

Original Sponsor/Funder: <u>NIH/NIAID</u>

CFDA #: <u>93.855</u> CFDA Program Name: Allergy and Infectious Diseases Research

FHI 360 (Prime) Award: HIV PREVENTION TRIALS NETWORK (HPTN) FHI 360 (Prime) Award No.: UM1 AI068619

	FHI 360 Grant Monitor	Grant	tee Point-of-Contact (Administrative Matters
Name:	Sarah Azimi	Name:	Sajid Shaikh
Title:	Budget Analyst III	_ Title:	Prin Admin Analyst
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	359 Blackwell Street		San Francisco, CA 94103
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			Grantee Point-of-Contact
			(Technical/Program Matters)
	FHI 360 Technical/Program Monitor	Name:	Susan Buchbinder, MD
Name:	Catilin Scoville	Title:	Director of HIV Bridge
Title:	Clinical Research Manager	_ Address:	25 Van Ness Ave, Suite 100
Address:	359 Blackwell Street	_	San Francisco, CA 94102
	Durham, NC 27701	_ Country:	USA
Country:	USA	Tel.: ,	415-437-7478
Tel.:	202-464-3750	_ Email:	susan.buchbinder@sfdp.org
Email:	cscoville@fhi360.org		

In witness of their agreement and their acceptance of the terms and conditions of this Grant, FHI360 and the Grantee have caused this Grant Agreement to be executed by their duly authorized representatives: Authorized by and accepted for the Grantee:

Authorized by and accepted for FHI 360:

Clevisty La. Danya Smith		-Docusigned by: Susan Philip	09/06/2024	10:34 AM PC
Signature_560D13C44473479	Date Si	-4C9D2E27476A474 gnature	Date	
Christy LaTonya Smith	C	Grant Colfax, MD		
Name Associate Director, Contract Managem	ent Services D	<sup>ame</sup> irector of Health		
Title	 Ti	tle		
	Appro	ved as to form, David Chiu,	City Attorney	/
	By:	DocuSigned by:		
		-Docusigned by: Henry Lifton		

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Pursuant to the terms and conditions of the Prime Award cited on the cover page, this Grant Agreement is entered into by and between Family Health International ("FHI 360") with its headquarters office in Durham, North Carolina, USA and the **City and County of San Francisco** ("Grantee") with its headquarters in **San Francisco**, **California**, USA, each a "Party" and, collectively, the "Parties."

The Parties therefore agree to the following terms and conditions:

#### **ARTICLE 1. PROGRAM DESCRIPTION**

The Grantee has been selected by FHI 360 to participate in the **HIV PREVENTION TRIALS NETWORK (HPTN)** to carry out activities under the program described in Attachment A, *Program Description*.

# **ARTICLE 2. TYPE OF GRANT**

This is a Standard Grant that provides the following:

- (a) **TOTAL ESTIMATED AMOUNT**. The total estimated value of this Grant is **US \$48,915**. The Grantee agrees to use its best efforts to implement the program within the total estimated budget in *Attachment B, Budget*.
- (b) TOTAL OBLIGATED AMOUNT. This Grant will be incrementally funded by FHI 360. The total obligated funding for this Grant is US \$48,915 through November 30, 2024. FHI 360 will not reimburse the Grantee for expenses greater than the total obligated amount or for costs incurred outside of the period of performance of this Grant. Changes to obligated funding will be in writing as a modification to this Grant.

#### **ARTICLE 3. CONDITIONS OF FUNDING**

(a) Payment will be on a cost reimbursement basis. FHI 360 will reimburse only those costs that are identified in the approved Grant budget in Attachment B and are determined to be allowable and allocable under the cost principles followed by FHI 360 and provided in 45 CFR Part 75

The cost principles can be downloaded from: www.ecfr.gov

Note: If the Grantee is not able to download, the FHI 360 Grant Officer can make their full text available upon request.

- (b) When incrementally funded, the continued funding of this Grant will be determined by the availability of funds from FHI 360's donor that is supporting this Grant. FHI 360 is not liable for reimbursing the Grantee or lower-tier grantee for any amount in excess of the total obligated amount, or outside of the Grant period.
- (c) The currency of payment is US dollars.
- (d) Advance payments, if any, shall be in accordance with Article 8 of this Grant.
- (e) When payment by electronic funds transfer is requested, it is the Grantee's responsibility to provide FHI 360 with the correct banking information.



(f) Lower-tier Grants are not authorized under this Grant without prior approval from the FHI 360 Grant officer.

# **ARTICLE 4. INDIRECT COSTS**

#### NEGOTIATED INDIRECT COST RATE AGREEMENT (NICRA)

Grantees may recover applicable indirect costs (i.e., overhead, G&A, etc.) if it is part of the Grantee's usual accounting procedures, consistent with <u>45 CFR 75.414</u> Indirect (F&A) Costs and Negotiated Indirect Cost Rate Agreement (NICRA) from their U.S. Government cognitive agency.

The Grantee agrees that their indirect cost rate at the time of the invoice submission will not exceed their current rate for current period of performance as approved by their cognizant agency.

#### **ARTICLE 5. COST SHARE REQUIREMENT**

Cost share is not required in this Grant.

#### **ARTICLE 6. MONITORING AND REPORTING REQUIREMENTS**

**TECHNICAL MONITOR.** Technical monitoring of this Grant will be performed by the designated FHI 360 Technical/Program Monitor. All Technical Reports will be submitted to the Technical/Program Monitor.

**FINAL REPORT.** At the conclusion of this Grant, the Grantee will prepare and submit to the FHI 360 Technical/Program Monitor a final report that will summarize the accomplishments of this Grant. The final report will document the results that were obtained, note particular successes as well as approaches that did not achieve the anticipated result(s). The final report is due 30 days after the end of the grant.

#### AUDIT REPORT.

- (a) U.S. Grantees must have an annual audit conducted in accordance with 45 CR 75 Subpart F. The Grantee must submit a copy of the audit report to the FHI 360 Technical Monitor within thirty (30) days of its completion, but no later than nine (9) months after the end of the period audited.
- (b) FHI 360 is responsible for ensuring accountability of NIH funding. FHI 360 maintains the right to review the Grantees records and arrange for an annual independent audit to be conducted, financed directly by FHI 360.

#### **ARTICLE 7. FINANCIAL REPORTING**

*FINANCIAL REPORTS.* For each Grant, the Grantee will prepare and submit to the FHI 360 Grant Monitor (listed on the Face Page of this document) a monthly financial report within 30 days after the close of the period in accordance with the payment instructions included in the Grant. Only allowable expenses that are authorized by each Grant will be approved.

The Grantee is required to submit financial reports following the format specified in Attachment C, *Subrecipient Financial Report (SFR)*. The Grantee will submit a labor summary, providing a list of employees by name, position title, and salary paid during the period reported. The



Grantee also will submit a detailed transaction list itemizing for all other reported expenses during the period.

Grantee must submit Subrecipient Financial Report (SFR) with appropriate backup detail for payment to:

- (a) HPTN Invoice at email address: <u>HPTNINVOICE@FHI360.org</u> Include "HPTN" in the subject line of the email. OR
- (b) FHI 360
   Attention Gloria Pherribo: HPTN 359 Blackwell Street, Suite 200
   Durham, NC 27701

#### **ARTICLE 8. PAYMENT PROCEDURES**

- (a) Advance payments are not authorized under this Grant.
- (b) On submission of the claim for final payment, the Grantee must certify in writing to the FHI 360 Technical/Program Monitor that the Grant is completed, and the Grantee will make no further claim against FHI 360 after final payment.

#### **ARTICLE 9. APPLICABLE REGULATIONS AND REQUIREMENTS**

The Grant is funded under the Prime Award, Grant Number UM1 AI068619 between FHI 360 and the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health. The Grantee is subject to 45 CFR Part 75, the NIH Grants Policy Statement, and the sponsor specific requirements that are set forth in Attachment E *HPTN NIH Flow-Down Terms and Conditions* and are incorporated herein by reference.

#### ARTICLE 10. FHI360 GRANT TERMS AND CONDITIONS

The Grant Terms and Conditions governing this Grant are set forth in **Attachment D**, FHI 360 Grant Terms and Conditions and are hereby incorporated into this Grant by reference.

#### FHI 360 Contracts Point of Contact

#### The FHI 360 Contracts Specialist Point of Contact for this award is:

Jackson Lee Contracts Specialist II Contract Management Services FHI 360 359 Blackwell St., Ste 200 Durham, NC 27701 JLee@fhi360.org 919-321-3715

#### FHI 360 Grant Officer

The FHI 360 Grant Officer for this award is:



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Christy Smith Contracting Officer Contract Management Services FHI 360 359 Blackwell St, Ste 200 Durham, NC 27701 <u>CFoster@fhi360.org</u> 919-321-3467

# ARTICLE 11. SPECIAL AWARD CONDITIONS

a) COI Requirements Promoting Objectivity in Research Applicable to Grantees (42 CFR Part 50 Subpart F)

42 CFR Part 50. 604 requires that institutions conducting PHS-funded research "Maintain an up-to-date, written, enforced policy on financial conflicts of interest." Further, "If the Institution carries out the PHS-funded research through a Grantee (e.g., subcontractors or consortium members), the Institution (awardee Institution) must take reasonable steps to ensure that any Grantee Investigator complies with this subpart by incorporating as part of a written agreement with the Grantee terms that establish whether the financial conflicts of interest policy of the awardee Institution or that of the Grantee will apply to the Grantee's Investigators."

#### Choose the applicable checkbox:

Grantee organization/institution does not have an active and/or enforced conflict of interest policy and hereby agrees to abide by NIH HIV/AIDS Clinical Trials Networks Financial Disclosure Policy and Procedure. The NIH HIV/AIDS Clinical Trials Networks Financial Disclosure and Conflict of Interest Guidelines: Standard Operating Procedures are located at

https://www.hptn.org/resources/manual-of-operations Note: The FHI 360 Grant Officer will provide this policy upon your request.

Grantee organization/institution hereby certifies that it has an active and enforced conflict of interest policy that is consistent with the provision of 42 CFR Part 50, Subpart F, "Responsibility of Applicants for Promoting Objectivity in Research." Grantee also certifies that, to the best of Institution knowledge (1) all financial disclosures have been made related to the activities that may be funded by or through a resulting agreement, and required by its conflict of interest policy; and (2) all identified conflicts of interest have or will have been satisfactorily managed, reduced or eliminated in accordance with Grantee's conflict of interest policy prior to the expenditure of any funds under any resulting agreement.

# **Reporting Requirements**

Grantee shall report any financial conflict of interest to the Grants Officer of FHI 360. Any financial conflicts of interest identified shall subsequently be reported to NIH. Such report shall be made before expenditure of funds authorized under this Grant and within 30 days of any subsequently identified financial conflict of interest.



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.

#### c) Human Subjects Data (Select One)

- ☑ Not Applicable
- □ Applicable
- □ Human subjects data will not be addressed in this agreement

#### Complete the below if the Applicable option is chosen.

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

□ From Subrecipient to FHI 360

□ From FHI 360 to Subrecipient

FHI 360 will set forth the terms of the exchange of Human Subjects Data (Select One):

- $\Box$  In the Special Award Terms and Conditions of this Subagreement
- □ Via a separate Data Use Agreement

Please refer to the HPTN Manual of Operations at the following site for further information: <u>https://www.hptn.org/resources/manual-of-operations</u>

If you have additional questions you can also contact your FHI 360 Program/Technical Monitor.

# ARTICLE 12. TITLE TO AND USE OF PROPERTY

Title to equipment costing US\$5,000 or more that is purchased or fabricated with research funds or Grantee cost sharing funds, as direct costs of the project or program, shall vest with the Grantee upon acquisition. Management of the property is subject to the conditions specified in 45 CFR 75.320(d).

- (a) The Grantee is responsible for the care, maintenance, and security of the equipment or property purchased under this Grant.
- (b) The Grantee must maintain property records and be reconciled with the results of a physical inventory at least every 2 years.
- (c) The Grantee is required to immediately report theft, loss, or damage to Grant-funded equipment or property to the FHI 360 Grant Officer.



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(d) Used equipment may not be purchased with Grant funds.

#### ARTICLE 13. ORDER OF PRECEDENCE

Any conflict between any of the provisions and attachments to this Grant shall be resolved by applying the following order of precedence:

- (a) Articles of this Grant;
- (b) Attachment A Program Description; and
- (c) Attachment B Budget Summary
- (d) Attachment D FHI 360 Grant Terms and Conditions; and
- (e) Attachment E HPTN NIH Flow-Down Terms and Conditions

#### **End of Section-**

#### ATTACHMENTS

ATTACHMENT A – PROGRAM DESCRIPTION ATTACHMENT B – BUDGET ATTACHMENT C – SUBRECIPIENT FINANCIAL REPORT ATTACHMENT D – FHI 360 GRANT TERMS AND CONDITIONS ATTACHMENT E – HPTN NIH FLOW-DOWN TERMS AND CONDITIONS



#### ATTACHMENT A PROGRAM DESCRIPTION

#### 1. Objectives

The purpose of this agreement is to provide **10%** level of effort salary support for **Dr. Buchbinder** as the HPTN Chair of HPTN 113, "Double Prevention: A Vanguard Study of an Integrated Strategy of HIV PrEP and STI PEP for Young Latino Gay, Bisexual, and other Cisgender Men who have Sex with Men in the Americas." In this role, **Dr. Buchbinder** will provide scientific leadership in the development, implementation, and day-to-day oversight and conduct of the **HPTN 113** protocol.

The primary study objectives:

- To determine the efficacy of the 3P mHealth package on PrEP uptake among Latino MSM in the Americas
- To determine the efficacy of the 3P mHealth package on PrEP adherence among Latino MSM in the Americas
- To assess DoxyPEP uptake, use, and acceptability, and factors associated with each

The main purpose of this study is to adapt and test a suite of mHealth tools to increase HIV pre-exposure prophylaxis (PrEP) uptake and adherence among young Latino gay, bisexual, and other cis-gender men who have sex with men (MSM) and evaluate the uptake, adherence, and acceptability of doxycycline for sexually transmitted infection (STI) post-exposure prophylaxis (DoxyPEP).

#### 2. KEYDELIVERABLES

As the Chair for **HPTN 113**, in close collaboration with other protocol team members, **Dr. Buchbinder's** responsibilities include:

- Actively participating in the protocol development process, bringing the approved concept to Protocol V1.0, including
  - Attending protocol development meetings
  - Participating in protocol reviews, including reviews by the Scientific Review Committee (SRC) and the DAIDS Prevention Sciences Review Committee (PSRC)
  - Responding to reviewer comments
- Providing site training and leadership, including preparation of materials for training
- Providing overall leadership to ensure that the study meets its projected accrual and retention goals within the specified timeframes.
- Facilitating decision-making within the protocol team to achieve agreement on scientific or operational issues; if agreement cannot be reached, referring the issue to the HPTN leadership for consideration.
- Participating in review of operational and safety data once the trial begins, as necessary.
- Participating in *ad hoc* review of safety data (AEs, SAEs, social harms), as required.
- Actively participating in drafting the primary endpoint manuscript once the trial is complete; the study Chairs are expected to serve as the lead authors on the writing team; the expectation is that a draft manuscript of the primary endpoint analyses will be completed within six months after the trial data for primary endpoints are finalized.
- Representing the HPTN and the study at meetings and conferences, if needed.
- Participating in site visits as needed.

Payment will be made to the Grantee upon submission of invoices to Family Health International. Funding for subsequent periods of performance, if necessary, is contingent upon satisfactory performance and additional funding from NIAID.



#### ATTACHMENT B BUDGET



Subawardee: <u>City</u>	and County of San Fra	r Start Date:	4/1/2024
PO# <u>PO24</u>	1002400	End Date:	11/30/2024
Subaward title: <u>HPT</u>	N 113 Leadership (Buc	<u>nbinder)</u>	
	Current Funding Period Obligation	Total Obligation	Total Life of Project
	Apr 1 2024 - Nov 30 2024	Apr 1 2024 - Nov 30 2024	Apr 1 2024 - Nov 30 2024
	Amount	Amount	Amount
	USD	USD	USD
1. SALARIES	29,587	29,587	29,587
2. FRINGE BENEFITS	10,356	10,356	10,356
3. CONSULTANTS	-	-	-
4. EQUIPMENT	-	-	-
5. TRAVEL/TRANSPORTATION	J -	-	-
6. SUBAWARDS	-	-	-
7. OTHER DIRECT COSTS	-	-	-
8. INDIRECT COST/G&A	8,972	8,972	8,972
TOTAL PROJECT COSTS	48,915	48,915	48,915



# fhi360

#### ATTACHMENT C Subawardee Financial Report

This report must be submitted to FHI 360 in accordance with the subaward's financial reporting requirements and indicated due dates.

Submit report to:	<u>HPTNInvoice</u>	<u>@FHI360.org</u>		Reporting	Cycle (check one):	
PO No.	PO24002400	Reporting Period		$\checkmark$	Monthly	
Subaward Start Date	4/1/2024	Today's Date	[date]		Quarterly	
Subaward End Date	11/30/2024	Currency:	USD		Other	
Subawardee Name	City and Coun	ty of San Francisco				
Subaward Title:	HPTN 113 Lead	ership (Buchbinder)				
			Total Expenses	Expended This	Total Expended	Obligated Funds

I. Budget Analysis	Current Obligation	Previously Reported	Reporting Period	to Date	Remaining
Amendment #					
Salaries	29,587				29,587
Fringe Benefits (if applicable)	10,356				10,356
Consultants / Professional Fees					
Equipment					
Travel, Transportation, and Per Diem					
Contractual/Subawards					
Other Direct Costs					
Indirect Costs / G&A	8,972				8,972
Other (Specify) =>					
TOTAL	48,915				48,915.00

Please note that all required supporting documentation per the Terms & Conditions of the subaward must be attached to this form.

#### **II.** Summary of Funds

		Amount
Funds Previously Received	Wire/Check No	
Funds Received this Period		
Total Funds Received from FHI 360		
Total Amount Expended		
Balance on Hand		
Total Interest Earned		

#### III. Certification and Approva

I certify that to the best of my knowledge and belief, this Financial Report is a correct, complete and accurate statement, that my organization is properly entitled to payment, and that all amounts requested are for appropriate purposes in strict accordance with the terms and conditions of the subaward.

Subawardee Authorized Official:

	Typed name, Title	Signature	Date
FHI 360 Review and Approval:			
FHI 360 Subaward Monitor :			
	Typed name, Title	Signature	Date
FHI 360 Finance:			



#### SUBAWARDEE FINANCIAL REPORT (SFR)

The Subawardee Financial Report must be submitted to FHI 360 in accordance with the terms and conditions of the Grant. All amounts must be entered in the same currency and in accordance with the terms and conditions of the Grant.

**Note:** if using the electronic version of this report, input should be entered into the shaded areas. Other areas are calculations.

#### **HEADER SECTION**

Submit Reports to:	Enter the name and FHI 360 office & city where the report is submitted.
ID/FCO No.:	Enter the ID/FCO Number shown in the Grant document.
Reporting Period:	Enter the period / dates covered by the report (month and year).
Subaward Start Date:	Enter the start date of the Grant according to the Grant document.
Today's Date:	Enter the day in which the report is completed.
Subaward End Date:	Enter the end date of the project based on the Grant or latest amendment / modification.
Currency:	Enter the type of currency used to report all financial information. This currency should be in accordance with the terms and conditions of the Grant.
Subawardee Name:	Enter the Grantee name as shown in the Grant document.
Project Title:	Enter the project name as shown in the Grant document.
Reporting Cycle:	Indicate the reporting cycle as indicated in the Grant document.
I. BUDGET ANALYSIS	
Current Obligations:	Enter the budget amount for each line item reflected on the Summary Budget in the latest Grant document. The budget amount for each line item must be in the currency indicated in the Grant document.
Total Expenses Previously	Enter the <i>Total Expended to Date</i> amounts in each line item from the previous
Reported:	report.
Expended This Reporting	Enter the amount spent during the period covered by this report into the
Period:	respective line items.
Total Expended to Date:	Enter the sum of <i>Total Expenses Previously Reported</i> and <i>Expended This Reporting Period</i> .
Obligated Funds Remaining:	Enter the Current Obligation less Total Expended to Date.
Total USD:	Enter the total current obligation in US dollars reflected on the Summary Budget in the latest Grant document.
Subaward Exchange Rate:	Enter the exchange rate used to convert US dollars to the currency used for reporting, if applicable. The rate is for INFORMATIONAL PURPOSES ONLY to show the conversion between the two currencies if applicable. This rate should match the rate on the Summary Budget of the latest Grant document (it is suggested that it be linked to the Summary Budget page if possible).
***Attachments Required	For budget categories marked with an asterisk (*), attach an itemized list of expenditures for the reporting period: Example:
	1. <u>Salaries</u> require a list of employees by name, position title, and salary paid during the period. The amount charged should reflect ACTUAL hours spent on the project and not merely the BUDGETED level of effort. A labor report detailing specifics is required.
	2. <u>Fringe Benefits</u> require a schedule of benefits/allowances given to employees.



	3. <b>Consultants and professional fees</b> requires a list of payments made during the period indicating the name of the payee, daily rate, total paid, and a brief description of the services performed.
	<ol> <li><u>Procurement</u> requires a description of the equipment, vendor name, amount paid, and the date of purchase.</li> <li><u>Other Direct Costs</u> requires a schedule of all direct costs associated with project activities that are not allocated to the categories above.</li> <li><u>Other</u> requires a description of other allowable costs in accordance with the Grant document. The type of expense must be specified.</li> </ol>
II. SUMMARY OF FUNDS	
Funds Previously Received:	Enter the amount received as of the beginning of the period. This amount should be equal to the Total Funds Received from FHI 360 line on the previous report.
Funds Received this Period:	Enter the amount of all wires or checks received this period. Upon review, FHI 360 Finance will enter the US dollar equivalent amount based on General Ledger information.
Wire/Check No.:	Enter the wire or check number from funds received.
Total Funds Received from FHI 360:	Enter the sum of <i>Funds Previously Received</i> line and the <i>Funds Received this Period</i> line.
Total Amount Expended Balance on Hand	Enter the total amount in the <i>Total Expended to Date</i> column above. Enter the differences between the Total Funds Received from FHI 360 and the Total Amount Expended lines. This should equal the total cash on hand at the end of the period. All unspent funds are to be returned to FHI 360 within the period stated in the Grant.
Interest Earned	Record interest earned if the bank account earns interest. Grantee is allowed to keep \$250 annually to cover administrative expenses
USD Current Obligated Amount USD Obligation Remaining: Total USD Obligation Less USD Sent as of this Rpt:	Enter the total current obligation amount in US dollars shown in the Grant or current amendment. This should be the same as the <i>Total USD</i> amount above. Enter the US Current Obligated Amount less Total Funds Received from FHI 360 (US dollars).
Note: FHI 360 Finance will enter amounts in US dollars based on FHI 360's General Ledger. This information	
as the US dollar amount prevai	rantee periodically to compare against the US dollar amount in the Grant Is in a majority of the Grants. The current bank rate should be used when I to estimated US dollar equivalent.

#### **III. CERTIFICATION AND**

#### **APPROVALS**

Certification and approval: This report must be certified and signed by the Grantee's Authorized Official and Monito approved by FHI 360's Technical/Program

Review:

In addition to being approved by FHI 360's Technical/Program Monitor, this report must also be reviewed by the FHI 360 Finance department.



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#### ATTACHMENT D NEGOTIATED FHI 360 GRANT TERMS AND CONDITIONS FOR CITY AND COUNTY OF SAN FRANCISCO

### 1. INDEPENDENT ENTITY

The relationship of the Grantee to FHI 360 is that of an independent entity, and nothing in this Grant will be construed as creating any other relationship. As such, the Grantee will comply with all laws and assume all risks incident to its status as an independent entity. This includes, but is not limited to, responsibility for all applicable income taxes, associated payroll and business taxes, licenses and fees, and such insurance as is necessary for the Grantee's protection in connection with work performed under this Grant. Neither the Grantee nor anyone employed by it will be, represent, act, purport to act, or be deemed to be an agent, representative, or employee of FHI 360.

This Grant is funded in whole or in part with funds from the funding sponsor. Neither the funding sponsor nor any of its departments, agencies, or employees is or will be a party to this Grant. All communications regarding this Grant must be directed to FHI 360.

#### 2. CONFIDENTIAL INFORMATION

During the term of this Grant, the Grantee and its employees may receive or have access to data and information that is confidential and proprietary to FHI 360 or the funding sponsor.

"*Confidential Information*" is defined as all technical information whether directly or indirectly disclosed, in verbal, written, graphic, photographic, electronic, prototypic, sample or any other form.

*Confidential Information* disclosed in written, graphic or electronic format will be marked on its face as "Confidential" and/or "Proprietary." *Confidential Information* disclosed in verbal or visual form will be summarized in writing and confirmed to the Grantee as "Confidential" and/or "Proprietary" within thirty (30) days following disclosure.

Confidential Information does NOT include information that:

- is or becomes generally available to the public other than as a result of a disclosure by the Grantee;
- becomes available to the Grantee on a non-confidential basis from a source that is not prohibited by a legal, contractual or fiduciary obligation from disclosing such information;
- is developed independently by the Grantee without use of *Confidential Information*, as demonstrated by written records and evidence;
- was in the Grantee's possession or known to the Grantee prior to receipt from the disclosing party; or
- is required by law to be disclosed, provided the Grantee notifies FHI 360 promptly and gives FHI 360 an opportunity to seek an appropriate protective order.

Confidential Information may be used by the Grantee or its employees only for purposes of performing the obligations under this Grant. The Grantee will not reveal, publish or otherwise disclose Confidential Information to any third party without the prior written consent of FHI 360.

All "*Confidential Information*" disclosed to or otherwise made known to the Grantee as a result of services under this Grant remains the sole property of FHI 360 and/or its funding sponsor.

These obligations of confidentiality and non-disclosure will remain in effect for a period of five (5) years after the termination of this Grant.



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#### 3. ORGANIZATIONAL CONFLICTS OF INTEREST

- a) The Grantee represents that, to the best of its knowledge and belief, there are no relevant facts or circumstances which could give rise to an organizational conflict of interest, or that the Grantee has disclosed all such relevant information.
- b) The Grantee agrees that if an actual or potential organizational conflict of interest is discovered after award, the Grantee will make a full disclosure in writing to the FHI 360 Grant Officer. This disclosure will include a description of activities which the Grantee has taken or proposes to take, after consultation with the FHI 360 Grant Officer, to avoid, mitigate, or neutralize the actual or potential conflict.
- c) Remedies The FHI 360 Grant Officer may terminate this Grant for convenience, in whole or in part, if it deems such termination necessary to avoid an organizational conflict of interest. If the Grantee was aware of a potential organizational conflict of interest prior to award or discovered an actual or potential conflict after award and did not disclose or misrepresented relevant information to the FHI 360 Grant Officer, FHI 360 may terminate the Grant for default.
- d) The Grantee further agrees to insert provisions which will conform substantially to the language of this clause, including this subparagraph (d), in any lower-tier Grants arising out of this Grant.

#### 4. STANDARDS OF ETHICS AND BUSINESS CONDUCT

The Grantee acknowledges and accepts FHI 360's emphasis on the importance of accountability to those who benefit from FHI 360's work, and the parties' mutual accountability to those who benefit from FHI 360's work, and the parties' mutual accountability to each other, to project collaborators, and to our sponsors. The Grantee confirms its accountability to participants in FHI 360 programs, children, any vulnerable populations and to all others whom its programs are intended to serve.

**4.1 Combating Trafficking in Persons:** FHI 360 requires that the Grantee uphold the principles of FHI 360's Combating Trafficking in Persons policy (located on the FHI 360 Ethics and Safeguarding website at <a href="https://www.fhi360.org/ethics-safeguarding/#our-policies-and-supplemental-guidance">https://www.fhi360.org/ethics-safeguarding/#our-policies-and-supplemental-guidance</a>). Grantee and its personnel must refrain from and take steps to prevent any conduct that violates the policy. Grantee or grantee personnel who witness conduct prohibited by the policy or who identify that Grantee personnel have engaged in such conduct should promptly report the conduct orally or in writing within 24 hours (or as soon as possible under the circumstances) to the FHI 360 Office of Compliance and Internal Audit (OCIA) by **one** of the following means: (1) via email at <a href="mailto:compliance@fhi360.org">compliance@fhi360.org</a>; (2) via OCIA's Ethics and Compliance Hotline: 1-800-461-9330 in the U.S or Country-specific hotline numbers listed on FHI 360's reporting website; Skype: +1-800-461-9300; or Country-specific hotline numbers listed on FHI 360's reporting website; or (3) via OCIA's anonymous reporting website (<a href="http://www.fhi360.org/anonreportregistry">http://www.fhi360.org/anonreportregistry</a>). FHI 360 requires all Suppliers and Supplier personnel to cooperate fully with investigations of policy violations and provide truthful information to investigators. In addition, Grantee must comply with any funder requirements incorporated into this grantee. Failure to comply with this provision may result in termination of this grant.

**4.2 Safeguarding of Children in FHI 360 Programs**: Grantee must uphold the principles of the FHI 360 Safeguarding of Children policy located on the FHI 360 Ethics and Safeguarding website at <a href="https://www.fhi360.org/ethics-safeguarding/#our-policies-and-supplemental-guidance">https://www.fhi360.org/ethics-safeguarding/#our-policies-and-supplemental-guidance</a>) and will undertake to ensure that no individual with any history of crimes against children will be placed in a position involving direct interaction with children as part of the work under this Grant. The Grantee and any employees, consultants, and volunteers of the Grantee ("*Grantee Personnel*") are prohibited from engaging in child abuse, exploitation, or



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neglect in its programs and activities, including without limitation, physical abuse; emotional ill-treatment; neglect or insufficient supervision; sexual abuse; exploitation through prostitution or production of pornographic materials; trafficking; or commercial, transaction or labor exploitation resulting in actual or potential harm to the child's health, well-being, survival, development or dignity. The Grantee Personnel must comply fully with host country and local child welfare and protection laws or with international standards, whichever gives greater protection, and must comply with US laws where applicable.

**4.3 Protecting Program Participants from Sexual Exploitation and Abuse (SEA):** The Grantee must uphold the principles of *the United Nations Interagency Standing Committee on Protection from Sexual Exploitation and Abuse in Humanitarian Crises* and FHI 360's policy on Protecting Program Participants from Sexual Exploitation and Abuse, located on the FHI 360 Ethics and Safeguarding website at <a href="https://www.fhi360.org/ethics-safeguarding/#our-policies-and-supplemental-guidance">https://www.fhi360.org/ethics-safeguarding/#our-policies-and-supplemental-guidance</a>). Grantee and Grantee Personnel are prohibited from committing any form of sexual exploitation or abuse of any adults or children who are served by FHI 360 programs or encounter Grantee Personnel engaged in activities under this Agreement ("*Program Participants*"). Sexual exploitation means any actual or attempted abuse of Program Participants that takes advantage of their position of vulnerability or trust for sexual purpose. Sexual abuse means any actual or threatened physical intrusion of a sexual nature by force or under unequal or coercive conditions. Grantee must take steps to develop a culture that does not tolerate SEA and prevent, detect, and/or stop any SEA by Grantee Personnel.

**4.4 Violence Within the Work Environment:** The Grantee must uphold the principles of FHI 360's Violence-Fee Workplace policy located on the FHI 360 Ethics and Safeguarding website <u>https://www.fhi360.org/ethics-safeguarding/#our-policies-and-supplemental-guidance</u>) and take steps to prohibit and prevent any form of violence or threats of violence in the work environment, by or against any Grantee Personnel while on the Grantee's premises or work locations of the Grantee, at any events sponsored by the Grantee or while engaged in the performance of employment duties for Grantee whether on or off the Grantee's premises. The Grantee's policy must prohibit Grantee Personnel from perpetrating any form or violence or threats of violence against any staff or any Grantee partner, Grantee, or client; program participants; or anyone else with whom they interact in work-related situations.

4.5 Harassment-Free Work Environment: Grantee must uphold the principles of FHI 360's Harassment-Free Environment policy located on the FHI 360 Ethics and Work Safeguarding website at https://www.fhi360.org/ethics-safeguarding/#our-policies-and-supplemental-guidance) and take steps to prohibit and prevent Grantee Personnel are prohibited from engaging in any form of harassment in the workplace or workrelated situations based on: race, color, ethnic or national origin, religion, age, sex, sexual orientation, gender identity, or perceived adherence to socially defined norms of masculinity and femininity, medical conditions, pregnancy, childbirth, and breastfeeding, nationality or citizenship, physical or mental disability, genetic information or characteristics (or those of a family member), protected U.S. military or U.S. veteran status, status as a victim of domestic violence, sexual assault or stalking, and/or any other class, status, or characteristic protected by local law. The Grantee must strictly prohibit Grantee Personnel from harassing any Grantee Personnel, employees of any Grantee partner, Grantee, or client; program participants; or anyone else with whom the Grantee Personnel interact in work-related situations.

**4.6 Dealing with Governments or Officials; Compliance with Foreign Corrupt Practices Act:** The Grantee acknowledges that FHI 360 corporate policy located on the FHI 360 Ethics and Safeguarding website at <a href="https://www.fhi360.org/ethics-safeguarding/#our-policies-and-supplemental-guidance">https://www.fhi360.org/ethics-safeguarding/#our-policies-and-supplemental-guidance</a>) requires that FHI 360's activities be conducted within the letter and spirit of the law. The Grantee, including any of its affiliates and their respective employees, agents officers, or other members of its management will not make any payment, either directly or indirectly, of money or other assets to government or political party officials, candidates for public



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office, or representatives of other businesses or persons acting on behalf of any of the foregoing (referred to collectively as "officials") where such payment would constitute a violation of any law. In addition, regardless of legality, the Grantee will make no payment either directly or indirectly to officials if such payment is for the purpose of influencing decisions or actions with respect to the subject matter of this Grant or any other aspect of FHI 360's operations.

**4.7 Reporting of any Violations**: For any referenced policies in Section 4 of this document that have a reporting requirement for Suppliers (which includes subrecipients), the Grantee and Grantee Personnel who observe, suspect, receive allegations of misconduct or violations of any of the above referenced policies and requirements in section 4 of this document are required to report the conduct immediately, either orally or in writing by contacting The Office of Compliance and Internal Audit (OCIA) via email at <u>compliance@fhi360.org</u> and OCIA's Ethics and Compliance Hotline (1-800-461-9330 in the US or Country-specific hotline numbers listed on FHI 360's reporting website), OCIA's reporting website either with your name or anonymously at (<u>http://www.fhi360.org/anonreportregistry</u>). Please note that anonymous reports are generally more difficult to investigate due to limited information. When reporting, individuals are urged to provide as much detail as possible about the conduct, if possible, including identifying people who were involved or who witnessed the conduct, so long as this will not put the persons identified at risk of immediate harm. The Grantee must maintain policies that require Grantee Personnel to report any misconduct or violations to any other appropriate management within the Grantee's organization, with any appropriate law enforcement agency or other regulatory agency as required by local laws.

**4.8 Consequences of Violations**: Violations by the Grantee or Grantee Personnel and/or the failure to follow the requirements of the policy may result in immediate termination of Grantee's award. FHI 360 may pursue any contractual or other legal or equitable remedies that may be available.

#### 5. PROTECTION OF HUMAN RESEARCH SUBJECTS

The Grantee is responsible for safeguarding the rights and welfare of human subjects involved in research under this Grant. The Grantee shall provide FHI 360 with written assurance satisfactory to the sponsoring federal department or agency that it will comply with the Common Federal Policy for the Protection of Human Subjects found in 22 CFR 225 of the Code of Federal Regulations. This policy applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency including research that takes place in foreign countries. In the case of research conducted outside of the United States and remains subject to 22 CFR 225, the Grantee shall submit to the FHI 360 Technical/Program Monitor written assurance that procedures followed by the Grantee to protect human research subjects are at least equivalent to those in 22 CFR 225. In lieu of a written assurance, FHI 360 shall accept the existence of a current assurance, appropriate for the research in question, on file with the Office for Human Research Protections, HHS, or any successor office, and approved for federal wide use by that office.

Any research supported under this Grant that will involve human subjects as defined in 22 CFR 225 shall not commence until the required assurance has been submitted to FHI 360 and Grantee has been notified in writing by the FHI 360 Technical/Program Monitor that all other requisite approvals of the Grantee's procedures pursuant to the protection of human research subjects have been obtained, as appropriate.

#### 6. RESEARCH INTEGRITY AND MISCONDUCT

FHI 360 requires that research is conducted with the highest standards of integrity and ethical behavior regardless of the funding source or type of research. FHI 360 employees and related personnel have a personal responsibility for implementing FHI 360's Research Integrity and Misconduct policy. The policy requires anyone having reason to believe that a person has engaged in research misconduct to report his/her concern of possible research



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misconduct to the FHI 360 Research Integrity Officer (RIO). When research is supported by the Public Health Service (PHS), National Science Foundation (NSF) and other Federal Agencies FHI 360 complies with special reporting requirements found in PHS Policies on Research Misconduct – 42 CFR Part 93 and NSF regulations at 45 CFR 689. FHI 360 subawardees and subcontractors are responsible for handling research misconduct in compliance with applicable federal regulations, local laws and agreement terms and conditions. In addition, FHI 360 subawardees and subcontractors are expected to inquire into, and if necessary, investigate and resolve promptly and fairly all instances of alleged research misconduct related to the subaward or subcontract, such review to comply with applicable federal regulations, local laws, and agreement terms and conditions. For determinations of research misconduct while engaged in FHI 360 research activities, subawardees and subcontractors are required to provide a report to the RIO that details the facts and analysis that supports the conclusion, identifies the type of research misconduct, describes any mitigating steps and/or administrative and disciplinary actions taken, list all individuals and/or organizations notified, includes any supporting documentation of the RIO may take custody of all research records and evidence to meet any applicable legal and/or regulatory requirements.

#### 7. PATIENT CARE

The Grantee assumes full responsibility and liability for the care and treatment of its patients. To the extent that the training and other support provided to the Grantee by FHI 360-employed personnel under this Grant encompasses treatment of Grantee's patients, the Grantee acknowledges and agrees as follows:

- (a) that the Grantee is ultimately responsible for such treatment;
- (b) that such treatment will be deemed to be done by and on behalf of the Grantee;
- (c) that the Grantee waives any claim against FHI 360 and/or FHI 360-employed personnel arising out of patient treatment;
- (d) that the Grantee will assume full responsibility for any claims made by patients arising out of patient treatment, whether patient treatment was provided by Grantee-employed personnel or by FHI 360-employed personnel; and,
- (e) that the Grantee will hold FHI 360 harmless from any liability arising out of any assistance provided under the terms of this Grant.

#### 8. INSPECTION AND ACCEPTANCE

Acceptance of the effort specified in the Program Description will be made by FHI 360's Technical/Program Monitor or his/her authorized representative. FHI 360 has the right to inspect and evaluate the activities performed under this Grant at all reasonable times and in a manner that will not unduly delay the activities.

All required deliverables will be submitted to the FHI 360 Technical/Program Monitor. Notwithstanding any other payment provision of this Grant, failure of the Grantee to submit required reports when due, or failure to perform or deliver required activities will result in the withholding of payment under the Grant unless such failure arises out of causes beyond the control and without the fault or negligence of the Grantee.

#### 9. CHANGES AND MODIFICATIONS

Any proposed change to this Grant must be authorized by a written modification to this Grant before performance of the change may begin. Any effort undertaken by the Grantee pursuant to oral instructions or technical directions issued other than in accordance with the provisions of this Grant will be at the Grantee's risk of performing activities outside the Program Description of this Grant and may not be eligible for payment of the costs incurred.



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#### **10. SUBGRANTS**

The Grantee will not execute Subgrants under this Grant without the prior written approval of the FHI 360 Grant Officer. The Grantee will submit to the FHI 360 Grant Officer information concerning the need for Subgrants including an assessment of the reasonableness of the costs to be paid to any Subgrantee. A copy of any proposed Subgrant must accompany the request for approval.

#### **11. WORKING FILES AND DATASETS**

The Grantee certifies that any working files maintained by the Grantee including calculations, assumptions, interpretations of regulations, sources of information, and other raw data required in the performance of this Grant will be maintained in an accurate and complete manner. Upon request, the Grantee will provide information contained in its working files to the FHI 360 Technical/Program Monitor.

#### **12. RECORDKEEPING AND ACCESS**

The Grantee will maintain books, records, documents, program and individual service records and other evidence of its accounting and billing procedures and practices which sufficiently and properly reflect all direct and indirect costs of any nature incurred in the performance of this Grant. These records will be subject at all reasonable times to monitoring, inspection, review or audit by authorized employees or agents of FHI 360 or its funding sponsor. The Grantee will retain all such records concerning this Grant for a period of three (3) years after the submission of the final financial report, unless a longer period is specified in the specific terms and conditions of the Grant and for U.S. Government funded grants, for a longer period if there is an applicable exception under 45 CFR 75.361. If any litigation, claim or audit is started before the expiration date of this three-year period, the records will be retained until all litigation, claims or audit findings involving the records have been resolved.

#### **13. PUBLICATION**

Unless otherwise specified in this Grant, the Grantee is encouraged to publish the results of its work under this Grant.

In the event the Grantee proposes any *academic* publication arising out of the Grantee's work under this Grant, the Grantee agrees to comply with HPTN Publication Policy that can be found at the following site: <u>https://www.hptn.org/resources/manual-of-operations</u>

#### Disclaimer.

For both *academic* and *non-academic* publications resulting from work performed under this Grant, the Grantee will include a disclaimer which is in substantially conformity with the following example:

"This publication was prepared under a Grant funded by Family Health International under Cooperative Agreement/Grant No. UM1 AI068619 funded by the National Institutes of Health. The content of this publication does not necessarily reflect the views, analysis or policies of FHI 360 or the National Institutes of Health, nor does any mention of trade names, commercial products, or organizations imply endorsement by FHI 360 or the National Institutes of Health."

The Grantee will notify the FHI 360 Technical/Program Monitor when any article, chapter or other publication is published, and will provide a copy of the published work to FHI 360.

#### **14. TERMINATION**

a) *Termination.* Funding for this Grant is contingent upon factors including the availability of funds to FHI 360, satisfactory progress by the Grantee, and overall direction of the program of which this Grant is a part. Either party may terminate this Grant at any time by providing five (5) calendar days written notice prior to the



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effective date of the suspension or termination to the Grantee. The Grantee will be responsible for satisfying all of its obligations relative to this Grant through the effective date of termination. FHI 360 will only be responsible for costs incurred after the effective date of suspension or termination as follows: (a) FHI 360 expressly authorizes such costs in the notice of suspension or termination or subsequently in writing, or (b) the costs result from non-cancelable obligations that were properly incurred before the effective date of suspension or termination, and the costs would be allowable if the Grant were not suspended or expired normally at the end of the funding period in which the termination takes effect.

- b) Terms upon Termination. Upon termination, the Grantee will:
  - 1. cease all work except to the extent that is minimally necessary to shut down operations;
  - 2. return or provide to FHI 360 all materials and work product related to this Grant; and,
  - 3. provide FHI 360 with such services related to the transfer of tasks under the Program Description to another Grantee as may be specified by FHI 360 upon termination.

The Grantee will be reimbursed for services provided up to the effective date of termination and any such transfer costs as are specified and approved in advance by FHI 360, provided such services are in accordance with the provisions of this Grant.

#### **15. DISPUTES**

All disputes and differences that may arise out of or in connection with the terms of this Grant will be settled by direct discussions between the FHI 360 Grant Officer and the Grantee's duly authorized representative. If after sixty (60) days resolution has not been reached, either party may exercise their legal right to any available remedy in a court of law

#### **16. INDEMNIFICATION**

The Grantee will indemnify, defend, and hold FHI 360 harmless from any loss, damage, liability, claims, costs, demands, suits, or judgments, including reasonable attorney's fees, as a result of any damage or injury to the Grantee, its employees, officers, or agents, or injury to the property of the Grantee, its employees, officers, or agents, or their property which is directly or indirectly caused by the Grantee, its employees, officers, or agents, in the course of performance of any of the work specified in this Grant.

#### **17. DEBARMENT AND SUSPENSION**

The Grantee certifies that neither it nor its principals is presently excluded or disqualified from participation in this transaction by any Federal department or agency.

#### **18. TERRORIST FINANCING**

The Grantee will not engage in transactions with, or provide resources or support to individuals and organizations associated with terrorism, including those organization and individuals identified in lists promulgated by the US Government, the United Nations and the European Union. It is the legal responsibility of the Grantee to ensure compliance with these laws. This provision must be included in all lower tier Grants issued under this Grant.

#### **19. PROHIBITION ON ASSISTANCE TO DRUG TRAFFICKERS**

FHI 360 reserves the right to terminate this Grant, to demand a refund or take measures if Grantee is found to have been convicted of a narcotic offence or engaged in drug trafficking activities.

#### **20. PROSTITUTION AND SEX TRAFFICKING**



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None of the funds made available under this Grant may be used to promote or advocate the legalization or practice of prostitution or sex trafficking. Nothing in the preceding sentence shall be construed to preclude the provision to individuals of palliative care, treatment, or post-exposure pharmaceutical prophylaxis, and necessary pharmaceuticals and commodities, including test kits, condoms, and, when proven effective, microbicides.

If this Grant is for the implementation of HIV/AIDS programs, and if the Grantee is a non-US organization, the Grantee agrees that it is opposed to the practices of prostitution and sex trafficking and hereby certifies that it does not and will not promote the legalization or decriminalization or practice of prostitution or sex trafficking.

#### **21. PROHIBITION ON ABORTION-RELATED ACTIVITIES**

No funds made available under this Grant will be used to finance, support or be attributed to the following activities:

- a. Procurement or distribution of equipment intended to be used for the purpose of inducing abortions as a method of family planning;
- b. Special fees or incentives to women to coerce or motivate them to have abortions;
- c. Payments to persons to perform abortions or to solicit persons to undergo abortions;
- d. Information, education, training, or communication programs that seek to promote abortion as a method of family planning; and
- e. Lobbying for abortion.

No funds made available under this Grant will be used to pay for any biomedical research which relates, in whole or in part, to methods of, or the performance of abortions or involuntary sterilizations as a means of family planning. Epidemiologic or descriptive research to assess the incidence, extend or consequences of abortions is not precluded.

#### 22. DELAYS

Whenever the Grantee knows, or reasonably should know, that any actual or potential condition is delaying, or threatens to delay, the timely performance of work under this Grant, the Grantee will, within five (5) days, notify the FHI 360 Grant Officer, in writing, providing all relevant information with respect to the delay.

#### **23. NOTICES**

All notices concerning business or administrative matters under this Grant will be in writing and will be directed to the FHI 360 Grant Officer named in the cover page.

All technical and program related notices and reports will be directed to the FHI 360 Technical/Program Monitor named in the cover page.

#### **24. ENTIRE AGREEMENT**

The parties acknowledge that they have read this Grant, understand it, and agree to be bound by its terms. The parties further agree that this Grant, together with all of the referenced and incorporated attachments, is the entire agreement between the parties and that it supersedes all prior agreements, written or oral, relating to the subject matter of this Grant.

If this Grant and any of its attachments are translated to a foreign language, the English version shall control.

#### **25. LIABILITY**

With regard to all aspects of this Grant, FHI 360 assumes no liability for any third-party claims or damages arising out of this Grant.



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#### **26. VALIDITY AND WAIVER**

The invalidity in whole or in part of any provision of this Grant will not affect the validity of other provisions. A waiver of a breach of any provision of this Grant will not constitute a waiver of any subsequent breach of that provision or a breach of any other provision of this Grant. The failure of FHI 360 to enforce at any time or from time to time any provision of this Grant will not be construed as a waiver of the provision.

#### **27. PERSONAL DATA PROTECTION**

Grantee is responsible for ensuring its compliance with any applicable data protection laws related to its services, including but not limited to, General Data Protection Regulation (GDPR), UK-GDPR, Protection of Personal Information (POPI) Act, Nigeria Data Protection Regulation (NDPR), Brazilian General Data Protection Law (LGPD) and the Kenya Data Protection Act. To the extent Grantee processes any personal data, as defined by applicable data protection laws, on behalf of FHI 360 and in relation to which FHI 360 is the Controller, as defined by applicable data protection laws, Grantee shall: (a) act only on instructions from FHI 360 when processing personal data and keep records of all processing activities; (b) take all appropriate technical and organizational measures to protect against unauthorized or unlawful processing of, or accidental loss, destruction, or damage to, personal data; (c) process personal data in accordance with applicable data protection laws; (d) not do or permit anything to be done which might cause FHI 360 or any of its affiliates to be in violation of applicable data protection laws; (e) immediately inform FHI 360 if it believes performance of the services or compliance with any FHI 360 instruction violates or might reasonably be considered to violate any applicable data protection laws; (f) immediately notify FHI 360 of receipt of any complaint, data subject access request, notice, or communication which relates directly or indirectly to the processing of personal data under this Agreement, and provide full cooperation and assistance to FHI 360 in responding to such complaint, request, notice, or communication; (g) notify FHI 360 promptly and without undue delay upon becoming aware of any unauthorized loss, corruption, damage, destruction, alteration, disclosure, or access to, or unauthorized or unlawful processing of, any personal data ("Personal Data Breach"), or any circumstances that are likely to give rise to a Personal Data Breach, timely providing FHI 360 with sufficient information for it to meet its obligation, if any, to report a Personal Data Breach under applicable data protection laws; (h) cooperate with FHI 360 and take commercially reasonable steps as may be directed by FHI 360 to assist in the investigation, mitigation, and remediation of any Personal Data Breach; (i) cooperate as requested by FHI 360 to enable it to comply with any exercise by a data subject of rights under applicable data protection laws with respect to personal data processed by Grantee under this Agreement, or to comply with any assessment, inquiry, notice, or investigation under applicable data protection laws; (j) only permit a third party sub-processor to process personal data subject to FHI 360's prior written consent and provided that the sub-processor's contract includes terms that are substantially the same as those set out in this section; and (k) not transfer, permit a third-party processor to transfer, or allow access to personal data outside a country with restrictions on transferring data to another country without FHI 360's prior written consent, subject to any conditions FHI 360 may impose, at its sole discretion. Grantee agrees that FHI 360 may from time to time have reasonable access to Grantee's premises, systems, and records in order to audit Grantee's security measures and procedures in connection with the processing of personal data and to ensure Grantee's compliance with this section. Grantee shall indemnify, defend, and hold FHI 360 and its affiliates harmless from and against all costs, claims, damages, or expenses incurred by them due to any failure by Grantee to comply with any of its obligations under this section.



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#### ATTACHMENT E HPTN NIH FLOW-DOWN TERMS AND CONDITIONS

#### PART I - CERTIFICATIONS/ASSURANCES

#### 1. Certification Regarding Lobbying (45 CFR 75.450)

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 45 CFR 75.450.

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 FHI 360.

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.

#### 2. Debarment, Suspension, and Other Responsibility Matters (45 CFR 75.213 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 45 CFR 75.213 and 2 CFR 180.

#### 3. Audit and Access to Records

Per 45 CFR 75.501-75.521, Subrecipient certifies that it will provide notice of any adverse findings which impact this Subaward and will provide access to records as required by 45 CFR 75.364, 75.365, and 75.201 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.

#### 4. 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 pilot 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.



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#### 5. Human Subjects (45 CFR 46)

Subrecipient certifies that it will comply with all requirements relating to human subject protections. The Subrecipient shall file and has filed will maintain all assurances or other documentation with the appropriate government agencies to the extend such assurances and documentation are required including but not limited to any requirements set forth at 45 C.F.R. Part 46 and 21 C.F.R. Part 50 (Protection of Human Subjects). Any Subrecipient enrolling/following human subjects will ensure appropriate study review and approval by Institutional Review Boards/Ethics Committees (IRBs/ECs) and other regulatory entities; including annual IRB/EC continuing reviews and submission of all required documentation in accordance to this subaward, program description and/or any applicable protocol.

The Subrecipient shall require that the language of the certifications above in this Attachment 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 including disclosing any changes in the status of the above provisions for the Subrecipient and any lower tiers of the Subrecipient.

#### PART II – DONOR 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: <a href="https://grants.nih.gov/grants/policy/awardconditions.htm">https://grants.nih.gov/grants/policy/awardconditions.htm</a>
- 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: https://grants.nih.gov/policy/nihgps/index.htm
  - a. NOTICE: Section **4.1.37 Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment** of the NIH Grants Policy Statement, updated April 2021 (<u>https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf</u>) applies to this Grant.
  - b. NOTICE: Section 15.2 Administrative and Other Requirements and 15.2.1 Written Agreement of the NIH Grants Policy Statement, effective January 1, 2024 (https://grants.nih.gov/grants/policy/nihgps/nihgps.pdf) applies to this Grant.

Any foreign entity that receives a subgrant must 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 primary recipient no less than once per year, in alignment with the timing requirements for Research Performance Progress Report submission. Such access may be entirely electronic.

- 4. Research Terms and Conditions, including any Federal Awarding Agency's Specific Requirements found at: <u>https://www.nsf.gov/awards/managing/rtc.jsp</u> except for the following:
  - a. No-cost extensions require the written approval of the FHI 360. Any requests for a no-cost extension shall be directed to the FHI 360 Contracting Officer not less than 30 days prior to the desired effective



date of the requested change.

- b. Any prior approvals are to be sought from FHI 360 and not the Federal Awarding Agency.
- c. Prior approval must be sought for a change in Subrecipient PI or change in Key Personnel.

#### 5. Treatment of program income:

□Additive □ Other, Prime Recipient specify alternative from NIH Agreement ⊠ Not Applicable

#### **Special Terms and Conditions:**

#### 1. Public Access

In accordance with P.L. 110-61, compliance with the NIH Public Access Policy is now mandatory. For more information, see NOT-OD-08-033 and the Public Access website: <u>http://publicaccess.nih.gov/</u>.

#### 2. 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.

#### 3. Certificates 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 apply. Accordingly, the Subrecipient 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").

#### 4. Data Sharing and Access:

Subrecipient agrees to comply with the Federal Awarding Agency's data sharing and/or access requirements as reflected in the special terms and conditions and can be provided upon request. You can contact the FHI 360 Program/Technical Monitor for additional questions.

#### 5. Data Rights

Subrecipient grants to FHI 360 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 FHI 360's obligations to the Federal Government under its FHI 360 Federal Award.

#### 6. Copyrights

Subrecipient grants to FHI 360 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 FHI 360's obligations to the Federal Government under its FHI 360 Federal Award.



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Subrecipient grants to FHI 360 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 FHI 360's obligations to the Federal Government under its Federal Award.

#### 7. Patents Rights and Inventions

Pursuant to 37 CFR 401, title to any invention or discovery made or conceived under this Subaward shall vest in the Subrecipient to the extent the Prime award does not specify specific requirements. Should it be necessary, the Federal Government shall authorize the Prime Recipient's right to practice a Subrecipients subject invention (as well as subject data or copyrights) on behalf of the Federal Government. Subrecipient hereby grants to FHI 360 a royalty-free, non-exclusive license for research purposes to any Subrecipient invention or discovery under this Subaward.

#### 8. Invention Reporting

In accordance with 37 CFR 401.14, Subrecipient agrees to notify both the Federal Awarding Agency via iEdison and FHI 360'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 FHI 360's Principal Investigator within 60 days of the end of the Project Period to be included as part of FHI 360s final invention report to the Federal Awarding Agency.

A negative report is required  $\Box$  Yes  $\boxtimes$  No  $\Box$  Upon Request

#### 9. Insurance

The Subrecipient assures that it carries sufficient insurance coverage to comply with the requirements of federal, state, and local laws as well as its obligations under this Subaward.



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