

## Section 8. Participant Retention

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This section presents information related to definitions, requirements, and procedures for participant retention in HPTN 035.

NOTE: Effective with Version 2.0 of this section, prior references to the HIV Prevention Trials Network (HPTN) have been replaced where applicable with references to the Microbicide Trials Network (MTN).

### 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 HPTN 035, 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 monthly follow-up visits will be defined based on whether participants complete scheduled visits within the allowable visit window. Participants who complete 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 HIV testing at a study exit visit. Although every effort must be made to complete each participant’s study exit visit within the allowable visit 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, and undergo HIV testing at that 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, 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 annually. Figure 8-1 presents the monthly retention rates that must be met over the course of the study to achieve the 95 percent annual target.

**Figure 8-1**  
**Monthly Retention Targets for HPTN 035**

| Month of Study | Target % Retained | Month of Study | Target % Retained |
|----------------|-------------------|----------------|-------------------|
| 1              | 99.58             | 16             | 93.33             |
| 2              | 99.17             | 17             | 92.92             |
| 3              | 98.75             | 18             | 92.50             |
| 4              | 98.33             | 19             | 92.08             |
| 5              | 97.92             | 20             | 91.67             |
| 6              | 97.50             | 21             | 91.25             |
| 7              | 97.08             | 22             | 90.83             |
| 8              | 96.67             | 23             | 90.42             |
| 9              | 96.25             | 24             | 90.00             |
| 10             | 95.83             | 25             | 89.58             |
| 11             | 95.42             | 26             | 89.17             |
| 12             | 95.00             | 27             | 88.75             |
| 13             | 94.58             | 28             | 88.33             |
| 14             | 94.17             | 29             | 87.92             |
| 15             | 93.75             | 30             | 87.50             |

The purpose of the 95 percent annual retention target is to ensure the accuracy of study results. The effectiveness of the microbicides tested in HPTN 035 will be estimated by comparing the HIV infection rates observed among participants assigned the product groups (BufferGel or PRO 2000/5Gel (P) to the rates observed among participants assigned to the study control groups (placebo gel or no gel). For each group, the HIV infection rate will be calculated as the number of participants in the group who become infected with HIV during follow-up divided by the total amount of follow-up time observed in that group. Low retention rates can have serious impacts on the HIV infection rates observed in each group because we cannot know if participants who do not return for scheduled study visits are HIV-infected or HIV-uninfected. In each group, the observed HIV infection rate could be higher or lower than the true rate, but it is not possible to determine the direction of the error. To avoid this problem, 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, and for updating the SOP and retention efforts undertaken to meet the study retention goal of 95 percent per year. 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, 2 weeks, and 3-4 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 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, 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?"). Also probe for additional information that the participant was not able or willing to provide at previous visits.

## **8.5 Participant Tracking Database**

The MTN Coordinating and Operations Center (CORE) will provide all study sites a Participant Tracking Database to support participant retention efforts in HPTN 035. Among other features and functions, the database will be pre-programmed to generate lists of participants who are due for visits and who have missed visits within specified timeframes. To facilitate off-site participant outreach and tracing activities, lists may be sorted by assigned outreach worker and geographic location. Lists also may be prioritized by the number of days remaining in the current visit window and whether confirmatory HIV testing is required at the next visit.

All sites must use the Participant Tracking Database provided by the MTN CORE unless approval is obtained from the CORE to use an alternative database. When using the database, all sites must follow user instructions provided by the CORE, and take part in database training, validation, and quality assurance activities specified by the CORE. The database may not be used to record source data or to generate source documents. All information entered into the database must be based on other source documents contained in participants' study charts.

## **8.6 Retention Tips**

Some general strategies for maximizing participant retention are presented in protocol Section 3.5. Additional tips for successful retention are as follows:

- 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.

- 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 comment their commitment, time, and effort devoted to 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 HPTN 035 Participant Tracking Database 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 monthly visits at the participant’s Enrollment Visit. Thereafter, at each monthly 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 (see also the Sample Participant Visit Tracking Sheet in Section 6 of this manual).
- 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 two weeks 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, particularly for quarterly visits at which primary study endpoints are assessed. 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.

- For home and other community based efforts, if applicable and allowed by local regulations, utilize staff with clinical training, so that clinical procedures can be conducted in the field.
- If a participant reports that she wishes to discontinue participation in the study, ask if she would be willing/interested to continue having quarterly HIV testing, or at least a final test at the end of the study, and document her responses to these options. If the participant refuses this level of involvement, reinforce site contact information and 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. 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:

- 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. For example, a participant who is not currently able to complete study visits may be willing to have study staff check in with her in several months time to see if her circumstances may have changed. In this case, study staff must document the timing and type of contact that the participant agreed to (e.g., in person, telephone, delivery/mail), as well as the participant's preferences for the location of the contact (e.g., at her home, at a family member's home, at her workplace).
- If the participant has any pending laboratory test results, whether and how she is willing to be contacted for purposes of receiving her results.
- If the participant is pregnant, whether and how she is willing to be contacted for purposes of ascertaining her pregnancy outcome.
- If the participant was assigned to gel, whether and how she wishes to be contacted for purposes of unblinding (when unblinding information is available).
- Whether and how the participant wishes to be contacted for purposes of learning the results of the study (when results are available).