

Section 6. Participant Retention

This section presents information related to definitions, requirements, and procedures for participant retention in MTN-014.

6.1 Retention Definitions and Requirements

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-014, retention will be defined based on whether participants complete each study visit. Participants who complete their scheduled visits within the allowable visit window will be considered “retained” for the study. A visit is considered missed for a participant once the allowable window closes, regardless of whether or not a participant is lost to follow-up or terminated early from the study. Participants who are terminated early for protocol specified reasons, however, are considered retained for the remainder of the study.

The target retention rate for each study visit is 100%. Therefore, once a participant is enrolled in the study, the study site will make every reasonable effort to retain her for the entire study duration so that she is evaluable and to minimize possible bias associated with loss-to-follow-up. An average overall retention rate of 95% will be targeted at the site.

The MTN Statistical and Data Management Center (SDMC) will present per-visit retention rates for each required follow-up visit in a monthly retention report. The per-visit retention percentage is calculated by taking the number of participants expected for a visit who complete the visit within the allowable time frame (the visit window) and dividing that by the number of participants expected for the visit. An overall (cumulative) retention rate (%) for the site will be calculated and provided in a monthly Data Summary Report. The SDMC also will generate a final end-of-study retention rate after the study is completed. Please see Section 13 of this manual for more information on the study reporting plan.

6.2 Retention SOPs

Site staff are responsible for establishing a standard operating procedure (SOP) for participant retention, and for updating the SOP and retention efforts undertaken to meet the study retention goals. 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 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)

6.3 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 visit, and to review/update this information at the enrollment and follow-up clinic visits. Provision of "adequate" locator information during screening is a study eligibility requirement and the site must specify its definition of adequate locator information in its retention SOP.

The study site is encouraged to develop an exhaustive locator form to maximize contact effectiveness and participant retention. Potential locator items include:

- Participant's full name, alias, and/or nickname; government-issued identification number; home address; home phone number; mobile phone number; pager number; work address; work phone number; fax number; 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.

- 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, etc; participant's child's school and health care provider.
- 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 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?"). Also, site staff should probe for additional information that the participant was not able or willing to provide at previous visits.

6.4 Retention Tips

Sites should dedicate adequate staff time and effort to retention efforts. Some general strategies for maximizing participant retention are as follows:

- 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.
- Actively review clinic flow in an effort to identify ways to minimize participant waiting time.
- Develop rapport and ensures participants feel welcome and comfortable during their visits.
- Emphasize the value of the participant's involvement in the study during the study informed consent process.
- 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. Give the participant an appointment card with the scheduled visit dates and times noted.
- 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 site retention SOPs 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.
- Attempt contact with the participant at different times during the day and the week, including evenings and weekends.

6.5 Participants who voluntarily discontinue study participation

If a participant wishes to discontinue participation in the study, her wishes must be respected. 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:

- Why 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, through what methods.
- If the participant has any pending laboratory test results, whether and how she is willing to be contacted for purposes of receiving her results.