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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 group from which study participants will come (e.g., a specific group of women at risk for HIV who use the services in a family planning clinic or people who inject drugs in a certain location). 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 can and should 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.

Community participation is solicited at all levels of HPTN operations, including at the Clinical Research Site (CRS), on protocol teams, Network Scientific Committees, Working Groups, cross-Network relationships and Community Partners. The HPTN supports partnerships between the community and researchers in research design, implementation, and dissemination of study information. Partnerships at sites are the foundation of the HPTN community program. 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.

The HPTN is committed to:

- Conducting ethical research of the highest scientific quality that is informed by community input
- Supporting local community education and building community partnerships at HPTN sites
- Supporting activities and infrastructure to build and sustain the community-research partnership
- Developing leadership, through the Community Working Group (CWG), to advise the Network on cross-cutting community issues
- Providing technical assistance and support to Network and CRS community activities through the Leadership and Operations Center (LOC) Community Involvement Program (CIP) staff
- Responding to concerns and misconceptions arising from study participants and communities, as needed

To support the goal of building community programs and partnerships at the HPTN sites, the HPTN encourages sites to have dedicated staff time available for coordination of the CRS community participation programs. The LOC CIP staff works closely with CRS community staff to develop local community involvement work plans that include community assessment, community education, support of CABs and other mechanisms for community input (see Section 5.1 for more details). LOC staff assists CRSs in community orientation and training, and facilitation of community input into protocol development and study implementation. Oversight, operational management, and technical assistance are also provided for CRS community program staff in the development and dissemination of

educational materials, the development of collaborative partnerships, and the ongoing education of trial participants, researchers, and affected communities. LOC CIP staff provides guidance to CRSs in the development of community program budgets and advocate for the inclusion of appropriate technology for participation by community members from the site in the Network (e.g., telephone and computer access; support for CAB member participation in local, regional, and international meetings; and training opportunities). The LOC CIP staff also support the CWG.

At the CRS level, the CRS Principal Investigator (PI) is responsible for supporting a community program that elicits involvement of community representatives in the design, development, implementation, and dissemination of results for HPTN studies. The program will include:

- Support from the CRS core budget for adequate staff and funding for a CRS community involvement program
- Development and submission of an annual CRS community involvement work plan
- Submission of routine reports on community activities per the community involvement work plan
- Adequate financial, logistical, administrative and infrastructure support for development or enhancement of CRS community advisory structures capable of working autonomously to determine their priorities, methods of organization, and activities, including the convening of routine meetings between site investigators, study staff, and the CAB for exchange of information on study progress and plans and community issues and questions.

The HPTN also ensures cross-Network community participation through its relationship with community partners. Elected site community representatives and LOC CIP staff participate on monthly conference calls to collaborate in identifying and developing programs to meet the training and support requirements of local CABs, increasing the representation and participation of community members from resource-limited settings and vulnerable populations, and identifying and addressing challenges to participation in clinical trials.

5.1 CRS Community Involvement Work Plans and Report

Developing sustained relationships and communication with community members is the responsibility of each CRS PI and assigned CRS research and community program staff. Each CRS will develop and implement a site-specific community involvement work plan to ensure broad community support for, and participation in, the HPTN. The [work plan guidance and template](#) can be found on the [HPTN website](#). The work plan will address how the CRS provides community education about HIV, HIV prevention research in general, and HPTN research, planned or ongoing, at the site.

The CRS community involvement work plan includes:

- A community assessment that identifies community education needs, potential benefits and barriers to study participation, and appropriate educational strategies
- Goals, objectives, and a description of educational strategies to increase community understanding of HIV prevention research, community and ethical questions in the design and implementation of clinical trials, and information and issues specific to studies at the CRS
- Methods of monitoring and evaluating implementation of the work plan, including whether objectives have been met

The CRS investigator, site/study coordinator, and CAB Chair (or designee) must sign off on the work plan prior to submission to LOC CIP staff as documentation that they were involved in its preparation and/or know and concur with its contents.

The CRS community education staff oversees the local implementation of the community involvement work plan. The HPTN leadership has suggested that each CRS budget includes financial and human resources for the ongoing development, implementation, and coordination of community education initiatives, and the support of community members' participation in HPTN activities.

CRS participating in HPTN research will report their community education activities during either monthly protocol team or CWG teleconferences. These calls will be used to:

- facilitate learning across sites by providing a mechanism to share experiences, best practices, and strategies;
- help to more quickly identify and address challenges (misconceptions and/or barriers to recruitment, enrollment, retention and adherence);
- provide the HPTN Community Program staff at the LOC with timely progress reports and updates that can be shared with the protocol chair/team; and
- allow the HPTN Community Program staff at the LOC to identify community-related technical assistance needs at sites.

5.2 CRS Community Advisory Boards

Typically, the CRS obtains community input into the research process through CABs, although a CRS may refer to this structure by any locally chosen name or establish an alternative structure. Community representatives provide input to protocol teams, particularly in adapting sample consent forms for local use and in developing other study materials.

The community involvement work plan should be developed with CAB (or similar community advisory) input, describing how CAB members are selected and how the CAB functions. For CRSs with an alternative mechanism for community input, the work plan should describe how the CRS obtains appropriate community input. The LOC must pre-approve any CRS community involvement work plan that does not include a CAB.

CAB and other advisory activities will be reported by the CRSs through reports on community involvement.

To ensure CAB autonomy and to reduce the potential for conflict of interest, CAB members are volunteers from the CRS community and are not paid staff members at the CRS. In order to serve on a CAB, members agree to certain terms of membership, generally having to do with roles, responsibilities, and meeting attendance. CAB members are expected to participate meaningfully so that issues requiring community dialogue can receive appropriate attention.

CAB members and community partners involved in the review of a protocol and related documents may be asked to sign a statement of confidentiality to ensure confidentiality of proprietary information and to protect CAB members and study participants from HIV-related stigma.

In-person meetings facilitated by CRS staff provide opportunities for CAB members to share their community expertise and gain new skills. Compensation for CAB members should be offered to offset legitimate costs of participation in the advisory process, such as reimbursement for transportation and meals and other reimbursements that are deemed appropriate at the local level but that do not include payment. Leadership, Central resource staff and protocol team members, can be available to participate in CAB meetings when on site. CRSs are encouraged to support representative CAB members' participation in HPTN meetings and trainings.

Local and Network-wide community education efforts include strategies to increase researchers' and staff members' knowledge of community participation and to foster strong partnerships between researchers and the community. These partnerships support research that is relevant to the community, appropriate plans for recruitment/retention, and dissemination of study findings to the community. CAB members work with site and study staff to lay the foundation for a viable research program by representing and speaking for the community. As volunteers, CAB members and other community representatives are not responsible for recruitment of study participants.