21 PUBLICATIONS AND DATA SHARING 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 and data sharing policy is designed to facilitate rapid and accurate dissemination of HPTN study results and facilitate sharing of data within and outside of the Network.

21.1 Publications Policy

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

21.1.1 Responsibilities

Protocol Publications Committee

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).

HPTN Statistical and Data Management Center (SDMC)

The central database for HPTN studies resides at the SDMC or designee. This includes electronic Case Report Form (eCRF) data, online questionnaires, results of protocol-specified laboratory analyses and ancillary study data. Section 21.2 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. Responsibilities for qualitative data (e.g., focus group and in-depth interview transcripts and recordings) management and analysis will be specified in the study protocol.

Analysis of HPTN data to address the primary and secondary objectives of an HPTN study (i.e., Tier 1 publications; see Section 21.1.3) is the responsibility of the SDMC, led by the designated protocol biostatistician. Analysis of Tier 2 publications (Section 21.1.3) 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.

Protocol Chair and Protocol Biostatistician

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.

Lead Author

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. For each manuscript, the Lead Author is responsible for manuscript development, monitoring timelines, and adhering to manuscript review procedures outlined in the Publications Guidance document. In addition, the Protocol Biostatistician is responsible for providing analyses for inclusion in manuscripts, abstracts, posters, or presentations within the specified time.

Leadership and Operations Center

For primary and other key manuscripts, the LOC is responsible for facilitating the PPC review and ensuring that authors are aware of this HPTN publication policy. The LOC, along with the Protocol Chair(s), will develop a protocol-specific Publication Guidance document to be distributed to and followed by the protocol team. Publication Guidance documents will refer to this section of the MOP and include a timeline from database lock to release of public use data set per this policy.

The PPC and the LOC are also responsible for tracking the progress of proposals through publication or presentation for each protocol. In addition, the LOC includes a current listing of published manuscripts and accepted presentations in the Monthly Study Operations Reports.

Manuscript Review Committee

The Manuscript Review Committee (MRC) is responsible for reviewing and providing recommendations to authors on manuscripts and abstracts related to the objectives of HPTN studies or the scope of HPTN work in general. The MRC will review manuscripts within **10 working days** of submission and abstract with **3 working days**. The MRC Coordinator will facilitate the review and response by the MRC members ensuring the MRC chair, Network Central Resources (Leadership and Operations Center (LOC), Statistical and Data Management Center (SDMC), Laboratory Center (LC)), and other relevant members of the committee, review the documents as appropriate. In addition to and in parallel with the MRC review, manuscripts reporting primary endpoint results, must also be reviewed by the HPTN Principal Investigators within the same timeframe as the MRC review. The composition of the MRC is described in Section 4.3.3.

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.

21.1.2 Conference Abstract Timelines

The SDMC will release specific timelines for the development and review of abstracts prior to submission to each major scientific conference (e.g., CROI, HIV R4P, etc.). The PPC should determine and incorporate timelines for reviews from all relevant partners per the agreements with NIH and/or other partners (i.e., CDC, pharmaceutical companies, etc.).

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 to be reviewed by the MRC and the total number of analyses to be performed by the SDMC.

21.1.3 Priorities

21.1.3.1 Tier 1

Tier 1 Priorities are those that report the results of primary and key secondary study objectives (as determined by the protocol team) as described in the study protocol. These are developed by HPTN Protocol Team members.

21.1.3.2 Tier 2

Tier 2 Priorities are those that report findings based on HPTN data, specimens or resources where the analysis is focused beyond the primary or key secondary study objectives; these may include findings from other secondary objectives, tertiary/exploratory objectives, baseline data, laboratory studies developed by the LC, SDMC methodology research, modelling manuscripts, ancillary studies, or results from more than one HPTN study. Any investigator irrespective of affiliation, may develop a Tier 2 Proposal. These may also include manuscripts or abstracts initiated by Clinical Research Site staff or staff at the Central Resource groups.

21.1.3.3 Tier 3

The HPTN generates manuscripts of many types that do not involve study data, such as viewpoints, ethics guidelines, community engagement, position/white papers. **All manuscripts are submitted to the MRC** to facilitate tracking of HPTN scientific output and to ensure appropriate acknowledgements however, MRC review is not required. At the request of the authors, a formal MRC review can occur. If study data are included, MRC review is required.

21.1.4 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 PPC
- Process for review, approval, and prioritization of manuscript or presentation concepts (refer to the guidelines in 21.1.3 and 21.1.5)
- Expected date of last participant follow-up visit, if applicable
- Estimated date of database lock
- Expected date of results meeting with protocol team (see Section 21.1.5)
- Estimated 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)

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 for conferences or publication prior to study completion is outlined below; permission for exceptions from these guidelines should be sought from HPTN leadership:

- Publications/abstracts/presentations 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 21.1.2). Publication of secondary outcomes typically follows the completion of the primary manuscript.

Using data obtained by chart review is generally 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.

21.1.4.1 Results Meetings

When a study is nearing the time of study database lock, the protocol team should plan for a Results Meeting (in-person or virtual) where the Protocol Statisticians review results of the study with members of the protocol team. The meeting may also include planning of the primary publication, abstract submissions to conferences, review of publications proposals, or a proposal or writing workshop.

21.1.4.2 Tier 1 and Tier 2 Proposals

Investigators and writing teams with a proposal for a Tier 1 or Tier 2 manuscript or presentation should complete a Publication Proposal Form (see Publication Guidance document) that outlines the planned analyses for the manuscript or presentation for PPC consideration and prioritization. However, the Protocol Chair(s) is not required to complete a Publication Proposal Form for the primary manuscript.

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.

21.1.4.3 Single Site Studies Proposals

Results of analyses using data or information from a single site may be developed into manuscripts, abstracts, posters or presentations following receipt of approval from the PPC. Single site manuscripts, abstracts, posters and presentations follow the same approval process and guidelines as described above. Sites may request a copy of the protocol Publication Guidance from the LOC CRM. 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.

21.1.4.4 Multi-Study Analyses Proposals

Results of analyses using data from more than one HPTN study must be sent for approval to each relevant PPC (at a minimum, the Protocol Chair and Statistician if the PPC is no longer active), and upon approval, then submitted to HPTN Leadership for approval. The lead author will be responsible for tracking 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.

21.1.5 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.

21.1.5.1 Protocol Publication Committee Review

The LOC CRM sends the draft manuscript or abstract to the PPC, sponsor(s) and product manufacturer (if applicable) for review and comment. For 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 approved, the LOC CRM submits the revised manuscript to the LOC MRC Coordinator review.

21.1.5.2 MRC Review of Abstracts and Manuscripts

All abstracts submitted to conferences must be reviewed by the MRC prior to submission. If accepted as a posted or oral presentation, review of the final product is the responsibility of the authors and is not reviewed by the MRC. If study data has been released by the SDMC as a Public Use data set for broad dissemination (see Section 21.1.7), presentations may be developed independent of Network oversight and do not require review of the PPC or MRC.

The primary focus of the MRC manuscript review is original research manuscripts presenting results based on data from HPTN-funded research. The MRC receives submission-ready manuscripts after PPC review. All manuscripts must be submitted with an MRC Submission Form. The MRC Coordinator will conduct an administrative check of the MRC Submission Form for completeness after which the tier of the manuscript is designated in consultation with the MRC Chair and reviewers are assigned.

Following review, the MRC will communicate back to the MRC Coordinator, who will forward to the LOC CRM for appropriate distribution. The possible MRC review outcomes are:

- Recommend for submission
- Recommend for submission with consideration of comments
- Not recommended for submission in its current form (with comments from reviewers)
- MRC review not required

Prior to conference or journal submission, a final copy of the abstract or manuscript must be provided by the lead author to the LOC CRM for tracking purposes.

The MRC will re-review a manuscript or abstract only at the request of the author(s) or if significant changes are made to the analysis or outcomes.

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.

21.1.6 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.

21.1.7 Public Use Data Sets

If study data has been released by the SDMC and posted to a public website or data repository as a Public Use data set intended for broad dissemination (see Section 21.2), 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 the HPTN.

21.1.8 Resolution of Disputes

Resolution of disputes at the PPC level (i.e. disputes over authorship or content) should be resolved by HPTN Leadership. Additionally, the HPTN Leadership will resolve disputes between MRC and authors.

21.1.9 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).

21.1.10 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.

21.1.11 Acknowledgements

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, or if using a public use dataset (see 21.1.7). The most current acknowledgement language is available on the HPTN website. 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.

21.2 Data Sharing

All priority analyses agreed-upon by the PPC should be completed within 2 years of last study visit, after which de-identified data sets will be made available by the SDMC for dissemination. Once all PPC-approved analyses for a study are published, submitted for publication or are in the process of analyzing and writing for future publication, public use de-identified data sets for any remaining data will be made available by the SDMC to the public for 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 as a Public Use data set, i.e., formally posted on a website or data repository that allows widespread access to the data by the public, 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 PPC, Scientific Committee (SC) or MRC.

Although not subject to MRC review, any work that utilizes HPTN data or specimens should acknowledge the HPTN, using the sample acknowledgements statement posted with the data.

In general, all identifying information is removed from Public Use data sets per HIPAA "Safe Harbor" guidelines, so that they protect participant identifies and also may be used without consulting an Institutional Review Board/Ethics Committee (IRBs/EC). De-identified data released to HPTN investigators and posted on the SDMC web portal does not, in most cases, constitute Public Use data, and manuscripts developed with such data sets may require review by the HPTN MRC.

21.2.1 Release of HPTN Study Data from the SDMC

Analysis of data related to the protocol objectives is the responsibility of the SDMC. In order to ensure rapid, high quality analysis and dissemination of study results, the protocol statisticians at the SDMC conduct these analyses centrally. Premature distribution of the data has the potential to:

- Jeopardize the integrity of the trial
- Compromise the quality of study results that are disseminated
- Divert the resources of the SDMC from the preparation, dissemination and support of protocol analyses

This section describes how HPTN study data is released by the SDMC without compromising the interests of trial participants or the integrity and credibility of the trial.

21.2.2 Release of Data During the Conduct of a Study

No study data beyond baseline will be available to the site, protocol team or any other body, other than as reports to the DSMB and to the SMC, or to the LC as needed, to perform protocol-related activities and assessments (e.g., for QC activities, to assist with protocol testing, and for assessments related to protocol objectives). Exceptions to this rule require approval by the Leadership Group/Executive Committee (EC) and/or the DSMB, as appropriate. Baseline data may be published or presented only after all sites have completed enrollment.

Publication or presentation of site-specific follow-up data or results during the trial is not approved under the HPTN Publications Policy (Section 21.1) and should not occur unless authorized by the HPTN Leadership group and/or EC. It is the responsibility of the site Principal Investigator (PI) and the IoR to ensure that inappropriate dissemination of results or analysis of data does not occur.

After enrollment is complete, and by request, the SDMC makes participant-level baseline data available to sites as electronic files, either securely posted on the SDMC web-portal, or through the Medidata Rave system. Publication of these data are per the Publication Policy (Section 21.1).

Certain types of data are never available while the study is ongoing:

- Data that constitute primary or secondary endpoints
- Coding (e.g., by MedDRA) of AEs
- PTID identified data from Computer-Assisted Self-Interviews (ACASI or CASI)
- Laboratory data not submitted on a CRF (e.g., submitted directly to the SDMC by the LC or other central laboratory)
- For blinded trials, the participant's random assignment

21.2.3 Release of Data after Completion of a Study

21.2.3.1 Final Release of Site-specific Data to Site Investigators

Final site-specific study data sets can be requested from the SDMC by the site investigators once the database is cleaned and locked and all intended manuscripts reporting primary results of the protocol objectives have been published.

21.2.3.2 Release of Data to Protocol Team and Scholars for Analysis

In general, the HPTN SDMC conducts analysis of primary and secondary objectives data for publication. Data sets for specific analyses to be conducted by HPTN investigators and HPTN Scholars without the assistance of the HPTN SDMC may be released after completion of primary and secondary publications. Release of these data are approved by the PPC and follow the Protocol Publications Guidelines (see Section 21.1). Submission of a Proposal that documents the data requested is also reviewed by the PPC.

21.2.3.3 Final Release of Data

The timeline for the SDMC to start preparation of data sets and documentation for dissemination is approximately one year after the last study visit. In general, only primary data from the HPTN LC that has been locked is included in these datasets, along with the CRF and behavioral questionnaire data. Timing of the release of other specialized data, for example SMS data or data received from the LC after the initial release of data from SDMC, is negotiated with the SDMC PI. Any public datasets required by journals for publication will be created by the SDMC and provided to the journal or the submitting author.

Access to study data before the creation of Public Data Sets may be available to HPTN Scholars or investigators with publication proposals that have been reviewed and approved by the PPC. Access to data before the creation of public datasets should be covered by a data use agreement (DUA) or confidentiality disclosure agreement (CDA).

Two years after the final study visit, complete de-identified datasets and data dictionaries and other supporting documentation are created by the SDMC and posted to Atlas and/or other appropriate data repositories. A link to the data access page will be created on the HPTN website. Access to data will follow HPTN SDMC (or other institutional) norms and process for user authentication and authorization.

The HPTN public data access page will require completion of a brief online application form that includes the investigator's name, institution, and short description of the proposed purpose/analysis. The application will be used to capture and report information about access of the data. The SDMC will not check or validate the accuracy of data summaries and analysis computations completed outside the SDMC.

21.2.4 Limited Release of Data to Non-HPTN Investigators

Prior to final release of study data from the SDMC and or pre-specified purposes, e.g., ancillary studies external to the HPTN or grant applications, investigators may request approval for release of data to HPTN and non-HPTN entities (information on approval of ancillary studies can be found in Section 17.2). These requests require approval of the HPTN leadership group.

- Release of follow-up data prior to the final study visit and study unblinding (if applicable) requires additional approval of the Protocol Chair, the SDMC PI, the LC PI, and the EC and would typically be approved only in extraordinary circumstances.

- Release of data after the final study visit but prior to database lock and completion of publications requires additional approval of the Protocol Chair(s), LC PI, and the SDMC PI.
- Release of baseline data after completion of enrollment requires only approval of the Protocol Chair(s), LC PI, and the SDMC PI.
- The timeline for release of the data is negotiated with the SDMC and the protocol team, taking data cleaning, database lock and study analysis commitments into consideration.

21.2.5 Release of Data from a Study with a Clinical Trials Agreement

The Clinical Trials Agreement (CTA) governs the release of study data to pharmaceutical or other partners. The guidelines in this policy will hold for studies with CTAs unless otherwise specified by the CTA. Data cannot be released from the SDMC unless it is in agreement with the terms of the CTA.

21.2.6 Other Release of Data from HPTN Studies

Requests for release of data not covered in Section 21 must be negotiated with the SDMC PI and the EC. Approval from the LC PI is required for release of any data sets that include laboratory data submitted by the HPTN LC.