

## Section 7. Participant Retention

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This section presents information related to participant retention definitions, requirements, and procedures. The primary objective of HPTN 057 is to evaluate the safety, tolerance and pharmacokinetics of tenofovir disoproxil fumarate (TDF) when administered to HIV-infected pregnant women during labor and/or to their infants during the first week of life. Low retention rates can seriously impact the accuracy of the safety and tolerance data and adverse events observed during a study, because we cannot know if those who did not return experienced health problems potentially related to the study product. Without high retention rates, we cannot be sure that study results are accurate or interpretable.

Study staff must make every effort to retain all enrolled 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 to a participant’s 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 057, two different retention measures will be used:

- The Statistical and Data Management Center (SDMC) defines retention based on whether participants complete scheduled visits within the allowable visit window. Participants who do so are considered “retained” for those visits.
- For the study monitoring committee Study Monitoring Committee (SMC) and Data Safety Monitoring Board (DSMB) reports, retention is based on whether mothers and infants complete the evaluations per study protocol within the allowable visit windows. Mothers and infants who complete their last expected visits within the allowable visit window and who are considered evaluable defined as having a complete set of pharmacokinetics (pk) specimens will be considered “retained.”

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 after a missed visit, participants return for their next scheduled visit.

The SDMC will report retention rates for key study visits designated by the Protocol Team. The SDMC will also generate a final end-of-study retention rate report for each site.

### 7.2 Retention Plan

Site staff is responsible for establishing a participant retention plan for the study, and for updating the plan and retention. Because elements of the retention plan will affect study participants, it is recommended that the site seek input from the Institutional Review Board (IRB) and the Community Advisory Board (CAB) before implementing the plan, however IRB approval is not required. 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)
- Acknowledgement that retention begins with screening and enrolling the right participants. During screening, a particular emphasis should be placed on the requirement that participants must be willing to attend all visits and do not plan to re-locate out of the study area for the duration of the study. In addition, a thorough explanation of the procedural requirements and the importance of both treatment arms to the overall success of the study should take place during the informed consent process and be re-emphasized at each study visit
- Methods and timeframes for visit reminders
- Plans for mobilization of trained outreach workers or “tracers” to complete in-person contact with participants at their homes or other community locations to remind them of the study visit or to deliver important study-related information, such as significant lab results.
- Methods and timeframes for identifying when an appointment has been missed
- Procedures for immediate and multifaceted follow-up on missed visits including what outreach/locator efforts, such as phone calls and home visits, 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
- Plans for regular communication with the community at large to increase awareness about HIV/AIDS and explain the purpose of HIV prevention research and the importance of retention in order to produce valid results
- 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)

### **7.3 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 (i.e., 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 must give permission for study staff to contact family members or other acceptable person if study staff is unable to contact the participant directly. Study staff should negotiate with the participant how they will identify themselves when locator sources are contacted. Arrangements agreed upon 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, 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.

## 7.4 Retention Strategies

General strategies for maximizing participant retention:

- Be judicious about participant enrollment. Do not enroll participants who seem ambivalent about study participation. Be sure volunteers fully understand what is involved and will be able to sustain the visit schedule for the duration of the study before they are enrolled.
- Treat all participants with respect at every encounter.
- Make each study visit as quick, easy and pleasant for the participant as possible. Do not keep participants waiting.
- Schedule appointments to fit participant needs when possible, such as offering evening or weekend appointments.
- Dedicate adequate staff time and effort to retention efforts.
- Build relationships with participants and ensure continuity by using the same staff for each visit (e.g., schedule appointments with the same nurse/retention worker for the duration of the study).
- Work with participants to determine the best way for 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 (e.g., newsletters).
- Inform local service providers who interact with the target population about the study, so they can express their support for the study.
- Emphasize the value of the participant's involvement in the study during the informed consent process and follow-up visits.
- Use a tracking database to identify individual scheduled visits. 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.
  - ◆ Schedule follow-up visits for the beginning of the allowable visit window 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 12.7 for allowable visit windows). Organize daily caseloads and work assignments based on these priorities.

- ◆ Follow-up on missed appointments as soon as possible 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. Keep information well organized so all staff members can easily contribute to re-contact efforts when necessary.
- ◆ Use all information on the participant's locator form. Even if a locator source is not useful/successful on one occasion, it may be another time.
- ◆ Use various contact methods (e.g., phone, mail, home visits, street outreach) and use other locator information sources, such as phone and post office directories and other public registries. Always respect participant's requests regarding contact.
- ◆ Post outreach workers at other local service organizations frequented 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 has been terminated from the study but decides at a later date to rejoin, resume follow-up if she is still within her study time frame, i.e., within 12 months after delivery.