CON # 122779

FDP Foreign Cost Reimbursement Subaward

Federal Awarding Agency: National Institutes of Health (NIH)

Pass-Through Entity (PTE):	**Subrecipient:**
Regents of the University of Minnesota	Fundação Médica do Rio Grande do Sul
PTE PI: Nathan Bahr	Sub PI: Alessandro C. Pasqualotto
PTE Federal Award No: 3R01AI195133-01S1	Subaward No: SUBA00001865-P012786401

Project Title: Histoplasmosis Induction and Consolidation Therapy Factorial Randomized Clinical Trial (HISTO-FACT)

Subaward Budget Period: Start: 09/03/2025 End: 08/31/2026	Amount Funded This Action (USD): $ 348,689.00
Estimated Period of Performance Start: 09/03/2025 End: 08/31/2032	Incrementally Estimated Total (USD): $ 3,113,978.00

Terms and Conditions

1. PTE hereby awards a cost reimbursable Subaward, (as determined by 2 CFR 200.331), 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 (b). 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 Principal Investigator Contact, as shown in Attachment 3A, NO LATER THAN 60 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 Budget Period(s) and Budget Unilaterally. Unilateral modifications shall be considered valid 14 days after receipt, unless otherwise indicated by Subrecipient. Requests for No Cost Extensions are as shown in Attachment 2.

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

9. Either party may terminate this Subaward with 30 days written notice. Notwithstanding, if the Awarding Agency terminates the Federal Award, PTE will terminate in accordance with Awarding Agency requirements. PTE shall direct written notice to the Subrecipient's Authorized Official contact, and Subrecipient shall direct written notice to the PTE'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, as applicable.

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

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

By an Authorized Official of Pass-through Entity:	By an Authorized Official of Subrecipient:
_____ Date	_____ Date
Name: Tracy Burdett	Name:
Title: Senior Grants and Contracts Officer	Title:

Attachment 1
Certifications and Assurances

Subaward Number:
SUBA00001865-P012786401

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 200.214 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 PTE 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 200.332 (a)(5), 200.337, and 200.338 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.

RESERVED

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.

Prohibition on Certain Telecommunication and Video Surveillance Services or Equipment
Pursuant to 2 CFR 200.216, Subrecipient will not obligate or expend funds received under this Subaward to: (1) procure or obtain; (2) extend or renew a contract to procure or obtain; or (3) enter into a contract (or extend or renew a contract) to procure or obtain equipment, services, or systems that uses covered telecommunications equipment or services (as described in Public Law 115-232, section 889) as a substantial or essential component of any system, or as a critical technology as part of any system.

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: SUBA00001865-P012786401

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	Assistance Listing No.
09/05/25	R01AI195133	93.855

Assistance Listing Program Title (ALPT): Allergy and Infectious Diseases Research

Key Personnel Per NOA: Alessandro Comaru Pasqualotto

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:
   http://grants.nih.gov/policy/notices.htm
2. 2 CFR 200 and 45 CFR Part 75.
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. Applicable Research Terms and Conditions, including any Federal Awarding Agency's Specific Requirements found at:
   https://www.nsf.gov/awards/managing/rtc.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 200.1 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

By signing this subrecipient agreement, Fundação Médica do Rio Grande do Sul agrees to provide access to copies of all lab notebooks, all data, and all documentation that supports the research outcomes as described in the progress report, to the University of Minnesota with a frequency of no less than once per year, in alignment with the timing requirements for Research Performance Progress Report described in Attachment 4 and on page 5 of the Prime Award. Fundação Médica do Rio Grande do Sul will make such data available via Redcap and UMN Google Drive..

The University of Minnesota must request prior approval from NIAID to add or change research protocols in Brazil. No funds for new protocols may be expended unless NIAID has approved the change via a revised Notice of Award (NoA).

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 *Principal Investigator* *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 its Institutional Review Board (IRB) and/or its Institutional Animal Care and Use Committee (IACUC), as applicable and that it will maintain current and duly approved research protocols for all periods of the Subaward involving human and/or vertebrate animal research. 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 9.

NIH Terms and Conditions

The Clinical Trial Indicator in Section IV of the PTE's NOA is stated as: Yes ?

The work being conducted by this subrecipient per this agreement is a clinical trial.

Multiple PIs (MPI)

This subaward is subject to an MPI Leadership Plan. Both parties will follow the finalized MPI Leadership Plan. ?

The PTE will make the MPI plan available upon request.

Certificate of Confidentiality:

The Parties agree that this research funded in whole or in part by the National Institutes of Health ("NIH"), is subject to NIH Policy NOT-OD-17-109 (the "Policy") and therefore is deemed under the Policy to be issued a Certificate of Confidentiality ("Certificate") should the conditions outlined within the Policy apply. Accordingly, the subrecipients who collect or receive identifiable, sensitive information are is required to adhere to the Policy and 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").

Attachment 3A
Pass-Through Entity (PTE) Contacts

Subaward Number: SUBA00001865-P012786

PTE Information

Entity UEI Name: Regents of the University of Minnesota

Legal Address: Office of Sponsored Projects Administration
450 McNamara Alumni Center
200 Oak Street SE, Minneapolis, MN 55455-2070

Website: https://research.umn.edu/units/spa

PTE Contacts

Central Email: awards@umn.edu

Principal Investigator Name: Nathan Bahr

Email: bahrx026@umn.edu Telephone Number: 612-624-9996

Administrative Contact Name: Tracy Burdett

Email: burde047@umn.edu Telephone Number: 612-624-5599

COI Contact email (if different to above): Jon Guden (jguden@umn.edu)

Financial Contact Name: Tracy Burdett

Email: burde047@umn.edu Telephone Number: 612-624-5599

Email invoices? (●) Yes ( ) No Invoice email (if different): sub-inv@umn.edu

Authorized Official Name: Tracy Burdett, Patrick Donnell, Amy Rollinger, David Hagen, April Coon

Email: awards@umn.edu Telephone Number: 612-624-5599

PI Address:

Medicine-Infectious Diseases and International Medicine
A620 Mayo
420 Delaware St SE
Minneapolis, MN 55455

Administrative Address:

Office of Sponsored Projects Administration
450 McNamara Alumni Center
200 Oak Street SE, Minneapolis, MN 55455-2070

Invoice Address:

Invoices shall reference the subaward number as shown on the face page of this agreement and signed certification statement and be submitted in electronic format to sub-inv@umn.edu. Final invoice must be marked "Final."

Attachment 3B

Subrecipient Contacts

Subaward Number: SUBA00001865-P012786401

Subrecipient Information for FFATA reporting

Entity's UEI Name: Fundação Médica do Rio Grande do Sul

EIN No.:

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

UEI: WT4HCAP3LB93

Currently registered in SAM.gov: ◯ Yes ◯ No

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

Parent UEI:

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: Alessandro C. Pasqualotto

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: SUBA00001865-P012786401

Subrecipient:

Institution Name: Fundação Médica do Rio Grande do Sul

PI Name: Alessandro C. Pasqualotto

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: SUBA00001865-P012786401

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 Principal Investigator . 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 Principal Investigator 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 Principal Investigator in order for the PTE to satisfy its reporting obligations to the Federal Awarding Agency.

Prior Approvals:

Carryover:

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

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

Submit carryover requests to the Principal Investigator .

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: SUBA00001865-P012786401

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

Statement of Work

( ) Below (•) Attached, 1 pages

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

Budget Information

Indirect Cost Rate Information	Rate Applied: 8 %	**Cost Sharing**	No
Type: Sponsor-Limited Rate	Base: Modified Total Direct Costs	If Yes, include Amount: $	

Budget Details

( ) Below (•) Attached, 4 pages

Budget Totals

Direct Costs	$ 322,860.00
Indirect Costs	$ 25,829.00
Total Costs	$ 348,689.00

All amounts are in United States Dollars

Subaward Number:

SUBA00001865-P012786401

Attachment 6

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:

I certify to the best of my knowledge and belief that the information provided herein is true, complete, and accurate. I am aware that the provision of false, fictitious, or fraudulent information, or the omission of any material fact, may subject me to criminal, civil, or administrative consequences including, but not limited to violations of U.S. Code Title 18, Sections 2, 1001, 1343 and Title 31, Sections 3729-3730 and 3801-3812.

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:

SUBA00001865-P012786401

Attachment 6, 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:

SUBA00001865-P012786401

Attachment 7

Notice of Award (NOA), DUA, and any additional documents

◉ The following pages include the NOA and if applicable any additional documentation referenced throughout this Subaward.

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

Scope of Work

Drs. Bahr and Pasqualotto will serve as MPI's. UMN will provide administrative support via the Department Medicine and the UMN IRB. Drs. Bahr and Pasqualotto will be intricately involved in all aspects of the project as outlined in budget justification and team. Dr. Pasqualotto has expertise in care for patients with histoplasmosis and clinical trials. He, along with the UFCSPA study coordinators will manage the clinical trial sites in Brazil via UFCSPA. The scope of work for this proposal includes regulatory processes, participant screening, consent and enrollment and site coordination. Duties also include randomization, dispensation of medication and administration of medication by pharmacy and nursing staff. Each site will have a sub-investigator working under Dr. Pasqualotto who organizes activities at each sub-site. Staff at each sub-site will also obtain laboratory studies as indicated in the study protocol that will be used for clinical care as well as obtaining one sample for storage and eventual shipment to UMN for drug level testing in all participants. Shipments will be coordinated with UMN staff. One follow up visit will also occur in the outpatient setting.

Drs. Bahr and Pasqualotto are part of the clinical study team and will all be responsible for meeting the objectives, carrying out/supervising the work to accomplish the aims and deliverables, but ultimate responsibility will rest with Drs. Bahr and Pasqualotto as the overall project MPI's.

Our overall objective is to reduce mortality and morbidity due to histoplasmosis through improved induction and consolidation anti-fungal therapies. To accomplish these objectives, the aims of this proposal are to: 1) Assess the safety and efficacy of a single high-dose liposomal amphotericin B (LAmB 10mg/kg) compared to the standard of care (SOC) daily dosing (3mg/kg) for induction therapy in moderate to severe histoplasmosis; 2) Assess the safety and efficacy of posaconazole for consolidation therapy compared to SOC itraconazole in moderate to severe histoplasmosis and 3); Assess the safety and efficacy of 6 months of consolidation therapy compared to the SOC 12 months of consolidation therapy in persons with HIV on appropriate antiretroviral therapy.

Deliverables: We seek to conduct a factorial design clinical trial to evaluate single high-dose liposomal amphotericin B compared to standard of care induction for severe disseminated or pulmonary histoplasmosis and to evaluate posaconazole in comparison to the standard of care for consolidation therapy. The results will be highly informative and will directly affect WHO/PAHO guidelines for histoplasmosis.

DESCRIPTION										BUDGET YEAR 1
A. Senior/Key Personnel/Other Personnel (green)			Y1	Y2	Y3	Y4	Y5	Y6	Y7	
Name	**Project Role**	**Base Salary**	**Effort**	**Effort**	**Effort**	**Effort**	**ffor**	**Effort**	**Effort**	
Alessandro Comaru Pasqualotto	*MPI*	*221,900*	*30.0%*	*30.0%*	*30.0%*	*30.0%*	*##*	*30.0%*	*30.0%*	66,570
Daiane Flores Dalla Lana	*Study coordinator*	*44,444*	*50.0%*	*40.0%*	*40.0%*	*40.0%*	*##*	*40.0%*	*50.0%*	22,222
Luana Bazana	*Study coordinator*	*44,444*	*50.0%*	*40.0%*	*40.0%*	*40.0%*	*##*	*40.0%*	*50.0%*	22,222
Renata Ascenco Soares	*Study coordinator*	*44,444*	*50.0%*	*40.0%*	*40.0%*	*40.0%*	*##*	*40.0%*	*50.0%*	22,222
Tarsila Vieceli	*Medical care coordinator*	44,444	*50.0%*	*40.0%*	*40.0%*	*40.0%*	*##*	*40.0%*	*50.0%*	22,222
Fringe Benefits										
Name	**Fringe Benefit Rate (%)**									
Alessandro Comaru Pasqualotto	*10.0%*									6,657
Daiane Flores Dalla Lana	*10.0%*									2,222
Luana Bazana	*10.0%*									2,222
Renata Ascenco Soares	*10.0%*									2,222
Tarsila Vieceli	*10.0%*									2,222
Total Senior/Key Personnel Costs										**171,003**
D. Other Direct Costs										
Domestic Travel										6,500
Foreign Travel										8,000
redcap setup/maintenance										300
TDM storage										1,190
per enrollee fee										118,947
Posaconazole										0
Itraconazole										7,920
liposomal amphotericin (donation)										0
Trial insurance										9,000
Total Other Direct Costs										**151,857**
E. Direct Costs										
Total Direct Costs (A thru D)										**322,860**
G. Facilities & Administrative Costs (Indirect Costs)										
F&A Cost Type	**F&A Cost Rate**	**F&A Cost Base**	**Year**							
Modified Total Direct Cost	*8.0%*	*322,860*	*1*							**25,829**
Modified Total Direct Cost	*8.0%*	*452,889*	*2*							
Modified Total Direct Cost	*8.0%*	*452,889*	*3*							
Modified Total Direct Cost	*8.0%*	*452,889*	*4*							
Modified Total Direct Cost	*8.0%*	*452,889*	*5*							
Modified Total Direct Cost	*8.0%*	*452,889*	*6*							
Modified Total Direct Cost	*8.0%*	*296,018*	*7*							
F&A Cost is not applied to equipment, scholarships, renovations, tuition, GRA fringe benefits, or any subcontract costs greater than $25,000										
H. Total Costs										
Total Direct and F&A Institutional Costs										**348,689**

BUDGET JUSTIFICATION

Univeridade Federal de Ciencias da Saude de Porto Alegre, Porto Alegre, Brazil

A. KEY PERSONNEL

Alessandro Pasqualotto MD, PhD, Multiple-Principal Investigator (3.6 calendar months in yrs. 1 – 7) is a Professor at Univeridade Federal de Ciencias da Saude de Porto Alegre, Porto Alegre, Brazil. Dr. Pasqualotto has extensive experience in mycology and in clinical trials. Specifically, Dr. Pasqualotto recently completed the first histoplasmosis clinical trial in >20 years despite histoplasmosis be the most common infection (tied with TB) in Latin America amongst persons with HIV. Dr. Bahr collaborated with Dr. Pasqualotto on that trial and that collaboration directly led to this proposal. Dr. Pasqualotto has extensive experience in conducting high impact mycology research and has close collaborations with WHO/PAHO and the U.S. CDC and has held leadership positions and/or served on clinical guideline panels for the European Confederation of Medical Mycology, the International Society for Human and Animal Mycology, the Pan American Health Organization and the World Health Organziation. For this proposal Dr. Pasqualotto is the multiple-PI based in Brazil. Drs. Bahr and Pasqualotto will oversee the entire clinical trial while Dr. Pasqualotto will oversee the sites in Brazil directly including clinical care directed by site sub-investigators, randomization, pharmacy, laboratories, data reporting and clinical care.

UFCSPA fringe rate for faculty, 10.0%

B. OTHER PERSONNEL

Daiane Flores Dalla Lana, Luana Bazana, Renata Ascenco Soares (n=3), study coordinators and Tarsila Vieceli, clinical care coordinator (6.0 calendar months each in yrs. 1 and 7, 4.8 calendar months in yrs. 2-6) will coordinate the trial in Brazil under the direction of Dr. Pasqualotto. Study coordinators will work with local sub-investigators to train local staff as to the study protocols, make sure supplies and processes for care of study participants and collection of data are in place, troubleshoot issues with local investigators and staff, assist with regulatory requirements and coordinate with UMN staff for transportation of samples to UMN for post-hoc TDM of all azoles. Dr. Vieceli as the medical care coordinator.

UFCSPA fringe rate 10.0% for staff.

C. EQUIPMENT – $0

D. TRAVEL – $101,500

Domestic Travel: Sample transport in Brazil and travel to study sites
Domestic travel in Brazil is budgeted at $2,500 per year for transportation of frozen samples from each site to Porto Alegre in preparation for shipping to UMN for drug level measurements for posaconazole and itraconazole as well as transportation of antigen test and medication transportation from Porto Alegre to the other sites. In addition, $4,000 per year is budgeted for Dr. Pasqualotto and/or the study coordinators to travel to local sites to conduct monitoring visits. The budget is to include local transportation via air or bus as required as well as hotel and per diem. Total domestic travel costs $45,500

Foreign Travel: International conference travel
Foreign travel to the U.S or Europe for one international conference budgeted at $4,000 per trip for Dr. Pasqualotto ($2,500 flight, $100 conference fee, $800 hotel, $100 ground transport and $500 per diem/meals). One additional trip per year is budgeted for either Dr. Pasqualotto to travel to UMN (planned in years 1,3,5,7) or a sub-investigator to travel to an international conference. Total budget for international travel, $56,000.

E. OTHER DIRECT COSTS (MINUS TRAVEL) - $1,641,441

Redcap maintenance: A yearly fee of $300 is budgeted for redcap maintenance. This will pay for local IT staff to assist with any redcap issues that arise. Total budget for redcap maintenance: $2,100.

Drug level measurement sample storage: We have budgeted $1,190 yearly for storage of samples at the sites and eventually at UFCSPA prior to shipment to UMN (shipped yearly). This will be for storage only, transportation costs within Brazil are budgeted above. Shipping costs will be paid by UMN and are budgeted at that site as are costs for running the assays. Total storage costs: $8,330

Per enrollee site payment: Given the expected variations in enrollment by each site and the number of sites, we have elected to budget a fee to be paid at each site rather than flat staff fees. We have budgeted for a flat fee of $2,973.67 per participant enrolled. This fee will cover costs for standard laboratory tests (complete blood count with differential, HIV screening, CD4 count, electrolytes, renal function, liver function tests, urine pregnancy test), specific tests for histoplasmosis diagnosis or treatment that will be universally performed for this study in each participant (itraconazole therapeutic drug monitoring, *Histoplasma* urine antigen enzyme immunoassay) and *Histoplasma* tests that will be done in some but not all participants such as fungal culture, PCR, histopathology and microscopy. Of note, the *Histoplasma* antigen tests are donated but we must still pay for the test to be run in the laboratory. This fee also will cover a chest x ray for each patient. Lastly we have estimated total time needed per participant with hourly rates for sub-investigators, nurses, pharmacist and pharmacy technicians. Laboratory staff are not included given the fee includes prices per test.

A complete breakdown of these estimates per participant and in total (for years 2-6) is included below. The per participant costs are the same for years 1 and 7 but the overall yearly costs are less. We have spread the total enrollment out for budgetary purposes over 7 years, however we expect enrollment to be completed by midway through year 6 with payments pushed into the next fiscal year for year 7 to allow for staffing, patient follow up, data cleaning and analysis. Total cost for enrollee fees: $1,558,202.

Table 1: Costs budgeted for laboratory studies and personnel time per participant

	Screening	Hospitalization	Hospital Discharge	outpatient visit				Misc Sick Visit			Annual Cohort =	90
	Tests by Study Week per patient											
Week	Scr	0	2	4	10	26	40	52	Sick	# units/pt	Total# units	Unit Cost ($)	Total Cost ($)
Test (number tests)													
CBC and differential	0	1	2	0	0	0	0	0.00	0.1	3.1	279	$10.00	$2,790
HIV-Rapid Screening Test	0.6	0	0	0	0	0	0	0.00	0.0	0.6	54	$3.75	$203
CD4 Count	0	1	0	0	0	1	0	0.00	0.0	2	180	$9.00	$1,620
BMP	0.0	1	2	0	0	0	0	0.00	0.1	3.1	279	$34.20	$9,542
Liver Function Tests (ALT, Bili)	0	1	2	1	1	0	0	0.00	0.2	5.2	468	$25.50	$11,934
Mg	0	1	2	0	0	0	0	0.00	0.0	3	270	$16.00	$4,320
hcG, urine	0.5	0.0	0.0	0	0	0	0	0.00	0.0	0.5	45	$6.50	$293
Histoplasma antigen	1	0	1	0	1	1	0.2	0.20	0.0	4.4	396	$4.00	$1,584
CXR	1	0	0.0	0	0	0	0	0.00	0.1	1.1	99	$ 35.00	$3,465
Histoplasma PCR	1	0	2.0	1	0	0	0	0.00	0.0	0.3	27	$ 30.00	$810
microscopy	0	0	0.2	0	0	0	0	0.00	0.0	0.3	27	$ 15.00	$405
fungal culture	0	0	0.2	0	0	0	0	0.00	0.0	0.3	27	$ 30.00	$810
histopathology (and read)	0	0	0.2	0	0	0	0	0.00	0.0	0.3	27	$ 79.75	$2,153
real-time itraconazole TDM	0	0	0.5	0	0	0	0	0.00	0.2	0.7	63	$ 60.00	$3,782
Personnel (total hours, not esimated per week)													
Sub-investigator time										6.2	558	$ 170.00	$94,860
Nurse time										13.0	1170	$ 90.00	$105,300
Pharmacy time (pharmacist and technician)										3.0	270	$ 88.00	$23,760
Total:											**Total Research / Safety Testing:**		**$267,630**
												Per Person Avg	$2,973.67

Medication: Medications will be procured centrally and distributed to sites as necessary. Itraconazole is estimated to cost $44 per 30 day supply. Itraconazole will be given to 50% of 524 participants in Brazil randomized in Aim 2. One half of participants will receive 12 months total of azole consolidation therapy and the other half 6 months of azole consolidation therapy. This will be supplied locally in Brazil. Posaconazole is estimated to cost $214.80 per 30 day supply and has the same number of participants estimated to receive the medication as was the case per itraconazole. Posaconazole pricing has been secured from Cost Plus Drugs and is much cheaper than much of the U.S. market and in Brazil. For instance as of 8 October in Minneapolis, MN the best price on GoodRx is $333.96 for the same 30 day supply. This will be budgeted at UMN and shipped to Porto Alegre and distributed from there to local sites. Liposomal amphotericin will be donated by Gilead and so will have no cost. Half of participants will receive a single high dose and half will receive standard dose for 2 weeks. Rescue amphotericin (14 days) is estimated to be need in 12% of patients (see Research Plan for citation).

Total cost for medications: $109,940

Table 2: Total persons receiving each medication by year at UFCSPA

year	1	2	3	4	5	6	7	total
total enrollment per year	40.00	90.00	90.00	90.00	90.00	90.00	34.00	524.00
LAMb x1	20.00	45.00	45.00	45.00	45.00	45.00	17.00	
LAmb 2 weeks	20.00	45.00	45.00	45.00	45.00	45.00	17.00	
Rescue (12% total)	4.80	10.80	10.80	10.80	10.80	10.80	4.08	
azoles								
itraconazole	20.00	45.00	45.00	45.00	45.00	45.00	20.00	265.00
posaconazole	20.00	45.00	45.00	45.00	45.00	45.00	20.00	

Trial Insurance: Clinical trial insurance will be purchased prior to the start of the trial. Based on prior purchases in Brazil with the sites involved in this study, we have budgeted $9,000 to be charged in year one of this study.

INDIRECT COSTS

Facilities and Administrative Costs are calculated at a fixed rate of 8% per year of Modified Direct Total Costs consistent with NIH policies.

Recipient Information

1. Recipient Name
REGENTS OF THE UNIVERSITY OF MINNESOTA
2221 UNIVERSITY AVE SE STE 100
MINNEAPOLIS, MN 55414

2. Congressional District of Recipient
05

3. Payment System Identifier (ID)
1416007513A5

4. Employer Identification Number (EIN)
416007513

5. Data Universal Numbering System (DUNS)
555917996

6. Recipient's Unique Entity Identifier
KABJZBBJ4B54

7. Project Director or Principal Investigator
Nathan Bahr, MD (Contact)
Associate Professor
bahrx026@umn.edu
612-624-4171

8. Authorized Official
Tracy Burdett
burde047@umn.edu
612-624-5599

Federal Agency Information

9. Awarding Agency Contact Information
Shirsa Roy

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
shirsa.roy@nih.gov

10. Program Official Contact Information
Dona Love
Program Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES
donalove@mail.nih.gov
301-761-7788

Federal Award Information

11. Award Number
3R01AI195133-01S1

12. Unique Federal Award Identification Number (FAIN)
R01AI195133

13. Statutory Authority
42 USC 241 42 CFR 52

14. Federal Award Project Title
Histoplasmosis Induction and Consolidation Therapy Factorial Randomized Clinical Trial (HISTO-FACT)

15. Assistance Listing Number
93.855

16. Assistance Listing Program Title
Allergy and Infectious Diseases Research

17. Award Action Type
Supplement

18. Is the Award R&D?
Yes

Summary Federal Award Financial Information	
19. Budget Period Start Date 09/03/2025 **– End Date** 08/31/2026	
20. Total Amount of Federal Funds Obligated by this Action	$348,689
20 a. Direct Cost Amount	$322,860
20 b. Indirect Cost Amount	$25,829
21. Authorized Carryover	
22. Offset	
23. Total Amount of Federal Funds Obligated this budget period	$348,689
24. Total Approved Cost Sharing or Matching, where applicable	$0
25. Total Federal and Non-Federal Approved this Budget Period	$348,689
26. Project Period Start Date 09/03/2025 **– End Date** 08/31/2032	
27. Total Amount of the Federal Award including Approved Cost Sharing or Matching this Project Period	$348,689

28. Authorized Treatment of Program Income
Additional Costs

29. Grants Management Officer - Signature
Sufiyan Saeed

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
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

SECTION I – AWARD DATA – 3R01AI195133-01S1

Principal Investigator(s):
Nathan Bahr (contact), MD
Alessandro Comaru Pasqualotto, MD

Award e-mailed to: awards@umn.edu

Dear Authorized Official:

The National Institutes of Health hereby awards a grant in the amount of $348,689 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to UNIVERSITY OF MINNESOTA in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

Acceptance of this award, including the "Terms and Conditions," is acknowledged by the 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 R01AI195133. 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,

Sufiyan Saeed
Grants Management Officer
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Additional information follows

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

Federal Direct Costs	$322,860
Federal F&A Costs	$25,829
Approved Budget	$348,689
Total Amount of Federal Funds Authorized (Federal Share)	$348,689
TOTAL FEDERAL AWARD AMOUNT	$348,689
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$348,689

SUMMARY TOTALS FOR ALL YEARS (for this Document Number)		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
1	$348,689	$348,689
2	$489,118	$489,118
3	$489,118	$489,118
4	$489,118	$489,118
5	$489,118	$489,118
6	$489,118	$489,118
7	$319,699	$319,699

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

Fiscal Information:

Payment System Identifier:	1416007513A5
Document Number:	RAI195133A001FS
PMS Account Type:	P (Subaccount)
Fiscal Year:	2025

IC	CAN	2025	2026	2027	2028	2029	2030	2031
AI	8472350	$348,689	$489,118	$489,118	$489,118	$489,118	$489,118	$319,699

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

NIH Administrative Data:
PCC: M31 / **OC**: 41023 / **Released**: 09/04/2025
Award Processed: 09/05/2025 01:19:36 PM

SECTION II – PAYMENT/HOTLINE INFORMATION – 3R01AI195133-01S1

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 – 3R01AI195133-01S1

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).

This institution is a signatory to the Federal Demonstration Partnership (FDP) Phase VII Agreement which requires active institutional participation in new or ongoing FDP demonstrations and pilots.

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

This award is subject to the requirements of 2 CFR Part 25 for institutions to obtain a unique entity identifier (UEI) and maintain an active registration in the System for Award Management (SAM). Should a consortium/subaward be issued under this award, a UEI 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) R01AI195133. Recipients must document the assigned FAIN on each consortium/subaward issued under this award.

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

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

This award provides support for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the “responsible party” must register “applicable clinical trials” on the ClinicalTrials.gov Protocol Registration System Information Website. NIH encourages registration of all trials whether required under the law or not. For more information, see http://grants.nih.gov/ClinicalTrials_fdaaa/
This award provides support for one or more NIH defined Phase III Clinical Trials. The NIH Policy for research supported as an NIH Phase III Clinical Trial has been amended in Section II.B. of the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research – Amended October 2001 (see http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm).

A description of plans to conduct analyses, as appropriate, by sex/gender and racial/ethnic groups must be included in clinical trial protocols. Cumulative subject accrual and progress in conducting subset analyses must be reported to NIH in the annual Progress Reports. Final analyses of sex/gender and racial/ethnic differences must be reported in the required Final Progress Report or Competitive Renewal Applications (or Contract Renewals/Extensions) as stated in Section II.B. of the Guidelines.

Recipients must administer the project in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient will comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals, see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution’s specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see http://www.hhs.gov/ocr/civilrights/understanding/disability/index.html.

- HHS funded health and education programs must be administered in an environment free of sexual harassment; see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.
- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws, see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

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 – 3R01AI195133-01S1

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

RESTRICTION: The recipient must request prior approval from NIAID to add or change research protocols in Brazil. No funds for new protocols may be expended unless NIAID has approved the change via a revised Notice of Award (NoA).

NIH and **UNIVERSITY OF MINNESOTA** have renegotiated the award structure of the research activities performed by **Fundação Médica do Rio Grande do Sul, BRAZIL**. Therefore, all funds to support the activities by **Fundação Médica do Rio Grande do Sul, BRAZIL** on the parent project, **1R01AI195133-01**, have been included in this award. No direct funds for **UNIVERSITY OF MINNESOTA** are included in this supplemental award. No rebudgeting is allowed between the parent project and this supplement during this budget period, and funds expended by **Fundação Médica do Rio Grande do Sul, BRAZIL** must be reported through a separate annual Federal Financial Report from funds expended by the parent award or any other performance site on this project.

Reporting: Activities supported by this supplemental award must be reported on the parent award's Research Performance Progress Report (RPPR). Specifically, accomplishments supported by this supplement should be reported in Section B.3 and expenditures from this supplement should be reported in Section E.4 of the parent award's RPPR. At the time of the RPPR, the recipient may request to rebudget future year funds between the supplement and parent award, provided the total cost does not change from the previously committed levels. The justification for why rebudgeting is necessary should be provided in Section G.1, and detailed budgets for both the parent award and foreign supplement should be provided in Section H.1.

The budget period anniversary start date for future year(s) will be **9/1**.

Foreign grant recipients and subrecipients that expend a total of $750,000 or more in Federal awards during their fiscal year are required to conduct a Single Audit. The audit must be performed in accordance with the requirements outlined in 2 CFR Part 200 Subpart F, or program-specific audit as required by award terms and conditions. See NOT-OD-24-151.

Research conducted at the following site(s) must be reported in the Research Performance Progress Report (RPPR), Section G.9 (Foreign component):

Fundação Médica do Rio Grande do Sul, BRAZIL.

NIAID requires annual Federal Financial Reports (SF425) for all awards to foreign recipients. All Federal Financial Reports must be submitted electronically in the Payment Management System (PMS). Recipients can directly access PMS via the NIH Commons available at https://commons.era.nih.gov/commons/.

Additional information on electronic submission of Federal Financial Reports is available at the Commons Homepage or by contacting the eRA Helpdesk at: commons@od.nih.gov or (866) 504-9552.

Commitment overlap is not permitted, and occurs when an individual's time commitment exceeds 100 percent (i.e., 12 person months), whether or not salary support is requested. Therefore, no individual's time commitment may exceed 100 percent (i.e., 12 person months). Reductions in NIH support due to commitment overlap must be made in accordance with NIH policy as outlined in the NIH Grants Policy Statement.

This Notice of Award (NoA) includes funds for **Fundação Médica do Rio Grande do Sul, BRAZIL.**

This award is subject to the NIAID Clinical Terms of Award incorporated by reference, and can be accessed via the following World Wide Web address: https://www.niaid.nih.gov/grants-contracts/niaid-clinical-terms-award All submissions required by the NIAID Clinical Terms of Award must be forwarded electronically to the NIAID Program Official identified on this Notice of Award.

This term is being included in this award because the recipient of this NIH award (grant, cooperative agreement, contract, or other transaction authority award) has sought access to National Death Index data from the Centers for Disease Control and Prevention's National Center for Health Statistics (NCHS). This term serves as NIH's agreement to the Supplemental Confidentiality Agreement of the Centers for Disease Control National Death Index (NDI) Application, with regard to any data for which the funding recipient applies to obtain from the NDI under this award. Specifically, this term provides assurance that NIH will not receive any of the identifying or identifiable death record information obtained from the NDI, state death records, and/or death record follow-back investigations. Additionally, consistent with 45 C.F.R. 75.303(e), the awardee must safeguard NDI data received from NDI consistent with applicable Federal, state, local, and tribal laws regarding privacy and obligations of confidentiality, which includes confidentiality requirements imposed by the CDC through the Supplemental Confidentiality Agreement of the NDI Application. For purposes of this award condition, consistent with the NDI Application, "Identifying or Identifiable death record data" means any information on death certificates, other paper documents, or in computer files which by itself, or if linked with other records, would permit the identification of one or more individuals or establishments; for example, name(s), Social Security number, exact dates, addresses, and death certificate number. Even with the removal of direct identifiers and linkable study subject identification numbers, there is still a special concern that some combinations of the remaining variables could potentially be used to identify an individual. For example, a combination of date of birth, date of death, and/or cause of death is considered identifiable. Upon demonstrated inclusion of this term, NCHS shall not require NIH officials to sign a Supplemental Confidentiality Agreement in order to grant recipient access to the requested NDI data, as NCHS will rely on this term as NIH's assurance as set forth herein.

This award includes human subject research studies and must conform to the DHHS policies for the Protection of Human Subjects research, which are a term and condition of award. Human subjects research is covered by the 2018 Common Rule, and may not be initiated until the associated protocols have received IRB approval as specified in 45 CFR 46. Failure to comply with the terms and conditions of award may result in the disallowance of costs and/or additional enforcement actions as outlined in Section 8.5 of the NIH Grants Policy Statement.

1. The clinical trial(s) supported by this award are subject to the plan dated 1/13/2025 which adheres to the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. As noted, the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant and primary summary results reported in ClinicalTrials.gov, not later than one year after the completion date. The reporting of summary results is required by this term of award even if the primary completion date occurs after the period of performance.

2. This award is subject to additional certification requirements with each submission of the Annual, Interim, and Final Research Performance Progress Report (RPPR). The recipient must agree to the following annual certification when submitting each RPPR. By submitting the RPPR, the AOR signifies compliance, as follows:

   In submitting the RPPR, the SO (or PD/PI with delegated authority), certifies to the best of his/her knowledge that, for all clinical trials funded under this NIH award, the recipient and all investigators conducting NIH-funded clinical trials are in compliance with the recipient's plan addressing compliance with the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded in whole or in part under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the completion date, even if the completion date occurs after the period of performance.

Data Management and Sharing Policy: Applicable

This project is expected to generate scientific data. Therefore, the Final NIH Policy for Data Management and Sharing applies. The approved Data Management and Sharing (DMS) Plan is hereby incorporated as a term and condition of award, and the recipient shall manage and disseminate scientific data in accordance with the approved plan. Any significant changes to the DMS Plan (e.g., new scientific direction, a different data repository, or a timeline revision) require NIH prior approval. Failure to comply with the approved DMS plan may result in suspension and/or termination of this award, withholding of support, audit disallowances,

and/or other appropriate action. See NIH Grants Policy Statement Section 8.2.3 for more information on data management and sharing expectations.

SPREADSHEET SUMMARY
AWARD NUMBER: 3R01AI195133-01S1

INSTITUTION: UNIVERSITY OF MINNESOTA

Facilities and Administrative Costs	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
F&A Cost Rate 1	8%	8%	8%	8%	8%	8%	8%
F&A Cost Base 1	$322,860	$452,887	$452,887	$452,887	$452,887	$452,887	$296,018
F&A Costs 1	$25,829	$36,231	$36,231	$36,231	$36,231	$36,231	$23,681

Subaward Number:

SUBA00001865-P012786401

Attachment 8

Research Subaward

Export Controls

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

Subaward Number:

SUBA00001865-P012786401

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

Human subjects data will be collected by the team in Brazil. Patient identifiable data will not be shared with the UMN team. Each participant will be assigned a code that will be stored separately by the local study team in a secure location. Human subjects data will be entered into a secure database (redcap) and stored electronically and securely via an established database at UMN. No human subjects will be enrolled at UMN and so no data will be sent from UMN to the Brazil site(s).