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5 COMMUNITY ENGAGEMENT IN THE HPTN

Clinical research of HIV prevention interventions is 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 research 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 research.

Community, in the context of HPTN research, is defined as the group of people who will participate in, are likely to be affected by, or influence the conduct of the research. The community will include people with lived experiences in the 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 activists interested 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 conceptualized and 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 is integrated at all levels in the HPTN, from concept and protocol development through implementation of the study and dissemination of the results. It is facilitated by the HPTN Leadership and Operations Center (LOC) at many operational levels, at the Network level through a network-wide HPTN Community Working Group (CWG), at the site level through Clinical Trials Units (CTU) and Clinical Research Sites (CRS), and within protocol teams and HPTN Science Committees. 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 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 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 of community representatives through the HPTN CWG
- Consulting with the HPTN 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 Community Engagement Program staff oversee HPTN's community engagement activities. Local engagement is typically done by CRSs with local community partners.

The HPTN Community Engagement Program is also responsible for overseeing stakeholder engagement, in collaboration with CTU/CRS community program staff, HPTN Communications Team, study leadership, and civil society/advocacy group representatives. Whenever community consultations for a specific protocol are undertaken, it is crucial that study leadership and the HPTN clinical research managers are 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 HPTN Community Engagement Program staff or CWG may engage national stakeholders whose reach goes beyond their local community.

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

- Ensuring a HPTN Community Program Manager and at least one HPTN 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
- Supporting the development of CRS Community Engagement Work Plans (CEWP)
- Developing mechanisms for sharing experiences, lessons learned and best practices for community involvement in research
- Coordinating trainings for community staff, CAB members, and HPTN 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 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 manage expectations, and communicate study outcomes at the community level

5.3 CTU/CRS Community Programs and Community Advisory Boards

5.3.1 CTU/CRS Community Programs

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 dedicated community education staff to coordinate its 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, mid-year, and end-of-year CEWP reports
- Participation in routine meetings with the HPTN Community Engagement Program staff to provide updates on the status of the goals of the CEWP and the objectives of community engagement program activities for HPTN protocols conducted at their CRS
- 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 sub-CABs to focus on specific HIV prevention modalities or priority populations

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

- Develop a local CEWP that includes community assessment, community education, recruitment strategies, retentions strategies, and support for CABs
- 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; development and implementation of recruitment and retention plans; and the ongoing education of trial participants, researchers and affected communities
- Provide guidance on developing community engagement program budgets
- Advocate appropriate resources for community engagement activities and support for participation in local and network-level capacity-building initiatives

5.3.2 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, retention, and product adherence 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 and guidance 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 Community Engagement Program staff through updates provided during routine virtual meetings, discussions during community site-assessment visits and periodic one-on-one virtual meetings with site community educators.

To protect their autonomy and to reduce possible conflicts of interest, CAB members 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 safeguard proprietary information and shield study participants' privacy.

The CTUs/CRSs are expected to support CAB representatives' participation in virtual and face-to-face HPTN meetings, 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 Clinical Research Managers, Protocol Chairs, protocol team members, and staff from the 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

At the Network level, 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 studies. At the study level, protocol-specific CWGs are established for some HPTN 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 engagement strategies and identifying possible study implementation challenges. Protocol-specific CWGs also assist in the development of communication plans for disseminating information and keeping community members informed of protocol updates. Protocol-specific CWG representatives also assist in the development of protocol-specific educational tool kits, review plans for site-specific community involvement activities, facilitate community preparedness and engagement activities, and support the successful conduct of studies through community-research 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 and external community stakeholders. 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, HPTN leadership and HPTN Scientific Committees.

At the HPTN leadership level, one of the two HPTN CWG Co-Chairs serves as a voting member on the HPTN Executive Committee (EC), and both Co-Chairs participate in HPTN EC virtual and in-person meetings.

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

HPTN leadership ensures community engagement is integrated throughout concept and protocol development. Community educators, CAB members, and CWGs work together to bring community perspectives into the research process, provide feedback on study materials, support informed consent development, advise on recruitment and retention strategies, and help address ethical and operational issues. They also serve as communication bridges between research teams and local communities.

CAB and CWG members should be involved early to ensure study materials are understandable and culturally appropriate. Their input is especially important for informed consent, comprehension procedures, incentives, and participant engagement strategies.

HPTN CWG Co-Chairs coordinate concept review and incorporate community feedback before submitting recommendations. Site investigators and community educators partner with CABs by including them in discussions, meeting regularly, and reviewing key protocol sections together.

The HPTN Community Engagement Program staff support this process by participating in protocol meetings, reviewing community feedback, facilitating follow-up discussions, and providing technical assistance.

The protocol development team considers input from leadership, CWGs, CABs, and CE staff throughout development and joins meetings as needed to explain concepts, share background information, and address questions.

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 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/protocol-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, 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, and the planned or ongoing HPTN research 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 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 CEWP. Study phase, target population, and intervention are the criteria that will be considered. HPTN Community Engagement Program staff assigned to the study will communicate the decision about developing and implementing a CEWP to the CTU/CRS community engagement teams. The CEWP 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 Community Engagement Program staff (community@hptn.org).

The CTU/CRS community education staff oversee the local implementation of the CEWP. 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 virtual meetings with HPTN Community Engagement Program staff to provide updates on community activities and progress reports on meeting the goals and objectives of the CTU/CRS CEWP.

Virtual meetings with the CTU/CRS are a means for:

- The community educators 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 of the timeline for results dissemination, how the results will be communicated, and potential next steps.

The HPTN 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 digital or 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.