UNIVERSITY OF CALIFORNIA
Research Policy Analysis & Coordination
Guidance Memo
14-10

December 23, 2014

To: Contract & Grant Officers

Subject: Family Health International Master Agreement for the HIV Prevention Trials Network (HPTN) No. HPTN-MGA-REGUC-1

Background

The Office of the President (UCOP) Research Policy Analysis & Coordination (RPAC) unit has finalized a Master Agreement (No. HPTN-MGA-REGUC-1) with Family Health International (FHI 360). A PDF of this new Agreement and the HTPN Publication Policy (HPTN011-09 effective April 17, 2012) can be found in the Sponsor Guidance module of REMS using sponsor code 7402.

The HIV Prevention Trials Network (HPTN) is a seven-year cooperative agreement (UM1 AI068619) with the National Institutes of Allergy and Infectious Diseases (NIAID) with additional support from the National Institute of Drug Abuse (NIDA) and the National Institute of Mental Health (NIMH). The HPTN's research portfolio aims to design and conduct rigorous clinical trials that will have a significant impact on public health and that will fundamentally inform guidelines and policies for the control of the global HIV epidemic. FHI 360 has been tasked with granting and administering the awards funding these clinical trials. The Master Agreement attempts to streamline the award process by standardizing the terms in the HPTN awards to UC campuses.

The Master Agreement's notable terms are highlighted below. It is important that campus Contracts and Grants personnel review the entire agreement and become familiar with its terms and conditions.

Guidance

1. **Agreement Period**
   The period of performance for the Master Agreement is from June 1, 2014 through August 20, 2020.

2. **Grant awards under this Master Agreement**

   FHI360 will make grant awards based on proposals submitted to and approved by the HPTN/NIH. Each Grant will describe the details specific to that activity including the award amount, obligation, program description for the Grant, budget, payment instructions, reporting requirements and special conditions

specific to the Grant. The terms and conditions contained in the Master Grant Agreement shall apply to all Grants authorized under it.

3. Publication delay

The executed Master Agreement in Attachment B, Section 11 states (see attached):

> Unless otherwise specified in this Master Grant Agreement, the Grantee is encouraged to publish the results of its work under this Master Grant Agreement.
>
> In the event the Grantee proposes any academic publication arising out of Grantee's work under this Master Grant Agreement, the Grantee agrees to comply with the requirements of the HPTN Publications Policy (attached).
>
> Notwithstanding the above, the Grantee can independently publish manuscripts based solely on data that the Grantee has collected performing work awarded under this Master Grant Agreement 1) only after the publication of the multisite results, or 2) 18 months after the conclusion of the study, if the Network has not published any multisite results. Any such publication will be submitted to the Protocol Team for review and comment thirty (30) days prior to publication, and will include the Disclaimer outlined below.
>
> Disclaimer.
>
> For both academic and non-academic publications resulting from work performed under this Master Grant Agreement, the Grantee will include a disclaimer which is in substantially conformity with the following example:
>
> > *This publication was prepared under a Subaward funded by Family Health International under Cooperative Agreement/Grant No UM1 AI 068619 funded by National Institute of Health. The content of this publication does not necessarily reflect the views, analysis or policies of FHI 360 or National Institute of Health, nor does any mention of trade names, commercial products, or organizations imply endorsement by FHI 360 or National Institute of Health.*
>
> The Grantee will notify the FHI 360 Technical Lead when any article, chapter or other publication is published, and will provide a copy of the published work to FHI 360.

Although the HPTN Publication Policy (HPTN011-09 effective: April 17, 2012) does require approval of multisite manuscripts, FHI 360 agreed to a delay of a publication that is based solely on data that a UC investigator (PI) has collected.

Before any grant under this Master Agreement is accepted, please secure informed participation of your PI(s) that documents his or her understanding of the following and that of the research personnel participating on that project:

- Any publication based on HPTN multisite data will be bound by the terms of the HPTN Publications Policy
- Any manuscript based solely on data that the PI has collected performing the work of the HPTN award can be published:
  1. Only after the HPTN has published, or
  2. Eighteen months after the conclusion of the award, if the HPTN has not published.
- Any independent publication needs to be submitted to the Protocol Team for review and comment thirty (30) days prior to publication
- Any independent publication will carry the Disclaimer set out in section 11. Publication
- A copy of the published work will be provided to FHI 360.

Contact
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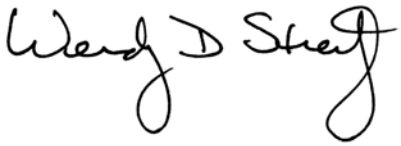

Wendy D. Streitz
Executive Director
Research Policy Analysis & Coordination

Attachments: Master Agreement
HPTN Publication Policy

The attachment may not be viewable in your web browser. Download this memo, and view it in a PDF viewer, such as Adobe Reader or Acrobat, to ensure your access to the attachments.

HPTN MASTER GRANT AGREEMENT
BETWEEN
FAMILY HEALTH INTERNATIONAL (FHI 360) AND THE REGENTS OF THE UNIVERSITY OF CALIFORNIA ("GRANTEE")
AGREEMENT NUMBER: HPTN-MGA-REGUC-1

Name of Grantee: The Regents of the University of California
Grantee TIN/Registration No.: See Attachment D Grantee DUNS Number: See Attachment D
Period of Grant Performance: JUNE 1, 2014 to AUGUST 30, 2020
Grantee Status: ☒US ☐Non-US ☐Non-Profit ☐For-Profit ☐Gov't ☒Other University
Original Sponsor/Funder: PHS/NIH/NIAID CFDA # 93.855
FHI 360 (Prime) Award: HIV PREVENTION TRIALS NETWORK (HPTN) FHI 360 (Prime) Award No: UM1 AI068619

FHI 360 Grant Officer
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Title: Contracting Officer
Address: FHI 360 Headquarters
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FHI 360 Administrative Monitor
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Grantee Point-of-Contact for Administrative Matters
Name: Andrew C. Boulter
Title: Research Policy Manager
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Email: Andrew.Boulter@ucop.edu

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

Authorized by and accepted for FHI 360:
Signature Date 8/26/14
Holly Dodge
Contracting Officer, Contract Management Services
Title

Authorized by and accepted for the Grantee:
Signature Date 8/25/14
Andrew C. Boulter
Research Policy Manager
Title

Pursuant to the terms and conditions of the Prime Award cited on the cover page, this HPTN Master Grant Agreement is entered into by and between Family Health International ("FHI 360") with its headquarters office in Durham, North Carolina, USA and The Regents of the University of California ("Grantee") with its headquarters in Oakland, 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. HPTN MASTER GRANT AGREEMENT AND PLACEMENT OF INDIVIDUAL GRANTS

This is a Master Grant Agreement between FHI 360 and The Regents of the University of California, ("Grantee") so that the Parties may execute individual Grants for specific activities under the broader HPTN program in accordance with the Master Grant Agreement terms and conditions. The Master Grant Agreement has no minimum or maximum value or obligation. Individual Grant award amounts will be specified in each Grant issued under this Master Grant Agreement. The terms and conditions contained in this Master Grant Agreement shall apply to all Grants authorized thereunder.

Individual Grants will be issued by FHI 360 for specific activities in support of the work of the HPTN. Each Grant will describe the details specific to that activity including the award amount, obligation, program description for the Grant, budget, payment instructions, reporting requirements and special conditions specific to the Grant.

Each Grant will be issued with a total estimated value and an obligation amount. Grants may be incrementally funded by FHI 360. FHI 360 is not liable for reimbursing the Grantee for any amount in excess of the total obligated amount of the Grant, or outside of the Grant period.

FHI 360 will not reimburse the Grantee for Grant expenses in excess of the total obligated amount or for costs incurred outside of the period of performance of the Grants. Each Grant will indicate whether funds remaining at the end of the obligated period may or may not be carried over into subsequent funding periods.

ARTICLE 3. GENERAL CONDITIONS OF FUNDING UNDER THE MASTER GRANT AGREEMENT

a) Grants may be issued on a fixed price by deliverable basis or a cost reimbursement basis. FHI 360 will reimburse only those direct costs that are identified in the approved budgets of the Grants and are determined to be allowable and allocable under the cost principles followed by FHI 360 and provided in OMB Circular A-122, or those applicable to the Grantee, currently or during the period of this Master Grant Agreement.

   The cost principles can be downloaded from: http://www.whitehouse.gov/omb/circulars_default

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

b) When Grants are incrementally funded, the continued funding of Grants will be determined by the availability of funds from FHI 360's donor that is supporting this Master Grant Agreement.

c) The currency of payment may be either the U.S. dollar or the local currency of the Grantee. The U.S. dollar value will control and shall not be exceeded, including when payment is made in local currency.

d) Advance payments, if any, shall be in accordance with Article 6 of this Master Grant Agreement.

e) Lower-tier Grants are not authorized under this Master Grant Agreement without prior approval from the FHI 360 Grant Officer. Lower-tiered subs in approved grants will be specifically identified in individual grants under this Master Grant Agreement.

ARTICLE 4. MONITORING AND REPORTING REQUIREMENTS

TECHNICAL MONITOR. Technical monitoring of each Grant will be performed by the designated FHI 360 Technical Lead indicated on the Grant cover page. All Technical Reports will be submitted to the Technical Lead identified in the Grant.

ANNUAL PROGRESS REPORT. For each Grant under a study issued under this Master Grant Agreement, the Grantee will prepare and submit an Annual Progress Report detailing the Grantee's progress and specifying the Grantee's proposed work plan for the next period. Progress reports are due 30 days after the close of the period.

FINAL REPORT. For each Grant issued under this Master Grant Agreement, at the conclusion of the Grant, the Grantee will prepare and submit to the FHI 360 Technical Lead a final report that will summarize the accomplishments of the 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).

ARTICLE 5. FINANCIAL REPORTING

FINANCIAL REPORTS. For each cost-reimbursable Grant, the Grantee will prepare and submit to the FHI 360 Accounting Manager a monthly invoice 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.

Invoices for fixed-price by deliverable grants the Grantee will be prepared and submitted to the FHI 360 Accounting Manager, in accordance with instructions included in the individual grant issued under this Master Grant Agreement.

ARTICLE 6. PAYMENT PROCEDURES

a) Advance payments are rarely authorized for Grants under this HPTN Master Grant Agreement. Requests for advances should be directed to the FHI 360 Administrative Monitor listed on the coversheet of the Master Grant Agreement.
b) On submission of the claim for final payment, the Grantee must certify in writing to the FHI 360 Grant Monitor that the Grant is completed and the Grantee will make no further claim against FHI 360 after final payment.

ARTICLE 7. APPLICABLE REGULATIONS AND REQUIREMENTS

The Grants issued under this Master Grant Agreement will be 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. This Master Grant Agreement is subject to the terms and conditions of the Prime Award. The Grantee is subject to OMB Circular A-110, "Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations" and the donor specific requirements that are set forth in Attachment C and are incorporated herein by reference.

ARTICLE 8. FHI360 GRANT TERMS AND CONDITIONS

The Grant Terms and Conditions governing this Master Grant Agreement are set forth in **Attachment B**, *Grant Terms and Conditions* and are hereby incorporated into this Master Grant Agreement by reference.

ARTICLE 9. SPECIAL AWARD CONDITIONS

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/Consultant 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.hanc.info/smctl/Documents/Cross-network%20FDCOI_SOP.pdf
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 must submit a Financial Conflict of Interest report as required under 42 CFR Part 50, Subpart F prior to expenditure of funds.

Grantee must submit a Financial Conflict of Interest report compliant with the federal regulations within 30 days of when a new interest has been identified and determined to be a FCOI.

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 all Grants issued under this Master Grant Agreement and within 45 days of any subsequently identified financial conflict of interest.**

ARTICLE 10. ORDER OF PRECEDENCE

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

a) Articles of this Master Grant Agreement;
b) Program Description – Attachment A;
c) FHI 360 Grant Terms and Conditions - Attachment B;
d) Donor Specific (NIH) Terms and Conditions – Attachment C

-End of Section-

ATTACHMENTS
ATTACHMENT A – PROGRAM DESCRIPTION
ATTACHMENT B – FHI 360 GRANT TERMS AND CONDITIONS
ATTACHMENT C – DONOR SPECIFIC TERMS AND CONDITIONS
ATTACHMENT D - DUNS #S AND TIN #S FOR THE REGENTS OF THE UNIVERSITY OF CALIFORNIA

ATTACHMENT A
PROGRAM DESCRIPTION

The HIV Prevention Trials Network is a seven-year cooperative agreement with the National Institutes of Allergy and Infectious Diseases (NIAID) with additional support from the National Institute of Drug Abuse (NIDA) and the National Institute of Mental Health (NIMH) under UM1 AI068619.

The HIV Prevention Trials Network (HPTN) goal is to reduce HIV incidence in populations at greatest risk for infection. The HPTN's approach aims to achieve public health impact in terms of decrease in HIV incidence. The framework of the HIV continuum/cascade will be utilized to shape the overarching research agenda with focus on the following four elements: 1) strategies to find at-risk populations or those with HIV who are unaware of infection; 2) HIV testing and counseling, since knowledge of HIV status is the linchpin for determining the tailored integrated package of interventions; 3) linkage to an appropriate package of interventions — biomedical, behavioral and/or structural — based on HIV status, the risk population and situation; and 4) adherence and retention to the intervention(s), whether for prevention for HIV acquisition or HIV transmission. The findings from the HPTN's current portfolio of studies and other research combined with the innovative laboratory and statistical methods identified by the Network will inform the HPTN's future research agenda, study designs and analytic methods.

The HPTN's immediate research priorities are centered on two objectives: 1) To design and implement *integrated strategy studies* for priority populations and 2) To identify efficacious agents/regimens for *pre-exposure prophylaxis* (PrEP).

The HPTN's research portfolio aims to design and conduct rigorous clinical trials that will have public health impact and that will be fundamental in informing guidelines and policies for the control of the global HIV epidemic.

FHI 360 will issue Grants under this Master Grant Agreement with scopes of work to support a HPTN study or activity. Grants may be issued to facilitate the following HPTN Network activities including (1) study-specific protocol funding, (2) Network, protocol and committee leadership salary support, (3) technical experts' salary support, (4) support of the HPTN scholars' program, and (5) any other study-specific activity that requires centralized support and oversight.

ATTACHMENT B
FHI 360 GRANT TERMS AND CONDITIONS

1. INDEPENDENT ENTITY

The relationship of the Grantee to FHI 360 is that of an independent entity, and nothing in this Master Grant Agreement 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 Master Grant Agreement. 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 Master Grant Agreement 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 Master Grant Agreement. All communications regarding this Master Grant Agreement must be directed to FHI 360.

2. CONFIDENTIAL INFORMATION

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

Confidential information is defined as all technical information disclosed in verbal, written, graphic, photographic, electronic, prototypic, sample or any other form which FHI360 or the Grantee considers proprietary or which it wishes to be held in confidence. In this case, the party disclosing the Confidential Information shall indicate its confidentiality prior to disclosure unless the information is required by law to be kept confidential. Confidential Information disclosed in written, graphic or electronic format shall be marked on its face as "Confidential" and/or "Proprietary." Confidential Information disclosed in verbal or visual form shall be summarized in writing and confirmed to the party receiving such Confidential Information 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 or Grantor;
- becomes available to the Grantee or Grantor 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 or Grantor without use of *Confidential Information*, as demonstrated by written records and evidence;
- was in the Grantee's or Grantor's possession or known to the Grantee or Grantor prior to receipt from the disclosing party; or
- is required by law to be disclosed, provided the one party notifies the other party promptly and gives the other party an opportunity to seek an appropriate protective order.

Confidential Information may be used by the Grantee, Grantor or their employees only for purposes of performing the obligations under this Master Grant Agreement. The Grantee /Grantor 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 by one party to the other as a result of services under this Master Grant Agreement remains the sole property of the disclosing party 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 Master Grant Agreement.

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 Master Grant Agreement 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 Master Grant Agreement 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 Grant or lower-tier Grant arising out of this Master Grant Agreement.

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 each other, to project collaborators, and to our sponsors. The Grantee confirms its accountability to children and to all others whom its programs are intended to serve. In the case of children, the Grantee 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 Master Grant Agreement.

The Grantee acknowledges that FHI 360 corporate policy requires that FHI 360's activities be conducted within the letter and spirit of the law. By signing this Master Grant Agreement, the Grantee agrees to implement the project in a manner which is consistent with applicable laws and regulations. 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 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 Master Grant Agreement or any other aspect of FHI 360's operations.

5. PROTECTION OF HUMAN RESEARCH SUBJECTS

The Grantee is responsible for safeguarding the rights and welfare of human subjects involved in research under this Master Grant Agreement. 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 Part 225 of Title 22 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 Lead 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 Master Grant Agreement 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 the Grantee has been notified in writing by the FHI 360 Technical Lead that all other requisite approvals of the Grantee's procedures pursuant to the protection of human research subjects have been obtained, as appropriate.

6. 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 Master Grant Agreement encompasses Grantee's 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, and,

e) that the Grantee will hold FHI 360 harmless from any liability arising out of any assistance provided under the terms of this Master Grant Agreement.

7. INSPECTION AND ACCEPTANCE

Acceptance of the effort specified in the Program Description will be made by FHI 360's Technical Lead or his/her authorized representative. FHI 360 has the right to inspect and evaluate the activities performed under this Master Grant Agreement 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 Lead. Notwithstanding any other payment provision of this Master Grant Agreement, 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 Master Grant Agreement unless such failure arises out of causes beyond

the control and without the fault or negligence of the Grantee.

8. CHANGES AND MODIFICATIONS

Any proposed change to this Master Grant Agreement or Grants issued under this Master Grant Agreement must be authorized by a written modification to the Master Agreement/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 Master Grant Agreement or Grants issued under the Master Grant Agreement will be at the Grantee's risk of performing activities outside the Program Description of the Master Grant Agreement/Grant and may not be eligible for payment of the costs incurred.

9. 2ND TIER GRANTS

The Grantee will not execute 2nd tier Grants under any Grants issued under this Master Grant Agreement without the prior written approval of the FHI 360 Grant Officer. The Grantee will submit to the FHI 360 Grant Monitor information concerning the need for 2nd tier Grants including an assessment of the reasonableness of the costs to be paid to any Sub-grantee. A copy of any proposed 2nd tier Grant must accompany the request for approval. 2nd tier grants included in the approved budget for a grant will be noted in the grant as approved.

10. RECORDKEEPING AND ACCESS

The Campus of the University of California receiving a grant under this Master Grant Agreement 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 the grant under Master Grant Agreement. 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 Campus receiving a grant will retain all such records concerning the grant under this Master Grant Agreement for a period of three (3) years after the submission of the Grant's final financial report, unless a longer period is specified in the specific terms and conditions of the Grant. 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.

11. PUBLICATION

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

In the event the Grantee proposes any ***academic*** publication arising out of Grantee's work under this Master Grant Agreement, the Grantee agrees to comply with the requirements of the HPTN Publications Policy.

Notwithstanding the above, the Grantee can independently publish manuscripts based solely on data that the Grantee has collected performing work awarded under this Master Grant Agreement 1) only after the publication of the multisite results, or 2) 18 months after the conclusion of the study, if the Network has not published any multisite results. Any such publication will be submitted to the Protocol Team for review and comment thirty (30) days prior to publication, and will include the Disclaimer outlined below.

Disclaimer.

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

> "This publication was prepared under a Subaward funded by Family Health International under Cooperative Agreement/Grant No UM1 AI 068619 funded by National Institute of Health. The content of this publication does not necessarily reflect the views, analysis or policies of FHI 360 or National Institute of Health, nor does any mention of trade names, commercial products, or organizations imply endorsement by FHI 360 or National Institute of Health."

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

12. TERMINATION

a) ***Termination.*** Funding for grants under this Master Grant Agreement 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 Master Grant Agreement is a part. FHI 360 may suspend or terminate a grant or this Master Grant Agreement in whole or in part, at any time, and for any reason, by providing thirty (30) calendar days written notice of the effective date of the suspension or termination to the Grantee. The Grantee will be responsible for satisfying all of its obligations relative to this Master Grant Agreement through the effective date of termination. FHI 360 will only be responsible for grant 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, were incurred not in anticipation of the suspension or termination, and the costs would be allowable if the grant under the Master Grant Agreement 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 specifically required as a deliverable and related to a Grant under this Master Grant Agreement; and,
   3. provide FHI 360 with such services related to the transfer of tasks described under the Grant's Program Description to another Grantee as may be specified by FHI 360 upon termination.

   The Grantee will be reimbursed for services provided and uncancellable obligations 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 Master Grant Agreement.

13. DISPUTES

All disputes and differences that may arise out of or in connection with the terms of this Master Grant Agreement will be settled by negotiations between the FHI 360 Grant Officer and the Grantee's duly authorized representative. For non-U.S. domiciled grantees, disputes which remain unresolved after sixty (60) days will be settled by arbitration in London, England, U.K. in accordance with the international arbitration rules of the International Chamber of Commerce. For U.S. based Grantees, disputes which remain unresolved after sixty (60) days will be settled by arbitration, in accordance with the arbitration rules of the American Arbitration Association. An arbitration panel of three (3) arbitrators will be selected, with each party designating a single arbitrator. The arbitrators designated by the parties will select the third arbitrator. The decision of the arbitration panel will be final. The provisions of the United Nations Convention for the International Sale of Goods are specifically excluded.

14. INDEMNIFICATION

Each party shall defend, indemnify, and hold each other, its officers, employees, and agents harmless from and against any and all liability, loss, expense (including reasonable attorney's fees), or claims for injury or damages arising out of the performance of this Agreement but only in proportion to and to the extent such liability, loss, expense, attorney's fees, or claims for injury or damages are caused by or result from the negligent or intentional acts or omissions of the indemnifying party, its officers, agents, or employees.

15. 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.

16. PROHIBITION ON ASSISTANCE TO DRUG TRAFFICKERS

FHI 360 reserves the right to terminate this Master Grant Agreement, 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.

17. PROSTITUTION AND SEX TRAFFICKING

As a condition of entering into this Master Grant Agreement, the Grantee hereby certifies that it will not use funds under this Master Grant Agreement to promote the legalization or decriminalization or practice of prostitution or sex trafficking. In addition, the Grantee will use its best efforts to ensure that its Grantees do not use their funds under this Master Grant Agreement to promote the legalization or decriminalization or practice of prostitution or sex trafficking.

18. PROHIBITION ON ABORTION-RELATED ACTIVITIES

No funds made available under this Master Grant Agreement 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;
e. Lobbying for abortion.

No funds made available under this Master Grant Agreement 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.

19. 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 Master Grant Agreement, the Grantee will, within five (5) days, notify the FHI 360 Grant Monitor, in writing,

providing all relevant information with respect to the delay.

20. NOTICES

All notices concerning business or administrative matters under this Master Grant Agreement 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 Lead named in the cover page of the relevant Grant.

21. ENTIRE AGREEMENT

The parties acknowledge that they have read this Master Grant Agreement, understand it, and agree to be bound by its terms. The parties further agree that this Master Grant Agreement, 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 Master Grant Agreement.

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

22. LIABILITY

With regard to all aspects of this Master Grant Agreement, neither party assumes any liability for any third party claims or damages arising out of this Master Grant Agreement.

23. VALIDITY AND WAIVER

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

ATTACHMENT C
DONOR SPECIFIC TERMS AND CONDITIONS

PART I - CERTIFICATIONS/ASSURANCES

1. **General**. Grantee certifies that it has filed and will maintain all assurances or other documentation with the appropriate government agencies to the extent such assurances and documentation are required including but not limited to Federal-wide Assurance for the protection of human subjects.

2. **Non-discrimination**. Grantee certifies that the Grantee is in compliance with the "Civil Rights Act of 1964", the "Age Discrimination Act of 1975", Title IX of the "Education Amendments of 1972"; the "Rehabilitation Act of 1973"; and the "Americans With Disabilities Act" and all implementing regulations.

3. **Debarment**. Grantee certifies that neither Grantee nor any of its employees or agents performing any service under this Master Grant Agreement (including the Project Director) are presently debarred, suspended, proposed for debarment, declared ineligible or voluntarily excluded from participation in this transaction, under investigation for a crime or otherwise engaged in conduct for which a person can be debarred by any federal agency, and Grantee will immediately notify FHI 360 if such debarment or exclusion should occur to previously mentioned persons during the term of this Master Grant Agreement.

4. **Terrorist Financing**. The Grantee agrees that it will use Grant funds in compliance with all applicable anti-terrorist financing and asset control laws, regulations, rules, U.S. Executive Orders and other U.S. laws including but not limited to the U.S. Patriot Act of 2001 and Executive Orders 13224.

5. **Federal Debt**. Grantee certifies that Grantee is not delinquent on any Federal debt in accordance with OMB Circular No. A-129.

6. **Lobbying**. Grantee certifies that no federally appropriated funds have been paid or will be paid 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 an Member of Congress in connection with this Master Agreement, and that if any funds other than federally appropriated funds have been paid or will be paid 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 an Member of Congress in connection with the Prime Award, grant loan or cooperative agreement the Grantee will complete and submit standard Form-LLL, "Disclosure Form to Report Lobbying."

7. **Scientific Misconduct**. Grantee certifies that it has established administrative policies as required by (1) 42 CFR Part 93, "Public Health Service Policies on Research Misconduct," and (2) 45 CFR 74.

8. **Human Subjects**. Grantee certifies that it will comply with all requirements relating to human subject protections, including but not limited to those set forth at 45 C.F.R. Part 46 and 21 C.F.R. Part 50 (Protection of Human Subjects). Any Grantee 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 Master Grant Agreement, program description and/or any applicable protocol.

9. **Personal Health Information**. Grantee agrees that it will use and disclose individually identifiable personal health information ("PHI") that it may gain through participation under this Master Grant Agreement in a manner consistent with the requirements of the "Health Insurance Portability and Accountability Act" (HIPAA) (45 C.F.R. 164 Subpart E). The parties agree to use or disclose PHI only as necessary to discuss and analyze the results of a Project, to ensure research integrity, to communicate with the FDA and other regulatory authorities, and as otherwise required or permitted by applicable law and as permitted under an authorization or consent signed by FHI 360.

10. **Drug-Free Workplace**. By signing this Master Grant Agreement, the Grantee assures that it is in compliance with the provisions of the "Drug-Free Workplace Act of 1988" (41 USC §701-707).

11. **Trafficking In Persons**. This Master Grant Agreement is subject to requirements of section 106(g) of the Trafficking Victims Protection Act of 2000, as amended (22 U.S.C. 7104).

12. **DUNS**. This Master Grant Agreement 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) database.

13. **Public Access**. In accordance with P.L. 110-61, compliance with the NIH Public Access Policy is now mandatory.

14. **Research Grants**. For any Research Grants, as defined by NIH, issued under this Master Grant Agreement then by signing, the Grantee makes the certifications and assurances specified in the Research Terms and Conditions Appendix C found at http://www.nsf.gov/bfa/dias/policy/rtc/appc_june11.pdf

15. **Changes**. Grantee agrees to notify FHI 360 promptly if there is any change of status in any of the above.

PART II - DONOR SPECIFIC REQUIREMENTS

1. Conditions on activities and restrictions on expenditure of federal funds in appropriations acts are applicable to this Master Grant Agreement to the extent those restrictions are pertinent. This includes any recent legislation noted on the NIH Award Conditions website: http://grants.nih.gov/grants/policy/awardconditions.htm. Any amendments to the FHI 360 prime award that occur as a result of changes to conditions on activities and restrictions on expenditure of federal funds, will be transmitted to the Grantee in a timely fashion.

2. 45 CFR Part 74 or 45 CFR Part 92 as applicable.

3. The NIH Grants Policy Statement, including addenda in effect as of the beginning date of the period of performance.

4. Research Terms and Conditions found at http://www.nsf.gov/pubs/policydocs/rtc/termsidebyside_june11.pdf and Agency Specific Requirements found at http://www.nsf.gov/pubs/policydocs/rtc/nih_1210.pdf as applicable, except for the following:
   a. The right to initiate an automatic one-time extension of the end date provided by Article 25(c)(2) of the Research Terms and Conditions is replaced by the need to obtain prior written approval from the Prime Recipient;
   b. The payment mechanism described in Article 22 and the financial reporting requirements in Article 52 of the Research Terms and Conditions and Article 8 of the Agency-Specific Requirements are replaced with Articles 3 through 6 of the this Master Grant Agreement and of the Grants issued under this Master Grant Agreement; and
   c. Any prior approvals are to be sought from the Prime Recipient and not the Federal Awarding Agency.

5. Title to equipment costing $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 in the Prime Recipient upon acquisition subject to the conditions specified in 45 CFR 74. 34.
   a. The Grantee is responsible for the care, maintenance, and security of the equipment or property purchased under any Grants issued under this Master Grant Agreement.
   b. The Grantee is required to immediately report theft, loss, or damage to Grant-funded equipment or property to the FHI 360 Grant Officer.

6. Treatment of Program Income **(Please choose one)**:

   ☐ Additive ☐ Other, Prime Recipient specify alternative from NIH Agreement ☒ Not Applicable

7. Copyrights
   Grantee grants to Prime Recipient 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 Master Grant

Agreement solely for the purpose of and only to the extent required to meet Prime Recipient's obligations to the Federal Government under its Prime Award.

8. Data Rights
   Grantee grants to Prime Recipient the right to use data created in the performance of this Master Grant Agreement solely for the purpose of and only to the extent required to meet Prime Recipient's obligations to the Federal Government under its Prime Award.

9. Patent Rights and Inventions

   37 CFR 40 governs rights and requirements for patents and inventions. To the extent the Prime Award specifies alternate or specific requirements, FHI shall notify the Campus Contractual Representative and state such alternative or specific requirements in the individual Grant. Such alternative or specific requirements shall be written in full and without reference to external documents and shall only be applicable to said Grant. FHI360 agrees to grant to Grantee intellectual property rights to the extent such are allowed under FHI360's Prime Award. Grantee reserves the rights to review, and negotiate to the extent feasible, such terms for acceptability in relation to its policies and to reject a Grant without prejudice.

10. Insurance
    The Grantee 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 Master Grant Agreement.

ATTACHMENT D:
DUNS #'S AND TIN #'S for
The Regents of the University of California

	DUNS
Office of the President	00-398-5512
Berkeley	12-472-6725
Davis	04-712-0084
Irvine	04-670-5849
Los Angeles	09-253-0369
Merced	11-364-5084
Riverside	62-779-7426
San Diego	80-435-5790
San Francisco	09-487-8337
Santa Barbara	09-487-8394
Santa Cruz	12-508-4723
LBNL	07-857-6738

	TIN
Office of the President	94-3067788
Berkeley	94-6002123
Davis	94-6036494
Irvine	95-2226406
Los Angeles	95-6006143
Merced	27-0093858
Riverside	95-6006142
San Diego	95-6006144
San Francisco	94-6036493
Santa Barbara	95-6006145
Santa Cruz	94-1539563
LBNL	94-2951741

OPERATING POLICY

Title: HPTN Publication Policy
Effective Date: *17 April 2012*

APPROVAL

Chairperson, HPTN Prevention Management Group (PMG)

DAIDS Prevention Science Branch (PSB) representative

PURPOSE

Define the guidelines and process by which the Network ensures that manuscripts and presentations resulting from research conducted within HPTN:

- Reflect accurate reporting of the design, conduct, and analysis of studies;
- Are developed in a collaborative fashion with the active participation of all investigators participating in the design and conduct of the study;
- Are published expeditiously and widely disseminated and;
- Protect the confidentiality of medical, personal and product information in accordance with the Privacy Act, the requirements for the protection of human subjects and any applicable clinical trials agreements.

SCOPE

This procedure applies to all activities associated with the authorship, review, and timeline of manuscripts and presentations.

RESPONSIBILITIES

Protocol Chair(s) and Protocol Biostatisticians are jointly responsible for developing or reviewing primary, secondary, and tertiary manuscript concepts, developing or reviewing manuscript timelines, identifying manuscript writing committees, prioritizing manuscript development, monitoring timelines, and adhering to manuscript review procedures outlined in this policy. In addition, the Protocol Biostatistician is responsible for providing analysis results for inclusion in the manuscript, abstract, or presentation within the specified time.

Manuscript Writing Committee is responsible for drafting manuscripts, abstracts, or presentations within the specified timeline.

Lead Author or HPTN Point of Contact is responsible for ensuring adherence to timelines and submission for reviews as described below.

Protocol Team (PT) is responsible for reviewing draft manuscripts, abstracts or presentations submitted by Writing Committees within the specified time.

Scientific Committee (SC) Chair is responsible for reviewing draft manuscripts submitted by Writing Committees within the specified time.

Manuscript Review Committee (MRC) is responsible for reviewing draft manuscripts, abstracts, and presentations and ensuring review by all Network Central Resources (CORE, Statistical and Data Management Center [SDMC], Network Laboratory) as appropriate within the specified time.

CORE Clinical Research Manager (CRM) is responsible for facilitating the Protocol Publication Committee, ensuring that authors are aware of the HPTN Publication Policy and submission of manuscripts, abstracts, and presentations to the MRC as well as the CORE Manuscript Coordinator.

CORE Manuscript Coordinator is responsible for tracking manuscripts, presentations and abstracts as received from CORE CRMs, and for forwarding them to the CORE Information and Communications staff for inclusion in the HPTN Operations Reports and cumulative HPTN bibliography.

DEFINITIONS

Primary Manuscript
Publications that are journal articles, meeting abstracts or presentations (oral or posters) at scientific meetings or conferences, that report the findings of primary, secondary and tertiary study objectives as described in an HPTN study protocol.

Secondary Manuscript
Journal articles, meeting abstracts and presentations that address scientific questions not identified as study objectives in an HPTN study protocol, but rely on data collected or analyses performed by HPTN investigators

Tertiary Manuscript
Publications, abstracts, and presentations resulting from research conducted in support of HPTN activities, such as literature reviews, that do not rely on HPTN data.

Public Use Data Sets
Study data made available to the public in special data sets prepared by the SDMC for wide scale dissemination. In general, all identifying information is stripped out of Public Use data sets so that they may be used without consulting the relevant IRBs. Data released to HPTN investigators per section 12.6 of the HPTN Manual of Operations does not constitute public use data.

PROCEDURES

1 PRIMARY MANUSCRIPTS

1.1 Concept Development

The PT Chair(s) (or designee) and lead statistician (or designee) develop one or more primary manuscript concepts. If the PT Chair(s) and lead statistician are not involved in the preparation of the concept, the concept must be submitted to them for review and approval prior to proceeding with development.

Manuscript concepts should contain the following:

- Short (one or two paragraph) explanation of the rationale, hypothesis and objectives of the manuscript;
- Short (one paragraph or outline) summary of analysis plan, data presentation (including shell tables) and required HPTN NL support for additional laboratory assessments, if necessary;
- Recommendation for writing team members.

1.2 Publication Planning Process

The PT Chair(s) (or designee), lead statistician (or designee), and CRM develop a publication planning process and timeline prior to the initiation of manuscript development.

A manuscript plan and timeline should minimally contain the following information:

- HPTN protocol number
- Membership in protocol publications committee
- Process for review, approval, and prioritization of manuscript or presentation concepts
- Expected date of last participant follow-up visit
- Date data expected to be locked
- Start date of manuscript preparation
- Expected date of submission of primary publications(s) for PT review

- Expected date of submission of primary publication(s) for SC Chair review
- Expected submission of primary publication(s) date to MRC

The Protocol Chair(s), lead statistician, and CRM are jointly responsible for monitoring progress and timelines set forth in the publication. Primary manuscripts should be submitted to the MRC for review within eight months following the last scheduled participant follow-up visit.

1.3 Monitoring publication progress

In addition to the Protocol Publication Committee, the SDMC is responsible for tracking progress on publication across protocols. Reports on the progress of manuscript development across protocols will be made to Network Leadership by the SDMC Principal Investigator (PI) on a regular basis.

1.4 Review

The lead author submits the manuscript, abstract, or presentation to the CORE CRM who coordinates the manuscript review processes.

1.4.1 Protocol Publication Committee Review

Prior to submission of the manuscript, abstract, or presentation for SC and/or MRC review, the CORE CRM will distribute the draft manuscript, abstract, or presentation to the protocol Publications Committee, sponsor(s) and product manufacturer (if applicable) for review and comment. Once all comments have been received and incorporated into the draft by the lead author, the CORE CRM may submit it to the Chair of the SC or designee.

1.4.2 Scientific Committee Chair Review

The SC Chair (or designee if SC Chair is an author or not available) reviews manuscripts submitted by the CORE CRM within 10 working days. Following completion of this review, once all comments have been received and incorporated into the manuscript draft by the lead author, the CORE CRM submits the manuscript to the MRC and the CORE Manuscript Coordinator.

1.4.3 MRC Review

The composition of the MRC is described in the HPTN Manual of Procedures. The MRC Chair designates a primary and secondary reviewer to provide comments, one of whom is from the SDMC. The MRC reviews the manuscripts within 10 working

days of receipt via conference call. Comments designated by the MRC as "Major" must be addressed by the manuscript author. Those designated as "Minor" are for consideration only and do not need to be addressed by the author. Following review, the MRC sends the comments and outcome back to lead author with a copy to the CORE Manuscript Coordinator. The possible MRC review outcomes are:

1. Endorse for publication or
2. Endorse with requested modifications to be reviewed by the MRC Chair
3. Require a second MRC review to obtain HPTN support

1.5 Publication

Prior to submission of manuscripts for publication or abstracts and presentations to conferences, a final copy is provided by the lead author to the CORE CRM for tracking purposes.

If a manuscript or abstract is not accepted and reviewer feedback indicates a need to reformulate the essential components before it can be resubmitted or submitted to another journal or conference, it must be reviewed again by the MRC.

1.6 Authorship

The HPTN criteria for authorship are defined in the International Committee of Medical Journal Editors' "Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publications" Section II.A "Authorship and Contributorship" (See Appendix A). Typically the second author listed in primary HPTN publications is the study statistician.

When US government (e.g., NIH, CDC) staff are co-authors, manuscripts must be approved by their institute/agency. The US government staff person is responsible for obtaining the necessary approvals. Different government agencies have different review time requirements, so authors and the CRM should take those requirements into consideration during the publication review process.

If a primary manuscript is accepted provisionally with required or recommended changes/additions, if a journal invites a revised draft of the same article, or if an article is being submitted to another journal with minimal changes, the lead author in consultation with the writing committee may respond to the editor without MRC review. It is the responsibility of the writing committee to differentiate between alterations that reflect mere editorial changes and those which essentially modify the analyses and/or conclusion of the study previously endorsed by the MRC.

1.7 Acknowledgments

All publications and presentations will include a statement acknowledging the HPTN and NIH's support for the work and listing the applicable cooperative agreement numbers unless the journal's policy precludes such an acknowledgment. (See Appendix D

1.8 Disputes

Disputes with respect to the manuscript development and preparation process will be resolved by the MRC. If the dispute cannot be resolved by the MRC, the MRC Chair will refer it to the HPTN PMG for final resolution.

1.9 Third Party Agreements

Third party agreements with product sponsors will include an agreement on publications policy and authorship in accordance with the guidelines set forth in the study's Clinical Trials Agreement (CTA).

1.10 Publicity

Refer to HPTN MOP section 7.5.

2 SECONDARY MANUSCRIPTS

2.1 Concept Development

Any investigator affiliated with the study may originate secondary manuscript concepts. These concepts should be submitted to the PT Chair(s) and lead statistician for review and approval. The PT Chair(s) will respond to the authors of the concept within 10 working days after receipt of the concept.

If study data has been released by the SDMC as a Public Use data set (see Section 6), concepts and manuscripts may be developed independent of Network oversight and do not require review of the PT, SC or MRC.

2.1.1 Single-site Study Data

Concepts using single site data may be developed into manuscripts, abstracts, or presentations following receipt of approval from the PT Chair and Protocol Statistician. Manuscripts, abstracts and presentations require PT, SC, and MRC review prior to submission to a journal or conference as per Section 2.3 below.

2.1.2 Multi-study Concepts

Concepts using data from more than one HPTN study must be sent to each relevant PT Chair(s) and study statistician, and then submitted to the PMG after completing applicable sections of the form found in Appendix C. A lead PT Point of Contact will be selected by the group to track the progress of manuscript development. Manuscripts, abstracts, or presentations developed using data from more than one HPTN study require PT, SC, and MRC review prior to submission to a journal or conference as per Section 2.3.

2.2 Review

All secondary manuscripts, abstracts, and presentations require PT, SC and MRC review. Refer to Section 1.4 above.

2.3 Publication

Refer to Section 1.5 above.

2.4 Authorship

Refer to Section 1.6 above. Note that the lead statistician may or may not serve in the role of the second author on secondary publications.

2.5 Acknowledgements

Refer to Section 1.7 above.

2.6 Disputes

Refer to Section 1.8 above.

2.7 Third Party Agreements

Refer to Section 1.9 above.

2.8 Publicity

Refer to Section 1.10 above.

3 TERTIARY MANUSCRIPTS

3.1 Concept Development

Any investigator affiliated with the study may originate tertiary manuscript concepts. These concepts should be submitted to the PT Chair(s) and lead statistician for review and approval. The PT Chair(s) will respond to the authors of the concept within 10 working days of receipt of the concept.

If study data has been released by the SDMC as a Public Use data set (see Section 6), concepts and manuscripts may be developed independent of Network oversight and do not require review of the PT, SC or MRC.

3.1.1 Single-site Study Data

Concepts using single site data may be developed into manuscripts, abstracts, or presentations following receipt of approval from the PT Chair and Protocol Statistician. Manuscripts require PT, SC, and MRC review prior to submission to a journal as per Section 2.3.

3.1.2 Multi-study Concepts

Concepts using data from more than one HPTN study must be sent to each relevant PT Chair(s) and study statistician, and then submitted to the PMG after completing applicable sections of the form found in Appendix C. A lead PT Point of Contact will be selected by the group to track the progress of manuscript development. Manuscripts, abstracts or presentations require PT, SC, and MRC review prior to submission to a journal as per Section 2.3.

3.2 Review

All tertiary manuscripts, abstracts, and presentations require PT, SC and MRC review.

3.3 Publication

Refer to Section 1.5 above.

3.4 Authorship

Refer to Section 1.6 above. Note that the lead statistician may or may not serve in the role of the second author on tertiary publications.

3.5 Acknowledgements

Refer to Section 1.7 above.

3.6 Disputes

Refer to Section 1.8 above.

3.7 Third Party Agreements

Refer to Section 1.9 above.

3.8 Publicity

Refer to Section 1.10 above.

4 ABSTRACTS

4.1 Review Requirements

The lead author submits the abstract to the CORE CRM who coordinates the abstract review processes.

All abstracts require an expedited MRC review; except for those developed from Public Use data sets (see Section 6). Prior to MRC review, the abstract should be reviewed by the Protocol Chair (or designee), Protocol Statisticians (or designee), and/or other PT members designated by the Protocol Chair. The MRC Chair will triage abstracts as necessary to the SDMC, to the HPTN NL, or to the SMC for review to determine that the analyses are appropriate and the data reported accurately. All abstracts will be reviewed by the MRC chair and a designated member statistician within three working days.

If study data has been released by the SDMC as a Public Use data set (see Section 6) abstracts may be developed independent of Network oversight and do not require review of the PT, SC or MRC.

4.1.1 Single-site Study Data

The completed abstract using single site data is sent to the CORE CRM who coordinates the MRC review.

4.1.2 Multi-site Study Data

Abstracts using data from more than one HPTN study must be sent to each relevant PT Chair(s) and study statistician, and then submitted to the PMG after completing applicable sections of the form found in Appendix C. A lead PT Point of Contact will be selected by the group to track the progress of abstract development.

5 PRESENTATIONS

5.1 Review Requirements

If the presentation has been developed from a MRC approved abstract, the abstract should be submitted with the presentation for informational purposes. The lead author submits the presentation (and abstract, as appropriate) to the CORE CRM who coordinates the review processes.

All presentations require an expedited (within 3 days) MRC review except for those developed from Public Use data sets (see Section 6). Prior to MRC review, the presentation should be reviewed by the Protocol Chair (or designee), Protocol Statisticians (or designee), and/or other PT members designated by the Protocol Chair. The MRC Chair will triage presentations as necessary to the SDMC, to the HPTN NL, or to the SMC for review to determine that the analyses are appropriate and the data reported accurately. All presentations will be reviewed by the MRC chair and a designated member statistician within three working days.

If study data has been released by the SDMC as a Public Use data set (see Section 6), presentations may be developed independent of Network oversight and do not require review of the PT, SC or MRC.

5.1.1 Single-site Study Data

Presentations using single site data are sent to the CORE CRM who coordinates the MRC review.

5.1.2 Multi-site Study Data

Presentations using data from more than one HPTN study must be sent to each relevant PT Chair(s) and study statistician, and then submitted to the PMG after completing applicable sections of the form found in Appendix C. A lead PT Point of Contact will be selected by the group to track the progress of abstract development.

6 PUBLIC USE DATA

Federal research sponsors often require that data be made available to the public in the form of "Public Use" data sets, which have been prepared by the SDMC for wide scale dissemination. If study data is released by the HPTN SDMC as a public use data set, the HPTN is not responsible in any way for the content of abstracts or manuscripts developed using these data, and such manuscripts will not be reviewed by the PT, SC or MRC.

APPENDICES

Appendix A – International Committee of Medical Journal Editors' "Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publications" Section II.A "Authorship and Contributorship"

Appendix B – Guidance on acknowledgement of support for manuscripts resulting from HPTN funded studies.

Appendix C – HPTN Prevention Management Group Notification of Testing Form for HPTN Stored Specimens

Appendix D – List of HPTN-related Cooperative Agreement numbers

REFERENCES

HPTN Manual of Operations

REVISION HISTORY

Version	Effective Date	Supersedes	Review Date	Change
HPTN011-00				*Initial Release*
HPTN011-01	*01 Jan 2007*	*HPTN011-00*	*01 Jan 2008*	*Clarified procedure; administrative changes*
HPTN011-02	*07 Feb 2007*	*HPTN011-01*	*07 Feb 2008*	*Administrative change*
HPTN011-03	*05 Mar 2007*	*HPTN011-02*	*05 Mar 2008*	*Administrative change*
HPTN11-04	*01 Apr 2008*	*HPTN011-03*	*01 Apr 2009*	*Annual review; no changes made*
HPTN11-05	*31 Jul 2008*	*HPTN011-04*	*30 Jul 2009*	*Administrative change*
HPTN11-06	*31 Jul 2008*	*HPTN 011-05*	*30 Jul 2009*	*Add correct version #; Administrative change*
HPTN11-07	*31 Jul 2008*	*HPTN 011-06*	*30 Jul 2009*	*Remove track changes; administrative change*
HPTN11-08	*16 April 2012*	*HPTN 11-07*	*16 April 2014*	*Revision of content and addition of presentations and abstracts*
HPTN11-09	*17 April 2012*	*HPTN11-09*	*17 April 2014*	*Effective date correction*