

Section 8. Participant Retention

This section presents information related to definitions, requirements, and procedures for participant retention in MTN-013/IPM 026.

8.1 Retention Definitions

The term “retention” generally refers to completion of follow-up visits and procedures as specified in a study protocol. This definition must be operationalized for any study, and operational definitions usually reflect the primary objectives and endpoints of a study. For MTN-013/IPM 026, two retention measures are planned to be used, one during the study and one at the end of the study. Additional retention measures may be defined and used during the study if desired by the Protocol Chair and/or Protocol Statisticians.

- During the study, retention for scheduled follow-up visits will be defined based on whether participants complete scheduled visits within the visit window. Participants who complete their scheduled visits within the visit window will be considered ‘retained’ for those visits.
- At the end of the study, retention will be defined based on whether participants complete the Day 52/Final Clinic/Termination Visit. Although every effort must be made to complete each participant’s study exit visit within the window, exit visits will be allowed to take place at any time through the study end date at each site. Participants who complete an exit visit, prior to the study end date will be considered ‘retained’ at the end of the study.

As indicated above, participants who do not complete a particular scheduled visit within the allowable window (when there is a visit window), but then complete the next scheduled visit, will not be considered retained for the missed visit, but will be considered retained for the next scheduled visit. Thus retention rates can fluctuate over time and across visits. Importantly, retention shortfalls can be made up by ensuring that participants return for their next scheduled visit after missing a visit.

The MTN SDMC will post reports on their ATLAS portal presenting retention rates for key study visits designated by the Protocol Team. The SDMC also will generate a final end-of-study retention rate after the study is completed. Please see Section 15 of this manual for more information on the study reporting plan.

8.2 Retention Requirements

Each study site will target retention of at least 95% of enrolled study participants for each scheduled follow up visit. The purpose of the 95% retention target is to ensure the accuracy of study results by minimizing bias that can be caused by missing data. Low retention rates can have serious impacts on the accuracy of the study results because we cannot know if participants who do not return for scheduled study visits used the product, liked the product or had poor effect from the use of the product. To avoid these problems, and thereby avoid bias in the study results, high participant retention rates must be maintained throughout the study.

8.3 Retention SOPs

Site staff are responsible for establishing a standard operating procedure (SOP) for Participant Retention to meet the study retention goal of 95%. The SOP should minimally contain the following elements:

- Site-specific retention goals
- Methods for tracking actual retention versus retention goals
- Procedures for completing and updating participant locator information
- Site-specific definition of “adequate” locator information (for purposes of determining participant eligibility)
- Visit reminder methods and timeframes
- Methods and timeframes for identifying when a visit has been missed
- Planned retention methods (including what outreach/locator efforts are taken within 24 hours, 1-3 days, 1 week, or 2 weeks after a missed visit)
- Methods for timely evaluation of the utility of retention methods
- Ethical and human subjects considerations
- Staff responsibilities for all of the above (direct and supervisory)
- QC/QA procedures related to the above (if not specified elsewhere)

8.4 Obtaining and Updating Locator Information

Successful retention begins with collection of locator information from each study participant. All study participants will be asked to provide locator information during the study screening process, and to continually review/update this information during follow-up. Provision of "adequate" locator information during screening is a study eligibility requirement and each site must specify its definition of adequate locator information in its retention SOP.

Each study site is encouraged to develop an exhaustive locator form to maximize contact effectiveness and participant retention. Sites also may wish to consider having outreach workers accompany participants to their homes or other community based locations to verify or further clarify their locator details.

Potential locator items include:

- Participant's full name, alias, and/or nickname; government-issued identification number; home address; home phone number; mobile phone number; work address; work phone number; fax number; or e-mail address
- Name, address, telephone number, and/or other contact information for stable community contacts (i.e., participant family members and friends) who typically know the whereabouts of the participant.

Note: Although contact information for a participant's current primary partner likely will be useful, contact information for other contacts also should be collected, since the participant's relationship with this partner could change during the course of the study.

During the informed consent process and when collecting locator information, study participants must be informed that their locator sources will be contacted if study staff are unable to locate the participant directly. Study staff will negotiate with the participant how they will identify themselves when locator sources are contacted. Arrangements agreed upon with the participant should be documented on the locator form.

Study staff should view every participant contact as an opportunity to update the participant's locator information. When updating locator information, actively review each item on the locator form to determine whether the information is still current (i.e., rather than simply asking "Has any of your information changed since your last visit?"). Site staff should also probe for additional information that the participant was not able or willing to provide at previous visits.

8.5. Retention Tips

Some general strategies for maximizing participant retention are as follows:

- Emphasize the value of the participant's involvement in the study during the study informed consent process and subsequently at follow-up visits. When participants complete scheduled visits, acknowledge and compliment their commitment, time, and effort devoted to the study.
- Keep locator information up-to-date and maintain thorough documentation of all efforts to contact the participant. Keep all this information in an organized manner, so that different staff members can easily review the information and contribute to re-contact efforts when necessary. Make use of all information collected on the participant's locator form. Even if a locator source is not useful/successful on one occasion, try it again later.
- Make use of all available contact methods (e.g. phone, mail, home visits, street outreach, newspapers, e-mail/internet). Also make use of other available locator information sources, such as phone and postal directories and other public registries.
- Dedicate adequate staff time and effort to retention efforts.
- Work with community members to identify the most applicable contact and retention strategies for the local study population, including the type and amount of participant incentives.
- Keep participants and community members up-to-date on study progress to foster a sense of partnership and ownership of the study (through the use of participant newsletters, for example).
- Inform local service providers who interact with the local study population about the study, so that they also can express their support for the study.
- Host gatherings, parties and/or other social events for participants. Host social, educational, and/or other "male involvement" events for participants' partners.
- Use tracking systems to identify when participants' scheduled visits are due and/or overdue. Establish routine mechanisms to remind both study staff and participants of upcoming scheduled visits.

- Schedule all follow-up visits at the participant's Enrollment Visit. Thereafter, at each follow-up visit, confirm the scheduling of the next visit and give the participant an appointment card with the scheduled visit date and time noted.
- Prepare a calendar of scheduled visits for each enrolled participant, based on her enrollment date, or offer a planner/calendar as an incentive and note all study appointments in the planner/calendar. Note the dates of all scheduled visits in the participant's file for easy reference.
- For participants who demonstrate a pattern of late or missed appointments, schedule follow-up visits for the beginning of the allowable visit window (i.e., up to one week before the actual target date) to allow maximum time for re-contact and re-scheduling if needed.
- Pay close attention to the allowable visit window and prioritize retention efforts for participants nearing the end of the window. Organize daily caseloads and work assignments based on these priorities.
- Follow-up on missed appointments with an attempt to re-contact/re-schedule within 24 hours (preferably on the same day). Continue these efforts per the local retention SOP until contact is made.

8.6 Participants Who Voluntarily Discontinue Study Participation

If a participant reports that she wishes to discontinue participation in the study prior to completing her scheduled Day 52/Termination Visit, explain that she is always welcome to come back if she wishes. If a participant wishes to discontinue participation in the study, her wishes must be respected. The following procedures should be followed for all participants who discontinue study participation:

- Ask if she would be willing/interested to continue having [early termination visit], or at least a final blood draw (for safety labs and HIV testing) and urine collection for pregnancy testing and document her responses to these options.
- If the participant refuses this level of involvement, at the time when the participant states that she wishes to discontinue participation, study staff must document the participant's stated wishes in detail, together with the following information:
 - Reason the participant wishes to leave the study.
 - Whether the participant is willing to have any further contact with study staff in the future and, if so, for what purpose, at what frequency, and through what methods.
 - Whether and how she is willing to be contacted for purposes of receiving her results (if the participant has any pending laboratory test results)
 - Whether and how she is willing to be contacted for purposes of ascertaining her pregnancy outcome (if the participant is pregnant)
 - Whether and how the participant wishes to be contacted for purposes of learning the results of the study (when results are available).

At the time when the participant states that she wishes to discontinue participation, contact the SDMC to determine which CRFs are required to be completed. Refer to Section 13 of this manual as needed.