

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 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. At the MTN 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 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
- 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 CWGs focused on relevant topics and needs for capacity building
- Participating in and facilitating the Community Resource Working Group (CRWG), MTN-wide CWG and study-specific CWGs
- Working with the MTN LOC (Pitt) Communications and External Relations 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 to manage expectations and communicate study outcomes at the community level

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
- Development and submission of an annual CTU/CRS CEWP
- 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, periodic one-on-one calls with site community educators, and during annual MTN CWG meetings.

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) 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. Study-specific CWGs (see Section 7.4.2) are established for many of MTN's studies.

7.4.1 MTN Community Resource Working Group

The membership of the MTN CRWG consists of the following:

- CWG Co-chairs (2)
- Network Evaluation Committee (NEC) CWG representative

- CWG Ethics representative
- At-large MTN CTU/CRS CAB members (2)
- CWG members named to represent MTN on Community Partners (4)
- MTN LOC (FHI 360) Community Engagement Program staff
- MTN LOC (University of Pittsburgh [Pitt]) Communications and External Relations representative
- MTN LOC (Pitt) representative
- DAIDS Community Liaison
- Behavioral Research Working Group (BRWG) Liaison
- Biomedical Science Working Group (BSWG) Liaison

The group provides guidance and support to the MTN CWG and advises MTN Leadership on matters concerning community engagement in all aspects of MTN's research agenda. The MTN CRWG serves as a conduit of information between the MTN CWG and MTN Leadership and other MTN working groups. See Section 4.2.3 of this Manual for further information on the CWG and CRWG's mission, goals, membership and structure.

7.4.2 Study-Specific Community Working Groups

Study-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. The goals of the study-specific CWGs are to:

- Ensure the development of a CEWP prior to study activation and the submission to MTN LOC (FHI 360) Community Engagement Program staff
- 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 and EC and community partners' decisions and discussions
 - to facilitate community preparedness and ongoing engagement activities and ensure the successful conduct of studies through partnerships

Study-specific CWG membership includes voting and non-voting members:

- Voting Members
 - MTN CWG Co-Chairs
 - 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
 - Ethics representative
 - Advocacy representatives
 - DAIDS community liaison

7.5 Community Engagement in the Research Process

7.5.1 Study Concept/Protocol Development

The MTN PI and co-PI ensure 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
- 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 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
- 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 MTN LOC (FHI 360) Community Engagement Program staff

CAB members as representatives of their communities, and members of the study-specific 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 MTN CWG Co-Chairs to:

- Submit concepts to the MTN CRWG and include the deadline and instructions for providing feedback
- Consider the MTN CRWG's feedback about concepts in preparation for submitting votes to the MTN Leadership

It is the responsibility of the Site Investigators, study-specific Investigators of Record, community educators/CAB coordinators/Community Liaison Officers 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 face-to-face CAB meetings immediately following the distribution of protocol Version 0.1 to the protocol team 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)

It is the responsibility of the MTN LOC (FHI 360) Community Engagement Program staff to:

- Participate in protocol development meetings and provide input to the protocol from the community perspective, along with a CWG member (if available)
- Participate in protocol team calls and meetings to clarify the community engagement program and answer any questions
- Participate in Sample Informed Consent calls during protocol development
- 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 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
- Track CWG participation on protocol team and study-specific CWG conference calls

It is the responsibility of the MTN LOC (Pitt) Protocol Development Team to:

- Consider input from the CRWG, and from the MTN CWG, and CABs as provided by the MTN LOC (FHI 360) Community Engagement Program staff, site investigators, and Protocol CWG representative when developing concept plans and throughout the protocol development process
- Join study-specific CWG, CRWG or full MTN CWG calls or meetings, if requested, 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

- Submit suggested questions, as needed or requested, to the MTN LOC (FHI 360) Community Engagement Program staff to obtain community feedback from CTU/CRS community stakeholders on study related topics
- Incorporate community feedback during the creation of the sample informed consent forms

7.5.2 Study Implementation

The study-specific CWG is actively engaged in study implementation, as described in Section 7.4.2. Much of its work is operationalized through the CEWPs (see 7.5.2.1). The goals of the CEWP are to build community support for MTN's research agenda, encourage participation in the development of the research agenda, and encourage community engagement in study-specific implementation activities. The CEWP outlines community education strategies to raise awareness and increase knowledge of general HIV prevention research and MTN'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.

7.5.2.1 Community Engagement Work Plans and 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. CTU/CRS community education teams develop and implement a site/study-specific CEWP to ensure broad community support for and participation in the MTN 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 work plan guidance document, CEWP template and a sample CEWP can be found on the MTN website (<http://www.mtnstopshiv.org/node/6741>). The CEWP should address how the CTU/CRS will provide community education about HIV, HIV prevention research in general and the MTN 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
- 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

MTN LOC (FHI 360) Community Engagement Program staff will consult with the MTN CRWG to decide on a case-by-case basis when CTU/CRS community education teams should submit a CEWP. Study phase, target population, and intervention are the criteria that will be considered.

MTN LOC (FHI 360) Community Engagement Program staff assigned to the study will communicate the decision about developing and implementing a CEWP to the CTU/CRS community education 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 MTN LOC (FHI 360) Community Engagement Program staff (mtncwgleaders@mtnstopshiv.org).

The CTU/CRS community education staff oversee the local implementation of the CEWP. The MTN Leadership expects that each (U.S. and non-U.S.) CTU/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 the MTN's activities.

The CTU/CRS community education staff participate in routine conference calls with MTN LOC (FHI 360) Community Engagement Program staff to provide updates on community activities and progress reports on meeting the goals and objectives of the CTU/CRS CEWP. Conference calls with the CTU/CRS community education staff are a means for:

- Staff 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

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.