Purpose

To define accrual, eligibility determination and informed consent procedures for MTN-045.

Scope

This procedure applies to all site staff involved in accrual, eligibility determination and informed consent procedures for MTN-045 (per Responsibilities section below).

1. *[MTN-045 staff members delegated by the Investigator of Record to perform accrual, eligibility determination and/or informed consent procedures for MTN-045]* are responsible for understanding and following this SOP.
2. [MTN-045 *Study Coordinator, Recruitment Coordinator or other designee]* is responsible for training study staff to determine and/or confirm participant eligibility and conduct informed consent procedures for MTN-045 in accordance with this SOP, and for day-to-day oversight of staff involved in eligibility determination and informed consent administration.
3. *[MTN-045 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.
4. MTN-045 Investigator of Record has ultimate responsibility for ensuring that all applicable MTN-045 staff members follow this SOP, and for ensuring that only participants who meet the protocol-specific eligibility criteria for MTN-045 are enrolled in the study.

**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, voluntary health workers or CBOs 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)?]*
2. **Accrual Targets and Timelines**
   1. SSP Manual Section 3: Accrual, Eligibility Determination and Study Procedures provides details on the study accrual timeline and site-specific accrual targets. *[Sites to outline in this section how they plan to meet protocol-specified enrollment targets and timelines, particularly those outlined in SSP Manual Sections 3.2 and 3.10.1. Plans should be specific (e.g. state how many couples will be targeted for enrolment within a certain timeframe of activation) yet allow for flexibility in recruitment pacing as needed. Ensure roles and responsibilities of relevant staff are included.]*
3. **Recruitment Activity**
   1. This section details potential recruitment strategies relevant to the study population (heterosexual couples) for MTN-045.
      * **Plans for recruiting couples:** *[Sites to include details specific to the recruitment of couples. Describe how potentially eligible couples will be identified and approached for possible inclusion in the study, as well as steps that will be taken to minimize the potential for partner coercion or intimate partner violence (IPV) during recruitment and prescreening. Refer to site IPV SOPs, as needed.]*
      * **Potential recruitment locations and venues:** *[Sites to include details here about what recruitment locations and venues will be targeted for MTN-045. Include details relevant to female and male members of couples, as applicable.]*
      * **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.]*
      * **Description of prescreening/presumptive eligibility evaluation activities (as applicable):** *[If applicable, site to describe any plans for prescreening/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 during prescreening for MTN-045, as inclusion criteria are simple and formal eligibility determination must take place after each member of the couple has provided IC and before their enrollment into the trial.]*
      * **Plans for referral to screening visits** (and how ineligible participants will be handled): *[Include details here about how couples will be scheduled for and reminded of their screening/enrollment visits and what procedures will be taken in the field should a couple be determined unsuitable for enrollment, including unsuitability due to known or suspected partner coercion or IPV. 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 relevant IRBs/ECs prior to use (See Site SOP XXX-XX, Communication with Responsible IRBs/ECs). *[Note to sites: if IRBs/ECs require that other materials such as community education, recruitment scripts and prescreening checklists also be reviewed/approved, specify that here as well.]*
4. **Screening and Informed Consent Procedures**
   1. Potential MTN-045 participants will be booked for their screening/enrollment visit together as a couple. Ideally, participants will complete screening and enrollment visit procedures in one day, however screening and enrollment procedures may be conducted over multiple visits, as needed. The procedures outlined in SSP Manual 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. Will any special arrangements or procedures be conducted to ensure couples screen and enroll at the same time? If sites plan to routinely split screening and enrollment visit procedures over multiple days (e.g., one visit to obtain IC and confirm eligibility for participation, followed by a separate visit to perform study procedures and/or conduct IDIs), specify these details here.]*

* 1. *[Note: Sites may choose to include MTN-045-specific informed consent procedures here, or issue an addendum to their standalone, site-specific SOP for Informed Consent Procedures. Issues specific to MTN-045 include procedures for conducting part of the IC process with couples together, if applicable, as well as procedures to ensure that IC is obtained in a setting free of coercion and undue influence as it relates to consenting of a couple. See SSP Manual Section 4.3 (Informed Consent) for a full listing of required elements for IC SOPs.]*
  2. Certain components of the IC process, including describing the steps of the IC process, determining presumptive eligibility and reviewing the informed consent form, may be done with both members of the couple together or with each member of the couple individually. Administration of the IC comprehension assessment, discussing participant questions related to IC, and obtaining signatures on the ICF will be done with each member of the couple individually, away from their partner. As part of the individual consent process, study staff should confirm with the participant that their participation in the study is voluntary and their choice alone. Should the participant decline to partake for matters related to their relationship (such as coercion), staff should discuss this with the participant and come to an agreement with them about how study staff will communicate the couple’s ineligibility to their partner. For further details, refer to SSP Manual Section 4: Informed Consent. *[If applicable, sites to detail any further considerations related to administering IC to individuals and couples.]*
  3. After obtaining written IC, the [Study Coordinator or designee] will assign each member of the couple a PTID by completing the PTID-Name Link Log. This document links the participant name to her/his MTN-045 PTID and must be kept in hardcopy and stored *[site to insert location; storage location must be double locked with limited access]*.

1. **Eligibility Determination and Enrollment Procedures**
   1. See protocol sections 5.3 and 5.4 for the full list of inclusion/exclusion criteria as well as SSP Manual Section 3: Accrual and Eligibility Determination, which outlines procedures for determining participant eligibility.
   2. The MTN-045 Eligibility Checklists (male and female) should be used to evaluate eligibility per the study inclusion and exclusion criteria (see SSP Manual Section 3 as well as form instructions for further details related to this form). This form should be administered to each member of the couple privately and away from their partner. *[Sites to indicate delegated staff]* are responsible for administering this form in the preferred language of the participant. *[Sites to indicate any special considerations surrounding the ‘dummy’ questions, as well as how potential for coercion from either member of the couple for their partner to join will be minimized and how risk of IPV will be minimized and managed. Describe the process for informing participants of their unsuitability for study participation based on responses recorded on the checklist (e.g., for known or suspected partner coercion or IPV.]*
   3. The MTN-045 Eligibility Confirmation Form should be used to document and sign off on final participant eligibility. One form will be used per couple. Staff delegated on the site MTN-045 DoD Log are responsible for completing this form and for final sign-off of eligibility. The act of completing and signing the Eligibility Confirmation Form is the act of enrolling participants into MTN-045. 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 details here on age verification procedures for female participants (must be 18-40 years) and male participants (must be 18+ years) 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.]*
  1. Should study staff identify that an ineligible participant has been inadvertently enrolled, the IoR or designee will contact the MTN-045 Management Team at [mtn045mgmt@mtnstopshiv.org](mailto:mtn045mgmt@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-045. This log will be maintained in hardcopy and stored *[insert where this will be stored]*.

*[Sites to modify as needed:]* Recruitment venue, total number of potential participants contacted, number of potential participants scheduled for screening/enrollment visit.

* + - Screening and Enrollment Log: *[Site to insert responsible staff]* will maintain the following information on screening and enrollment logs for MTN-045. This log will be maintained in hardcopy and stored *[insert where this will be stored]*.
      * Screening date, PTID (female and male), Enrollment Date (or N/A

if not enrolled), IDI Date (if IDI completed at a separate visit), Screening Failure/Discontinuation Code (or N/A if enrolled).

* 1. *[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.]*
  2. Screening and enrollment information will be recorded on the *Weekly Screening Tracker* and sent to RTI International and FHI 360 on a weekly basis at [mtn045tracker@mtnstopshiv.org](mailto:mtn045tracker@mtnstopshiv.org). *[Insert staff responsible for compiling and sending screening and enrollment information.]* No participant identifiers will be sent as part of these screening and enrollment updates, only participant PTIDs.
  3. 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 Trials Network

PTID Participant Identifier

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-045 SSP Manual Section 3 (Accrual, Eligibility Determination and Study Procedures)

MTN-045 SSP Manual Section 4 (Informed Consent)

Site SOP for Communication with Responsible IRBs/ECs

Site SOP for Informed Consent Procedures

[List any additional as needed]

**History**

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| --- | --- | --- | --- | --- |
| **Version** | **Effective Date** | **Supersedes** | **Review Date** | Change |
| 1.0 | *Xx Mon YR* | NA | *Xx Mon YR* | Initial Release |

Approval

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|  | Reviewer, Reviewer’s Title |  |  | Date |