

Section 8. Participant Retention

This section presents information related to definitions, requirements, and procedures for participant retention in MTN 002.

8.1 Retention Definition

The term “retention” generally refers to completion of the subsequent evaluation visit and follow up 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.

During the study, retention will be defined based on whether participants complete required visits and follow-up procedures within the allowable visit windows. Participants who complete their scheduled gel administration, 24 hour evaluation visit and two week follow up phone call within the allowable visit windows will be considered “retained” for those visits.

As indicated above, participants who do not complete the gel administration, 24 hour evaluation visit and two week follow up phone call within the allowable windows, 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 evaluation visit and follow up. Thus retention rates can fluctuate over time and across visits. Importantly, retention shortfalls can be made up by ensuring that participants return for their subsequent evaluation visit and follow up.

The MTN Statistical and Data Management Center (SDMC) will generate reports during the study presenting retention rates for study visits. The SDMC also will generate a final end-of-study retention rate after the study is completed.

8.2 Retention Requirements

The study site will target retention of 100 percent of enrolled study participants at each required follow-up visit.

The purpose of the 100 percent retention target is to ensure the accuracy of study results. The pharmacokinetics measures tested in MTN 002 will be estimated by comparing these measures observed in each participant at seven time points following gel administration and compared to baseline measures.

8.3 Retention SOPs

Site staff is 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 at the scheduled gel administration, 24 hour evaluation visit and two week follow up phone call. 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 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 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 and enrollment process, and to continually review/update this information during the subsequent 24 hour evaluation period and two week phone call. 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; 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 should also 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 Retention Tips

With the consent of the participant, study staff will obtain contact information from people who would be expected to know the whereabouts of the participant enrolled in this study. The need to attend the subsequent evaluation visit and follow up must be emphasized to each study participant. If a participant misses a scheduled study visit, the study site staff will try to establish communication with the participant through all possible means (e.g., telephone, field contact, and writing), without breaching the participant's confidentiality. Study site staff is responsible for developing and implementing site-specific SOPs to achieve complete follow up.

Once participants are enrolled in this study, the study site staff will make every effort to ensure the participation of participants for the evaluation visits and follow up, in order to minimize possible bias associated with loss-to-follow-up. Each site will establish participant retention procedures to target an average retention rate of 100%. Study site staff is responsible for developing and implementing site-specific SOPs to target this goal.

Suggestions for such procedures include:

- Thorough explanation of the study visit schedule and procedural requirements during the informed consent process and re-emphasis at follow up.
- Collection of detailed locator information at the study Screening and Enrollment Visit, and active review and update of this information at follow up.
- Use of mapping techniques to establish the location of participant residences and other locator venues.
- Regular communication with the study community at large to increase awareness about HIV/ Acquired Immunodeficiency Syndrome (AIDS) and explain the purpose of HIV prevention research and the importance of completing research study visits.
- 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 commend their commitment, time, and effort devoted to the study.
- Schedule all follow-up visits at the participant's Screening and 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 time noted.
- Prepare a calendar of scheduled visits for each enrolled participant, based on her enrollment date and gel administration time, Note the times of all scheduled visits in the participant's file for easy reference.
- 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.
- 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 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.
- 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, ask if she would be willing to complete a final test at the end of the study. If the participant refuses this level of involvement, explain that she is always welcome to come back if she wishes.