

Section 7. Participant Retention

This section presents information related to participant retention definitions, requirements, and procedures. Study staff must make every effort to retain all randomized study participants for the duration of the study. Successful retention begins with inclusion of participants who fully understand what study participation involves and collection of exhaustive locator information from each study participant. It also relies on development and implementation of a comprehensive retention plan.

7.1 Retention Definitions

The term “retention” refers in general to completion of study follow-up visits and procedures as specified in the 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 046, two different retention measures will be used:

- During the study, retention is defined in routine retention reports sent out by the SDMC based on whether participants complete scheduled visits within the allowable visit window. Participants who complete their visits within the allowable visit window will be considered “retained” for those visits.
- For SMC and DSMB reports and at the end of the study, retention is based on whether infants complete the HIV testing schedule per study protocol within the allowable visit windows. Infants who complete their last expected visits within the allowable visit window and undergo HIV testing at these visits, if applicable, will be considered “retained.” As the HPTN 046 primary endpoint is HIV infection in the infant at 6 months (for those infants determined to be uninfected at 6 weeks), HIV testing within the 6 month visit window is of particular importance.

As indicated above, during the study, participants who do not complete a particular scheduled visit within the allowable window but do complete the next scheduled visit, will not be considered retained for the visit that they missed, but will be considered retained for the next scheduled visit. Thus, retention rates can fluctuate over time and across visits. Importantly, retention can be improved by ensuring that participants return for their next scheduled visit after missing a visit.

The SDMC will generate retention reports during the study presenting retention rates for key study visits designated by the Protocol Team. The SDMC will also generate a final end-of-study retention rate for each site after the study is completed (see also Section 13).

7.2 Retention Requirements

Each study site will target retention of at least 95% of randomized study participants annually (or 97.5% every six months). The purpose of this retention target, as explained in Section 7.3 below, is to ensure the accuracy and interpretability of the study results. Note that the general retention goal is to retain ALL randomized mothers and infants throughout the entire 18-month follow period.

7.3 Rationale for Retention Goals

The primary objective of HPTN 046 is to compare the rate of HIV infection in the two study arms at 6 months in infants who are HIV uninfected at 6 weeks. HIV infection rates are calculated as the number of study participants who become infected with HIV during a study divided by the total amount of

participant follow-up time observed in a study. Follow-up time in a study is usually expressed in “person-years” and depends on the number of participants randomized and how long each participant stays in a study. Low retention rates can seriously impact the accuracy of the HIV infection rates and adverse events observed during a study because we cannot know whether or not those participants who have not returned for study visits have become HIV infected or experienced health problems potentially related to the study product. The observed 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, high rates of participant retention must be maintained throughout a study. Without high retention rates, we cannot be sure that study results are accurate or interpretable.

7.4 Retention Plan

Site staff are responsible for establishing a participant retention plan for the study, and for updating the plan and retention efforts to meet the study retention goal of 95% per year. The retention plan 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 an appointment has been missed
- Planned retention methods, including what locator efforts are taken after a missed appointment
- 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
- QC/QA procedures related to the above (if not specified elsewhere)
- Attached copies of locator forms, tracking reports, worksheets, etc.

7.5 Obtaining and Updating Locator Information

Collection of accurate locator information from each study participant is critical. All study participants will be asked to provide locator information at their first screening visit. Sites are encouraged to have home visitors escort participants home to confirm locator information, if feasible and culturally acceptable.

Sites should develop an exhaustive locator form to maximize contact effectiveness and participant retention. Potential locator items include:

- Participant's name, alias, and/or nickname; government-issued identification number; physical and mailing home address; home phone number; mobile phone number; work address; work phone number
- Walking/driving/public transport directions and/or pictorial map to the participant’s home, workplace, etc.
- Name, physical address, telephone number, and/or other contact information for at least one stable community contact (e.g., participant’s family members and friends) who typically knows the whereabouts of the participant
- Permissions for contacting participants and family members or other acceptable contacts

- Information to maintain participants' confidentiality

During the informed consent process and when collecting locator information, study participants should be informed that their other locator sources will be contacted if study staff are unable to locate the participant directly. Study staff should negotiate with the participant how they will identify themselves when locator sources are contacted.

Study staff should view every participant contact as an opportunity to update the participant's locator information. When updating locator information, study staff should actively review *each* item on the locator form to determine whether the information is still current, rather than simply asking if any of the information has changed since the last visit. It may also be helpful to probe for additional information that the participant was not able or willing to provide at previous visits.

7.6 Participant Tracking Database

The CORE will provide all sites with a computer database (Microsoft Access) that can be used to assist with participant retention. The database has the capability to produce lists of participants who are due for scheduled visits within a certain time period and those who are overdue for scheduled visits. To aid in completion of home visits for participant reminders and follow-up on missed visits, the lists may be sorted by home visitor and geographic region. Sites are encouraged to use the database, but it is not required.

7.7 Retention Tips

Several additional tips for successful retention are as follows:

- Be judicious about participant enrollment. Do not enroll participants who seem ambivalent about study participation. Be sure that volunteers fully understand what is involved before they are enrolled and randomized.
- Treat all participants with respect at every encounter.
- Work to make each study visit as quick, easy and pleasant for the participant as possible. Do not keep participants waiting. Make them feel comfortable and welcome at each visit.
- Dedicate adequate staff time to retention efforts.
- Assign a staff member to oversee the retention of a specific set of participants (e.g., one home visitor/outreach worker for every 12-15 participants) to ensure continuity and to establish and maintain rapport and contact with each participant.
- Work with participants to determine the best and most desirable way for the staff to contact them to remind them of scheduled visits or to inform them of other study related matters; record preferences clearly in the locator records so that others will also handle contacts in this way.
- 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.
- Use the Participant Tracking Database to easily identify when participants' scheduled visits are due. 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 based on the infant's date of birth (considered Day 0). Thereafter, at each scheduled 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 the infant's date of birth (or offer a planner/calendar as an incentive and note all study appointments). 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 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 (see Section 12.5.4 for allowable visit windows). Organize daily caseloads and work assignments based on these priorities.
- Follow-up on missed appointments with an attempt to re-contact/re-schedule within a short period of time. Continue these efforts per the local retention plan until contact is made.
- Keep locator information up-to-date and maintain thorough documentation of all efforts to contact the participant. Maintain all 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). Also make use of other available locator information sources, such as phone and post office directories and other public registries. Respect the requests of participants with regard to contacting them.
- 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 no longer wants to participate in the study, explain that she is always welcome to come back if she wishes.
- If a participant has been terminated from the study but decides to rejoin at a later date, resume follow-up if she is still within her study time frame, i.e., within 18 months after delivery.