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

Note: Procedures for HPTN SDMC and HPTN LC publications are described in Section 21.11.

21.1 RESPONSIBILITIES

The Protocol Chair and Protocol Biostatistician are responsible for generating the first draft of the primary manuscript 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.

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 that relate to a particular study or studies. 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.

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 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, identified by the PPC, is responsible for establishing a writing team consisting of protocol team members for HPTN initiated manuscripts or abstracts and of 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 this policy. 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 data, 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.

Primary manuscripts must be reviewed by the HPTN PI and Co-PI at the time of the MRC review.

The LOC Manuscript Coordinator is responsible for tracking all manuscripts and abstracts as received from LOC CRMs.

21.2 Timelines

The SDMC will release specific timelines for each major conference.

Figure 21-1 Example timeline for Abstracts submitted to major conferences.

	Weeks before conference deadline			
Timing % type of analysis	MRC review	PPC Review	SCHARP analysis	Total lead time
SCHARP analysis underway	2 weeks	1 week	4 weeks	7 weeks
New SCHARP analysis	2 weeks	1 week	6 weeks	9 weeks
No analysis needed	2 weeks	1 week	0 weeks	3 weeks

Additional considerations for deadlines and lead time:

MRC: Total number of abstracts submitted
SCHARP: Total number of analyses

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 that use 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/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 is 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 not related to the scope of HPTN work in general or study objectives that utilizes HPTN data or specimens should acknowledge the HPTN.

In general, all identifying information 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 constitute public use data.

21.5 PROCEDURES

21.5.1 Publication Planning Process

A publication plan (contained within the Publication Guidance) and timeline should 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 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.

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 Proposal Submission

Investigators and writing teams with a proposal for a manuscript or presentation should complete a Publication Proposal Form (see Publication Guidance) that outlines the planned analyses for the manuscript or presentation for Protocol Publication Committee (PPC) consideration and prioritization in addition to 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 submission.

21.5.3 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 EC. Baseline data may not be published or presented until after all sites have completed enrollment.

21.5.4 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 meeting or journal.

If study data has been released by the SDMC as a Public Use data set intended for broad dissemination (see Section 21.3), 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.

21.5.5 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.

21.5.6 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 EC for approval. A lead point of contact will be selected by the EC 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.

21.5.7 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 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 Publication Committee Review

The LOC CRM firstly sends the draft 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 approves, the LOC CRM submits for MRC review and to the LOC Manuscript Coordinator.

21.6.2 MRC Review of Manuscripts

The MRC receives the proposed document after PPC approval. 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 with one another and send collated comments and the outcome back to the lead author, copying the LOC CRM and Manuscript Coordinator. The possible MRC review outcomes are:

- Endorse for publication
- Endorse 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.

MRC review primarily focusses on 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.

21.7 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.

21.8 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. 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.

21.9 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.

21.10 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).

21.11 HPTN LC AND SDMC MANUSCRIPTS

In addition to assisting with Tier 1 and Tier 2 publications initiated by the study team or other investigators, the HPTN LC or SDMC also publish more technological or methods 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 or SDMC-related data analyses or statistical/analytic methods.

For work that includes use of data and/or specimens from 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. In some cases, 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.

21.12 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 12.6 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.

21.13 RELEASE OF INFORMATION TO THE PUBLIC

21.13.1 Public Information Policy

Investigators and CTU staff may have access to proprietary and sensitive information as a result of their participation in HPTN protocols. The following guidelines relate to disclosure of product and study-related information to the public. These guidelines are in keeping with the policies and procedures of the DAIDS Office of Program Operations and Scientific Information (OPOSI), the NIAID Office of Communications and Government Relations (OCGR) and the NIAID News and Public Information Branch (NPIB).

Inquiries from the press, community representatives, and public officials concerning general study status may be addressed by the study investigators to whom questions are addressed; however, more specific comments related to study outcomes or adverse events will be coordinated between the investigators and HPTN leadership as well as the protocol team and the DAIDS (and other NIH institutes as necessary).

Press inquiries more specifically or generally about HPTN activities should be referred to the Network leadership and DAIDS.

Proprietary information about study products in development or used in a trial conducted under an Investigational New Drug (IND) application may not be discussed publicly by anyone without written permission of the product's manufacturer.

21.13.2 Disclosure of Study Results

In general, results from HPTN studies are not released until completion of the study at all participating sites. Any exceptions to this policy require explicit approval of the HPTN Leadership in consultation with the study chair(s).

The release of study results at the end of the study provides an opportunity to share findings that could influence the standard of care in the communities where HPTN studies are conducted, or the design and/or conduct of ongoing or future HIV prevention trials. The protocol team should create a study results communications plan well before the end of the study. The plan should identify key members of the communication team (i.e., Protocol Chair, Protocol Biostatistician, designated spokespeople, etc.) and their roles, specify the

timeline and activities planned for release of the study results within the team and externally, and identify the key stakeholders (protocol team members/site staff, sponsors, community advisory boards, host country officials, collaborating institutions, other US government and non-US public health agencies, and investigators/sponsors of other studies that may be impacted by the study results) to be informed of the results. Disclosure of study results, particularly of Phase IIb/III trials, by the protocol statisticians to study investigators, other protocol team members, HPTN leadership (Network PIs, LC PI, LOC Project Director, SDMC PI and others as necessary) and sponsors should be part of the study communications plan. Ideally, study results are revealed to the protocol team and sponsor at an in-person meeting that includes a review of the key analyses and planning for public release of results and coordination of future publications.

Results will be released to host country officials, study participants, community representatives, sponsoring industry collaborators, relevant non-governmental organizations and other governments in an accurate, well-controlled and timely manner. Ideally this will happen before, or at the same time, as the results are released to the general public.

Particular care is to be taken to coordinate release of results with officials in host countries and in the communities where the study was conducted.

21.13.3 Press and Public Announcements Related to Data and Safety Monitoring Board Reviews

A NIAID Data and Safety Monitoring Board (DSMB) typically oversees all HPTN Phase IIB or Phase III clinical trials. NIAID has overall responsibility for the public release of information following DSMB reviews of HPTN studies. When an NIAID press release or public statement related to a DSMB review is required, DAIDS and NIAID communications staff develop these materials in consultation with the DAIDS Medical/Program Officer, the HPTN PI, the Protocol Chair and others. The DAIDS Medical/Program Officer, Protocol Chair, HPTN LOC and SDMC will work together to ensure that each study site and investigator is adequately prepared in advance of DSMB reviews and, as needed, coordinate implementation of appropriate communication strategies, including dissemination of statements at the site level.

Prior to each DSMB review, the DAIDS Medical/Program Officer, in consultation with the DSMB Executive Secretary, key members of the study team and others, assesses the potential for clinically significant and/or newsworthy review outcomes and considers the most likely scenarios (e.g., study discontinuation or change of study design) and is responsible for communicating this internally at NIAID as appropriate (i.e., notifying the OPOSI which will in turn notify OCGR and NPIB) and with key members of the study team and Network leadership. As needed, a draft “schedule of events” – a timing and communications planning document for activities related to the DSMB review and its outcome - will be developed in advance of the review by the HPTN LOC, in consultation with the DAIDS Medical/Program Officer, Protocol Chair, protocol statistician and DSMB Executive Secretary. The DAIDS Medical/Program Officer is responsible for seeking input from and coordinating communications with OPOSI, NPIB, and OCGR. If necessary, draft statements and Question & Answer documents for the press will be prepared by NPIB or OCGR, in consultation with OPOSI and the DAIDS Medical/Program Officer, the DSMB Executive Secretary, and key members of the study team. For scheduled reviews, draft documents are typically provided to study team representatives for review in advance of the DSMB review.

NIAID is under no obligation to provide study team members with draft press releases/ statements in advance of their official release. However, in special circumstances, confidential drafts may be provided. Immediately following each DSMB review, the Board’s recommendation is communicated to the Director of NIAID who decides whether to adopt

the recommendation. NIAID and the HPTN then proceeds with the planned communications activities for the actual DSMB review outcome. Only NPIB may issue an official statement or press release on behalf of NIAID concerning a NIAID DSMB review of an HPTN study. All NIAID press releases and public statements must undergo standard review with clearance granted by the Office of the Director, NIAID; Office of the Director, NIH; and the US Department of Health and Human Services (DHHS).

Study sites and study co-sponsors may not issue their own press releases or public statements prior to the NIAID press release or public statement being released. When a co-sponsor is a publicly traded company on either a US or non-US exchange, NIAID and the co-sponsor will coordinate the release of statements in accordance with public disclosure requirements and in accordance with the terms of any applicable Clinical Trials Agreements (CTAs).

If a DSMB review of an HPTN study is being coordinated with review of another study, communications planning and strategies must also be coordinated. On communications matters, only NIAID, NPIB, or OCGR may serve as the primary point of contact with the counterpart at the other research organization.

When the DSMB recommends modification to a study, this information will be immediately communicated by the study Protocol Chair and HPTN leadership. This leadership team includes:

- Network PIs
- LC PI
- LOC Project Director
- SDMC PI
- Others as deemed necessary

Prior to NIAID's release of a press release or public statement, it is imperative that the DSMB findings remain confidential. To ensure study confidentiality, all study team members must sign a confidentiality agreement.

Recognizing that in some cases DSMB findings may require immediate action, communication of DSMB results with network constituents and study participants will be coordinated with the Protocol Chair, HPTN leadership and NIAID in a timely fashion. Advance communication planning and development of possible DSMB outcomes will expedite this process.

21.13.4 Public Communications Regarding Changes in Ongoing Studies Not Overseen by a NIAID DSMB

Significant changes (e.g., early closure, re-design) to ongoing Network studies that are not overseen by a DSMB (e.g., Phase I clinical trials, observational cohort studies) may need to be made, and communication of these changes will also need to be carefully planned to ensure that key stakeholders are adequately informed and understand the rationale for the changes. In such cases, the HPTN LOC, Protocol Chair and DAIDS Medical/Program Officer will work with other members of the protocol team to develop a communications plan including many of the same elements described above for release of study results. The DAIDS Medical/Program Officer is responsible for seeking input from and coordinating communications with OPOSI, NPIB, and OCGR, as needed.

21.13.5 Press Releases/Public Announcements

All Network related press releases and public statements will be developed or approved by NIAID and, as appropriate, by its co-sponsors. When such materials are developed by the sponsor(s), the DAIDS Medical/Program Officer and HPTN LOC will coordinate review by Network and/or study leaders as needed. When these materials are developed within the Network, the DAIDS Medical Officer/Program Officer and HPTN LOC will ensure that they are reviewed and approved by DAIDS program leadership, OPOSI, OCGR and NPIB (NIAID), and, as appropriate, by the NIMH and NIDA program leadership and their respective communications offices. Before any materials undergo NIH review, the HPTN LOC ensures they have been reviewed and/or approved by relevant parties within the Network. Study-related press releases and materials must be approved by the Protocol Chair and the HPTN PIs. General HPTN press releases and materials must be approved by the HPTN PIs. The HPTN LOC sends draft materials to the DAIDS Medical/Program Officer for review (and ensures that copies are provided to OCGR, NPIB, and OPOSI) and, as appropriate, to the NIMH and NIDA Program Officers. Following DAIDS Medical Officer/Program Officer review, OPOSI and NPIB will review the drafts for messaging and terminology. OCGR or NPIB compiles NIAID's comments and edits for consideration and/or incorporation by the HPTN LOC.

To ensure accuracy of information and proper identification of the HPTN, NIAID, and other funding sources, all press releases generated by HPTN CRSs, Core Resources, or study co-sponsors must be reviewed by the HPTN LOC, which will as necessary, coordinate additional review by the appropriate funding institutes. Investigators should allow sufficient time for this process.

When study results are to be published or presented at a scientific meeting, the HPTN LOC, DAIDS Medical Officer/Program Officer, OPOSI, OCGR, and NPIB coordinate press announcements with the authors and the publishing journal or scientific meeting organizer to comply with all required embargo guidelines. For studies conducted under a CTA with a product manufacturer, the publication guidelines and procedures described in the CTA also must be followed. In case of specific points of discordance between CTA requirements and this policy, the CTA requirements shall be followed.

All press releases, statements, and public announcements must properly acknowledge that the activities of the HPTN are performed cooperatively with NIAID, NIMH, and NIDA.

The HPTN LOC ensures that NIAID, NIMH, and NIDA program leadership and their respective communications offices are notified in advance of all HPTN news releases and statements before they are publicly disseminated.

21.13.6 Press Releases/Public Announcements Regarding Openings of New Trials

The CTU is responsible for sending a draft of any press release or public statement regarding opening or initiation of a new trial to the DAIDS Medical Officer/Program Officer and HPTN LOC for review and approval by the appropriate Network and NIAID entities in advance of release.

Note: This excludes recruitment materials developed by a CRS.