HPTN Manual of Operations Network Meetings and Communication

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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 and virtual 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 Communications Team at the LOC is primarily responsible for creation and dissemination of HPTN material.

6.1 HPTN Annual Meeting

In collaboration with the HPTN leadership, the LOC organizes an HPTN Annual 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 Annual 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 may 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 Meeting may provide NIH training opportunities.

6.2 Conference Calls and Virtual Meetings

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

The LOC provides a broad range of administrative support for conference calls and virtual meetings, such as 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. LOC staff also document and distribute summaries of EC, SC, WG, protocol team and investigator conference calls.

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, and mail and shipping services.

Key HPTN information is posted on the HPTN website and/or other shared web-based portals for access by all Network members and study team members. Information from HPTN central resources and from the <u>Division of AIDS (DAIDS)</u> at the 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: <u>Regulatory Support Center (RSC)</u>, <u>Office of Human Research Protections (OHRP)</u>, <u>US Food and Drug Administration (FDA)</u>, <u>NIH</u>, <u>Office of Clinical Site Oversight (OCSO) and US Centers for Disease Control and Prevention (CDC)</u>.

6.4 HPTN Website and Social Media

The <u>HPTN website</u> provides a wide range of materials, as discussed below. 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 HPTN website includes information about the HPTN's structure, ongoing studies, community engagement programs, presented research, and publications. Study-specific pages are developed to suit the needs of each study. At a minimum, each study-specific page includes the Study Protocol and current study status, as well as Clarification Memos, Letters of Amendments and Full Protocol Amendments as needed. The study pages may also include key study personnel, participating sites and publications.

The HPTN website also includes Network resources such as the HPTN Manual of Procedures (MOP), a searchable Network directory, regulatory information, current announcements, and the HPTN newsletter.

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

6.4.2 HPTN Use of Social Media

The HPTN uses social media (e.g., <u>Facebook</u>, <u>Twitter</u> and <u>YouTube</u>) 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 HPTN engagement efforts on those sites primarily focus 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 Study-Specific Communications

6.5.1 Study-Specific Roles and Responsibilities

The HPTN Communications Team will provide study-specific communications guidance to HPTN protocol teams. The Communications Team will be responsible for developing a comprehensive study-specific communications plan which will include study-specific roles and responsibilities, media communications, and plans for dissemination of study results. They will coordinate with the Protocol Team leadership to provide timely responses to emerging issues while reinforcing key messages about the study. This may include the need for a press release, official public statement or talking points. The HPTN Communications Team tracks all media coverage for HPTN and individual studies.

Study sites are responsible for monitoring how the study is portrayed/discussed by local media outlets in their respective regions. Any issues should be reported to the Protocol Team leadership, who will consult with the HPTN Communications Team, as necessary. This allows the team to identify any potential crisis communication issues and craft appropriate responses.

For each study, spokespersons/leaders who can speak on behalf of the study will be identified and listed in the study-specific plan. Site spokespersons and backup contacts will be identified for each site, who can respond to emergent issues. Additionally, site staff will develop a list of key local contacts for information dissemination as needed, including their respective institutions, community stakeholders, advocacy groups, health/scientific journalists, scientific leaders, websites, blogs, etc.

6.5.2 Development of Study Materials

If development of web-based, print, or other materials are required for a study (dependent on the phase of study), this will be managed by the HPTN Communications team, in collaboration with study site and/or community representatives. If materials are developed locally for site-specific use, these should be shared with and approved by the HPTN Communications Team. When discussing study-related information and results with media, community or other key stakeholders, study personnel will use communication documents generated and approved by the HPTN Communications team. The HPTN Communications team is responsible for ensuring that review of materials is obtained from the study team and HPTN leadership as appropriate. This includes, but is not limited to, fact sheets, FAQs, brochures, flyers, study websites, study advertisements (print and web), and talking points. Guidelines for the development of manuscripts, research presentations, and posters may be found in Section 21 and the study-specific publication guidance document (as applicable). (Note: *All press releases, statements, and public announcements must include an approved statement acknowledging NIH funding.) Documents related to the dissemination of study results MUST be shared with the applicable NIH communications representative(s).

Materials developed for study participant use must be reviewed and/or approved by all responsible review bodies, including Institutional Review Boards/Ethics Committees (IRB/ECs), and in-country or site-specific Community Advisory Boards (CAB) or Community Advisory Groups (CAG) as applicable.

For any study that will be conducted at more than one US site, materials developed for study participant use are submitted by the LOC for single Institutional Review Board (sIRB) review on behalf of all US sites.

6.5.3 Study-Specific Media Inquiries

The HPTN Communications Team should be notified of <u>all</u> inquiries regarding the study from reporters/news organizations/bloggers and other media contacts. Media inquiries may be handled by the HPTN Communications Team, or a study or site spokesperson in coordination with the HPTN Communications Team. When discussing study-related information and results with the media, community or other key stakeholders, the spokesperson's responses should be consistent with any messaging/materials already developed by the study communications team.

6.5.4 Press Releases/Public Announcements

All press releases and public statements developed by HPTN must be approved by NIAID and, as appropriate, other sponsors. 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 Principal Investigators (PIs). For all press releases and public statements, it is the responsibility of the NIAID Communications Office, DAIDS Program staff, and HPTN LOC to ensure that all appropriate Network, study leadership, and NIH program leadership reviews and approvals are obtained. For any locally-developed press releases or public statements (not including recruitment materials/advertisements), sites are responsible for sending a draft to the DAIDS Medical Officer and HPTN Communications Team for review and approval.

When study results are to be published or presented at a scientific meeting, the HPTN LOC and NIAID Communications Office 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 Clinical Trials Agreement (CTA), 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.

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.

6.5.5 Study-Specific Documentation for Communications Purposes

The HPTN Communications Team will work with protocol teams to remain apprised of noteworthy study updates and story ideas for possible dissemination across communications channels of the HPTN. Whenever possible, the HPTN Communications Team will encourage sites and study staff to take photos and/or video to capture the various aspects of the study on-the-ground, as appropriate. All subjects of photos or video will be required to give written consent. The HPTN Communications Team has a template consent form for photos/videos. Photos and video should not violate IRB policies, informed consent for study participants, nor the multimedia policies of local partners/establishments where photos are taken. Any photos or video should be shared with the HPTN Communications Team for archiving and possible dissemination, which may include updates in the HPTN newsletter or on HPTN social media.

6.5.6 Study-Specific Results Dissemination

Protocol leadership will develop a timeline and plan for communications activities related to the dissemination of results for the HPTN study which will be detailed in the study-specific Communications Plan. For Phase III studies that are overseen by a Data and Safety Monitoring Board (DSMB), these plans will include scenarios related to early stopping or unblinding of the trial based on DSMB recommendations.

In preparation for results dissemination, sites will work with the HPTN Communications Team to ensure local contacts, spokespersons and community stakeholders are up to date.

The HPTN Communications Team will work in collaboration with the protocol leadership and study sponsor(s) to develop and review materials/tools for communicating results of the study. This may include the development of press releases, fact sheets and FAQs.

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).

Prior to results dissemination, the HPTN Communications Team will work with protocol leadership and the study sponsor(s) to ensure that the results dissemination section of the study-specific communications plan is updated with specific information relevant to the dissemination process. Ideally, study results are revealed to the protocol team, sponsor(s), and other relevant parties at a meeting that includes a review of the key analyses and planning for public release of results and coordination of future publications (see section 21.1.4.1).

Results will be released to host country officials, sites, 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.

6.6 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 and are aligned with NIAID policies.

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.

6.7 HPTN Branding

6.7.1 Identity

When referencing an HPTN study in manuscripts, presentations, posters, study-specific printed materials, or other study-related documents or communications, the full study name/number must always be used (e.g., "HPTN [Insert Study Number]"). If the study has a branded name (i.e., "The LIFT Trial") it may be written as "HPTN 123, The (NAME) Trial."

When submitting abstracts, manuscripts, posters and presentations, the corresponding author should list the named authors and then recognize the study team (e.g., "Ann Smith, William Jones and the HPTN [Insert Study Number] Study Team.")

6.7.2 Acknowledgement and Logo Use

The HPTN logo or an official study logo should be used on all study-specific materials as well as general HPTN materials. The current HPTN logo is available on the <u>HPTN website</u>. If materials are developed for local use only AND space is limited, it is permissible for in-country sites to use their logos, with prior approval of the HPTN Communications Team.

Per NIH policy, NIH/NIAID/NIDA/NIMH logos should not be used on any study communications materials (presentations, posters, brochures, websites, etc.). As an NIH grantee, **HPTN is required to acknowledge NIH funding support through text only** (see Section 21.1.11).

6.7.3 Slides, Posters and Printed Materials

General and study-specific HPTN templates for posters and presentations will be developed by the HPTN LOC. These templates should always be used for communicating about a study. Logos and sponsor text already incorporated in these templates should not be moved, re-sized, overlapped or deleted. Templates are available on the HPTN website and in internal LOC file libraries (i.e., SharePoint and Teams).