

## Section 6. Participant Retention

This section presents information related to definitions, requirements, and procedures for participant retention in MTN-011.

### 6.1 Retention Definitions

The term “retention” generally refers to completion of follow-up visits and procedures as specified in a study protocol. For MTN-011, retention will be determined by the number of evaluable couples. 20 evaluable couples will be required for each Matched-Pair Visit Set. In order to be considered evaluable, couples must complete the following study procedures.

Study Procedure	Matched-pair Visit Sets for Group 1	Matched-pair Visit Sets for Group 2
Completed Coitus* at Gel/Sex Visit for matched-pair visits	-1hr Matched Set: 3b -24hr Matched Set: 5b, BAT Matched Set: 3b, 7b	-1hr Matched Set: 3b -72hr Matched Set: 7b
Cervicovaginal lavage (CVL) collected for matched-pair visits	-1hr Matched Set: 3b, 4b -24hr Matched Set: 5b, 6b BAT Matched Set: 3b, 7b	-1hr Matched Set: 3b, 5 -72hr Matched Set: 7b, 9
Plasma collected for matched-pair visits	-1hr Matched Set: 3b, 4b -24hr Matched Set: 5b, 6b BAT Matched Set: 3b, 7b	-1hr Matched Set: 3b, 5 -72hr Matched Set: 7b, 9
Group 1: Single dose of gel inserted; Group 2: at least 5 of the 7 doses of gel inserted prior to sampling study visits	-1hr Matched Set: 3a, 4a -24hr Matched Set: 5a, 6a BAT Matched Set: 3a, 7a	-1hr Matched Set: 3b, 5 -72hr Matched Set: 7b, 9

\*Defined as male partner ejaculation into female partner’s vagina

The MTN Statistical and Data Management Center (SDMC) will post reports on their ATLAS portal presenting retention rates throughout the period of study implementation. The SDMC also will generate a final end-of-study retention rate after the study is completed. All reports will include site-specific and cross-site information. Please see Section 14 of this manual for more information on the study reporting plan.

### 6.2 Retention Requirements

As this is a short-term Phase 1 study, a retention rate of 100% is targeted across sites to minimize possible bias associated with loss-to-follow-up. Couples will be considered enrolled in MTN-011 after completion and final sign-off of the non-datafax Eligibility checklist for both female and male participants. Once a couple is enrolled, the study staff should make every reasonable effort to retain the couple in order to reach the retention rate of 100%.

### 6.3 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 100 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 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)

#### 6.4 Obtaining and Updating Locator Information

Successful retention begins with collection of exhaustive locator information from each study participant (both female and male). 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 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. 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 primary partner likely will be useful, contact information for other contacts also should be collected, since the participant's partner will also be a study participant.*

- 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.
- 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. For example, rather than simply asking "Has any of your information changed since your last visit?", probe for additional information that the participant was not able or willing to provide at previous visits.

## **6.5 Retention Tips**

Some general strategies for maximizing participant retention are as follows:

- Only enroll participants who fully understand the visit schedule and appear able and willing to follow it.
- 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.
- Actively review clinic flow to minimize participant waiting time.
- Develop rapport and ensure the participants feel welcome and comfortable during their visits.
- Emphasize the value of the participant's timely visits to meet study objectives (PK/PD measurements) 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.
- Work with the female and male participant to schedule each follow-up visit at their enrollment visit. Give both the participants a listing of scheduled appointments with the visit dates and times noted.
- Pay close attention to the allowable visit window for each visit and prioritize retention efforts for participants nearing the end of the window.

- 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.
- If a participant wishes to discontinue participation in the study, his/her wishes must be respected. At the time when the participant states that s/he 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 s/he is willing to be contacted for purposes of receiving his results.
- If one partner wishes to discontinue from the study his/her partner must also discontinue from the study.