21 PUBLICATIONS POLICY

Timely communication with the scientific community is an essential function of the HPTN and generally is accomplished by presentations at scientific meetings and the publication of manuscripts in peer-reviewed journals. The HPTN publication policy is designed to be flexible and to facilitate rapid and accurate dissemination of HPTN study results. HPTN protocol team members are responsible for drafting manuscripts, abstracts, posters and presentations. Others affiliated with the HPTN, as well as individuals external to the HPTN, may also develop manuscripts, abstracts, posters and presentations that include HPTN-related data, specimens and/or are supported by HPTN resources. All documents are reviewed at several levels to ensure that they:

- Reflect accurate and consistent reporting of the design, conduct, and analyses of studies or other research sponsored by the Network
- Are developed collaboratively with the active participation of relevant investigators participating in the design and conduct of the studies
- Protect 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 Trial Agreements (CTAs)
- Meet criteria for authorship, disclosure, scientific integrity, and other requirements of peer-reviewed scientific journals
- Ensure accurate acknowledgment of HPTN resources

21.1 Responsibilities

Each protocol has a Protocol Publications Committee (PPC), which is a subset of each protocol team and is responsible for prioritizing, reviewing and approving all submitted draft manuscripts, abstracts, posters and presentations related to that protocol. The PPC will include the Protocol Chair, Protocol Biostatistician, and a representative of each of the Central Resource groups. Others may be included as deemed necessary by the Protocol Chair. Each Central Resource member will determine if representatives from their group should be included as authors on a manuscript or abstract and will depend on authorship limitations of the journal or conference. Disagreements will be adjudicated by the protocol chair(s).

The LOC CRMs are responsible for facilitating the PPC review and ensuring that authors are aware of the HPTN Publication Policy. All manuscripts, posters and abstracts are sent to the LOC CRM, who will also draft a protocol-specific Publication Guideline document to be approved and followed by the protocol team. A template/example can be found on the HPTN website.

The Lead Author, approved by the PPC, is responsible for establishing a writing team consisting of protocol team members for HPTN initiated manuscripts or abstracts and, potentially, non-protocol team members for non-HPTN initiated concepts with assistance from the LOC Clinical Research Managers (CRMs). For each manuscript, the Lead Author is responsible for manuscript development, monitoring timelines, and adhering to manuscript review procedures outlined in the Publications Guideline document. In addition, the Protocol Biostatistician is responsible for providing analyses for inclusion in manuscripts, abstracts, posters, or presentations within the specified time.

Collaborating organization(s) should be given the chance to review the confidential results, abstracts for presentation and publications before submission to any conference or journal.

The Manuscript Review Committee (MRC) is responsible for reviewing and approving manuscripts and abstracts related to the objectives of HPTN studies or the scope of HPTN work in general within a maximum of 5 working days for review of manuscripts and 3 working days for abstracts. The MRC coordinator will facilitate the review and response by the MRC members ensuring Network

Central Resources (Leadership and Operations Center (LOC), Statistical and Data Management Center (SDMC), Laboratory Center (LC)) review the documents as appropriate. In addition to and parallel to the MRC review, all primary manuscripts are to be reviewed by the HPTN Principal Investigators within the identical specified timeframe to the MRC review. The composition of the MRC is described in Section 4.3.3.

The Protocol Chair and Protocol Biostatistician or their designee(s) are responsible for generating the first draft of the primary manuscript within approximately 8 months of the last participant visit and distributing the draft to the co-authors (subset of the protocol team that typically includes representatives from SDMC, LOC, LC, NIH, Protocol Chairs and site representatives) for review and comment.

21.2 Conference Abstract Timelines

The SDMC will release specific timelines for each major conference. The PPC is required to determine and incorporate timelines for reviews from third party partners per the relevant agreements with NIH and/or HPTN (i.e. CDC).

Figure 21-1 Example Timeline for Abstracts Submitted to Major Conferences

	Weeks Before Conference Deadline			
Type of SDMC Analysis	**MRC Review**	**PPC Review**	**SDMC Analysis**	**Total Lead Time**
SDMC analysis underway	2 weeks	1 week	4 weeks	7 weeks
New SDMC analysis	2 weeks	1 week	6 weeks	9 weeks
No analysis needed	2 weeks	1 week	0 weeks	3 weeks

The total lead time for abstract preparation may increase based on the total number of abstracts that will be reviewed by the MRC and the total number of analyses that will be performed by the SDMC.

21.3 Definitions

21.3.1 Tier 1 Priorities

Tier 1 Priorities are those that are publications in peer-reviewed journals or are abstracts, posters or presentations at scientific meetings or conferences that report the findings of primary and secondary study objectives as described in the study protocol. These are developed by HPTN Protocol Team members.

21.3.2 Tier 2 Priorities

Tier 2 Priorities are those that are publications in peer-reviewed journals or are abstracts, posters, and or presentations at scientific meetings or conferences that report findings based on HPTN data, specimens or resources where the analysis is focused beyond the primary or secondary study objectives; these may include findings from baseline data, ancillary studies or from more than one

HPTN study. These may also include manuscripts or abstracts initiated by the Central Resource groups with a few guidelines:

- Using data obtained by chart review is not acceptable as it is not official study data - unless the concept is approved by the PPC with this information noted AND the study is complete at all sites
- Proposals/abstracts using baseline data including the number and type of participants recruited are not accepted until a study is fully enrolled at all sites

21.4 Public Use Data Sets

Federal research sponsors, and increasingly scientific journals, 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 are released by the HPTN SDMC as a Public Use data set and posted on a website that allows widespread access, 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 Protocol Publications Committee, Scientific Committee (SC) or MRC.

Although not subject to MRC review, any work that utilizes HPTN data or specimens should acknowledge the HPTN.

In general, all identifying information is removed from Public Use data sets per HIPAA "Safe Harbor" guidelines, so that they may be used without consulting an Institutional Review Board/Ethics Committee (IRBs/EC). De-identified data released to HPTN investigators per Section 12.6 of the HPTN Manual of Operations and posted on the SDMC web portal does not, in most cases, constitute Public Use data.

21.5 Procedures

21.5.1 Publication Planning Process

A publication plan (contained within the Publication Guidance document) and timeline should be developed well before the last study visit, and minimally contain the following information:

- Membership in Protocol Publications Committee
- Process for review, approval, and prioritization of manuscript or presentation concepts (refer to the guidelines in 21.1, 21.2.1 and 21.2.2)
- Expected date of last participant follow-up visit, if applicable
- Date data are expected to be locked
- Start date of manuscript preparation
- Expected date of submission of primary publications and presentations for PPC review
- Expected submission of primary publication(s) date to MRC (per SDMC timeline for major conferences where a number of abstracts would be expected to be submitted, or a minimum 3 working days for review of abstracts with a minimum of 5 working days for review of manuscripts; see Figure 21-1)

The Protocol Chair, Protocol Biostatistician, and LOC CRM are jointly responsible for monitoring progress and timelines set forth in the publication plan. Every effort should be made for primary manuscripts to be submitted to the MRC for review within eight months following the last scheduled participant follow-up visit.

Guidance for using study data prior to study completion are outlined below; however, permission for exceptions from these guidelines should be sought from HPTN leadership.

- Publications based on screening and baseline data are typically permitted prior to the completion of the study so long as information on any study objectives is not part of the findings and all sites have completed enrollment. For a randomized clinical trial, publication of any post-randomized data is not permitted until the study is complete or stopped.
- Publication of post baseline data in HPTN trials is not typically permitted until study completion. (See Section 21.14.2.) Publication of secondary outcomes typically follows the completion of the primary manuscript. Permission for exceptions may be sought from the HPTN Leadership.

21.5.2 Results Meetings

Once the study the study database is locked, the protocol team should plan for a Results Meeting where the Protocol Statisticians review results of the study with members of the protocol team. This meeting may be in person (preferred) or presented as a webinar. The meeting may also include planning of the primary publication, abstract submissions to conferences, review of publications proposals, or a proposal or writing workshop.

21.5.3 Proposal Submission

Investigators and writing teams with a proposal for a manuscript or presentation should complete a Publication Proposal Form (see Publication Guidance template) that outlines the planned analyses for the manuscript or presentation for PPC consideration and prioritization. A proposal for review by the PPC is required for all planned manuscripts or conference presentations except for the primary publication(s). The proposal should include the rationale, hypothesis and objectives, summary of the analysis plan and recommended writing team members.

Once approved by the PPC, the proposal is prioritized by the PPC against other planned analyses and progress of the work is tracked. Tier 1 projects will be prioritized ahead of Tier 2 projects regardless of date of proposal submission.

21.5.4 Tier 1 Proposals

The Protocol Chair(s) is responsible for the development of all Tier 1 manuscripts.

Queries regarding the publishing of data, other than baseline data, prior to the release of the primary manuscript should be directed to the HPTN Leadership. Baseline data may not be published or presented until after all sites have completed enrollment unless permission is granted by HPTN Leadership.

21.5.5 Tier 2 Proposals

Any investigator irrespective of affiliation may develop a Tier 2 Analysis Proposal. Investigators proposing manuscripts or abstracts that include findings from more than one HPTN study or use HPTN resources, specimens or data should submit a Publication Proposal Form to the appropriate PPC (or to the HPTN Leadership when it is not clear which protocol publications committee to submit) for review and approval.

All Tier 2 manuscripts or abstracts must be vetted through the MRC for approval prior to submission to a journal or conference.

If study data has been released by the SDMC as a Public Use data set intended for broad dissemination (see Section 21.4), proposals and manuscripts may be developed independent of Network oversight and do not require review of the PPC, Scientific Committee (SC) or MRC but should acknowledge funding of the HPTN.

21.5.6 Single-site Study Data

Proposals using data or information from a single site may be developed into manuscripts, abstracts, posters or presentations following receipt of approval from the Protocol Publications Committee. Single site manuscripts, abstracts, posters and presentations follow the same approval process and guidelines as described above. With the exception of baseline publications, most reports are not published prior to the primary manuscript(s). In some cases, laboratory-focused reports may be published prior to the primary manuscript; publication of these papers should be coordinated with the protocol leadership.

21.5.7 Multi-study Proposals

Proposals using data from more than one HPTN study must be sent for approval to each relevant Protocol Publications Committee (at a minimum the Protocol Chair and Statistician if the PPC is no longer active), and upon approval, then submitted to the HPTN Leadership for approval. A lead point of contact will be selected by the Leadership to track the progress of manuscript development. Manuscripts, abstracts, posters or presentations developed using data from more than one HPTN study follow the same approval process described above.

21.5.8 Monitoring Publication Progress

The PPC and the LOC are responsible for tracking the progress of proposals through publication or presentation for each protocol. In addition, updates by LOC CRMs on the progress of manuscript and presentation development are included in the Monthly Study Operations Reports and publication progress across protocols will be made to Network Leadership by the LOC Manuscript Coordinator on a regular basis.

21.6 Manuscript, Abstract, Poster and Presentation Review Process

The lead author submits the manuscript, abstract, poster or presentation to the LOC CRM who coordinates the review processes through finalization.

21.6.1 Protocol Publication Committee Review

The LOC CRM firstly sends the draft manuscript or abstract to the PPC, sponsor(s) and product manufacturer (if applicable) for review and comment. If there are some Tier 2 manuscripts that are not study specific, the draft will be sent to the HPTN Leadership for appropriate delegation for review. Once all comments have been received and incorporated into the draft by the lead author and the PPC has reviewed, the LOC CRM submits the revised manuscript to the LOC Manuscript Coordinator for MRC review.

21.6.2 MRC Review of Manuscripts

The MRC receives the proposed document after PPC review. An *ad hoc* reviewer may be appointed if additional expertise is required. The MRC reviews manuscripts within 5 working days of receipt, and it is recommended that any comments designated by the MRC as "Major" be addressed by the manuscript authors. Those designated as "Minor" are for consideration only and do not need to be addressed. Abstracts will be reviewed within 3 working days (see Figure 21-1 above for review timelines for major conferences). Following review, the MRC will communicate back to the Manuscript Coordinator, who will forward to the LOC CRM for appropriate distribution. The possible MRC review outcomes are:

- Approve for publication
- Approve with recommended modifications to be reviewed by the MRC Chair
- Recommend a second MRC review after modifications are made to obtain HPTN support

Prior to submission of manuscripts or abstracts for publication to conferences, a final copy is provided by the lead author to the LOC 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.

If any of the following occur the lead author, in consultation with the writing committee, may respond to the editor without MRC review:

- A manuscript is accepted for publication provisionally with required or recommended changes/additions
- A journal invites a revised draft of the same article
- An article is being submitted to another journal with minimal changes

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.

The primary focus of the MRC is review of original research manuscripts presenting data from the HPTN. Opinion pieces written by HPTN researchers must acknowledge support received from the HPTN, should be reviewed by the MRC, but do not need to be approved by the MRC. However, all such documents must provide a disclaimer that the opinions of the authors do not necessarily reflect the views of the HPTN.

21.6.3 MRC Review of Abstract

All abstracts for major conferences should seek an expedited MRC review (3 working days). After approval by the PPC or the HPTN leadership (for those that are not study-specific), the LOC will coordinate the review process. Refer to Figure 21-2 for a timeline. If study data has been released by the SDMC as a Public Use data set for broad dissemination (see Section 21.3), presentations may be developed independent of Network oversight and do not require review of the PPC or MRC.

21.6.4 Authorship

The HPTN criteria for authorship are defined in the International Committee of Medical Journal Editors' "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals" Section II.A "Authorship and Contributorship". Typically, the second author listed in primary HPTN publications is the study statistician.

When United States (US) government (e.g., National Institutes of Health (NIH); US Centers for Disease Control and Prevention (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 LOC CRM should take those requirements into consideration during the publication review process.

21.7 Resolution of Disputes

Resolution of disputes with respect to the manuscript development and approval process will be managed by the MRC. If a dispute cannot be resolved by the MRC, the MRC will refer it to HPTN Leadership for final resolution.

21.8 Third Party Agreements

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

21.9 HPTN LC and SDMC Manuscripts

In addition to assisting with Tier 1 and Tier 2 publications initiated by study teams or other investigators, the HPTN LC or SDMC also publish more technological or methods manuscripts that include work initiated within these groups. This work may or may not involve use of HPTN data and specimens. HPTN LC publications include reports of protocol-related laboratory assessments; findings from HPTN LC Quality Assurance/Quality Control assessments; work related to assay development, evaluation, and validation; and other laboratory investigations relevant to HIV prevention. SDMC publications may include reports of analytic methods, mathematical modeling, SDMC-related data analyses or statistical/analytic methods.

For work that includes use of HPTN study data and/or specimens for SDMC publications that are done to support HPTN studies, consensus will be reached with the relevant study chair(s) prior to initiation of the work by the HPTN LC or SDMC. Additionally, efforts will be made to ensure that other study team members are aware of this work and have opportunities to provide input, and that appropriate study team members are included as authors on publications that result from this work. Preparation and submission of HPTN LC and SDMC manuscripts and abstracts should be coordinated with preparation and submission of primary or secondary protocol reports. In these cases, the HPTN LC and/or SDMC will work closely with the Protocol Chair(s) to ensure that these activities are executed appropriately. For work that includes analysis of data and/or specimens from HPTN studies that extends beyond planned protocol assessments and study objectives, the HPTN LC and SDMC will obtain approval from the relevant Protocol Chair(s); in these cases, Ancillary Study approval may be required.

HPTN LC and SDMC manuscripts that use data and/or specimens from HPTN studies will be submitted to the MRC prior to journal submission. The MRC will determine what type of review is appropriate, given the content and focus of each manuscript. To ensure optimal utilization and prioritization of resources, the HPTN LC and SDMC will discuss on-going and planned work as well as publications with the HPTN LOC leadership so that this work can be considered in the context of other network activities and priorities. The HPTN LC and/or SDMC will provide updates on the status of manuscripts and abstracts to the relevant PPC(s), MRC and LOC on a regular basis.

21.10 Responsibility of the SDMC in HPTN Data and Publications

The central database for HPTN studies resides at the SDMC or designee. This includes Case Report Form (CRF) data, (A)CASI data (online questionnaires), results of protocol-specified laboratory analyses and ancillary study data. Section 12.7 describes the policy for site, Network investigator and non-Network investigator access to study data during conduct of a trial and after study closure and database lock.

Analysis of HPTN data to address the primary and secondary objectives of an HPTN study (i.e. Tier 1 publications) is the responsibility of the SDMC, led by the designated protocol biostatistician. Analysis of Tier 2 publications occur at the SDMC as resources permit, according to the PPC priorities. Following HPTN data sharing policies and with external funding, permission can be sought from the PPC for analysis of Tier 2 publications with non-SDMC statisticians.

Publication and presentation at conferences of HPTN trial data is generally done in collaboration with the SDMC. As a member of the Manuscript Review Committee (MRC), the SDMC PI or designee reviews all manuscripts and abstracts describing data or results of HPTN studies.

21.10.1Acknowledgements

All publications and presentations that result directly from HPTN studies will include a statement acknowledging the HPTN and NIH's (and others as appropriate) support for the work and listing the applicable cooperative agreement numbers unless the journal's policy precludes such an acknowledgment. For manuscripts related to the network goals, but not linked to a particular study, the HPTN and NIH will be acknowledged as above if support is provided by the HPTN to the author(s) (examples: manuscripts in collaboration with other investigators, editorials, reviews etc.). Manuscripts that are authored by investigators with HPTN support, but the work described is tangential to the HPTN science agenda, it is the responsibility of the investigator to acknowledge HPTN support, where appropriate. Work that is completely unrelated should not cite HPTN support.