Section 8. Participant Retention

This section presents information related to definitions, requirements, and procedures for participant retention in MTN 001.

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 001, 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 (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.

- Overall retention is calculated as the percentage of the total number of visits completed by all participants (within their allowable visit window) divided by the number of visits expected for all participants. A visit is considered expected 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.

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. 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. The pharmacokinetics and adherence measures tested in MTN 001 will be estimated by comparing these measures observed in each participant in all three study product periods to other participants assigned to various sequence groups. 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 have varying levels of study drug absorbed into their bodies or have varying levels of adherence. In each sequence group, the observed levels of absorbed vaginal and oral tenofovir could be higher or lower than the true amount, but it is not possible to determine the direction of the error. Furthermore, because this is a crossover study, it is important to obtain complete data for each participant as she will be assigned to each of the three study periods. 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 is responsible for establishing a standard operating procedure (SOP) for participant retention to meet the study retention 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 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, 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 specified elsewhere)
- QC/QA procedures related to the above (if not specified 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 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; pager number; work address; work phone number; fax number; e-mail address; daytime and nighttime locations, meeting places, hangouts.

- Walking/driving/public transport directions and/or pictorial map to the participant's home, workplace, etc.

- 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 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.; 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?"). 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:

- Thorough explanation 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.

- Thorough explanation of the importance of completing all study periods to the overall success of the study.
- Collection of detailed locator information at the study screening visit, and active review and updating of this information at each subsequent visit.
- Use of mapping techniques to establish the location of participant residences and other locator venues.
- Mobilization of trained outreach workers or “tracers” to complete in-person contact with participants at their homes and/or other 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 (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 the visit calendar created for the participant 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.

- 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.

- 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 she wishes to discontinue participation in the study, explain that she is always welcome to come back if she wishes.

- If a participant reports that she wishes to discontinue her participation in the study, ask if she would be willing to complete an early Study Exit Visit, or at least a final blood draw (for safety labs and HIV testing) and urine collection for pregnancy testing. Please document her response in her chart notes. If the participant is willing to complete an early Study Exit Visit, complete all Week 21 Visit procedures and CRFs. If the participant is only willing to give blood and urine for safety labs, HIV, and pregnancy testing, complete the following CRFs: Interim Visit, Safety Laboratory Results, Termination, and End of Study Inventory. If the participant is unwilling to complete any additional study procedures, reinforce site contact information and explain that she is always welcome to return to the clinic if she wishes. Then complete a Termination form and End of Study Inventory form for her, and fax these forms to SCHARP.

  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 a detailed chart note that includes 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, for what purpose, at what frequency, and 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.

- Whether and how the participant wishes to be contacted for purposes of learning the results of the study (when results are available).

- Please remember that for MTN 001, home visits are not allowed except to collect remaining unused study product, if necessary.