Purpose

To define procedures for recruiting potential participants, and determining eligibility of Phase 2 MTN-032 participants.

Scope

This procedure applies to all staff involved in conducting and/or overseeing participant recruitment and eligibility confirmation for MTN-032, Phase 2.

Responsibilities

*[MTN-032 staff members delegated by the Investigator of Record to conduct MTN-032 recruitment]* are responsible for understanding and following this SOP. In the remainder of this SOP these staff are referred to as “Recruitment Staff.”

*[MTN-032 Study Coordinator, Recruitment Coordinator or other designee]* is responsible for training study staff to recruit potential participants, and/ or confirm participant eligibility for MTN-032 in accordance with this SOP, and for day-to-day oversight of recruitment staff, and of staff involved in eligibility determination.

*[MTN-032 Study Coordinator, Recruitment Coordinator or other designee]* are jointly responsible for tracking participant contact, screening and enrollment rates, and for working with Recruitment Staff to increase participant contact frequency/ modify recruitment strategies as needed to meet the site-specific participant accrual targets to ensure that the site goals are met within the accrual time period.

*[MTN-032* *staff members delegated by the Investigator of Record per the Delegation of Authority log]* to perform eligibility determination and/or confirmation procedures for MTN-032 are responsible for understanding and following this SOP.

MTN-032 Investigator of Record has ultimate responsibility for ensuring that all applicable MTN-020 staff members follow this SOP, and for ensuring that only participants who meet the protocol-specific eligibility criteria for MTN-032 are enrolled in the study. The Investigator of Record also has ultimate responsibility for ensuring that the MTN-032 participant accrual targets are met.

Introduction

1. MTN-032 study staff will recruit MTN-025/HOPE participants and male partners of HOPE participants (See protocol section 5.3 and 5.4 for full listing of inclusion/exclusion criteria).
2. Accrual should be completed approximately 9 months from the time the first participant is enrolled into MTN-032 Phase 2. *[Sites can update timeline to be specific to their site based on activation date]*
3. The term “screening” refers to the administration of the Screening/ Recruitment Checklist to obtain verbal expression of willingness to join/enroll in the study and schedule an MTN-032 visit. “Enrollment” is defined as signing the informed consent and confirmation that eligibility criteria has been met. See protocol section 5.3 and 5.4 for full listing of inclusion/exclusion criteria, and SSP Section 3 for additional details on Screening and Enrollment. Each inclusion and exclusion criterion must be source documented per DAIDS Source Documentation SOP.

**Procedures**

1. Recruitment Activity
	1. For Female Participants:
		1. In collaboration with the MTN Statistical Data Management Centre (SDMC), a sample of potentially eligible women will be pre-selected for participation in MTN-032 Phase 2. MTN-032 Recruitment Lists will be distributed to sites and will contain the following information as available: 3 listings of HOPE PTIDs, first ring drug level, seroconverter status, target or actual date of visit 9/study exit visit, place to document other eligibility criteria.
		2. Using the MTN-032 Phase 2 Recruitment List, the *[Study Coordinator or other designee]* willcontact the former HOPE participant to determine whether she is willing to be screened/ enrolled into MTN-032, Phase 1 or Phase 2. The MTN-032 Recruitment List must be followed in sequential order, and *[Study Coordinator or other designee]* must review the HOPE participant’s files to ensure that a Permission to Contact (PTC) form was completed **prior** to contacting the former HOPE participant. The [*MTN-032 Screening/ Recruitment Checklist or site-specific tool*] will be used by the *[Study Coordinator or other designee]* when discussing the MTN-032 study with the potential participant. If there is a significant time gap between participants on one of the recruitment lists, sites should contact the management team to discuss.
	2. For Male Partner Participants:
		1. In collaboration with the MTN Statistical Data Management Centre (SDMC), a list of selected HOPE participants will be provided to sites. From this list of HOPE participants, site staff will identify those women who have provided permission to contact their male partners, and proceed to contact these male partners to offer them the opportunity so screen for MTN-032 Phase 2. This Recruitment List will be distributed to sites and will contain the following information: two listings of HOPE PTIDs (one for each FGD).
	3. All written recruitment and participant information materials will be reviewed and approved by all responsible IRBs/ECs prior to 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 and recruitment scripts also be reviewed and approved, specify that here as well.]*
2. Accrual targets
	1. The current accrual target for the *[Site]* is 10 total female IDI participants, and two male participant FGDs (with approximately 4-8 participants in each group) enrolled into Phase 2 as of *[insert date]*. Accrual targets, particularly with regards to male participants and female focus groups, will be reviewed periodically by the Management Team and may be adjusted/updated as necessary.
	2. The *[Study Coordinator or other designee]* will review the site specific target and adjust the frequency of contacting former HOPE participants and/or their male partners, as necessary.
	3. Based on the current accrual targets listed for this site *[sites can choose accrual targets and time frames, if desired]*
3. Screening Activity
	1. Potentially eligible participants will be pre-selected by the MTN SDMC and/or dependent upon female partner permissions. Sites may conduct additional pre-screening activities that include review of HOPE charts for permission to contact (PTC) and other eligibility criteria.
	2. **For female participants:** Only potential participants who have provided PTC will be contacted in sequential order as listed on the MTN-032 Phase 2 Recruitment List, provided by the MTN SDMC. The *[Study Coordinator or other designee]* will update the Screening and Enrollment Logs as each participant is contacted for screening using the Obs. # listed on the SCHARP-generated Recruitment List as the participant identifier.

**For male participants:** Only male partners of HOPE participants who have provided written permission to contact their male partners will be contacted in sequential order as listed on the MTN-032 Phase 2 Recruitment List, provided by the MTN SDMC. The *[Study Coordinator or other designee]* will update the Screening and Enrollment Logs as each participant is contacted for screening using the Obs. # listed on the SCHARP-generated Recruitment List as the participant identifier.

* + 1. Individuals (male or female) who are considered for enrollment but do not enroll (i.e. do not sign informed consent, or do not meet all eligibility criteria) will be assigned a non-enrolled MTN-032 PTID. Documentation containing the HOPE PTIDs related to these individuals should be kept separate from MTN-032 participant files.
	1. Once a participant enrolls into the study, the PTID/Name Link Logs will be completed by the *[Study Coordinator or other designee]*. This document links the participant name to her/his MTN-032 Phase 2 PTID and must be kept in hardcopy, and will be stored *[site to insert location; storage location must be double locked with limited access].*
	2. Participants may only screen a total of 2 times for MTN-032 Phase 2. *[Insert site specific procedures for determining/confirming screening attempt number.]* Note: Only one PTID will be assigned to a participant in Phase 2.
1. Tracking and Evaluation Activity
	1. The *[Study Coordinator or other designee]* will develop materials and methods (e.g., Screening and Enrollment logs) to document the following accrual information:
		* For female participants: SCHARP Obs#; Screening date; MTN-032 Phase 2 PTID; date of enrollment; MTN-032 Phase 2 non-enrolled PTID if screening or enrollment failure; staff initials.
		* For male participants: MTN-032 PTID; Screening date; date of enrollment; MTN-032 Phase 2 non-enrolled PTID if screening or enrollment failure; staff initials.
		* The Screening and Enrollment log will be maintained in hardcopy and stored *[insert where this will be stored]*.
		* *[Insert responsible staff]* will be responsible for updating and maintaining the screening and enrollment log.
	2. *[Insert staff responsibilities and procedures if maintaining electronic participant tracking database. Include procedures for entering new participants and updating scheduled and actual visit dates.]*
	3. Screening and enrollment information will be sent to FHI 360 and RTI on a weekly basis. *[Insert staff responsible for compiling and sending screening and enrollment information, and whether any tool/ tracker/ log will be sent to FHI 360, such as the Screening and Enrollment Log or another tool.]* No participant identifiers will be sent to RTI or FHI 360 when sending the screening and enrollment updates; the HOPE PTID column should be removed from the RL prior to its submission.
	4. *[Insert staff responsibilities and procedures for comparing actual versus targeted accrual].*
	5. All tracking information as described in this section will be discussed with *[Recruitment Staff]* in weekly meetings and used as a basis to increase the frequency of participant contacts to reach the study accrual goals. Recruitment and screening and enrollment rates and activities also will 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].*
2. Determining Eligibility
	1. Written informed consent for screening/ enrollment will be obtained by *[staff roles indicated on Site Delegation of Responsibilities/Signature Log]* prior to initiation of any MTN-032 study visit procedures (see site’s SOP for Obtaining Informed Consent).
	2. See protocol section 5.3 and 5.4 for full listing of inclusion/exclusion criteria. For MTN-032 Phase 2, the MTN SDMC will provide a list of HOPE participants stratified by adherence as reflected by her first residual drug results.
	3. For Phase 2, MTN-032 site staff will need to document verification of:

 For all participants:

* + - Exclusion criteria 1

For female participants:

* + - Phase 2 HOPE Participants inclusion criteria 2-5

For male participants:

* + - Phase 2 HOPE male partner inclusion criteria 1-5

 *[Insert responsible staff who will verify these criteria, and how confirmation will be documented at the enrollment visit. We suggest inserting a table of inclusion and exclusion criteria, including how these will be verified, in the appendix to this SOP. The MTN-032 Phase 2 Visit Checklists may be used for documentation (available on the MTN-032 website under Study Implementation Tools), or sites may choose to develop a separate eligibility checklist.]*

* 1. Any questions related to eligibility criteria or determination will be directed to the [*insert responsible staff*] for the study.
	2. *[Key study staff who are involved in determining eligibility for this study will be required to read and understand the protocol and attend trainings such as* *study site training, internal study start-up meeting and mock subject enrollments to ensure that they understand the eligibility requirements.]*
	3. Should study staff identify that an ineligible participant has been inadvertently enrolled, the IoR or designee will contact MTN-032 study management team at mtn032mgmt@mtnstopshiv.org for guidance on action to be taken.
1. Accrual/ Enrollment
	1. MTN-032 staff will meet potential participants at the designated time and venue agreed by the individual during screening contact. The first step of the visit will be to undergo the informed consent process. After the administration of the informed consent and all individual’s questions have been addressed; but before signing the informed consent, site staff should administer the informed the consent comprehension checklist. Participants will be considered enrolled in MTN-032 after they have provided written informed consent and all eligibility criteria are confirmed. At this point, they should be assigned a MTN-032 Phase 2 PTID as per the SSP. If written informed consent is not obtained or eligibility criteria are not met, they should be assigned a MTN-032 Phase 2 non-enrolled PTID. MTN-032 documentation should be maintained separate from study documentation containing the HOPE PTIDs related to these individuals.
	2. Qualitative data collection should ideally be conducted the same day written informed consent is obtained. If it is not possible to conduct the interview or focus group discussion until a later date than IC administration, the IC should be reviewed again immediately prior to the interview, and this should be documented in the participant file. Further information on the informed consent process is provided in the *[site’s Obtaining Informed Consent SOP]*.

**List of Abbreviations and Acronyms**

EC Ethics Committee

ICF Informed Consent Form

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*: Screening and Enrollment Log

 *[List any additional as needed]*

**References**

MTN-032 SSP Manual Section 3

MTN-032 SOP for Communication with Responsible IRBs/ECs

 *[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 |