

## **Section 8. Participant Retention**

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This section presents information related to definitions, requirements and procedures for participant retention in MTN-007.

### **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-007, two retention measures are planned: 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 (required) follow-up visits will be defined based on whether participants complete some part of the required scheduled visits within the allowable visit window. Participants who complete all or part of their scheduled visits within the allowable 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 Final Phone Assessment Visit/Termination Visit. Although every effort must be made to complete each participant’s study Final Clinic Visit and subsequent Follow-up Phone Assessment Visit/Termination Visit within the allowable visit window, these visits will be allowed to take place through the study end date. Participants who complete this visit will be considered retained.

As indicated above, participants who do not complete a particular scheduled visit within the allowable 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 that was completed. 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 Statistical and Data Management Center (SDMC) will generate reports during the study presenting retention rates for key study visits designated by the Protocol Team. The SDMC also will generate a final end-of-study retention rate for each site after the study is completed.

### **8.2 Retention Requirements**

Each study site will target retention of at least 95 percent of enrolled study participants for each scheduled follow-up visit. The purpose of the 95 percent 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 ill effect from the use of the product.

### **8.3 Retention SOPs**

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

- Site-specific retention goals
- Methods for tracking actual retention versus retention goals
- Procedures for collecting and updating participant locator information
- Site-specific definition of “adequate” locator information (for purposes of determining participant eligibility)
- Visit reminder methods and time frames
- Methods and timeframes for identifying when a visit has been missed
- Planned retention methods, including what outreach/locator efforts are taken with 24 hours, 1-3 days, 1 week and 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)
- Staff training requirements (if not elsewhere)
- QC/QA procedures related to the above (if not elsewhere)

### **8.4 Obtaining and Updating Locator Information**

Successful retention begins with collection of exhaustive 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 site is encouraged to develop a 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. Practical 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; e-mail address; daytime and nighttime locations, meeting places and hangouts.
- Walking/driving/public transport directions and/or other contact information for stable community contacts (i.e., family members and friends) who typically know the whereabouts of the participant.
- Note: Although contact information for a participant’s current primary partner will likely 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.
- Name, address, telephone number, and/or other contact information for the participant’s health care provider, school or training program; church or other place of worship; social service case worker; counselor; rehabilitation provider, etc.

- Name, address, telephone number and/or other contact information for support groups, shelters, food pantries and other social service organizations used by the participant.

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 contact with the participant 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 (rather than simply asking "Has any of your information changed since the last visit?"). 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:

- Thoroughly explain of the study visit schedule and procedural requirements during the informed consent process and re-emphasis at each study visit. When participants complete scheduled visits, acknowledge and comment on their commitment, time and effort devoted to the study.
- Thoroughly explain of the importance of completing all study visits to the overall success of the study.
- Collect detailed locator information at the study screening visit and active review and updating of this information at each subsequent visit.
- Use mapping techniques to establish the location of participant residences and other locator venues.
- Mobilize trained outreach workers or "tracers" to complete in-person contact with participants at their homes and/or community locations
- 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
- 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.
- Use the visit calendar created for the participant to identify when the participant's 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/Baseline Evaluation 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.
- For participants who demonstrate a pattern of late or missed appointments, schedule follow-up visits for the beginning of the allowable visit window to allow maximum time for re-contract and re-scheduling, if needed.

- Play 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.
- 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 form 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.
- Post outreach workers at other local service organizations utilized by the study population.
- Attempt contact with the participant at different times during the day and the week, including evenings and weekends.
- If a participant reports that he/she wishes to discontinue participation in the study, explain that he/she is always welcome to come back if he/she wishes.