, oral presentations at scientific meetings, seminars, and any other forum in which results of this co-funded research are presented must include a formal acknowledgement of the **NIDA/NICHD/NHLBI/NIAAA/NIDDK/NCI/FIC/NIAID** support, citing the NIAID grant number as identified on this award document.

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-15-017, "**Limited Competition: International Epidemiology Databases to Evaluate AIDS (IeDEA) (U01 Clinical Trial Not Allowed)**," posted date **April 8, 2020** 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

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In accordance with the NIAID Financial Management Plan, NIAID does not provide funds for inflationary increases. Committed future year (s) funding was adjusted accordingly. See: https://www.niaid.nih.gov/grants-contracts/financial-management-plan.

SPREADSHEET SUMMARY
AWARD NUMBER: 2U01AI069923-17

INSTITUTION: VANDERBILT UNIVERSITY MEDICAL CENTER

Budget	Year 17	Year 18	Year 19	Year 20	Year 21
Salaries and Wages	$540,104	$636,152	$636,152	$636,152	$636,152
Fringe Benefits	$117,288	$136,865	$136,865	$136,865	$136,865
Personnel Costs (Subtotal)	$657,392	$773,017	$773,017	$773,017	$773,017
Materials & Supplies	$6,002	$3,200	$2,800	$3,200	$2,800
Travel	$85,390	$95,850	$96,750	$95,850	$87,150
Other	$28,203	$26,955	$26,955	$26,955	$36,955
Subawards/Consortium/Contractual Costs	$1,675,440	$1,542,486	$1,580,666	$1,504,001	$1,297,870
Publication Costs	$11,474	$17,000	$13,000	$17,000	$13,000
TOTAL FEDERAL DC	$2,463,901	$2,458,508	$2,493,188	$2,420,023	$2,210,792
TOTAL FEDERAL F&A	$786,099	$677,174	$666,141	$668,696	$666,433
TOTAL COST	$3,250,000	$3,135,682	$3,159,329	$3,088,719	$2,877,225

Facilities and Administrative Costs	Year 17	Year 18	Year 19	Year 20	Year 21
F&A Cost Rate 1	73%	73%	73%	73%	73%
F&A Cost Base 1	$1,076,848	$927,635	$912,522	$916,022	$912,922
F&A Costs 1	$786,099	$677,174	$666,141	$668,696	$666,433

Attachment 7
ADDITIONAL TERMS
Universidade Federal de Sao Paulo (UNIFESP)

1. Performance of the Statement of Work. Subrecipient will participate in the Studies by performing or arranging for the performance of the activities described in the Statement of Work in Attachment 5 of this Subaward (the "SOW"). Capitalized terms that are not defined in these Additional Terms will have the meaning given in the SOW.

a. **Fundação de Apoio a Universidade Federal de Sao Paulo** ("FUSP") is a private, nonprofit foundation that provides financial and administrative management for certain projects conducted by **Universidade Federal de Sao Paulo** ("UNIFESP" or "Subrecipient"). The parties acknowledge and agree **Regina Succi MD and Daisy Machado, MD**, employees of UNIFESP will serve as Co-PIs of the Subaward. PTE acknowledges that any term herein obligating the Subrecipient to agree, act, or perform or to refrain from acting or performing shall be interpreted as the Subrecipient causing UNIFESP and/or Co-PI, as applicable, to do such things; provided however that Subrecipient agrees that it will remain ultimately responsible for the performance of the Subaward. Subrecipient represents and warrants that it is authorized to enter into this Subaward and that it has the authority to direct or to otherwise ensure that UNIFESP and Co-PI perform the Studies and carry out all other activities and obligations of Subrecipient as described in the SOW and the National Institutes of Health ("NIH") grant submission dated August 18, 2020 (the "Grant Submission") all in accordance with the terms of this Subaward.

b. Subrecipient will perform the SOW in accordance with (i) the Grant Submission, (ii) the provisions of UNIFESP's DHHS Federal Wide Assurance number; (iii) the requirements of the Prime Award No. 2U01AI069923-17 (the "Prime Award") applicable to Subrecipient; and (iii) in accordance with all applicable U.S. federal, state, and local laws, rules, and regulations (including without limitation 45 CFR 46, the "Common Rule") and all applicable international, national, and local laws, rules, and regulations applicable to the country where the SOW will be carried out by or on behalf of Subrecipient, including, but not limited, any and all applicable laws and regulations related to import/export control, the conduct of human research, data privacy, and anti-bribery and anti-corruption (collectively, "Applicable Law").

c. Subrecipient shall obtain the appropriate approvals of each Study from the appropriate Institutional Review Board ("IRB") or Ethics Committee including the Brazilian National Research and Ethics Commission ("CONEP") of the Ministry of Health and UNIFESP's local Ethics Committee (collectively, "ECs"), as required by Applicable Law. Subrecipient will carry out each Study and all of its activities in connection with each Study in accordance with all requirements of the EC pertaining to the Study, including with respect to obtaining informed consent from Study participants.

d. Subrecipient will carry out each Study in accordance with the applicable separate written protocol, agreed to by the PTE's Principal Investigator ("PTE PI") and the Co-PI and approved by the ECs, which describes in detail the Subrecipient's activities and responsibilities in connection with each respective Study (each, a "Protocol" and collectively, the "Protocols").

e. Subrecipient shall be responsible for providing, at its sole cost and expense, adequate personnel, equipment, supplies, and other resources necessary to perform the Studies and all other activities and obligations of Subrecipient under this Subaward; provided however, the PTE shall provide funding to Subrecipient as set forth in this Subaward.

2. Revisions and Amendments to a Protocol, the SOW, or Subaward. The Protocol for a Study may only be revised by a Protocol amendment executed by the PTE PI and the Co-PI and such revisions will be subject to the approval of the appropriate IRB or EC. In the event that a Protocol amendment materially alters the activities or obligations of Subrecipient or Co-PI as described in the SOW, the parties will negotiate in good faith appropriate amendments to the SOW. Any amendments to the SOW will require amendment of the Subaward. Any amendment of the Subaward must be executed by the respective Authorized Officials of the PTE and the Subrecipient and is subject to any required approvals by the NIH. PTE may terminate the Subaward immediately in writing, in the event that PTE and Subrecipient are unable to reach an agreement on an amendment to the Subaward or in the event that a Subaward amendment is not approved by the NIH.

3. Co-Principal Investigator, Study Personnel, Sub-Investigators.

a. Subrecipient and Co-PI are responsible for the conduct and supervision of Subrecipient's employees, agents, and contractors performing the SOW on behalf of Subrecipient (collectively "Subrecipient Personnel"). Subrecipient shall ensure that the Co-PI and all Subrecipient Personnel have sufficient qualifications, expertise, training, and experience to carry out the Subaward. Subrecipient shall ensure that the Co-PI and Subrecipient Personnel are made aware of the obligations contained in this Subaward and are bound to comply with such obligations. Subrecipient will not and will ensure that the Co-PI and Subrecipient Personnel do not, at any time during the Term of this Subaward, participate in any other study or undertake any obligation which, by its nature or its terms, would prevent Subrecipient or Co-PI's ability to perform the Studies and all other obligations of Subrecipient under this Subaward.

b. Subrecipient will ensure that all Subrecipient Personnel comply with the terms of this Subaward. If necessary to achieve such compliance, Subrecipient will execute an agreement with Subrecipient Personnel, in a form acceptable to PTE, obligating such compliance of Subrecipient Personnel. Any sub-investigators shall be approved in advance by PTE.

c. The parties acknowledge that the participation of the Co-PI is essential to the successful performance of this Subaward. If, for any reason, the Co-PI's employment with Subrecipient ends or the Co-PI becomes unavailable, unwilling, or otherwise unable to complete Co-PI's responsibilities under this Subaward, Subrecipient shall immediately notify the PTE, and the PTE may, in its sole discretion and subject to any requirements of Subrecipient's the applicable IRB, EC and/or the NIH, terminate this Subaward upon written notice to Subrecipient, accept Subrecipient's assignment of this Subaward, or work with Subrecipient to appoint a replacement investigator reasonably acceptable to both parties.

4. Participating Sites. Subrecipient acknowledges and agrees that UNIFESP is the only institution participating in the Studies or otherwise performing any obligations of Subrecipient under this Subaward. Subrecipient may not use the facilities of any other institution or otherwise

engage any other institution for the performance of any of its activities or obligations under the Subaward without PTE's prior written consent. Subrecipient may not subcontract any work under this Agreement to a third party

5. Data and Results.

a. "Data" shall mean all information, documents and records provided to or generated or collected by or on behalf Subrecipient as a result of performing the Studies or in carrying out any of Subrecipient's activities and obligations as required by this Subaward. Data does not include original patient medical records, research notebooks, source documents, or other routine internal documents kept in the ordinary course of Subrecipient or UNIFESP's business operations, which are and will remain the property of Subrecipient.

b. PTE will own Data collected or generated by Subrecipient in Subrecipient's performance of the Studies and its other activities and obligations under the Subaward. Notwithstanding the foregoing, PTE acknowledges that Data collected by Subrecipient for the AYANI Study may be owned or otherwise subject to the rights of other entities that sponsor or facilitate the AYANI Study, including institutional members of the International Epidemiology Databases to Evaluate AIDS ("IeDEA").

c. Subrecipient acknowledges that PTE must have access to AYANI Study Data in order to meet PTE's reporting and other obligations under the Prime Award.

d. To the extent any Data collected or generated for the AYANI Study is owned by or subject to the rights of any other party, Subrecipient will ensure that Subrecipient has the right to grant, and Subrecipient hereby does grant, a non-exclusive, worldwide, royalty-free, fully-paid up, perpetual, irrevocable license for PTE to use such AYANI Study Data for purpose of PTE's compliance with the Prime Award.

e. Subrecipient will ensure that any agreements executed by Subrecipient in connection with the AYANI Study do not prevent Subrecipient from sharing AYANI Study Data with PTE for purposes of this Subaward PTE's obligations under the Prime Award. Further, Subrecipient will take all actions requested by PTE, including the execution of any agreements, necessary for PTE to obtain rights to use AYANI Study Data for purposes of its compliance with the Prime Award.

f. Subject to the rights of any third party in AYANI Study Data, the rights of PTE in this Subaward and Subrecipient's confidentiality obligations in Section 7 (Confidentiality) of these Additional Terms, Subrecipient shall retain the right to use the Data for its internal research, clinical and educational purposes and for purposes of publication as set forth in Section 14 (Publication) of these Additional Terms.

g. The parties acknowledge and agree that the Results will be reported in compliance with applicable laws, the Protocol, and this Subaward.

h. PTE shall own the Results and have the right to use the Results for any purpose in accordance with the applicable signed informed consent and/or authorization form, and Applicable Law.

i. Subject to Recipient's obligations under Section 7 (Confidentiality) and Section 14 (Publication) of these Additional Terms, Subrecipient has the right to use the Results for its internal research clinical and educational purposes, as necessary for any communications or reports required under Applicable Law to any regulatory authority or EC; and for purpose of publication in accordance with Section 14 (Publication) of these Additional Terms. The Results shall be communicated by the Subrecipient to the Brazilian competent authorities if and to the extent required by and accordance with Applicable Law, including Resolution CNS No. 466/2012, whenever they can contribute to the improvement of the living conditions of the community.

6. Use of Name.

a. Neither party may use the name, trade or service marks, or logos of the other party or the names of the other party's officers, directors, employees, faculty or staff, for any reason, including in any advertisement, marketing, promotion, or other form of publicity or news release without the prior written approval of an authorized representative of the party whose name is being used. The terms of this Section will not be construed as a restriction against either party's use of the other party's name as may be required by academic journals, professional societies, funding agencies and Applicable Law.

b. Notwithstanding anything herein to the contrary, each party shall have the right to post the other party's name, the Study Title, and the Period of Performance, and funding amount, on such party's publicly accessible lists of research being conducted by such party.

7. Confidentiality.

a. It is anticipated that in the performance of this Subaward, each party (the "Disclosing Party" may disclose to the other party (the "Receiving Party") certain Confidential Information during the Term of this Subaward. "Confidential Information" means: any scientific, technical, business, or financial information in written, oral or visual form that are by appropriate marking, identified as confidential or proprietary at the time of disclosure; or if disclosed orally, are identified in writing within thirty (30) days of disclosure as being confidential. The parties will make reasonable efforts to mark Confidential Information as stated above. However, Confidential Information that is disclosed without such markings, that a reasonable person familiar with the Subaward would understand to be confidential or proprietary from the context or circumstances of disclosure, shall be deemed as confidential even if it is not marked as such. For the avoidance of doubt, all Data and Results are the Confidential Information of PTE, subject to the rights of any third party as described in this Subaward.

b. Confidential Information is and will remain the sole property of the Disclosing Party. During the Term and for a period of ten (10) years thereafter, the Disclosing Party will: (i) maintain the confidentiality of Confidential Information using appropriate safeguards that it uses to protect its own Confidential Information (but in no event will Receiving Party use less than a reasonable standard of care) (ii) not disclose Confidential Information to any third party without the prior written consent of the Disclosing Party (except that Receiving Party may disclose Confidential Information to those of its employees, staff, contractors and agents who have a need to know such Confidential Information for purposes of carrying out Receiving Party's obligations or enforcing any right of Receiving Party under this Subaward); (iii) not use Confidential Information except

for as necessary to carry out its activities or fulfill its obligations under the Subaward. The Receiving Party will immediately notify the Disclosing Party of any unauthorized disclosure of Confidential Information. The Receiving Party's confidentiality obligations will not apply to any Confidential Information of Disclosing Party that:

i. is at the time of disclosure, or becomes generally available to the public through no breach of this Subaward by the Receiving Party;

ii. is already in Receiving Party's possession at the time of disclosure;

iii. is disclosed to Receiving Party by a third party that, to Receiving Party's knowledge, has the legal right to disclose such information to Receiving Party; or

iv. is independently developed by Receiving Party without use of or reference to such Confidential Information of Disclosing Party.

c. If Receiving Party is required by a governmental authority or court order to disclose Confidential Information, Receiving Party will immediately (within three (3) business days) notify the Disclosing Party and the Receiving Party will cooperate with Disclosing Party, at Disclosing Party's expense, in Disclosing Party's efforts to seek a protective order.

d. Upon request, or upon expiration or termination of this Subaward and subject to the requirements of the Record Retention Period specified in Section 12 (Record Retention) of these Additional Terms, the Receiving Party will destroy or return all of Disclosing Party's Confidential Information in its possession to the Disclosing Party, at the Disclosing Party's direction; provided however that that Receiving Party may retain one (1) copy of such Confidential Information a secure location solely for purposes of identifying and satisfying its continuing obligations and exercising its rights under this Subaward.

8. Human Subjects Protections.

a. Subrecipient will comply with all Applicable Law pertaining to the protection of human research subjects in carrying out the Studies and all other activities and obligations of Subrecipient in connection with the Subaward.

b. Retrospective Studies. To the extent that Subrecipient will collect pre-existing patient data from certain records, electronic records or databases, including those owned or controlled by Subrecipient or UNIFESP (collectively, "Database(s)") for purposes of a Study:

i. Subrecipient represents and warrants that it, UNIFESP and Co-PI each has valid authorization from the owner of the applicable Database ("Database Owner") to access patient data and information in each Database as and to the extent necessary to complete such Study and that such authorization (or waiver, as the case may be) was obtained and is documented in accordance with Applicable Law.

ii. Subrecipient shall ensure that the Database Owner obtained, in accordance with all Applicable Laws and either (i) a properly executed, written informed consent (in a form approved in writing by the applicable IRB or ECs) from each patient to be accessed by

Subrecipient agreeing to be included in such Database and to have their information used for the purposes contemplated by the Study and this Subaward; or (ii) a waiver from the IRB or ECs of any such consent requirement.

c. Prospective Studies. Prior to prospectively enrolling a patient in a Study, Subrecipient shall obtain either (i) a properly executed, written informed consent (in a form approved in writing by the applicable IRB/ECs) from the patient to participate in the Study; or (ii) a waiver from the IRB/EC of any such consent requirement. The informed consent or waiver, as applicable, must comply, with the Applicable Laws of Brazil and with all Applicable Laws of the U.S. law including, but not limited to 45 CFR Part 46, all other Applicable Law of any other countries applicable to Subrecipient or to any patient to be enrolled in a Study.

d. If an individual whose data is included in the Data withdraws their consent obtained under a signed data consent form the Subrecipient will notify the PTE immediately.

9. Data Privacy.

a. Subrecipient will collect, receive, process, store and transfer Protected Health Information as defined by HIPAA ("PHI") and any other Personal Data, as that term is defined under Applicable Law (PHI and Personal Data, are collectively referred to as "Personal Data") in accordance with all Applicable Laws pertaining to the collection, receipt, use, processing, storage, and transfer of Personal Data, including HIPAA and Brazilian Law No. 13,709/2018 and its regulations, as amended from time to time, known as the Brazilian General Data Protection Act ("LGPD") (collectively, "Privacy Laws"). Additionally, Subrecipient will and will ensure that UNIFESP, Co-PI and Subrecipient Personnel comply with all Privacy Laws in their collection, processing, and/or transfer of Personal Data in connection with the Subaward

b. Prior to collection of Personal Data for a Study, Subrecipient shall ensure that the Personal Data in Databases (i) was and will be originally collected, received, used, processed, stored and transferred by the Database Owner in accordance with all Applicable Laws and Privacy Laws; (ii) to the extent required by Applicable Law and Privacy Laws, such Personal Data was and will be collected, received, used, processed, stored and transferred pursuant to a duly executed informed consent or authorization in a form approved by the IRB or EC in compliance with Applicable Law and Privacy Laws; (iii) that such consent or authorization permits, at all times, the collection, receipt, use, processing, storage and transfer, including specifically the international transfer, of such Personal Data for purposes of this Subaward, as required by Applicable Law and Privacy Laws; and (iv) that it has obtained and will obtain all necessary authorization from any applicable governmental or regulatory authority to permit the transfer and sharing of the Personal Data (including specifically the international transfer and sharing) with PTE, consistent with this Subaward and the Grant Submission. Subrecipient represents and warrants, and will ensure that its collection, receipt, processing, storage, transfer (including specifically the international transfer) and use of Personal Data will not, at all times, exceed the extent of the actions to which the individual to whom the Personal Data relates has consented, except when the processing is required for fulfillment of legal or regulatory obligations.

c. Subrecipient shall serve and assume the relevant responsibilities as the sponsor and/or data controller of the Study in Brazil under Applicable Law, including any registration requirements

for the Study with the appropriate regulatory agency or other authority, as applicable (including those requirements under the Brazilian Resolution No. 196/1996, the Brazilian Resolution No. 340/2004 and the Brazilian Resolution No. 466/2012 of the Brazilian National Health Council ("CNS"), as well as the Brazilian Privacy Laws. Subrecipient agrees that for purposes of all Applicable Law and all Privacy Laws, it is the controller as well as the processor of all Personal Data collected, received, processed, stored, used and/or transferred (including specifically the international transfer) by Subrecipient in connection with the Subaward. To the extent PTE is determined to also be a controller under Applicable Law and/or Privacy Laws, Subrecipient and PTE acknowledge and agree that Subrecipient and PTE are not "joint controllers" of the Personal Data collected, received, processed, stored, used and/or transferred (including specifically the international transfer) by Subrecipient and that each party is acting independently under its own discretion and control with respect to its collection, receipt, processing, storage, use and transfer (including specifically the international transfer) of Personal Data.

d. PTE will process and use Personal Data only for purposes of the Grant Submission and this Subaward and in compliance with Applicable Law.

e. In respect to the international transfer of Personal Data, the parties represent and warrant that they have complied with and shall ensure the confidentiality and integrity of the Personal Data, as well as the transparency of any such transfer to the Personal Data subject, including the purpose of such international transfer, which shall be corroborated by the prior informed consent referenced in Section 9(b) above.

f. Subrecipient represents that it has implemented and agrees that it shall implement, and represents that UNIFESP has implemented and agrees to ensure that UNIFESP will implement, appropriate technical and organizational measures to ensure the security of the Personal Data, including protection against security breach leading to accidental or unlawful destruction, loss, alteration, unauthorized disclosure, or access to Personal Data during the international transfer of Personal Data. In assessing the appropriate level of security, Subrecipient shall consider industry best practices, the costs of implementation, the nature, the scope, the context, the purpose(s) and the risks involved in the international transfer of Personal Data and in the receipt, processing, storage and use of Personal Data.

g. Subrecipient will make available to individuals from whom, or about whom, Personal Data is collected, information about its policies and practices relating to the collection, receipt, processing, storage, use and transfer (including specifically the international transfer) of Personal Data, including what Personal Data is or will be collected, how it will be used and disclosed, contact information for submitting inquiries or complaints, and any rights or choices available to individuals in connection with the Personal Data under Subrecipient's control.

h. Subrecipient will, and will ensure that UNIFESP will, only collect, receive, process, store, use and/or transfer the types of Personal Data reasonably needed for the relevant purposes for which it will be used, retained and as otherwise needed to the extent Subrecipient and/or UNIFESP, as applicable, has a legitimate legal or business justification to do so.

i. Subrecipient will and will ensure that UNIFESP will, limit its use of Personal Data to uses reasonably expected by the Personal Data subjects based on the informed consent or authorization

from them and the information and notice provided to them, as well as the nature of the relationship or context in which the Personal Data was collected.

j. In the quality of Personal Data controller, Subrecipient will provide reasonable access to Personal Data collected upon request and satisfactory proof of identity and will respond to requests to correct or update Personal Data in a reasonable time and manner. If Subrecipient declines to provide access, it will provide reasons for such decline to the individual. Subrecipient will take appropriate steps to keep Personal Data accurate and up to date.

k. Subrecipient will implement reasonable measures to protect Personal Data against loss, unauthorized access, use, destruction, modification, or disclosure appropriate to the level of risk and sensitivity of the Personal Data collected.

l. Any breach or suspected breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to, Personal Data shall be handled in accordance with Applicable Laws and Privacy Laws.

m. The parties who may have access to the Personal Data shall not use any type of tool, technology, reverse engineering, or other method intended to identify Personal Data subjects, where Personal Data have been shared in such a manner that does not permit direct identification of the Personal Data subject without cross-checking with other information or with access to the identification key.

n. The retention of Personal Data, subject of this Subaward, shall last only to the strict extent and for the period required for the purposes for which the Personal Data has been collected, ensuring in all cases the confidentiality of all Personal Data including as set forth in the applicable protocols and research plans developed in connection with the Studies.

o. This Subaward does not create joint and several liability between the parties for any penalties relating to the Personal Data processing activities performed, so each party shall be liable within the limit of its activities.

10. Certificates of Confidentiality.

a. The parties understand that all biomedical, behavioral, clinical, or other human subjects research funded wholly or in part by NIH, whether supported through grants, cooperative agreements, contracts, other transaction awards, or conducted by the NIH Intramural Research Program, that collects or uses identifiable, sensitive information (including identifiable biospecimens or individual-level genomic data) as defined by NIH Policy NOT-OD-17-109 (the "Policy") (hereinafter, "ISI"), and that was commenced or ongoing on or after December 13, 2016, is deemed under the Policy to be issued a Certificate of Confidentiality ("Certificate") automatically. All institutions and investigators collecting or receiving ISI under a Study that has been issued a Certificate are required to protect the privacy of individuals who are subjects of such research in accordance with the Policy and subsection 301(d) of the Public Health Service Act (the "PHS Act").

b. In compliance with the Policy, Subrecipient hereby acknowledges that the Studies are subject to a Certificate and the requirements of the Policy. Subrecipient understands and agrees

that its use and disclosure of ISI is subject to a Certificate issued pursuant to the Policy, and Subrecipient shall ensure that Co-PI and all Subrecipient Personnel will comply with the Policy, the NIHGPS and 301(d) of the PHS Act, including but not limited to the disclosure restrictions therein, in their use and disclosure of ISI. This term survives the expiration of this Subaward and the close of the Study.

11. Biological Specimens. In the event that the Protocol for a Study requires the collection, storage or transfer of biologic material of human origin, including, without limitation tissues, blood, plasma, urine, spinal fluid or any other bodily fluid ("Biological Specimens"), such collection, storage or transfer will be carried out in accordance with all Applicable Laws, including any informed consent or authorization requirements under Applicable Law. The parties will execute any additional Material Transfer Agreement or other agreement that may be necessary under Applicable Law or as required by a party's institution in order to accomplish the transfer of Biological Specimens as required by the applicable Study Protocol.

12. Record Retention.

a. Subrecipient shall retain a copy of the all financial and programmatic records, supporting documents, statistical records and all other Study-related records for a period of four (4) years following expiration or termination of this Subaward, or for such longer time as required by the record retention requirements in Applicable Law, including 2 CFR 200.333 and 45 CFR 46 (the "Record Retention Period").

b. For a period of four (4) years after the performance of any activities pursuant to this Subaward or for such longer period as required under Applicable Law, the parties shall upon written request, make available to the Secretary of Health and Human Services or the Comptroller General or their duly authorized representative the contract, books, documents, and records necessary to verify the nature and extent of the cost of such performance. If either Subrecipient carries out any of its obligations under this Subaward by means of a subcontract with a value of $10,000 or more, Subrecipient will include this requirement in any such subcontract.

13. Inventions, Discoveries, and Patents.

a. The determination of rights in ownership and disposition of inventions and discoveries resulting from the performance of the Subaward ("Inventions") and the administration of patents will be in accordance with 37 CFR 401 and the terms of this Subaward.

b. Project Inventions created as a direct result of PTE's performance of its obligations under the Prime Award shall be the sole property of PTE. Project Inventions created jointly by both PTE and Subrecipient Personnel shall be owned jointly by PTE and Subrecipient. Subrecipient represents and warrants that it shall own all right, title, and interest to all Project Inventions created by Subrecipient, CO-PI, UNIFESP, Subrecipient Personnel, and that such individuals and entities have a written obligation to assign their ownership rights in Project Inventions to Subrecipient.

c. Subrecipient shall disclose promptly to PTE any Project Invention pursuant to the reporting requirements provided in Attachment 4.

d. Any patent application filed in the U.S. or in foreign countries and each license agreement entered into concerning such invention, shall contain a statement that the invention was made through support from the U.S. Government.

e. The project Inventions resulting from the Project shall be communicated to the competent authorities, whenever they can contribute to the improvement of the living conditions of the community, if and to the extent required by, and in accordance with the Resolution CNS No. 466/2012.

14. Publication.

a. Subrecipient acknowledges and agrees that, prior to either party issuing a press release concerning the outcome of a Study, the PTE PI must notify the NIH in advance to allow for coordination.

b. Authorship of all publications related to the Study will be as described in the MPI Plan, Grant Submission and/or Protocol.

c. Subrecipient shall not individually publish the final Study results until after the first occurrence of one of the following: (i) the final joint publication is published; (ii) no joint publication is submitted within eighteen (18) months after conclusion, abandonment, or termination of the Study at all sites; or (iii) There will be no joint or multi-center publication of the Data and PTE agrees in writing for Subrecipient to independently publish.

d. Subrecipient agrees that all publications that result from work under this Subaward will include the following statement "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 R21AI145686. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health."

e. Subrecipient agrees that qualification for authorship of any publication shall be in keeping with the criteria of the International Committee of Medical Journal Editors (ICMJE) and/or any other requirements of the applicable journal or congress.

f. Subrecipient agrees that activities, reports, and publications resulting from this grant must adhere to the Acknowledgement standards set by the NIH. (http://grants.nih.gov/grants/acknow.htm#requirements).

g. Subrecipient acknowledges that any publication will be subject to the NIH Public Access Policy (NOT-OD-08-033).

15. Indemnification and Insurance.

a. Subrecipient will indemnify, defend and hold harmless PTE and its affiliates, directors, officers, faculty, staff, agents and employees from and against any and all losses, damages, costs, expenses, and liabilities, including reasonable attorney's fees and court costs (each a "Loss" and collectively, "Losses") resulting from any demands, claims, actions, or proceedings (each a "Claim" and collectively, "Claims") to the extent such Claim arises from or is caused by: (i) any

inaccuracy, misrepresentation or breach of any representation or warranty made by Subrecipient in this Subaward or in any documents or agreements relied upon by PTE in its issuance of this Subaward; (ii) any violation by Subrecipient, UNIFESP, CO-PI, or Subrecipient Personnel of any Applicable Laws in its performance of a Study or any of its obligations or activities in connection with this Subaward; (iii) any negligent act or omission or willful misconduct of Subrecipient, UNIFESP, CO-PI, or Subrecipient Personnel in its performance of a Study or any of its obligations or activities connection with the Subaward or (iv) any failure of Subrecipient, UNIFESP, Co-PI or Subrecipient Personnel to obtain the appropriate consent or authorization as required by Applicable Law to share any Data (including personal data or sensitive information) with PTE in connection with a Study or this Subaward; or (v) any claims for infringement on any third party's rights, or any violation of any licenses or other agreements with respect to any third party's rights in connection with a Study or any of Subrecipient's obligations or activities in connection with this Subaward.

b. Subrecipient will be fully responsible and liable for all acts or omissions of its officers, directors, employees, contractors and subcontractors, in connection with the Subaward, including, but not limited to, UNIFESP, CO-PI, and Subrecipient Personnel.

c. The indemnified party shall (i) provide the indemnifying party with prompt written notice(within seven (7) days after becoming aware) of any Claim for which the indemnified party may seek indemnification hereunder; (ii) allow the indemnifying party to control the defense or settlement of the claim; provided, however, the indemnifying party shall not enter into any admissions, agreements, or settlements which may admit fault by the indemnified party, require further action by the indemnified party, or which may otherwise affect the rights of the indemnified party, or which does not include an unconditional release of the indemnified party, without the prior written consent of the indemnified party; and (iii) provide the indemnifying party with reasonable assistance and information necessary for the indemnifying party to perform its obligations hereunder. Notwithstanding anything herein to the contrary, any failure of the indemnifying party to comply with the conditions in this Section will not alter the indemnifying party's indemnification obligations, except to the extent that such failure to comply with any such condition actually materially compromises the ability of the indemnifying party to defend the matter.

d. During the Term of this agreement, each party shall maintain insurance in amounts and coverages sufficient to cover its obligations hereunder. Subrecipient will maintain (and will required its subcontractors including UNIFESP and Co-PI to maintain) the following insurance with limits not less than the amount specified with companies rated A or better by A.M. Best & Company or by way of an established self-insurance program and, will require its subcontractor(s) to maintain similar insurance coverage:

i. Workers' Compensation (or equivalent coverage, to the extent it is available, according to the applicable laws) with statutory limits and Employers Liability with limits of $500,000 per accident, $500,000 per illness per employee and $500,000 per illness aggregate.

ii. Commercial General Liability: $2,000,000 per occurrence, bodily injury and property damage liability; $2,000,000 personal and advertising injury liability; $2,000,000 products and completed operations policy aggregate and $3,000,000 policy general aggregate

applicable to lines other than products and completed operations. The required limits may be satisfied in combination of primary and excess insurance.

iii. Cyber (Network and Security) insurance with an aggregate limit of $5,000,000 including coverage for Privacy Notification Cost and providing protection against liability for: (1) privacy breaches, including but not limited to liability arising from the loss or disclosure of confidential information, no matter how such loss or disclosure occurs; (2) system breach; (3) denial or loss of service; (4) introduction, implantation, or spread of malicious software code; and (5) unauthorized access to or use of computer systems.

iv. Professional Liability/Errors and Omissions insurance, with minimum limits of $5,000,000 for each wrongful act and in the aggregate. Claims-made coverage is permitted, provided the policy retroactive date for coverage is no later than the Effective Date and the policy is continuously maintained during the Term and during all other periods in which Subrecipient is performing activities in connection with this Subaward. Coverage shall stay in force with the retroactive date maintained for an additional period of three (3) years after the performance of such activities. The required limits may be satisfied by a combination of primary and excess insurance.

v. Any self-insurance arrangement must be through an actuarially sound program of self-insurance.

vi. Upon request, Subrecipient shall furnish certificates of insurance that provide sufficient information to verify that Subrecipient (or its subcontractors including UNIFESP and Co-PI) has complied with the insurance requirements of this agreement.

16. Termination and Suspension. The term of this Subaward will be the Period of Performance as indicated on the first page of this Subaward (the "Term"). In addition to the termination rights set forth in Paragraph 9 of the Subaward Terms and Conditions:

a. The PTE may immediately, upon written notice to Subrecipient, suspend performance of or terminate this Subaward, in whole or in part, if:

i. the Subrecipient fails to comply with the terms and conditions of the Federal Award;

ii. the Co-PI's affiliation with Subrecipient or UNIFESP ends or the Co-PI becomes unavailable, unwilling, or otherwise unable to complete Co-PI's responsibilities under this Subaward; or

iii. the NIH reduces or terminates funding for the Prime Award.

b. Either party may suspend performance of a Study under this Subaward or terminate this Subaward if:

i. in the judgment of the PTE PI, the CO-PI, the PTE's IRB, and/or the Subrecipient's IRB, it is determined that performance of the Study should be stopped in order to protect the Study patients' rights or welfare; or

ii. the PTE's IRB and/or the Subrecipient's IRB suspends or otherwise disapproves the Study; or

iii. upon the other party's material default or breach of this Subaward, provided that the defaulting/breaching party fails to remedy such material default, or breach of this Subaward within fifteen (15) business days after written notice of such breach.

c. In the event that this Subaward is terminated or suspended prior to completion of the Study, for any reason, Subrecipient shall:

i. notify its IRB that the Subaward has suspended or terminated, as applicable;

ii. cease collecting Data for the Study;

iii. terminate, as soon as practicable, all other activities under the Subaward and cooperate with PTE to provide for an orderly wind down of the Study;

iv. cease spending under the Subaward;

v. provide adequate documentation to allow both parties to facilitate an orderly close out of the Study, if applicable; and

vi. provide the information necessary for the PTE to meet its obligations to the NIH.

d. The PTE shall pay Subrecipient for termination costs as allowable under Uniform Guidance 2 CFR 200, or 45 CFR 75, Appendix IX, "Principles for Determining Cost Applicable to Research & Development under Grants and Contracts with Hospitals", as applicable.

e. Survival: The following sections of these additional terms shall survive the termination or completion of the Subaward: 3(b), 5, 6, 7, 8, 9, 11, 12, 13, 14, 15, 24, 25, 28, and 30. Additionally, any term of the Subaward that by its nature and intent are intended to survive termination, will survive termination.

17. Assignment; Sub-Contracts.

a. Subrecipient may not assign this Subaward, in whole or in part, without the written permission of the PTE.

b. Except for UNIFESP and Database Owners, Site Subrecipient shall not enter into a subcontract with any third-party for the performance of any SOW-related activity without the prior written approval of the PTE. Any permitted subcontracts must contain terms and conditions substantially similar to this Subaward and are subject to the approval of the PTE.

18. Force Majeure. If either party hereto shall be delayed or hindered in, or prevented from, the performance of any act required hereunder for any reason beyond such party's direct control, including but not limited to, strike, lockouts, labor troubles, riots, insurrections, war, acts of God, inclement weather, or other reason beyond the party's control (a "Disability") then such party's performance shall be excused for the period of the Disability. Any timelines affected by a

Disability shall be extended for a period equal to the delay and the budget shall be adjusted to account for cost increases or decreases resulting from the Disability, if any. The party affected by the Disability shall notify the other party of such Disability as provided for herein.

19. DUNS and SAM Registration; SAM reporting. This Subaward 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). If and to the extent applicable, Subrecipient will comply with the reporting requirements of 45 CFR 75.113 and Appendix XII to 45 CFR Part 75.

20. Counterparts. This Subaward may be executed in any number of counterparts, each of which shall be an original and all of which together shall constitute one and the same document and is binding on all parties notwithstanding that each of the parties may have signed different counterparts. The parties of this agreement accept electronic, and/or PDF signatures in lieu of original signatures which comply with 2 CFR 200.335.

21. Waiver and Severability. A waiver by either party of a breach of any provision of this Subaward shall not operate as or be construed to be a waiver any other breach of such provision, or of any breach of any other provision of this Agreement. Should any provision of this Subaward be held invalid, unenforceable or in conflict with any Applicable Law, the parties will negotiate in good faith to amend this Subaward and replace such provision with a provision which accomplishes, to the extent possible, the original business purpose of such provision in a valid or enforceable manner.

22. Headings. Section and clause headings are used herein solely for convenience of reference and are not intended as substantive parts of this Subaward.

23. Entire Agreement; Amendment; Binding Effect. This Subaward incorporates the attachments referenced herein and constitutes the entire agreement between the Parties concerning the Subaward and Studies, and supersedes all other or prior agreements or understandings, whether written or oral, with respect to that subject matter of this Subaward. Any changes made to the terms, conditions or amounts cited in this Subaward require a written amendment signed by authorized representatives of the Parties. This Subaward shall be binding upon the Parties, their successors, and assigns. Notwithstanding NIH guidelines for contract terms, this Subaward shall not exceed sixty (60) months in duration.

24. Conflict. In the event of a conflict between the terms of this Subaward and the Protocol, the Protocol shall govern all medical and scientific matters, and this Subaward will govern all other matters. Subrecipient will immediately notify PTE upon becoming aware that the terms of this Subaward conflict with the terms of any agreement that Subrecipient (or UNIFESP or Co-PI) may have with any third party regarding any obligations or activities of Subrecipient in connection with this Agreement. In the event of such conflict, the parties will confer and make reasonable efforts to amend the terms of this Subaward as may be necessary to resolve such conflict with any such third party agreement.

25. Export Controls. The parties will comply with the export control terms set forth in Attachment 8 of the Subaward.

26. Foreign Corrupt Practices Act. Subrecipient will not, and will not permit any of its or its subcontractors' (including UNIFESP) respective directors, officers, employees, faculty, staff or subcontractors, promise, authorize or make any payment to, or otherwise contribute any item of value to, directly or indirectly, to any third party, including any non-U.S. official, in each case, in violation of the Foreign Corrupt Practices Act of 1977 (the FCPA), the U.K. Bribery Act 2010, or any other applicable antibribery or anti-corruption law.

27. Authority. Subrecipient represents and warrants that each of it and UNIFESP are duly organized and validly existing under the laws of Brazil and that Subrecipient has all powers necessary to conduct its respective role in the Studies and to direct or otherwise ensure that Subrecipient's obligations and activities in connection with this Subaward are carried out in accordance with the terms and conditions of this Subaward.

28. Governing Language. In the event that a translation of this Subaward is prepared and signed by the parties, this English language version shall be the official version and shall govern if there is a conflict between this English language version and the translation. All disputes (litigation and arbitration) under this Agreement shall be resolved and conducted, regardless of the means or authority, in the English language.

29. Discrimination. In compliance with federal law, including the provisions of Title XI of the Education Amendments of 1972, Sections 503 and 504 of the Rehabilitation Act of 1973, the Age Discrimination in Employment Act of 1967 and the Americans with Disabilities Act of 1990, each party hereto will not discriminate on the basis of race, sex, religion, color, national or ethnic origin, age, disability, or military service in its administration of its policies, including admissions policies, employment, programs or activities.

30. Arbitration. Any dispute, controversy or claim arising under, out of or relating to this Agreement and any subsequent amendments of this Agreement, including, without limitation, its formation, validity, binding effect, interpretation, performance, breach or termination, as well as non-contractual claims, shall be referred to and finally and exclusively determined by arbitration in accordance with U.S. Federal and New York state law and governed by the rules for the International Centre for Dispute Resolution. The place of arbitration shall be New York, New York, United States. The language to be used in the arbitral proceedings shall be English.

Subaward Number:

VUMC98406

Attachment 7

Research Subaward

Invoice

BILL TO: PTE
Attention
Address line 1
Address line
email
Subaward Agreement number

Invoice #:
Invoice Date:
Contract/Award#:
Federal ID #:

Contract Term:

Start Date: End Date:

Period Covered By This Invoice:

From: To:

EXPENDITURES		BUDGETED	CURRENT	CUMULATIVE
SALARIES AND WAGES				
FRINGE BENEFITS				
EQUIPMENT				
MATERIALS				
PUBLICATION COSTS				
OTHER (Specify)				
TUITION				
F&A base	%			
TOTALS				

LESS ADVANCES –

TOTAL DUE THIS INVOICE

CERTIFICATION:

By signing this report, I certify to the best of my knowledge and belief that the report is true, complete, and accurate, and the expenditures disbursements and cash receipts are for the purposes and objectives set forth in the terms and conditions of the Prime Award. I am aware that any false, fictitious, or fraudulent information, or the omission of any material fact, may subject me to criminal, civil or administrative penalties for fraud, false statements, false claims or otherwise.

Subrecipient Authorized Officer (Signature) *Title* Date

REMIT TO ADDRESS

PAYMENT AUTHORIZATION:

The subrecipient has demonstrated satisfactory project performance and progress, and the charges represented on this invoice appear to be appropriate with that progress. As Principal Investigator, I approve this payment.

PTE's Authorized Signature

Subaward Number: VUMC98406

Attachment 7, Page 2

Research Subaward

Contributions to Project

Complete only if cost share or matching is required by the Subaward.

Period Covered by this Cost Share report _____ ***to*** _____

EXPENDITURES		BUDGETED	CURRENT	CUMULATIVE
SALARIES AND WAGES				
FRINGE BENEFITS				
EQUIPMENT				
MATERIALS				
PUBLICATION COSTS				
OTHER (Specify)				
TUITION				
F&A base	%			
TOTAL CONTRIBUTIONS				

CERTIFICATION:

I certify that the funds contributed to this PTE project or projects listed above were expended, and do not and will not duplicate any requests for reimbursement of costs or services from the PTE.

_____

Signature of Authorized Officer

Subaward Number:
VUMC98406

Attachment 8

Research Subaward

Export Controls

List any Export Controls that apply to this Subaward here. Leave this blank if not applicable.

Export Control. It is understood that VUMC is subject to United States laws and regulations controlling the export of technical data, software, and information ("Technology"), and commodities, laboratory materials, and other physical items ("Items"). VUMC's obligations hereunder are contingent on compliance with applicable U.S. export laws and regulations. The transfer or sharing of any such Technology or Items subject to the various U.S. export laws and regulations may require a license or authorization from the United States Government, and/or may require written assurances by the receiving party that it shall not re-export or share such Technology or Items to certain foreign destinations and/or to certain recipients without prior approval of the U.S. Government, and/or may require that the involved individuals and entities will comply with conditions or such government license(s) or authorization(s). While VUMC agrees to cooperate in securing any license(s) deemed necessary in connection with this Agreement, VUMC cannot guarantee that such licenses will be granted. No party shall share, disclosed, or release any Technology or Items with any person, party, location, or territory subject to U.S. trade sanctions, as listed at https://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx

Subaward Number:

VUMC98406

Attachment 9

Research Subaward

Human Subjects Data

Include data exchange language here if Human Subjects Data is Applicable and you will not address Data in a separate DUA

Terms regarding human subjects data are contained in Attachment 7 (Additional Terms)

Appendix A
Anti-Corruption Compliance Certification

I, _____, a duly authorized representative of the **Universidade Federal de Sao Paulo** ("Subrecipient"), confirm that I, my organization, and anyone retained by me or my organization, will strictly adhere to and comply with all applicable laws, rules and regulations, including but not limited to Brazil and international anti-bribery and anti-corruption laws such as the U.S. Foreign Corrupt Practices Act (collectively, "Anti-Corruption Laws").

In connection with activities on behalf, or in the interest, of PTE, neither I, nor my organization nor any of its officers, directors, stockholders, employees or agents have offered, paid, promised to pay, or authorized – and will not offer, pay, promise to pay, or authorize – the payment of any money or the giving of any other thing of value to any individual with the intention of inducing improper conduct on the part of the recipient or securing an undue or improper advantage.

I confirm that, if I learn of or have reason to know of any activities in connection with this Subaward that may constitute a violation of Anti-Corruption Laws, I will immediately advise PTE.

I also authorize PTE to use any information contained in this certification and any related information provided by my organization for the purpose of determining whether I or my organization will be contracted by PTE.

The only bank account into which we will be paid by PTE is a business account. The account is in the name of my organization, which is lawfully organized in the country in which we operate. I have provided the account details to PTE.

Completed by:
Authorized Representative Signature: _____
Printed Name of Representative: _____
Representative Title: _____
Organization: **Universidade Federal de Sao Paulo - UNIFESP**
Date: _____