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6. COMMUNITY PARTICIPATION IN THE MTN

Clinical trials of HIV prevention interventions are more likely to succeed when all stakeholders—study participants, researchers, government, nongovernmental 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 is imperative for successful scientific and ethical conduct of Microbicide Trials Network (MTN) trials during the research process and beyond.

Within the context of MTN research, “community” 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 are chosen (i.e., a specific group of women at risk for HIV who use services in a family planning clinic). 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.

Community participation is solicited at many operational levels, including from the Clinical Trial Units (CTUs) and their accompanying Clinical Research Sites (CRSs), protocol teams, the Community Working Group (CWG), and Network committees. The MTN supports partnerships between the community and researchers in research design, implementation, and dissemination of study information. CRS researchers work with and rely on the CRS Community Advisory Boards (CABs) to represent the participant community and raise issues and/or concerns regarding and affecting the research and the community. In addition, a community perspective is solicited on all key MTN committees and working groups through inclusion of community representatives, such as a member of the CWG and/or a CORE (FHI) Community Program staff member. At the Network 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.

The MTN is committed to:

- conducting ethical research of the highest scientific quality that is supported and informed by local community input;
- supporting local community education and building community partnerships at MTN study sites, including 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 Network on cross-cutting community issues;
- providing technical assistance and support to Network and CRS community activities through CORE (FHI) Community Program staff;
- ensuring community consultation and input into the research agenda, from concept and protocol development to the dissemination of study results; and
- responding to concerns and misconceptions arising from study participants and communities, as needed.

To support the goal of building community programs and partnerships with local communities, the MTN Leadership expects a minimum level of dedicated community education staff time at each site for coordination of the CRS community participation program. The CORE (FHI) Community Program staff work closely with CRS community staff to develop local community involvement work plans that include community assessment, community education, and support of CABs and other mechanisms for community input (see Section 6.3). The CORE (FHI) Community Program staff assist CRSs in community orientation and training, facilitation of community input into protocol development (see Section 6.2), and clinical trial conduct/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. The CORE (FHI) Community Program staff provide guidance to CRSs on the development of community program budgets and advocate for appropriate technology that would allow for participation by community members from the site in the Network (i.e., telephone and computer access; support for CAB member participation in local, regional, and international meetings; and training opportunities). The CORE (FHI) Community Program staff also support the CWG. The CORE (University of Pittsburgh [PITT]), through the Director of Communications and External Relations, works closely with CRS staff, including community staff, to develop programs for engaging news media and advocacy and activist organizations (see Section 7.3).

At the CRS level, the CRS leader is responsible for supporting a community program that elicits involvement of community representatives in the design, development, implementation, and dissemination of results for MTN studies. The program will include:

- solicitation of input from Community Educators/Liaisons on funding needs to implement CAB-related activities on an annual basis;
- support from the CRS core budget for adequate community education staff and funding for a CRS community program;
- development and submission of an annual CRS Community Involvement Work Plan;

- submission of bi-monthly reports on community involvement program activities and an update on the status of work plan goals and objectives; and
- support for development or enhancement of CRS community advisory structures capable of working autonomously to determine their priorities, methods of organization and activities.

6.1 MTN Community Working Group (CWG)

The MTN CWG is a group of site-based community representatives and advocacy group representatives who provide consultation on and input into the MTN's efforts to ensure community involvement in its research agenda at the site and leadership levels. Its mission is to conduct community preparedness and engagement activities to ensure the successful conduct of MTN studies. See Section 4.2.3 for information on the membership and objectives of the CWG.

6.2 Community Involvement in Concept/Protocol Development

It is important to engage the community at the concept/protocol development stage of the research. The following defines the responsibilities of various members of the research team and community representatives in engaging the community in the concept/protocol development processes.

The MTN CWG and CAB members share the following responsibilities:

- Attempt to fill gaps in knowledge and/or expertise
- Provide real-life experiences when engaging the community
- Provide input about community/study participant concerns, beliefs, and norms, in conjunction with the site staff
- Consider the input of scientists when developing concept plans and protocols
- Advise the site research team and MTN Protocol Team in the development of informed consent forms and other study-related documents
- Participate in the development and implementation of study participant recruitment and retention strategies
- Suggest strategies to address ethical and operational aspects of study conduct
- Serve as a resource to the community liaison officer/community educator and the research team
- Share information, questions, and concerns with local CAB members, CORE (FHI) Community Program staff, and the CWG
- Function as a conduit of information between the site and potential research communities (i.e., 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 CORE (FHI) Community Program staff and ensure a complete feedback loop in terms of information flow
- Provide protocol development updates to fellow community representatives at the site or Network level
- Provide written feedback concerning concepts and protocols via an on-line questionnaire

Responsibility of the MTN PI includes:

- Ensure the Network's adherence to community participation in all aspects of the research process

Responsibilities of Concept and Protocol Teams include:

- Consider the input of community representatives when developing concept plans and protocols
- Share information, questions, and concerns with CORE (FHI) Community Program staff and the CWG

Responsibility of the CTU PI includes:

- Include sufficient funds in site annual budget request to support participation of community representatives in protocol development (i.e., local transportation costs or the cost of participation in conference calls)

Responsibilities of Site Investigators, study-specific Investigator of Record, Community Educators/CAB Coordinators/Community Liaison Officers, and other site staff in partnering with the community representative include:

- Via face-to-face meetings, provide information about the concept/protocol and general research that is easily comprehensible
- Meet with community representatives to discuss and obtain feedback on concepts/protocols throughout the development process
- Include community representatives in concept/protocol team conversations and communications regarding protocol development (i.e., facilitate inclusion on the conference calls or e-mail exchanges) to the greatest extent possible

Responsibilities of the CORE (FHI) Community Program staff include:

- Participate on protocol team calls and meetings to clarify the community involvement program process and answer any questions
- Prior to attending face-to-face protocol team meetings, convene with the community representatives and site staff following distribution of the draft concept and protocol to discuss questions, concerns, and suggested changes to the concept or protocol
- Be available to site staff and community representatives to answer questions and provide technical assistance to support community participation in concept and protocol development
- Provide technical assistance and support for community engagement activities at the CRS/CTU level
- Track CRS submission of community involvement work plans (CIWPs) and bi-monthly reports

Because it is important that the community has the opportunity to provide input before defining and translating trial-related terms into local languages and formats that are understandable, the community should be allowed to review the various versions of the protocol during development and implementation.

At a minimum, the community 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; and
- incentives and reimbursements offered as part of study participation.

6.3 CRS Community Involvement Work Plans and Bi-Monthly Reports

Developing sustained relationships with community members is the responsibility of each CTU PI and CRS leader, as well as the CRS research and community program staff. Each CRS community education team will develop and implement a site/study-specific, community involvement work plan (CIWP) to ensure broad community support for and participation in the MTN research agenda. The work plan guidance document, CIWP template, sample CIWP, and the bi-monthly report template can be found on the MTN website (www.mtnstopshiv.org). The CIWP should address how the CRS will provide community education about HIV, HIV prevention research (in general), and MTN research (planned or ongoing) at the site.

The CRS Community Involvement Work Plan should include:

- 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;
- 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 the objectives have been met; and
- suggested budget and justification for CAB-related activities for the upcoming year.

The CIWP should be developed by the site's community educator with input from the CAB or similar community advisory body, CRS leader, and 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 submission to CORE (FHI) Community Program staff (mtncwleaders@mtnstopshiv.org).

Any site receiving funds to conduct MTN research, regardless of whether there is an active MTN study being conducted, is expected to submit a CRS Community Involvement Work Plan.

The CRS community education staff oversee the local implementation of the CIWP. The MTN Leadership expects that each (U.S. and non-U.S.) CRS budget will include financial resources and community education staff for the ongoing development, implementation, and coordination of community education initiatives and the support of community members' participation in MTN activities.

Local and Network-wide community involvement efforts include strategies both to increase researchers' and staff members' knowledge of community participation and to foster strong researcher-community partnerships. These partnerships support community-relevant research, appropriate plans for recruitment/retention, and dissemination of study findings to the community. CAB members work with study staff to lay the foundation for a viable research program by representing and speaking for the community. Community education/recruitment staff are directly responsible for the recruitment of study participants. However, CAB members and other community representatives indirectly influence recruitment.

CRSs are responsible for submitting bi-monthly community reports to CORE (FHI) Community Program staff (mtncwgleaders@mtnstopshiv.org) to provide an update on the progress of meeting work plan objectives. Reports from the CRS provide:

- bi-monthly updates based on community program goals and objectives to assess community activities;
- an outline for community educators to update the CAB and CORE (FHI) Community Program staff; and
- a mechanism for information exchange between CRSs regarding successes and challenges to their community involvement activities.

6.4 Community Involvement in Study Implementation

Investigators should allow community representatives to provide input with respect to improving research participants' study involvement experience. Protocol amendments must be clearly presented to community advisors, as well as any subsequent changes in the existing consent materials.

6.5 Community Involvement in Study Completion, Results Dissemination, and Potential Next Steps

As studies are nearing completion, research sites should inform study participants, CAB members, community partners, and agencies about when to expect results, how the results will be communicated, and the nature of any potential next steps.

CORE (FHI and PITT), through the Director of Communications and External Relations, work with CRSs and Protocol Teams to make plans for timely dissemination of appropriate information in settings where a wide variety of community partners, including participants and/or local community groups, can be informed about 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 other additional investigations that might build on the completed work.

Communities should participate in discussions about how to disseminate research results. Communities should have access to published results of the study. When study results are published in journals that are not open access, sites should provide hard copies of papers upon request.

6.6 MTN Community Advisory Boards (CABs)

The CRS usually 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 reviewing protocol development, adapting sample consent forms for local use, and developing other study-related materials.

CAB activities will be reported to CORE (FHI) Community Program staff by the CRSs through submission of CAB meeting agendas, through attendance rosters and documentation on bi-monthly reports, through discussions during community site assessment visits, and through periodic one-on-one calls with site community educators.

To ensure CAB autonomy and to reduce the potential for conflicts of interest, CAB members are volunteers from the CRS community and are not paid staff members at the site. To serve on a CAB, members adhere to CAB by-laws and governance regarding 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 review of the protocols and related documents should sign a statement of confidentiality to ensure confidentiality of proprietary information and to protect members and study participants from HIV-related stigma.

CRSs allow CAB members to share their community expertise and gain new skills through participation in face-to-face meetings and conference calls. CAB members should be offered reimbursement for legitimate costs associated with participation in the advisory process, such as for transportation, childcare, and meals, at a level deemed appropriate by the individual CRS, and should not be construed as payment. CRS staff and other MTN members (i.e., CORE [FHI], protocol team members, the Statistical and Data Management Center, or the Network Laboratory) conducting training or assessment visits at study sites are available to participate in CAB meetings as needed. CRSs are encouraged to support representative CAB members' participation in MTN meetings, protocol-specific training, and regional community workshops.