

MTN Manual of Operational Procedures (MOP)

Section 7: Community Engagement

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7. Community Engagement

Clinical trials of HIV prevention interventions are more likely to succeed when stakeholders — study participants, researchers, government, nongovernmental organizations, service providers, community leaders, advocates and study communities — regard the trials as relevant and the process as collaborative. An aware, knowledgeable and engaged community is imperative for the successful scientific and ethical conduct of Microbicide Trials Network (MTN) trials during the research process and beyond.

Within the context of MTN's research, *community* is defined as the group of people who are most likely to participate in, be affected by or influence the conduct of the research. The community may include the group or population from which study participants are chosen. It may also include the broader geographic community in which the study is 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 the research findings back to the community in a manner that is relevant and meaningful.

7.1 Overview

Community engagement on behalf of the MTN is facilitated at many operational levels, including through Clinical Trials Units (CTU) and CTU-affiliated Clinical Research Sites (CRS), protocol teams, the MTN Community Working Group (CWG), MTN resource committees and the MTN Leadership and Operations Center (LOC) [(FHI360) Community Engagement Program and the

University of Pittsburgh (Pitt)]. The MTN 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 (CAB) to represent the participant community and raise issues and/or concerns regarding and affecting the research and the community. In addition, the inclusion of a representative of the CWG and/or MTN LOC (FHI 360) Community Engagement Program) staff on key MTN committees, working groups and on each protocol team ensures that a community voice and perspective are considered in all deliberations.

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

- Conducting research that is ethical, of the highest scientific quality and supported and informed by input from local communities
- Supporting local community engagement and building community partnerships at MTN 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 MTN on cross-cutting community issues
- Providing technical assistance and support to MTN and CRS community activities through the LOC (FHI 360) Community Engagement Program staff
- Ensuring community consultation and input into the research agenda, from development of the concept and protocol to dissemination of study results
- Responding to concerns and misconceptions arising from study participants and communities as needed

7.2 MTN Community Engagement Program

Local and MTN-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 MTN LOC (FHI 360) Community Engagement Program staff oversee MTN's community engagement activities. The MTN LOC (Pitt) is responsible for overseeing national and global stakeholder engagement, often in collaboration with CTU/CRS community program staff, civil society leaders and organizations, and the MTN LOC (FHI 360) Community Engagement Program. Specifically, the Community Engagement Program staff are responsible for the following:

- Ensuring an MTN LOC (FHI 360) 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 MTN study sites
- Developing mechanisms for sharing experiences, lessons learned and best practices in community involvement in research
- Facilitating training for community staff, CAB members and the CWG focused on relevant topics and needs for capacity building

- Participating in and facilitating the CWG

7.3 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 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 MTN studies. In this regard, MTN 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 program to support study-related community engagement plans
- Participation on routine conference calls with the MTN LOC (FHI 360) 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 work 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 MTN LOC (FHI 360) 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 (see Section 7.2)
- Assist the CTUs/CRSs in community orientation and training, facilitation of community input into protocol development (see Section 7.2) 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 program budgets
- Advocate for appropriate resources for community engagement activities and support for participation in local and network-level capacity-building initiatives

7.3.1 CTU/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 MTN LOC (FHI 360) 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 MTN 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 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 MTN LOC (FHI 360) Clinical Research Managers, Protocol Chair(s) and protocol team members. Staff from the MTN Statistical and Data Management Center or Laboratory Center should also avail themselves when at a site for training, assessment visits or any other MTN-related business.

7.4 MTN Community Working Group

The MTN CWG is a group of site-based community representatives (both community education staff and CAB members), CWG Chair, and advocates who provide consultation on and input into MTN'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 MTN's studies.

The group is responsible for enhancing protocol-specific community strategies and identifying possible study implementation challenges. Goals of the CWG are to:

- Assist in the development of study-specific educational toolkits and communication plans for disseminating information intended:
 - to keep community members informed of protocol updates, site-specific community involvement activities, MTN leadership and community partners' decisions and discussions
 - to facilitate community preparedness and ongoing engagement activities and ensure the successful conduct of studies through partnerships

CWG membership includes voting and non-voting members:

- Voting Members
 - MTN CWG representatives from each CTU/CRS participating in the protocol (one CTU/CRS community educator and one CTU/CRS CAB representative)
- Non-Voting Members
 - MTN LOC (FHI 360) Community Engagement Program staff

7.5 Community Engagement in the Research Process

7.5.1 Study Concept/Protocol Development

The MTN PI ensures MTN's commitment to community engagement in the study concept/protocol development stage and throughout all aspects of the research process. Likewise, CTU/CRS Community Education Program staff, CAB members and the study-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
- Advise the site research team in the development of informed consent forms and other study-related materials, such as fact sheets and backgrounders
- 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 others, i.e., local CAB members, the MTN LOC (FHI 360) 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 MTN LOC (FHI 360) Community Engagement Program staff, among others, and ensure a complete feedback loop for information flow

7.5.2 Community Engagement Routine Conference Calls

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.

7.5.3 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 MTN LOC (Pitt) Communications and External Relations Team, together with the MTN LOC (FHI 360), 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 suggest follow-up studies or additional investigations that might build on the completed work.

Communities should have access to the published results of the study and participate in discussions on how to disseminate research results. 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. See Section 19 of this Manual for more information about results dissemination planning and activities.