Purpose

To define procedures for retaining MTN-020 participants during study follow-up.

Scope

This procedure applies to all staff involved in the conduct and oversight of participant retention activities for MTN-020.

Responsibilities

*[MTN-020 staff members delegated by the Investigator of Record]* who conduct retention procedures for MTN-020 are responsible for understanding and following this SOP. In the remainder of this SOP these staff are referred to as “Retention Staff.”

*[MTN-020 staff members delegated by the Investigator of Record]* who conduct adherence counseling (and retention check-in) for MTN-020 are responsible for understanding and following this SOP. *[Staff members]* are responsible for communicating with the Retention Staff and [*others as designated by the Investigator of Record]* on a regular basis regarding participant- reported barriers to retention that may be clinic-driven or reduced through clinic intervention.

*[MTN-020 Study Coordinator or Retention Coordinator or other designee]* is responsible for training study staff to retain study participants in accordance with this SOP, and for day-to-day oversight of Retention Staff.

*[MTN-020 Study Coordinator or Retention Coordinator or other designee]* is responsible for generating and tracking retention rates, assessing the effectiveness and efficiency of retention strategies against site targets, and working with *[Retention Staff]* to implement retention strategies required to meet the MTN-020 participant retention targets.

*[MTN-020 Study Coordinator or Retention Coordinator or other designee]* is responsible for generating reports of upcoming visits for reminder calls, generating reports of frequent defaulters, and generating reports of missed scheduled visits (but still within visit window) and overseeing follow-up on all participants’ monthly visit retention issues.

MTN-020 Investigator of Record has ultimate responsibility for ensuring that the MTN-020 participant retention targets are met. The Investigator of Record also has ultimate responsibility for ensuring that all applicable MTN-020 staff members follow this SOP.

Procedures

1. **MTN-020 Retention Targets**

Members of the MTN-020 Protocol Team will routinely monitor participant visit retention to assure the retention target of 95 percent per visit is being met. Therefore, 95% of the expected participants for a visit should complete that visit. A participant is expected for every visit after she has enrolled up until the study has reached it’s natural end and the participant is terminated or the participant has reached a primary study endpoint (HIV seroconversion). For more information see Section 8 of the SSP Manual

1. **Retention Activities**

*[Note to sites: Included in this entire section is illustrative text. Please adapt/tailor to local needs.]*

* 1. Community Input

[*Study Coordinator, Retention Coordinator, or other designee*] will seek initial and ongoing input on retention methods and materials from the site [*Community Educator, Community Advisory Board/Group, Community Education Coordinator, PI, Community Educators, Research nurses, Community Advisory Board, current and previous study participants*.]

* 1. Informed Consent

During the enrollment informed consent process, study participants will be informed of planned retention procedures, so that they are aware of number of study visits, all study procedures (including randomization), and all efforts that will be undertaken to contact them in the event that they miss a scheduled study visit. See SOP MTN-020-XXX-XX, Obtaining Informed Consent.

* 1. Collection of Locator Information/Definition of Adequate Locator Information

Locator information first will be collected at potential participants’ study screening visit, using the *[insert name of site-specific locator form]*. Study staff will negotiate with participants how staff will identify themselves when calling or visiting the participant or their contacts; participant preferences will be recorded on the Locator Forms.

“Adequate” locator information is defined as provision of all of the following items:

*[Each site to specify locally-relevant items, the following is an example.]*

* Participant’s legal name
* Participant’s home address (with detailed instructions/map for locating the residence)
* Other participant contact information (e.g., telephone numbers, work address/location)
* Name and address/contact information for at least one family member who does not live with the participant and is not expected to leave the area within the next *[XX]* months
* Name and address/contact information for at least one friend or community contact who does not live with the participant and is not expected to leave the area within the next *[XX]* months

[*Describe the process for reviewing and updating location information at study follow-up visits.]*

* 1. [*Describe any additional retention activities here. These could include retention parties or events, small tokens of appreciation that are provided to participants who meet milestone visits, or any other site specific plan to ensure good retention throughout ASPIRE].*

1. **Follow-up Visit Scheduling and Reminder Methods**

Monthly visit target dates are based on the MTN-020 enrollment date. The allowable visit windows are contiguous between visits. This means there is a -14/+13 day window before and after each target follow-up visit date.

* 1. Visit Scheduling and Reminder Methods
* [*Define process for setting visit schedule after participant enrollment is confirmed. Will the MTN-020 visit calendar (on the MTN website) be used to project all target dates, or will this be generated from the participant tracking database? It is strongly recommended that a copy of this for the duration of the trial be placed at the front of each participant binder for tracking purposes. Who is responsible for these activities?]* 
  + - *[Insert responsible staff]* will review the target dates and allowable visit windows at the enrollment visit, and when scheduling visit dates with the participant.
* The time and date of subsequent visits will be confirmed at the prior visit by *[designated staff person],* who will enter the scheduled visit date/time in *[insert where documented, i.e. participant chart notes, visit table at front of participant binder.]*
* Visits will be scheduled for the target date whenever possible, however all dates within the allowable visit window are acceptable. [*Include a reference to the Off-site visit SOP as appropriate: If a participant is unable to attend her next visit, an off-site visit may be scheduled per SOP MTN-020-XXX-XX, Off-site Visit.*]
* *[Specify site procedures for contacting and reminding participants between scheduled visits in order to facilitate high levels of retention. Sites may do this through various methods e.g., home visit, phone call, text message, etc]*
* *[Describe the system for updating the participant tracking database (or other tracking system) when a visit has been completed. Include the staff responsible and timeline for doing this]*

1. **Identification and Follow-up of Missed Visits**
   1. *[Describe the system that will be utilized to identify that visits have been missed. Include the staff positions involved in identifying missed visits and following up on missed visits]*
   2. *[Describe site procedures for participants who miss their scheduled visit and are still in the visit window, , and those who miss the visit window altogether. Indicate how participants will be prioritized in terms of retention/follow-up activities]*
   3. *[Describe documentation that will be in place for all follow-up related to missed visits].*
   4. For participants who do not complete a scheduled visit within the allowable visit window, *[designated staff person]* will complete a Missed Visit DataFax form as specified in the MTN-020 Study-Specific Procedures Manual.
2. **Participants Determined to be ‘Chronic Defaulters’**
   1. For the purposes of MTN-020 a ‘chronic defaulter will be someone who has missed three or more visits in a row.
   2. *[Specify how site will determine a participant to be a chronic defaulter and how procedures may be modified from the above section].* Participant requests around visit tracking and follow-up from clinic staff will be honored and documented.
   3. Participants who are chronic defaulters will continue to be followed per above. Participants who are not expected to come back for study visits (due to relocation, work schedule etc) will remain in the study and will only be considered lost to follow up at study end. These participants will be terminated from the study at the natural end of the study, unless they wish to withdraw participation prior to this.
3. **Participant Decision to Withdraw**

Regardless of having provided informed consent to take part in the study at enrollment, participants are free to withdraw their consent and discontinue study participation at any time. All study staff will inform the *[designated staff person]* of any participant who states that she would like to discontinue participation, and the reasons why. After consultation with the *[Study Coordinator and Investigator of Record]*, the *[designated staff person]* will oversee any further action to be taken with the participant, including negotiation of any reduced level of participation that the participant may be willing to continue. As a final effort, participants will be asked if they are minimally willing to complete a final product use end visit.

*[Add any other local considerations here.]*

1. **Evaluation of Retention Activities**

* The *[designated staff person]* will routinely evaluate the implementation of the retention SOP based on the specifications of Section 4.
* *[Describe how and when the designated staff person will communicate retention progress and challenges to the site team.]*
* The following methods and materials will be used to track the success of retention efforts: [*include listing of methods and materials, such as SCHARP retention reports, site generated reports, etc*]
* The *[designated staff person]* will track participant retention rates to ensure that targets are being met, based on the materials listed above.
* In the event that retention rates fall below target, the Investigator of Record is responsible for working together with the *[designated staff person, Study Coordinator, Retention Staff, Community Educator/Liaison, and Community Advisory Board]* to enhance/modify retention procedures and/or mobilize resources to meet protocol-specified retention targets.
* *[Specify procedures for communicating retention progress and challenges with the full site team, as retention should be emphasized as a full team priority.]*

1. **Utilizing Participant Feedback**

The participant experience within the clinic is critical to her retention in the study and valuable information may be provided during counseling sessions when challenges and facilitators to retention are discussed. *[Specify which staff will be responsible for conducting the adherence counseling/retention check-in and the method for which the information learned (both positive and negative) will be communicated to other staff members. Will this be a part of a team weekly meeting, a one-on-one check-in with the Study Coordinator on a regular basis? Outline how this information will be consolidated to expedite reporting for clinic follow-up as needed. Specify other ways in which participant feedback on clinic satisfaction will be gathered (if any).]*

**List of Abbreviations and Acronyms**

DAIDS Division of AIDS

MTN Microbicide Trial Network

SDMC Statistical Data Management Center

SOP Standard Operating Procedure

SSP Study-Specific Procedures

*[Insert additional as applicable]*

**Attachments**

Attachment 1:

*[Insert as applicable]*

**References**

SOP MTN-020-XXX-XX, Obtaining Informed Consent

SOP MTN-020-XXX-XX, Off-site visits

MTN-020 Protocol

MTN-020 SSP Manual

*[Insert additional as applicable, including the MTN 020 Participant Tracking Database User’s Manual]*

**History**

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| --- | --- | --- | --- | --- |
| **Version** | **Effective Date** | **Supersedes** | **Review Date** | Change |
| xxx-xx | Xx Mon Yr | NA | Xx Mon Yr | Initial Release |

Approval

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|  | Approver’s Name, Approver’s Title |  |  | Date |

[Include Attachments here]