

5	COMMUNITY ENGAGEMENT IN THE HPTN	2
5.1	Overview.....	2
5.2	HPTN Community Engagement Program.....	3
5.2.1	Ethics Training for Community Representatives	3
5.3	CTU/CRS Community Programs and Community Advisory Boards	4
5.3.1	CRS Community Advisory Boards	5
5.4	HPTN Community Working Group	5
5.4.1	Protocol-Specific Community Working Groups.....	5
5.4.2	HPTN Community Working Group Steering Committee.....	6
5.5	Community Engagement in the Research Process.....	6
5.5.1	Concept/Protocol Development.....	6
5.5.2	Study Implementation	8
5.5.2.1	Community Engagement Work Plans and Routine Calls and Meetings....	8
5.5.3	Study Completion, Results Dissemination and Potential Next Steps	9

5 COMMUNITY ENGAGEMENT IN THE HPTN

Clinical trials of HIV prevention interventions are most likely to succeed when all stakeholders — study participants, researchers, government, non-governmental organizations, service providers, community leaders, advocates and the study communities regard the trials as relevant and the process as collaborative. An aware, knowledgeable, and engaged community throughout the research process and beyond is imperative for successful scientific and ethical conduct of HPTN trials.

Community, in relation to HPTN research, is defined as the group of people who will participate in, are likely to be affected by, or have an influence on the conduct of the research. The community may include the particular group or population from which study participants are chosen. It may also include the broader geographic community in which the study will be conducted, as well as national and international activists who have an interest in the proposed research. Local traditional or governmental leaders, professionals, or volunteers who work with HIV prevention or research programs may also be key community representatives. Community members play an integral role in advising on research conducted in their community and disseminating research findings back to the community in a manner that is relevant and meaningful.

5.1 Overview

Community engagement on behalf of the HPTN is facilitated at many operational levels, including through Clinical Trials Units (CTU) and CTU-affiliated Clinical Research Sites (CRS), protocol teams, the Community Working Group (CWG), HPTN Science Committees, and the HPTN Leadership and Operations Center (LOC). The HPTN fosters a culture that supports partnerships between the community and researchers as a study is being designed, throughout its implementation, and leading up to and including dissemination of study results. CRS researchers work with and rely on the CRS Community Advisory Boards (CABs) to represent the participant community and raise issues and concerns regarding and affecting the research and the community. In addition, the inclusion of at least one representative of the CWG and/or HPTN Leadership and Operations Center (LOC) Community Engagement Program staff on key HPTN committees, working groups and on each protocol team ensures that a community voice and perspective are considered in all deliberations. At the HPTN leadership level, one of the two CWG Co-Chairs serves as a voting member of the Executive Committee (EC), and both Co-Chairs participate in EC conference calls and meetings.

In terms of community engagement, the HPTN is committed to:

- Conducting ethical research of the highest scientific quality that is supported and informed by input from local communities
- Supporting local community education and building community partnerships at HPTN CRSs, including through the provision of regular and ongoing scientific updates
- Supporting activities and infrastructure to build and sustain the community-research partnership
- Developing leadership, through the CWG, to advise the HPTN on cross-cutting community issues
- Providing technical assistance and support to HPTN and CRS community activities through the LOC Community Engagement Program staff
- Responding to concerns and misconceptions arising from study participants and communities, as needed

5.2 HPTN Community Engagement Program

Local and HPTN-wide community engagement efforts include strategies both to increase researchers' and staff members' knowledge of community engagement and to foster strong researcher-community partnerships. These partnerships support community-relevant research; appropriate plans for recruitment, retention, study product adherence; and the dissemination of study findings to the community. The HPTN LOC Community Engagement Program staff oversee HPTN's community engagement activities. Local engagement is typically done by the clinical research sites with community partners who operate on a local level.

The HPTN LOC Community Engagement Program is also responsible for overseeing stakeholder engagement, often in collaboration with CTU/CRS community program staff, HPTN LOC Communications Program, study leadership and civil society/advocacy group representatives. Whenever community consultations for a specific protocol are undertaken, it is crucial that study leadership is involved with the planning and implementation. It may be necessary to partner with a national stakeholder to conduct a consultation if they already have rapport established with stakeholders that we need to engage.

The Community Engagement Program staff or CWG may engage national stakeholders whose reach goes beyond their local community.

Specifically, the HPTN LOC Community Engagement Program staff are responsible for the following:

- Ensuring a HPTN LOC Community Program Manager and a CWG representative are assigned to each protocol team
- Facilitating appropriate community input into the scientific agenda and the research process at the Network level
- Building capacity for local communities to provide input into research at HPTN study sites
- Facilitating the development of CRS Community Engagement Work Plans (CEWP)
- Developing mechanisms for sharing experiences, lessons learned and best practices in community involvement in research
- Facilitating training for community staff, CAB members and CWG focused on relevant topics and particular needs for capacity building
- Participating in and facilitating the HPTN CWG, protocol-specific CWGs, and HPTN CWG Steering Committee
- Working with the HPTN Communications Team to ensure that community representatives are adequately prepared prior to the launch of new studies, study milestones (e.g., Data and Safety Monitoring Board reviews) and study results, to help them manage expectations and communicate study outcomes at the community level

5.2.1 Ethics Training for Community Representatives

The [FHI 360 Research Ethics Training Curriculum for Community Representatives](#) was designed to educate community representatives about their roles and responsibilities and inform community representatives, members of research teams, CABs, and research ethics committees, about the general principles of research ethics. It also reviews the need for ethics committees, their importance, and the roles and responsibilities of community representatives in the research process. The curriculum includes easy-to-use materials, such as slides, case studies, activities, facilitator notes, as well as an ethics training certificate.

Community education staff, community advisors and partners are encouraged to complete this training.

5.3 CTU/CRS Community Programs and Community Advisory Boards

It is the responsibility of the CTU principal investigator (PI) to ensure sufficient funds are in the CTU annual budget to support a community engagement program at each of the CTU's affiliated CRSs to facilitate the engagement of community representatives in the design, development, implementation and dissemination of results for HPTN studies. In this regard, HPTN Leadership expects that each CRS has a dedicated community education staff to coordinate a CRS community engagement program. The CTU PI and CRS Leader will ensure that the CRS community engagement program will include the following:

- Solicitation of input from community educators/liaisons on funding needs to implement CAB-related activities on an annual basis
- Support from the CTU/CRS core budget for adequate community-education staff and funding for a CTU/CRS community engagement program to support study-related community engagement plans
- Development and submission of an annual CTU/CRS CEWP
- Participation on routine conference calls with the HPTN LOC Community Engagement Program staff to provide updates on the status of the goals of the CEWP and the objectives of community engagement program activities
- Support for developing or enhancing CTU/CRS community advisory structures to be capable of working autonomously to determine their priorities, methods of organization and activities
- Development of a community advisory structure consistent with the research agenda and target priority population. In some instances, it may be prudent for CTUs/CRSs to establish priority population-specific CABs

The HPTN LOC Community Engagement Program staff work closely with the CRS community staff to:

- Develop a local CEWP that includes community assessment, community education, support from CABs and other mechanisms for community input
- Assist the CTUs/CRSs in community orientation and training, facilitation of community input into protocol development and implementation of the clinical trial
- Provide oversight, operational management and technical assistance in the development and dissemination of educational materials; the development of collaborative partnerships; and the ongoing education of trial participants, researchers and affected communities
- Provide guidance on developing community engagement program budgets
- Advocate for appropriate resources for community engagement activities and support for participation in local and network-level capacity-building initiatives

5.3.1 CRS Community Advisory Boards

A CAB is a mechanism through which a research site obtains community input into the research process; although, a CRS may refer to this structure by any locally chosen name or establish an alternative structure. CAB members work with study staff to lay the foundation for a viable research program by representing and speaking for the community. The CAB members support the site in developing appropriate plans for recruitment and retention and they advise on the dissemination of study findings to the community. They also provide feedback on draft protocols to study teams and offer advice in the development of informed consent forms, participant support materials and programs.

CTU/CRS staff will report on their CAB's activities to the HPTN LOC Community Engagement Program staff through updates provided on routine conference calls, discussions during community site-assessment visits and periodic one-on-one calls with site community educators.

To ensure their autonomy and to reduce possible conflicts of interest, CAB members are not paid site staff members; rather, CAB members are volunteers from the CRS community. They must adhere to CAB by-laws and governance regarding roles, responsibilities, and meeting attendance. They are expected to participate meaningfully so that issues requiring community dialogue can receive appropriate attention. CAB members and community partners involved in review of protocols and related documents should sign a statement of confidentiality to ensure the confidentiality of proprietary information and to protect fellow CAB members and study participants from HIV-related stigma.

The CTUs/CRSs are expected to support CAB representatives' participation in virtual and face-to-face HPTN meetings, conference calls, protocol-specific training, and regional community workshops. CTUs/CRSs should reimburse CAB members for legitimate costs associated with participating in the advisory process, such as for airtime, transportation, childcare, and meals at a level deemed appropriate by the individual CTU/CRS. This reimbursement should not be construed as payment. CTU/CRS staff should be readily available to participate in CAB meetings, as needed, as well as HPTN LOC Clinical Research Managers, Protocol Chair(s), protocol team members, and staff from the HPTN Statistical and Data Management Center or Laboratory Center should also avail themselves when at a site for training, assessment visits or any other HPTN-related business.

5.4 HPTN Community Working Group

The HPTN CWG is a group of site-based community representatives (both community education staff and CAB members) and advocates who provide consultation on and input into HPTN's efforts to ensure community engagement in its research agenda at the site and leadership levels. Its members conduct community preparedness and engagement activities to ensure the successful conduct of HPTN's studies. Protocol-specific CWGs are established for many of HPTN's studies and are comprised of CWG members from the CTUs/CRSs that are conducting the particular study.

5.4.1 Protocol-Specific Community Working Groups

Protocol-specific CWGs are created for larger studies (for example, Phase II, Phase III and open-label extension trials) with multiple study sites. They are responsible for enhancing protocol-specific community strategies and identifying possible study implementation challenges. Protocol-specific CWGs also assist in the development of study-specific educational tool kits and communication plans for disseminating information intended to keep community members informed of protocol updates, site-specific community involvement activities and to facilitate community preparedness and ongoing engagement activities and ensure the successful conduct of studies through partnerships.

5.4.2 HPTN Community Working Group Steering Committee

The HPTN CWG Steering Committee is comprised of a small subset of representatives from the HPTN CWG. The group provides guidance and support to the HPTN CWG and advises HPTN Leadership on matters concerning community engagement in all aspects of HPTN's research agenda. The HPTN CWG Steering Committee serves as a conduit of information between the HPTN CWG and HPTN Leadership and other HPTN working groups and scientific committees. See Sections 4.2.1.1 and 4.2.1.2 of this manual for further information on the CWG and steering committee's mission, goals, membership and structure.

5.5 Community Engagement in the Research Process**5.5.1 Concept/Protocol Development**

The HPTN PI and co-PI ensure HPTN's commitment to community engagement in the concept/protocol development stage and throughout all aspects of the research process. Likewise, CTU/CRS Community Education Program staff, CAB members and the protocol-specific CWGs have primary or shared responsibility to:

- Attempt to fill gaps in the community's knowledge and/or expertise
- Provide real-life experiences when engaging the community
- Provide input about community/study participants' concerns, beliefs and norms
- Consider the input of scientists when developing concept plans and protocols
- Advise the site research team in the development of informed consent forms and other study-related materials, such as fact sheets and backgrounders
- Provide input on the language in the sample informed consent forms via written comments and/or participation in conference calls regarding the development of the forms
- Participate in developing and implementing strategies for recruiting and retaining study participants and facilitating adherence to study products
- Suggest strategies to address ethical and operational aspects of study conduct
- Serve as a resource to the community educator and the research team
- Share information, questions and concerns with others, i.e., local CAB members, the HPTN LOC Community Engagement Program staff and the CWG
- Function as a conduit of information between the site and potential research communities, such as CABs, nongovernmental organizations or social organizations
- When concerns arise, have discussions with local community representatives, community representatives from the other sites involved in the trial, the CRS leader and the HPTN LOC Community Engagement Program staff; among others, and ensure a complete feedback loop for information flow
- Provide protocol-development updates to fellow community representatives at the site or Network level
- Provide timely written feedback concerning concepts and protocols via an online questionnaire or email to the HPTN LOC Community Engagement Program staff

CAB members as representatives of their communities, and members of the CWG, should have the opportunity to provide input before trial-related terms are defined and translated into local languages and formats to ensure they are understandable. It is therefore important for the community to review the various versions of the protocol during its development and implementation. At a minimum, they should provide input into:

- The development of the informed consent processes and documents to enable prospective participants to provide voluntary informed consent
- Procedures for assessing individual comprehension of study-related information
- Incentives and reimbursements offered as part of participation in the study
- Study accrual, retention and product adherence strategies

It is the responsibility of the HPTN CWG Co-Chairs to:

- Submit concepts to the HPTN CWG and include the deadline and instructions for providing feedback
- Consider the HPTN CWG's feedback about concepts in preparation for submitting recommendations to the HPTN Leadership

It is the responsibility of the Site Investigators, study-specific Investigator of Record, community educators/CAB coordinators and other site staff in partnering with the CAB to:

- Include the CAB in concept and protocol team conversations and communications regarding protocol development to the greatest extent possible (for example, facilitate inclusion on conference calls or email exchanges)
- Meet regularly with the CAB to discuss and obtain feedback on concepts and protocols throughout the development process
- Conduct virtual or face-to-face CAB meetings immediately upon site selection to provide a clear explanation of the draft protocol with emphasis on the following protocol sections:
 - Background
 - Schema
 - Inclusion criteria
 - Exclusion criteria
 - Study procedures (including collection of lab specimens)
 - Informed consent forms

It is the responsibility of the HPTN LOC Community Engagement Program staff to:

- Participate in protocol team calls and meetings to clarify the community engagement program process and answer any questions
- Review written community feedback about the protocol and convene conference calls or exchange email (as necessary or possible) to further address questions, concerns and suggested changes to the concept or protocol prior to attending virtual or face-to-face Protocol Development Meetings
- Be available to site staff and community representatives to answer questions and provide technical assistance to support community participation in concept and protocol development
- Record CWG participation on study-specific CWG conference calls

It is the responsibility of the Protocol Development Team to:

- Consider input from the HPTN Steering Committee, and from the HPTN CWG, and CABs as provided by the HPTN LOC Community Engagement Program staff, site investigators, and Protocol CWG representative when developing concept plans and throughout the protocol development process
- As needed, join protocol-specific CWG, steering committee or Network CWG calls or meetings to explain the background of the concept, share information (such as peer-reviewed journal manuscripts relevant to the concept), respond to questions and address concerns

5.5.2 Study Implementation

The protocol-specific CWG is actively engaged in study implementation, as described in Section 5.4.1. Much of its work is operationalized through the CEWPs (described in more detail below). The CEWP outlines community education strategies to raise awareness and increase knowledge of general HIV prevention research and HPTN's clinical trials. It also facilitates an assessment of community education needs and enables study teams to implement educational and community entry strategies in support of study implementation.

5.5.2.1 Community Engagement Work Plans and Routine Calls and Meetings

Developing sustained relationships with community members is the responsibility of each CTU PI and CRS leader, as well as the CTU/CRS research and community program staff. CTU/CRS community engagement teams develop and implement a site/study-specific CEWP to ensure broad community support for and participation in the HPTN research agenda. Development of a CEWP prior to study activation serves to:

- Ensure that recruitment and retention plans are developed in conjunction with the site community educators (CE), outreach teams and CAB members
- Inform clinical research staff of potential social harms that may emerge prior to study activation or during implementation and ensure that these social harms are addressed as part of the sites' CEWP

The CEWP should address how the CTU/CRS will provide community education about HIV, HIV prevention research in general and the HPTN research (planned or ongoing) at the site.

The CTU/CRS CEWP should include the following:

- A community assessment that identifies community education needs, potential benefits and barriers to study participation and appropriate educational and community-entry strategies to facilitate the trials
- Measurable goals, objectives and a description of educational strategies to increase community understanding of HIV prevention research; that are responsive to community and ethical questions in the design and implementation of clinical trials; and that address issues specific to CTU/CRS studies
- Methods of monitoring and evaluating the implementation of the CEWP, including whether the objectives have been met
- Suggested budget and justification for CAB-related activities for the upcoming year

HPTN LOC Community Engagement Program staff will request CEWPs for site activation and determine on a case-by-case basis when CTU/CRS community education teams should submit an updated annual CERP. Study phase, target population, and intervention are the criteria that will be considered. HPTN LOC Community Engagement Program staff assigned to the study will communicate the decision about developing and implementing a CERP to the CTU/CRS community engagement teams. The CERP should be developed by the site's community educator with input from CAB members or a similar community advisory body, a CRS leader and a site/study coordinator. The CRS leader, site/study coordinator and CAB Chair (or designee) must approve and sign off on the work plan prior to its submission to the HPTN LOC Community Engagement Program staff (community@hptn.org).

The CTU/CRS community education staff oversee the local implementation of the CERP. The HPTN Leadership expects that each CTU/CRS budget will include financial resources and community engagement staff for the ongoing development, implementation and coordination of community engagement initiatives and the support of community members' participation in the HPTN's activities.

The CTU/CRS community education staff participate in routine conference calls with HPTN LOC Community Engagement Program staff to provide updates on community activities and progress reports on meeting the goals and objectives of the CTU/CRS CERP. Conference calls with the CTU/CRS are a means for:

- The CEs to provide routine updates based on community-program goals and objectives for assessing community activities
- Exchanging information among CTUs/CRSs regarding the successes and challenges of the community-involvement activities

5.5.3 Study Completion, Results Dissemination and Potential Next Steps

As studies near completion, research sites should inform their study participants, CAB members, community partners, key stakeholders and agencies as to when they can expect results, how the results will be communicated and potential next steps. The HPTN LOC Communications Team works with CTUs/CRSs and protocol teams to disseminate the results of the research study. Dissemination efforts should enable any interested community members to learn about the study findings, pose questions and have the opportunity to suggest follow-up studies or additional investigations that might build on the completed work.

Communities should participate in discussions on how to disseminate research results have access to the published results of the study and. When study results are published in journals that are not accessible, sites should provide hard copies of papers upon request. The CTU/CRS community education/recruitment staff and CAB members should be supported and encouraged to develop publications (such as abstracts, manuscripts and posters) describing community efforts that contributed to the successful implementation of the research.