Purpose

To define procedures for recruiting potential participants, and determining eligibility of Phase 1 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 1.

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 former MTN-020/ ASPIRE participants (See protocol section 5.3 and 5.4 for full listing of inclusion/exclusion criteria).
2. Accrual must be completed within 4-6 months from the time the first participant is enrolled into MTN-032. *[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. “Enrollment” is defined as signing the informed consent and confirmation of eligibility criteria. 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. 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. A MTN-032 Recruitment List will be distributed to sites and will contain the following information: a listing of ASPIRE PTIDs, and which interview modality each ASPIRE PTID will receive (either an IDI or FGD).
	2. Using the MTN-032 Recruitment List, the *[Study Coordinator or other designee]* willcontact the former ASPIRE participant to determine whether she is willing to be screened/ enrolled into MTN-032, Phase 1. The MTN-032 Recruitment List must be followed in sequential order, and *[Study Coordinator or other designee]* must review the ASPIRE participant’s files to ensure that a Permission to Contact (PTC) form was completed **prior** to contacting the former ASPIRE 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.
	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 32 total participants enrolled into Phase 1 as of *[insert date]*. Accrual targets 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 ASPIRE participants, as necessary.
	3. Based on the current accrual target listed for this site *[sites can choose to use any of these examples, or other measureable goals that are not listed below]:*
* *[Site]* will aim to enroll *[XX]* women within *[X]* months of activation.
* *[Site]* anticipates accruing *[XX]* participants per [*week/month*]
* A screening to enrollment ratio of *[X:X]* is anticipated. To achieve these accrual targets *[site]* will aim to screen *[XX]* participants per week.
1. Screening Activity
	1. There will be no prescreening activities for MTN-032, since potentially eligible participants will be pre-selected by the MTN SDMC.
	2. Potential participants will be contacted in sequential order as listed on the MTN-032 Recruitment List, provided by the MTN SDMC. The *[Study Coordinator or other designee]* will update the Screening and Enrollment Log as each participant is contacted for screening.
	3. Once a participant enrolls into the study, the PTID/ Name Link Log will be completed by the *[Study Coordinator or other designee]*. This document links the participant name to her MTN-032 PTID and must be kept in hardcopy, and will be stored *[site to insert location; storage location must be double locked with limited access].*
	4. Participants may only screen a total of 2 times for MTN-032. *[Insert site specific procedures for determining/confirming screening attempt number.]* Note: Only one PTID will be assigned to a participant.
2. 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:
		* ASPIRE PTID; Screening date; MTN-032 PTID; date of enrollment; reason for 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 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.
	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].*
3. 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, the MTN SDMC will only select participants who meet the product use criteria, as well as the PK criteria, so as to obviate the need for MTN-032 staff to verify Phase 4-7 inclusion criteria from the participant’s ASPIRE files.
	3. Therefore, MTN-032 site staff will only need to document verification of Phase 1 inclusion criteria 1-3; and exclusion criteria 1. *[Insert responsible staff who will verify these criteria, and how confirmation will be documented at the enrollment visit. The MTN-032 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.]*
	4. Any questions related to eligibility criteria or determination will be directed to the [*insert responsible staff*] for the study.
	5. *[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.]*
	6. 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.
4. Accrual/ Enrollment
	1. MTN-032 staff will meet potential participants at the designated time and venue agreed by the participant 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 participant’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 PTID as per the SSP.
	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 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 |