Purpose

To define procedures for recruiting and determining the eligibility of (potential) participants, for MTN-041.

Scope

This SOP applies to all staff involved in conducting and/or overseeing participant recruitment and eligibility confirmation for MTN-041.

Responsibilities

*[MTN-041 staff members delegated by the Investigator of Record to conduct MTN-041 recruitment]* are responsible for understanding and following this SOP. In the remainder of this SOP, such staff are referred to as “Recruitment Staff.”

*[MTN-041 Study Coordinator, Recruitment Coordinator or other designee]* is responsible for training study staff to recruit potential participants and/ or confirm participant eligibility for MTN-041, in accordance with this SOP, and for day-to-day oversight of recruitment staff and staff involved in eligibility determination.

*[MTN-041 Study Coordinator, Recruitment Coordinator or other designee]* are jointly responsible for tracking participant contacts and monitoring and documenting screening and enrollment rates. These staff members will work with recruitment staff to increase the frequency of participant contact or modify recruitment strategies as needed in order to meet site-specific participant accrual targets, thus ensuring that site goals are met within the accrual time period.

*[MTN-041* *staff members delegated by the Investigator of Record per the Delegation of Authority log]* to perform eligibility determination and/or confirmation procedures for MTN-041 are responsible for understanding and following this SOP.

MTN-041 Investigator of Record has ultimate responsibility for ensuring that all applicable MTN-041 staff adhere to this SOP, and that only participants who meet the protocol-specific eligibility criteria for MTN-041 are enrolled in the study. The Investigator of Record also has ultimate responsibility for ensuring that MTN-041 participant accrual targets are met.

Procedures

1. **Community Sensitization Plans** 
   1. *[Sites to include details, as applicable, for any community sensitization plans. For example, will any meetings with CAB members be held?* *If so, what will be the goal of this/these meetings (e.g. to generate list of stakeholders, to seek input on recruitment locations and/or strategies for engaging target study population for community (FGD participants and key informant (IDI) participants)?]*
2. **Accrual Targets and Timelines** 
   1. **Accrual Targets:** Each MTN-041 site will enroll approximately a total of 60 men and women. MTN-041 SSP Section 3: Accrual and Eligibility Determination provides details on the number and types of FGDs/IDIs to be conducted by each site. In sum:
      * Approximately **50 participants will be enrolled in focus group discussions (FGDs),** including:
        + HIV-uninfected women aged 18-40 who are currently pregnant or breastfeeding, or who were pregnant or breastfeeding within the previous two years (hereafter referred to as “P or BF Women”)
        + Men aged 18 or older whose partners are currently pregnant or breastfeeding, or whose partners were pregnant or breastfeeding within the previous two years (hereafter referred to as “Male Partners”)
        + Maternal and paternal grandmothers whose daughters or daughters-in-law are currently pregnant or breastfeeding, or were pregnant or breastfeeding within the previous two years (hereafter referred to as “Grandmothers”)
      * Up to **10 in-depth interviews (IDI)** with individual key informants will be conducted, including persons who:
        + Currently work as a clinician (e.g., obstetrician, nurse, pharmacist, etc.), traditional care provider (e.g., TBA, healer, midwife, etc.), social service provider (e.g., social worker, family planning counselor, etc.) or community health worker in one of the study countries, verified per site SOPs.
        + Currently acts in a community leadership role (e.g., local chief, religious leader, etc.).
   2. **Accrual Timelines:** Accrual should be completed approximately 3-6 months from the time the first participant is enrolled at each site.
      * *[Sites to outline in this section how they plan to meet protocol specified accrual timelines. Plans should be specific (e.g. state how many FGDs and IDIs will be targeted to be scheduled within a certain timeframe of activation), yet allow for flexibility in recruitment pacing as needed.]*
3. **Recruitment Activity:**
   1. This section details potential recruitment strategies relevant to each key study population (P or BF Women, Male Partners, Grandmothers, and Key Informants) for MTN-041.
      * **Potential recruitment locations and venues**: *[Sites to include details here about what recruitment locations and venues will be targeted for MTN-041. Include details relevant to each study group type as bulleted below.]*
        + P or BF Women:
        + Male Partners:
        + Grandmothers:
        + Key Informants: *[Sites to specify details for recruitment of KI. See Section 2.1 of this SOP for a list of KI types for possible inclusion.]*
      * **Plans for education about the study:** *[Site to include details here about how participants will be educated about the study. Include any information about materials for study education as appropriate. If education about the study will vary depending on study group or interview type, include details here.]*
      * **Description of presumptive eligibility evaluation activities** **(as applicable):***[If applicable, site to describe any plans for evaluation of presumptive eligibility prior to scheduling participants for screening /enrollment visits. Include any information about eligibility evaluation tactics /checklists that may be used, as appropriate. Note that minimal eligibility evaluation tactics are encouraged for MTN-041, as inclusion criteria are simple and formal eligibility determination must take place after a participant has provided IC and before his/her enrollment into the trial.]*
      * **Plans for referral to screening visits** (and how ineligible participants will be handled):*[Include details here about how participants will be scheduled for screening/enrollment visits and what procedures will be taken in the field should a participant be determined unsuitable for enrollment. Include any information about materials to be used, as appropriate (e.g. clinic contact card or appointment card)]*
   2. All written recruitment and participant information materials will be reviewed and approved by all responsible IRBs/ECs prior to their use (See Site SOP XXX-XX, Communication with Responsible IRBs/ECs). *[Note to sites: if your IRBs/ECs also require that other materials such as community education, recruitment scripts and prescreening checklists also be reviewed and approved, specify that here as well.]*
4. **Screening Procedures** 
   1. Potential MTN-041 participants will be booked for their screening/enrollment visit based on study group assignment (P and BF Women, Male Partner, Grandmother, Key Informant) and interview type (FGD/IDI). Participants may complete screening and enrollment visit procedures over multiple visits, as needed. The procedures outlined in SSP Section 3 related to participant screening and enrollment should be followed.
      * *[Sites to include any pertinent details here related to booking screening and enrollment visits. How will participants be booked to ensure there is an ideal number of participants per FGD? If sites plan to routinely split screening and enrollment visit procedures over multiple days (e.g. one visit to provide IC and confirm eligibility for participation in an FGD, followed by a separate visit to conduct the FGD), specify these details here.]*
   2. Written informed consent for screening and enrollment will be obtained by staff as delegated on site DoA logs prior to initiation of any MTN-041 study visit procedures *(see site’s SOP for Obtaining Informed Consent).*
   3. After obtaining written IC, the *[Study Coordinator or designee]* will assign the PTID by completing the PTID-Name Link Log. This document links the participant name to her/his MTN-041 PTID and must be kept in hardcopy and stored *[site to insert location; storage location must be double locked with limited access].*
5. **Determining Eligibility and Enrollment Procedures**
   1. See protocol sections 5.3 and 5.4 for full listing of inclusion/exclusion criteria as well as SSP Section 3: Accrual and Eligibility Determination, which outlines procedures for determining participant eligibility.
   2. The MTN-041 *Behavioral Eligibility Worksheet* should be used to evaluate inclusion and exclusion criteria that rely on participant self-report (see SSP Section 3.1.5 as well as form instructions for further details related to this form). *[Sites to indicate delegated staff]* are responsible for administering this form in the preferred language of the participant.
   3. The MTN-041 *Eligibility Checklist* should be used to document and sign off on final participant eligibility. As delegated on the site MTN-041 DoA log, *[sites to indicate delegated staff]* are responsible for completing this form and for final sign-off of eligibility. Any questions related to eligibility criteria or determination will be directed to the [*insert responsible staff*] for the study.

Further information about source documentation and site-specific procedures for a subset of eligibility criteria are as follows:

* + - **Age Verification Procedures:** *[sites to include here details on age verification procedures as well as source documentation for this criterion]*
    - **Verification of Key Informant (health care providers) role**: *[sites to include here details on and additional verification procedures beyond self-report of the role of the health care provider key informant, as well as source documentation for this criterion.]*
    - **Exclusion for IoR Discretion:** *[sites to include here any relevant details related to how this criterion will be evaluated or documented]*
    - **HIV Status for P or BF Women Cohort**: *[sites to include here any relevant details related to verification of HIV negative status beyond self-report, as applicable – for example, will site make certified copies of health passport, ANC, HIV test card or similar health record? In the event these records are not available, note that per protocol self-report of this criterion is acceptable.]*
  1. The act of completing and signing the eligibility checklist is the act of enrolling participants into MTN-041.
  2. Should study staff identify that an ineligible participant has been inadvertently enrolled, the IoR or designee will contact the MTN-041 Management Team at [mtn041mgmt@mtnstopshiv.org](mailto:mtn032mgmt@mtnstopshiv.org) for guidance on action to be taken.

1. **Tracking and Evaluation Activity**
   1. The site will maintain the following documentation to track accrual information:
      * **Recruitment Logs:** *[Site to insert responsible staff]* will maintain the following information on recruitment logs to document recruitment/field activities for MTN-041. This log will be maintained in hardcopy and stored *[insert where this will be stored]*.
        + Recruitment venue, study group (P or BF Women, Male Partners, Grandmothers, and Key Informants), number of potential participants contacted, number of potential participants scheduled for screening/enrollment visit, date of scheduled screening/enrollment visit
      * **Screening and Enrollment Log**: *[Site to insert responsible staff]* will maintain the following information on screening and enrollment logs for MTN-041. This log will be maintained in hardcopy and stored *[insert where this will be stored]*.
        + MTN-041 PTID, Study Group, Screening date, and Enrollment Date or if not enrolled, reason for not enrolling).
   2. *[Insert staff responsibilities and procedures if maintaining electronic participant tracking database (e.g. for participant scheduling). Include procedures for entering new participants and updating scheduled and actual visit dates.]*
   3. Screening and enrollment information will be sent to RTI on a weekly basis. *[Insert staff responsible for compiling and sending screening and enrollment information.]* This information will be recorded on the Screening and Accrual Tracker provided by RTI. No participant identifiers will be sent to RTI as part of these screening and enrollment updates, only participant PTIDs.
   4. All tracking information as described in this section will be discussed with *[Recruitment Staff]* in *[site to indicate frequency: weekly/biweekly, etc.]* meetings and used as needed to increase the frequency of participant contacts to reach the study accrual goals. Recruitment and screening and enrollment rates and activities will also be discussed with all study staff in monthly staff meetings. *[Site to update accordingly with respect to type and frequency of meetings with which these issues are discussed].*

**List of Abbreviations and Acronyms**

EC Ethics Committee

IRB Institutional Review Board

MTN Microbicide Trial Network

PTID Participant Identification

SOP Standard Operating Procedure

SSP Study-Specific Procedures

*[Insert additional as applicable]*

**Attachments**

Attachment *X*: Recruitment Materials and Methods

Attachment X: Recruitment Log

Attachment X: PTID Name Link Log

Attachment *X*: Screening and Enrollment Log

*[List any additional as needed]*

**References**

MTN-041 SSP Manual Section 3

MTN-041 SOP for Communication with Responsible IRBs/ECs

MTN-041 SOP for Informed Consent

*[List any additional as needed]*

**History**

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Approval

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