6 NETWORK MEETINGS AND COMMUNICATION

The Leadership and Operations Center (LOC) supports and coordinates much of the communications within the HPTN through conference calls, in-person meetings, electronic and written materials, social media and through the HPTN's website. The website includes study-specific information and postings about Network-wide activities. The Senior Communications Officer at the LOC is primarily responsible for creation and dissemination of HPTN material.

6.1 Annual Network Meeting

In collaboration with the HPTN leadership, the LOC organizes an annual Network meeting to bring together HPTN members and collaborators to discuss study designs and research goals, review data from ongoing trials, examine cross-cutting issues, and provide an overview of the HPTN scientific agenda. In addition, the meeting provides opportunities for training, identifying key issues, defining and discussing Network procedures, and clarifying roles and responsibilities of HPTN members. The meeting generally includes plenary sessions to update HPTN members on the latest scientific research concerning HIV prevention. The Executive Committee (EC), Science Committees (SCs), Working Groups (WGs), and protocol teams schedule meetings in conjunction with this yearly event. The LOC is responsible for the overall logistics of the meeting; preparation of agendas and background materials; and subsequently, dissemination of summaries for the EC, SCs, WGs, protocol teams, and protocol-specific sessions in collaboration with the chair of the respective committee, team, or group. Additionally, the annual Network meeting may provide NIH training opportunities.

6.2 Conference Calls

Conference calls are used extensively to facilitate the Network's research activities.

The LOC provides a broad range of administrative support for conference calls; preparation and/or distribution of call agendas and pre-meeting materials; sending email meeting reminder notices; and preparation, distribution, and archiving of pre-determined conference call summaries. As part of their support of these groups, LOC staff document and distribute summaries of EC, SC, WG, protocol team and investigator conference calls.

In addition, webinar support is provided to allow for interactive slide presentations and other media rich methods for sharing of information and data.

6.3 Material Distribution

Staff of the HPTN central resources (LOC, Statistical and Data Management Center [SDMC] and Laboratory Center [LC]) disseminate HPTN information and study materials using a variety of techniques including newsletters, email, social media, website postings, facsimile, mail, and express mail services. To ensure information transfer, each Network organization must:

- Have the capacity to send, access, and receive materials distributed using the above techniques
- Ensure that HPTN communications and materials are distributed to all appropriate staff members
- Maintain all key study and HPTN communications

Key HPTN information is posted on the HPTN website for access by all Network members. Information from Central Resources and from National Institutes of Health (NIH) is included and maintained regularly to ensure timeliness of material availability and dissemination. Other websites with information relevant to the Network include: Regulatory Support Center (RSC), Office of

Human Research Protections (OHRP), US Food and Drug Administration (FDA), NIH, Office of Clinical Site Oversight (OCSO) and US Centers for Disease Control and Prevention (CDC).

6.4 HPTN Website and Social Media

The HPTN website provides a wide range of materials.

The general philosophy governing the design, maintenance, and content of the website is to provide a site that contains useful and up-to-date information on the Network organization and studies.

6.4.1 Website Structure and Organization

The website includes HPTN protocols, Clarification Memos Letters of Amendments and full protocol amendments.

Study-specific pages are developed to suit the needs of each study. An updated list of site names and numbers, with contact information, and a list of protocols (numbers and titles) that includes participating sites and status of each study is also posted. The website also features a searchable HPTN publications database.

The design and maintenance of the HPTN website is the responsibility of the LOC. Questions and comments on the website may be sent to: hptn@fhi360.org.

6.4.2 HPTN Use of Social Media

The HPTN uses social media tools to increase community engagement in all aspects of HPTN's research agenda among members of communities that are disproportionately impacted by HIV/AIDS but are traditionally underrepresented in HIV prevention research. The primary social media tools utilized by the HPTN are Facebook, Twitter and YouTube. The HPTN engagement efforts on those sites primarily focuses on building a dialogue with HIV and non-HIV specific health organizations, advocacy, professional, academic and civic groups in an effort to encourage community partners to build a more comprehensive understanding of the critical need for an ongoing, robust HIV prevention research agenda and, in turn, transfer that knowledge to their staff and to the community members whom they serve.

Posts made to the HPTN's social media sites include announcements and updates about HPTN studies and about activities such as webinars, conference presentations and publications. In addition, information about relevant articles, conference announcements, and links to other materials such as community partner and HPTN sites' community events are posted by HPTN staff as well as by social media followers. Other HPTN social media activities include promoting posts and hosting and participating in Twitter Chats and Facebook Events.

6.5 Release of Information to the Public

6.5.1 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.

6.5.2 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 (see section 21.5.2).

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.

6.5.3 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.

6.5.4 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.

6.5.5 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.

6.5.6 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.