FDP Cost Reimbursement Subaward

Federal Awarding Agency: National Institutes of Health (NIH)

Pass-Through Entity (PTE):	**Subrecipient:**
Magee-Womens Research Institute & Foundation	San Francisco Dept of Public Health
PTE PI: Sharon Hillier, PhD	Sub PI: Dr. Albert Liu
PTE Federal Award No: UM1 AI068633	Subaward No: 9649

Project Title: Leadership and Operations Center (LOC): Microbicide Trials Network

Subaward Period of Performance (Budget Period): Start: 12/01/2019 End: 11/30/2020	Amount Funded This Action (USD): $ 134,610.00
Estimated Project Period (if incrementally funded): Start: End:	Incrementally Estimated Total (USD): $

Terms and Conditions

1. PTE hereby awards a cost reimbursable subaward, (as 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.

2. Subrecipient shall submit invoices not more often than monthly and not less frequently than quarterly for allowable costs incurred. Upon the receipt of proper invoices, the PTE agrees to process payments in accordance with this Subaward and 2 CFR 200.305. All invoices shall be submitted using Subrecipient's standard invoice, but at a minimum shall include current and cumulative costs (including cost sharing), 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 Financial Contact, shown in Attachment 3A.

3. A final statement of cumulative costs incurred, including cost sharing, marked "FINAL" must be submitted to PTE's Financial Contact, as shown in Attachment 3A, not later than 60 days after the Budget Period end date. The final statement of costs shall constitute Subrecipient's final financial report.

4. All payments shall be considered provisional and are 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.

5. Matters concerning the technical performance of this Subaward 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.

6. Matters concerning the request or negotiation of any changes in the terms, conditions, or amounts cited in this Subaward, and any changes requiring prior approval, shall be directed to the PTE's Administrative Contact and the Subrecipient's Administrative Contact 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 to the Period of Performance and budget Bilaterally. Unilateral modification shall be considered valid 14 days after receipt unless otherwise indicated by Subrecipient when sent to Subrecipient's Administrative Contact, as shown in Attachment 3B.

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. PTE notice shall be directed to the Administrative Contact, and Subrecipient notice shall be directed to the Administrative 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. 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 the PTE:	By an Authorized Official of the Subrecipient:
Name: Yoel Sadovsky, MD	Name: Tomás J. Aragón, MD, DrPH
Title: Executive Director	Title: Director, Population Health Division (PHD)
Date: 11/25/19	Date: 12/03/19

DocuSigned by: Tomás Aragón 0BDB2B95DBC0442...

Attachment 1
Certifications and Assurances

Subaward Number: 9649

Certification Regarding Lobbying (2 CFR 200.450)
By signing this Subaward, the Subrecipient Authorized Official certifies, to the best of his/her knowledge and belief, that no 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 Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement in accordance with 2 CFR 200.450.

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)
By signing this Subaward, the Subrecipient Authorized Official certifies, to the best of his/her knowledge and belief that neither the Subrecipient nor its principals are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from participation in this transaction by any federal department or agency, in accordance with 2 CFR 200.213 and 2 CFR 180.

Audit and Access to Records
Per 2 CFR 200.501- 200.521, Subrecipient certifies that it will provide notice of any adverse findings which impact this Subaward and will provide access to records as required by parts 2 CFR 200.336, 200.337, and 200.201 as applicable. If Subrecipient is not subject to the Single Audit Act, then Subrecipient will provide notice of the completion of any required audits and provide access to such audits upon request.

Program for Enhancement of Contractor Employee Protections (41 U.S.C 4712)
Subrecipient is hereby notified that they are required to: inform their employees working on any federal award that they are subject to the whistleblower rights and remedies of the program; inform their employees in writing of employee whistleblower protections under 41 U.S.C §4712 in the predominant native language of the workforce; and include such requirements in any agreement made with a subcontractor or subgrantee.

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.

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.

Attachment 2
Federal Award Terms and Conditions

Subaward Number: 9649

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.
11/19/19	UM1AI068633	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:
   http://grants.nih.gov/grants/policy/nihgps/nihgps.pdf
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/policy/notices.htm
4. 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 200.33 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.

Provided upon request is a Data Management and/or Sharing Plan that incorporates additional requirements as submitted to the Federal Awarding Agency.

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.

Work Involving Human or Vertebrate Animals (Select Applicable Options)

☒ No Human or Vertebrate Animals

This section left intentionally blank.

Human Subjects Data (Select One) Not Applicable

This section left intentionally blank

This section left intentionally blank

Additional Terms

The MTN Data Management/Sharing Plan can be found at:

Data Management/Sharing Plan can be found at:

https://mtnstopshiv.org/manual-operational-procedures

Section 19: Data Access, Public Release and Communications

Attachment 3A
Pass-Through Entity (PTE) Contacts

Subaward Number: 9649

PTE Information

Entity Name: Magee-Womens Research Institute & Foundation

Legal Address: 3339 Ward Street
Pittsburgh, PA 15213

Website: mwrif.org

PTE Contacts

Central Email:

Principal Investigator Name: Sharon Hillier, PhD

Email: hillsl@mwri.magee.edu Telephone Number: 412-641-6435

Administrative Contact Name: Cheryl Richards

Email: crichards@mwri.magee.edu Telephone Number: 412-641-8983

COI Contact email (if different to above):

Financial Contact Name: Kim Comer

Email: comekj@mwri.magee.edu Telephone Number: 412-641-6159

Email invoices? (●) Yes ( ) No Invoice email (if different): mwrinvoices@mwri.magee.edu

Authorized Official Name: Yoel Sadovsky, MD

Email: ysadovsky@mwri.magee.edu Telephone Number: 412-641-2675

PI Address:

Magee-Womens Research Institute
204 Craft Ave
Pittsburgh, PA 15213

Administrative Address:

Magee-Womens Research Institute and Foundation
3339 Ward Street
Pittsburgh, PA 15213

Invoice Address:

Attn: Kim Comer
204 Craft Ave
Pittsburgh, PA 15213
invoices should be emailed if possible as indicated above

Attachment 3B

Subrecipient Contacts

Subaward Number: 9649

Subrecipient Information for FFATA reporting

Entity's DUNS Name: City and County of San Francisco

EIN No.: 94-6000417

Institution Type: local government

DUNS: 103717336

Currently registered in SAM.gov: (x) Yes ( ) No

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

Parent DUNS: 103717336

This section for U.S. Entities:

Congressional District: 12

Zip Code Look-up

Zip Code+4: 94102-6045

Place of Performance Address

25 Van Ness Ave, SF, CA 94102

Subrecipient Contacts

Central Email:

Website: www.sfdph.org

Principal Investigator Name: Dr. Albert Liu

Email: albert.liu@sfdph.org Telephone Number: 415-437-7408

Administrative Contact Name: Sajid Shaikh

Email: sajid.shaikh@sfdph.org Telephone Number: 415-255-3512

Financial Contact Name: Sajid Shaikh

Email: sajid.shaikh@sfdph.org Telephone Number: 415-255-3512

Invoice/Payment Email: David.Anabu@sfdph.org

Authorized Official Name: Tomas Aragon

Email: tomas.aragon@sfdph.org Telephone Number: 415-787-2583

Legal Address:

25 Van Ness Ave, SF, CA 94102

Administrative Address:

1380 Howard St, 4th Fl, SF, CA 94102

Payment Address:

1380 Howard St, 4th Fl, SF, CA 94102

Attachment 3B-2

Highest Compensated Officers

Subaward Number: 9649

Subrecipient:

Institution Name: San Francisco Dept of Public Health

PI Name: Dr. Albert Liu

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: n/a

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: 9649

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 within 90 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 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 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 Principal Investigator 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: No

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

Additional Technical and Reporting Requirements:

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

Subaward Number: 9649

Statement of Work

(•) Below ( ) Attached, [ ] pages

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

As Protocol Chair of MTN-038, Dr. Liu will provide overall leadership and guidance to the protocol team throughout the development, implementation, and operation of the protocol. He will establish and maintain conference calls and meetings to develop and manage the study and coordinate the establishment of study-specific working groups as needed to achieve the aims of the study. He will also be responsible for monitoring participant safety through the Protocol Safety Review Team, maintaining high data quality, adhering to the proposed project schedule, and facilitating decision making within the Protocol Team. Dr. Liu will oversee analysis and manuscript preparation to ensure timely publication of results and dissemination of findings from the study. He will also act as a liaison regarding this protocol with key leadership and operational groups within the MTN and DAIDS. Dr. Liu is being provided additional support to complete primary manuscripts for MTN-036 and MTN-038 prior to the end of the grant period.

Budget Information

Indirect Information Indirect Cost Rate (IDC) Applied: 25 %

Rate Type: Other (add in blank box) — 25% of Personnel Costs

Cost Sharing: No

If Yes, include Amount: $

Budget Details

( ) Below (•) Attached, 4 pages

Budget Totals

Direct Costs	$ 107,688.00
Indirect Costs	$ 26,922.00
Total Costs	$ 134,610.00

All amounts are in United States Dollars

Attachment 5

Check Form for Errors | Save

RESEARCH & RELATED BUDGET - Budget Period 1

OMB Number: 4040-0001
Expiration Date: 10/31/2019

*** ORGANIZATIONAL DUNS:** 1037173360000 **Enter name of Organization:** City & County of SF - Dept of Public Health

*** Budget Type:** ☐ Project ☒ Subaward/Consortium **Budget Period: 1** *** Start Date:** 12/01/2019 *** End Date:** 11/30/2020

A. Senior/Key Person

Prefix	* First	Middle	* Last	Suffix	Base Salary ($)	Months Cal.	Months Acad.	Months Sum.	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
	Albert		Liu		192,300.00	4.80			76,920.00	30,768.00	107,688.00

*** Project Role:** Consortium PI

Additional Senior Key Persons: Add Attachment | Delete Attachment | View Attachment

Total Funds requested for all Senior Key Persons in the attached file:

Total Senior/Key Person: 107,688.00

B. Other Personnel

* Number of Personnel	* Project Role	Months Cal.	Months Acad.	Months Sum.	* Requested Salary ($)	* Fringe Benefits ($)	* Funds Requested ($)
	Post Doctoral Associates						
	Graduate Students						
	Undergraduate Students						
	Secretarial/Clerical						

Total Number Other Personnel:

Total Other Personnel:

Total Salary, Wages and Fringe Benefits (A+B): 107,688.00

C. Equipment Description

List items and dollar amount for each item exceeding $5,000

Equipment item	* Funds Requested ($)

Additional Equipment: Add Attachment | Delete Attachment | View Attachment

Total funds requested for all equipment listed in the attached file	
Total Equipment	

D. Travel

	Funds Requested ($)
1. Domestic Travel Costs (Incl. Canada, Mexico and U.S. Possessions)	
2. Foreign Travel Costs	
Total Travel Cost	

E. Participant/Trainee Support Costs

	Funds Requested ($)
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other	
Number of Participants/Trainees	**Total Participant/Trainee Support Costs**

F. Other Direct Costs

		Funds Requested ($)
1.	Materials and Supplies	
2.	Publication Costs	
3.	Consultant Services	
4.	ADP/Computer Services	
5.	Subawards/Consortium/Contractual Costs	
6.	Equipment or Facility Rental/User Fees	
7.	Alterations and Renovations	
8.		
9.		
10.		
	Total Other Direct Costs	

G. Direct Costs

	Funds Requested ($)
Total Direct Costs (A thru F)	107,688.00

H. Indirect Costs

Indirect Cost Type	Indirect Cost Rate (%)	Indirect Cost Base ($)	* Funds Requested ($)
25% of Total Personnel Cost	25.00	107,688.00	26,922.00

Total Indirect Costs	26,922.00

Cognizant Federal Agency
(Agency Name, POC Name, and POC Phone Number)

I. Total Direct and Indirect Costs

	Funds Requested ($)
Total Direct and Indirect Institutional Costs (G + H)	134,610.00

J. Fee

	Funds Requested ($)

K. Total Costs and Fee

	Funds Requested ($)
Total Costs and Fee (I + J)	134,610.00

L. * Budget Justification

(Only attach one file.) Add Attachment | Delete Attachment | View Attachment

RESEARCH & RELATED BUDGET - Cumulative Budget

	Totals ($)
Section A, Senior/Key Person	107,688.00
Section B, Other Personnel	
Total Number Other Personnel	
Total Salary, Wages and Fringe Benefits (A+B)	107,688.00
Section C, Equipment	
Section D, Travel	
1. Domestic	
2. Foreign	
Section E, Participant/Trainee Support Costs	
1. Tuition/Fees/Health Insurance	
2. Stipends	
3. Travel	
4. Subsistence	
5. Other	
6. Number of Participants/Trainees	
Section F, Other Direct Costs	
1. Materials and Supplies	
2. Publication Costs	
3. Consultant Services	
4. ADP/Computer Services	
5. Subawards/Consortium/Contractual Costs	
6. Equipment or Facility Rental/User Fees	
7. Alterations and Renovations	
8. Other 1	
9. Other 2	
10. Other 3	
Section G, Direct Costs (A thru F)	107,688.00
Section H, Indirect Costs	26,922.00
Section I, Total Direct and Indirect Costs (G + H)	134,610.00
Section J, Fee	
Section K, Total Costs and Fee (I + J)	134,610.00

Subaward Number:
9649

Attachment 6

Notice of Award (NOA) 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.

Attachment 6

Notice of Award

Multi-Component Research Project Co-op Agreements **Federal Award Date:** 11/19/2019
Department of Health and Human Services
National Institutes of Health

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

Grant Number: 5UM1AI068633-14
FAIN: UM1AI068633

Principal Investigator(s):
Sharon L. Hillier, PHD

Project Title: Leadership and Operations Center (LOC): Microbicide Trials Network

Yoel Sadovsky
DIR., OF GRANTS & CONTRACTS
MAGEE-WOMEN'S RES INST/FDN
OFFICE OF RESEARCH ADMIN
3339 WARD STREET
PITTSBURGH, PA 152133180

Award e-mailed to: mwrifnih@mwri.magee.edu

Period Of Performance:
Budget Period: 12/01/2019 – 11/30/2020
Project Period: 06/29/2006 – 11/30/2020

Dear Business Official:

The National Institutes of Health hereby awards a grant in the amount of $6,662,220 (see "Award Calculation" in Section I and "Terms and Conditions" in Section III) to MAGEE-WOMEN'S RES INST AND FOUNDATION in support of the above referenced project. This award is pursuant to the authority of 42 USC 241 31 USC 6305 42 CFR 52 and is subject to the requirements of this statute and regulation and of other referenced, incorporated or attached terms and conditions.

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

Each publication, press release, or other document about research supported by an NIH award must include an acknowledgment of NIH award support and a disclaimer such as "Research reported in this publication was supported by the National Institute Of Allergy And Infectious Diseases of the National Institutes of Health under Award Number UM1AI068633. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health." Prior to issuing a press release concerning the outcome of this research, please notify the NIH awarding IC in advance to allow for coordination.

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

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

Sincerely yours,

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

Additional information follows

SECTION I – AWARD DATA – 5UM1AI068633-14

Award Calculation (U.S. Dollars)

Salaries and Wages	$736,003
Fringe Benefits	$184,001
Personnel Costs (Subtotal)	$920,004
Consultant Services	$130,393
Materials & Supplies	$16,906
Travel	$322,759
Other	$693,759
Subawards/Consortium/Contractual Costs	$3,918,106
Federal Direct Costs	$6,001,927
Federal F&A Costs	$1,229,454
Approved Budget	$7,231,381
Total Amount of Federal Funds Obligated (Federal Share)	$7,231,381
Less Unobligated Balance	$569,161
TOTAL FEDERAL AWARD AMOUNT	$6,662,220
AMOUNT OF THIS ACTION (FEDERAL SHARE)	$6,662,220

SUMMARY TOTALS FOR ALL YEARS		
YR	**THIS AWARD**	**CUMULATIVE TOTALS**
14	$6,662,220	$6,662,220

Fiscal Information:

CFDA Name:	Allergy and Infectious Diseases Research
CFDA Number:	93.855
EIN:	1251462312A1
Document Number:	UAI068633B
PMS Account Type:	P (Subaccount)
Fiscal Year:	2020

IC	CAN	2020
HD	8014710	$3,000,000
AI	8017492	$600,000
AI	8029655	$2,023,351
AI	8472297	$1,038,869

NIH Administrative Data:
PCC: A22C / **OC**: 41029 / **Released**: ADEVINE 11/18/2019
Award Processed: 11/19/2019 12:03:32 AM

SECTION II – PAYMENT/HOTLINE INFORMATION – 5UM1AI068633-14

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

SECTION III – TERMS AND CONDITIONS – 5UM1AI068633-14

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

a. The grant program legislation and program regulation cited in this Notice of Award.
b. Conditions on activities and expenditure of funds in other statutory requirements, such as those included in appropriations acts.
c. 45 CFR Part 75.
d. National Policy Requirements and all other requirements described in the NIH Grants

Policy Statement, including addenda in effect as of the beginning date of the budget period.

e. Federal Award Performance Goals: As required by the periodic report in the RPPR or in the final progress report when applicable.
f. This award notice, INCLUDING THE TERMS AND CONDITIONS CITED BELOW.

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

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

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

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

This award has been assigned the Federal Award Identification Number (FAIN) UM1AI068633. 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 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.
This award represents the final year of the competitive segment for this grant. See the NIH Grants Policy Statement Section 8.6 Closeout for complete closeout requirements at: http://grants.nih.gov/grants/policy/policy.htm#gps.

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

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

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

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

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

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

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

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

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)

In accordance with the regulatory requirements provided at 45 CFR 75.113 and Appendix XII to 45 CFR Part 75, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts with cumulative total value greater than $10,000,000 must report and maintain information in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently the Federal Awardee Performance and Integrity Information System (FAPIIS)). Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75. This term does not apply to NIH fellowships.

Treatment of Program Income:
Additional Costs

SECTION IV – AI Special Terms and Conditions – 5UM1AI068633-14

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

This Notice of Award includes a cumulative amount of **$2,023,351** Total Costs awarded for Protocol Funding.

***

This noncompetetive award reflects a portion of the funding amount anticipated for FY 20. An adjustment upward is anticipated.

***

This award provides funds in the amount of **$2,023,351** Total Costs (**$1,914,373** Direct Costs and **$108,978** F&A Costs) for Protocol Funds (PF). These funds provide support for the period 12/01/19 – 11/30/20. Funds are provided for PF as requested by Yoel Sadovsky / Magee-Women's Research Institution and Foundation on 10/01/2019.

The unobligated balance stated in the Notice of Award, **$569,161**, represents a portion of the unobligated balance reported on the 12 year FFR. This amount is now available for PF for your expenditure.

Protocol Funds (PF): The LOC has chosen to distribute Network Protocol Funds (PF) directly to the Clinical Trial Unit (CTU) and/or Clinical Research Sites (CRS) affiliated with the Network. The LOC is required to:

Establish a consortium agreement or nonmonetary agreement with each CRS affiliated with the Network.

Establish a consortium agreement or nonmonetary agreement with the Clinical Trial Unit (CTU) affiliated with the CRS. Agreements with the CTU must state whether the PF will be provided directly to the CRS by the LOC or whether the funds will be provided directly to the CTU for CRS use. In either case, the CTU will have the primary responsibility for all PF accounting. The agreement must include the purpose, amount of funds, and time frame for the LOC to provide PF to each CRS associated with the specific CTU. When PF support is provided to the CRS, the amount and purpose must be provided to the CRS's CTU at the same time.

The annual PF distribution plan must be submitted to your NIAID/DAIDS NLG Program Officer and Grants Management Specialist for NIAID approval prior to implementing.

Summary of Requirements:

- Ensure executed nonmonetary agreement(s) and/or consortium agreement(s) are in place prior to funding of PF.
- Include the CTU on all communications regarding protocol funding.
- Ensure the consortium agreement(s) with the CRS indicates that they must provide at minimum quarterly information on actual grant expenditure to either the CTU (if the CRS is affiliated with a CTU) or the Network (if strictly a protocol specific site not affiliated with a CTU).
- For protocol specific sites not affiliated with a CTU, the LOC must keep records of actual expenditures, and ensure GCP and HSP training is completed for all personnel, and that time and effort is accounted for in the progress report.
- For protocol specific sites not affiliated with a CTU, the LOC will report all actual protocol fund expenses to NIAID annually.
- For all CTU/CRS disbursements during the -14 budget period the LOC will report actual expenses for all protocol funds disbursed during the -14 budget period to NIAID by March 31, 2020.
- LOC will verify invoices/participant enrollment against SDMC data.

***

This award authorizes the use of the Protocol Implementation Funds (PIF) to purchase Clinical Trial Insurance required by South Africa. This is in accordance with the request dated 09/20/2019 from Sara Arvay, Magee-Women's Research Institute and Foundation. These funds are restricted per protocol as noted below and may not be used for another purpose without NIAID award agency approval.

- MTN 042 - $3,197

This award authorizes the use of the Protocol Implementation Funds (PIF) to purchase Clinical Trial Insurance required by Uganda. This is in accordance with the request dated 11/05/2019 from Sara Arvay, Magee-Women's Research Institute and Foundation. These funds are restricted per protocol as noted below and may not be used for another purpose without NIAID award agency approval.

- MTN 042 - $20,340

This award authorizes the use of the Protocol Implementation Funds (PIF) to purchase Clinical Trial Insurance required by Peru. This is in accordance with the request dated 11/04/2019 from Sara Arvay, Magee-Women's Research Institute and Foundation. These funds are restricted per protocol as noted below and may not be used for another purpose without NIAID award agency approval.

- MTN 035 - $506

***

Funds may vary in future years depending on NIAID scientific priorities, availability, network needs and the ability of the Network to coordinate an appropriate study participant base with which to conduct the research proposed with the clinical trial units and sites. If the volume of research activities changes in a given year, NIAID/NIH reserves the right to renegotiate effort and funds upward or downward for the given year.
***

This award is issued as a Cooperative Agreement, and as such, substantial NIH scientific and 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 Administration Information of RFA AI-12-008, Leadership Group for a Clinical Research Network on Microbicides to Prevent HIV Infection (UM1) release date 01/27/2012, which are hereby incorporated by

reference as special terms and conditions of this award. This RFA may be accessed at: https://grants.nih.gov/grants/guide/rfa-files/RFA-AI-12-008.html
***

This award is subject to the Clinical Terms of Award included in Monitoring of Clinical Trials and Studies - NIAID (see NIH Guide for Grants and Contracts, July 8, 2002, NOT AI-02-032). These terms and conditions are hereby incorporated by reference, and can be accessed via the following World Wide Web address: http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf. All submissions required by the NIAID Clinical Terms of Award must be forwarded electronically or by mail to the responsible NIAID Program Official identified on this Notice of Grant Award.
***

In addition to the NIAID Clinical Terms of Award and all NIH clinical research policies, awardees must comply with the applicable DAIDS Clinical Research Policies and Standard Procedures Documents for all new studies. All clinical trial protocols must be reviewed and approved by the DAIDS Prevention Science Review Committee prior to implementation.
***

Grantees may contact the appropriate NIAID DAIDS staff with questions regarding these policies and standard procedures. For general questions, the assigned Network Leadership Group Program Officer (NLG PO) should be contacted.
***

Laboratories performing testing in support of clinical trials funded and/or sponsored by NIAID DAIDS must comply with the Policy on Requirements for DAIDS Funded and /or Sponsored Laboratories in Clinical Trials (Refer to: https://www.niaid.nih.gov/research/daids-clinical-research-laboratory-specimens-management. The purpose of this policy is to safeguard participants enrolled in clinical trials and to ensure the reliability and validity of all laboratory measurements taken to determine eligibility, identify and manage adverse events, and assess outcomes during the course of the clinical trial. Grantees may contact the appropriate NIAID DAIDS staff with questions regarding this policy and associated appendices (Appendix 1-DAIDS Requirements for U.S. Laboratories, Appendix 2- DAIDS Requirements for Non-U.S. Laboratories, Appendix 3-DAIDS Good Clinical Laboratory Practices (GCLP) Standards. For general questions, the assigned NLG PO should be contacted.
***

The Network Leadership Group (NLG) comprised of the Principal Investigators of the three linked MTN Network awards (LOC, LC, SDMC) is responsible for ensuring that the Networks major structural components are capable of carrying out their respective responsibilities and operate in a well-coordinated fashion. The Network bylaws, policies and operating procedures for all aspects of Network activities must be in concert with NIH, NIAID and DAIDS policies.
***

Addition or deletion of major research protocols will require review and recommendations made by the SWG, followed by NIAID DAIDS approval. A major research protocol or trial is currently defined as $5,000,000 total costs in any given year of its implementation or more than $20,000,000 total costs for all years. This includes the costs at the LOC, LC, and SDMC, as well as the sites. When a major research protocol concludes early or is cancelled, any planned future funding for that protocol will be adjusted accordingly.
***

CLINICAL TRIAL INSURANCE: Clinical trial insurance requires prior approval and must be requested on a per protocol basis. No funds may be authorized to provide clinical trial insurance unless specifically indicated on a revised Notice of Award.
***

Written approval must be obtained for any changes in personnel or any change in the level of effort for the following individual (s):
Jared Baeten
***

The grantee (and sub recipient for data management activities) will continue to demonstrate progress in the implementation of the Medidata RAVE clinical trials data management system (CTDMS).

***

The grantee will continue to demonstrate improvement in quality systems management and improved adherence to good clinical data management practices (GCDMP) in response to site audit findings from September 2013. The DAIDS may conduct follow up site audit visit, at a date to be determined, to assess level of compliance.

The grantee will ensure that the data management systems are compatible with other Networks and the NIAID Clinical Research Management System (CRMS) in order to ensure seamless transfer and sharing of data and information. This includes implementation of data reconciliation and monitoring procedures established by NIAID/DAIDS to ensure data quality and integrity.
***

The awardee institution must coordinate with the NIAID Office of Communications and the appropriate Program Officer **any** media communications which describe projects or programs funded in whole or in part with Federal money.
***

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:

- University of Manitoba, Canada
- Kenyatta National Hospital, Kenya
- Wits Health Consortiu (Pty), South Africa
- University of Cape Town, South Africa
- Univeristy of Zimbabwe, Zimbabwe
- Blantyre Health Research and Training Trust, Malawi
- Associcacion Civil Impacta Salud y Educacion Jr., Peru
- University of KwaZulu-Natal-CAPRISA- eThekwini Clinical Research Site, South Africa
- Emavundleni (EMA) CRS, South Africa
- Chiang Mai University HIV Prevention CRS, Thailand
- Makerere U. John Hopkins U. Research Collaboration / MUJHU Care Ltd CRS, Uganda
- Seke South CRS, Zimbabwe
- Zengeza CRS, Zimbabwe
- Spilhaus CRS, Zimbabwe

***

This award reflects current Federal policies regarding Facilities & Administrative (F&A) Costs for foreign grantees including foreign sub-awardees, and domestic awards with foreign sub-awardees. Please see: Chapter 16 Grants to Foreign Organizations, International Organizations, and Domestic Grants with Foreign Components, Section 16.6 "Allowable and Unallowable Cost" of the NIH Grants Policy Statement effective October 1, 2017.
***

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

This Notice of Award (NoA) includes funds for activity with the following:

- University of Pittsburgh
- Albert Einstein College of Medicine
- Family Health International (FHI 360)
- Hekteon Institute for Medical Research
- Kenyatta National Hospital, Kenya
- Johns Hopkins University
- Population Council
- Research Foundation for Mental Hygiene
- San Francisco Department of Public Health
- RTI International

- University of Pennsylvania
- University of Alabama at Birmingham
- University of Washington
- Wits Health Consortium, South Africa
- University of Cape Town, South Africa
- University of Zimbabwe, Zimbabwe
- University of Malawi
- University of Miami
- University of Manitoba, Canada
- Blantyre Health Research and Training Trust, Malawi
- Associcacion Civil Impacta Salud y Educacion Jr., Peru
- University of KwaZulu-Natal-CAPRISA- eThekwini Clinical Research Site, South Africa
- Emavundleni (EMA) CRS, South Africa
- Chiang Mai University HIV Prevention CRS, Thailand
- Makerere U. John Hopkins U. Research Collaboration / MUJHU Care Ltd CRS, Uganda
- Seke South CRS, Zimbabwe
- Zengeza CRS, Zimbabwe
- Spilhaus CRS, Zimbabwe

***

No funds in this award shall be used to pay the salary of an individual at a rate per year in excess of the amounts reflected in the following NIH Guide Notice: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-18-137.html. Therefore, this award is issued at the committed level but reflects a rebudgeting of **$452** from the Personnel category in the RTI Subaward to the Other Direct Cost category in the RTI Subaward budget.

***

The no-cost extension provision of the NIH Standard Terms and Conditions of Award has been removed from this award.

STAFF CONTACTS

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

Grants Management Specialist: Jason A. Lundgren
Email: lundgrenj@mail.nih.gov **Phone**: 240-669-2973 **Fax**: 301-493-0597

Program Official: Roberta J. Black
Email: rblack@niaid.nih.gov **Phone**: 301-496-8199

SPREADSHEET SUMMARY
GRANT NUMBER: 5UM1AI068633-14

INSTITUTION: MAGEE-WOMEN'S RES INST AND FOUNDATION

Budget	Year 14
Salaries and Wages	$736,003
Fringe Benefits	$184,001
Personnel Costs (Subtotal)	$920,004
Consultant Services	$130,393
Materials & Supplies	$16,906
Travel	$322,759
Other	$693,759
Subawards/Consortium/Contractual Costs	$3,918,106

TOTAL FEDERAL DC	$6,001,927
TOTAL FEDERAL F&A	$1,229,454
TOTAL COST	$6,662,220

Facilities and Administrative Costs	Year 14
F&A Cost Rate 1	59%
F&A Cost Base 1	$2,083,821
F&A Costs 1	$1,229,454