

Section 8 Participant Retention

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Section 8 Participant Retention

This section presents information related to participant retention definitions, requirements, and procedures. 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.

Low retention rates can seriously impact the accuracy of the HIV infection rates and adverse events observed during a study, because we cannot know if those who do not return for testing are HIV infected or uninfected, dead or whether or not they have experienced health problems potentially related to the study product. The observed rate of HIV infection or death 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 the study. Without high retention rates, we cannot be sure that study results are accurate or interpretable.

8.1 Retention Definition

The term “retention” refers in general to the 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 058, two retention measures will be used:

- During the study, in routine retention reports sent out by the SDMC, retention is 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.
- At the end of the study, retention will be based on whether participants complete HIV testing at the participants’ study exit visits. 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 earlier than planned (i.e. Week 48) and complete the algorithm for HIV testing 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 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 routinely 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 SSP Section 13).

8.2 Retention Requirements

Ideally, each study site should strive for 100% retention. Recognizing that this ideal may not always be attainable, each study site will target retention of at least 90% of enrolled study participants who are alive at 104 weeks. Stopping or modifying the study may be considered if the study team fails to meet retention goals. Figure 8-1 presents the monthly retention rates that must be met over the course of the study to achieve the retention target.

Figure 8-1 Monthly Retention Targets for HPTN 058

Week of Study	Target % Retained
26	97.5
52	95.0
78	92.5
104	90
130	87.5
156	85.0

The primary objective of HPTN 058 is to compare the rate of HIV infection and death in the two study arms after 104 weeks of study participation. HIV infection and death rates are calculated as the number of study participants who become infected with HIV or dies 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 enrolled in a study and how long each participant stays in a study. Low retention rates can seriously affect the accuracy of the HIV infection rates observed during a study as described above.

8.3 Retention Plan

The site staff is responsible for establishing a participant retention plan for the study, and for updating the plan and retention efforts undertaken to meet the study retention goal. Because elements of the retention plan will affect study participants, it is recommended that the site seek input from both the Institutional Review Board (IRB) and Community Advisory Board (CAB) before implementing the plan. However, IRB approval is not required for the retention plan.

The retention plan should minimally contain:

- Site-specific retention goals.
- Methods for tracking actual retention versus retention goals.
- Procedures for collecting detailed locator information at the study Screening Visit, and active review and update of this information at each subsequent visit.
- Site-specific definition of “adequate” locator information (for purposes of determining participant eligibility) including use of mapping techniques to establish the location of participant residences and other locator venues.
- 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 relocate 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.

- Use of appropriate and timely visit reminder strategies, such as post cards the week before and phone calls or home visits the day before a scheduled visit.
- 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. **No study specific assessments or evaluations can be conducted off-site, and no study drug can be routinely dispensed off-site.**
- Methods and timeframes for identifying when a visit 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 (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 at their Screening Visit and to update this information at each subsequent visit. Each study site is encouraged to develop an exhaustive locator form to maximize contact effectiveness and participant retention (see sample form at end of the section). 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 name, alias, and/or nickname; home address; home phone number; mobile phone number; work address; work phone number; e-mail address; daytime and night-time 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.
- Name, address, telephone number, and/or other contact information for the participant's health care provider, school or training program, case worker, or religious leader.
- Name, address, and/or other contact information for other locations frequented by the participant, such as bars, sports venues, or temples.

During the informed consent process and when collecting locator information, study participants must give permission for contacting participants and family members or other acceptable contacts. 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, site staff should 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?"). In addition, site staff should probe for additional information that the participant was not able or willing to provide at previous visits.

8.5 Participant Tracking Database

Due to the potential complexities that may be encountered when scheduling and completing follow-up visits, it is recommended that sites use a participant visit tracking sheet similar to the example provided in Section 5.3. Sites may also choose to develop a database containing the same information. Any participant tracking database that is developed is to be used for tracking purposes only. The database may not be used to record source data or to generate source documents unless specified in the site SOP for Source Documentation. All information entered into the database must be based on other source documents contained in participants' study charts.

8.6 Retention Strategies

Some general strategies for maximizing participant retention are presented below:

- Dedicate adequate staff time and effort to retention efforts. This will mean dedicating staff to evening and weekend hours.
- The visit schedule for both arms of HPTN 058 is demanding. At screening, it is important that the staff assess the likelihood a particular participant will be able to sustain the visit schedule for at least two years (three in some cases for the first enrollees).
- 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.
- Treat every participant with respect. Keep their information confidential.

- Make the visits as short and pleasant as possible for the participants. Do not keep participants waiting.
- Whenever possible, make appointments to fit participants' needs, such as offering evening or Saturday appointments.
- Build relationships with the participants by using the same staff for each visit. For example, try to schedule individual participants with the same counselor, nurse and retention worker for the study duration.
- 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 study newsletters, or quarterly meetings, for example).
- Inform local service providers who interact with the study population about the study so that they can express their support for the study and inform potential participants about 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 a 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.
- Always schedule the participants' next contact and/or visit before she/he completes the prior contact or visit. Give the participant an appointment card with the scheduled contact or visit date and time noted.
- Prepare a calendar of scheduled visits for each enrolled participant, based on the enrollment date (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.
- If a participant has demonstrated difficulty attending visits, schedule follow-up visits for the **beginning** of the allowable visit window (i.e., up to 14 days 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 six-month visits at which primary study endpoints are ascertained. Organize daily caseloads and work assignments based on these priorities.
- Follow-up on missed appointments with an attempt to re-contact/reschedule as soon as possible (preferably on the same day). 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. 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.

- Use all information collected on the participant's locator form while being careful to protect participant's privacy. Even if a locator source is not useful/successful on one occasion, try it again later.
- Use all available contact methods (e.g. phone, mail, home visits [with consent], street outreach, and e-mail/internet). Also make use of other available locator information sources, such as phone and post office directories and other public registries.
- Post outreach workers at other local service organizations used by the study population, such as temples and health care clinics.
- Attempt contact with the participant at different times during the day and the week, including evenings and weekends.
- Assist participants in making transportation arrangements if necessary. This may be done with vouchers, site-owned vehicles, or instructions about other modes of transportation.
- If a participant reports that she/he wishes to discontinue participation in the study, ask if she/he would be willing to continue having biannual HIV tests, or at least a final HIV test at the end of the study. If the participant refuses this level of involvement, explain that she/he is always welcome to come back if she/he wishes.
- If a participant has been terminated from the study but decides at a later date to rejoin, resume follow-up if she/he is still within her study time frame, i.e., within 104 weeks of enrollment or 156 weeks dependent upon the participant's original follow-up schedule.
- If a participant dies during the study (even if that participant is lost to follow up), every effort should be made to locate copies of official paperwork if it exists (eg. a death certificate) to verify this information.

PARTICIPANT LOCATOR INFORMATION SHEET--SAMPLE

(Additional information from the participant may be written on the reverse of this form)

1. Personal Details

Full name _____

Name commonly used in the community? _____

Home Address _____

Address Change #1: (date and initial) _____

Address Change #2: (date and initial) _____

Please describe how to get to your home from the Clinic (draw map on back if needed)

Home Phone Number _____

Phone Change #1: (date and initial) _____

Phone Change #2: (date and initial) _____

Cell Number: _____

Cell Change #1: (date and initial) _____

Cell Change #2: (date and initial) _____

Email: _____

Email Change #1: (date and initial) _____

Email Change #2: (date and initial) _____

Can we visit you at home? Yes No
Can we phone you at home? Yes No

2. Contact Information

Please tell us names of two people who will always know how to find you even if you move. We will contact these people if needed, but we will not tell them why we are looking for you.

Contact #1: _____

What is your relationship to this person? _____

What is the phone number for this person? _____

What is the address of this person? _____

Contact #2:

What is your relationship to this person? _____

What is the phone number for this person? _____

What is the address of this person? _____

3. Workplace or School Details

Workplace or School Name _____

Workplace or School Address _____

Work or School Phone Number: _____

Can we visit you at work or school? _____

When are you usually at work or school? _____

Workplace Change #1 (date and initial):

Workplace Name: _____

Workplace Address: _____

Workplace Phone: _____

Workplace Change #2 (date and initial):

Workplace Name: _____

Workplace Address: _____

Workplace Phone: _____

4. Places Frequently visited in Community

Please tell us names and addresses of other places that you like to visit or where you often can be found such as bars, temples, or health care organizations.

5. Other details regarding how to contact this participant. Document how staff will identify themselves when locator sources are contacted.