

Section 7. Participant Retention

7.1 Overview of Section 7

This section provides an overview of participant retention and termination for the study.

7.2 Retention Definition

The term “retention” refers in general to the completion of study follow-up visits and procedures as specified in the study protocol. Throughout the study, SCHARP will generate monthly retention reports that present weekly and cumulative retention rates for all sites individually and combined.

7.3 Retention Targets

Ideally, each study site should strive for 100% retention. However, recognizing that this ideal may not always be attainable, per the protocol, each study site will target retention of at least 95% of enrolled study participants completing follow-up visits at the 26-week visit and 90% at the 52-week visit.

7.4 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 of 90-100% for the 52-week follow-up period. Because elements of the retention plan will affect study participants, it is recommended that the site seek input from both the IRB and CAB before implementing the plan. However, IRB approval is not required by the HPTN for the retention plan (although it may be by the IRB).

The retention plan should at a minimum contain the following elements:

- The determination should be made at prescreening that the participant does not have any plans to move out of the study area during the time of study participation. In addition, a thorough explanation of the study visit schedule and procedural requirements should take place during the informed consent process and be re-emphasized at the 26-week study visit.
- Thorough explanation of the importance of study visits to the overall success of the study.
- Collection and verification of detailed locator information at the study enrollment visit, and active review and update of this information at the 26-week follow up visit and during health navigation visits.

- Use of appropriate and timely visit reminder mechanisms.
- Immediate and multifaceted follow-up on missed visits.
- Mobilization of trained outreach workers or “tracers” to complete in-person contact with participants at their homes or other community locations.
- Procedures for the PHNs to communicate with their participants regarding the study and the visit schedule.
- Procedures for tracking participants who are incarcerated after enrollment and for re-establishing contact with the participants after release.
- Regular communication with the study community at large to increase awareness about HIV/AIDS and explain the purpose of HIV prevention research and the importance of completing research study visits.
- Procedures for conducting off-site visits for participants that will be unavailable to come to the clinic during their follow-up visit window (See SSP Section 5.9 for further information about the use of off-site visits).
- Procedures for participants that transfer sites during the study (see SSP Section 5).

Additional elements such as the ones described below may be added to the retention plan:

- Study retention goals.
- Methods for tracking actual retention versus retention goals.
- Planned retention methods, including what steps are taken within 24 hours, 1-3 days, and 1-3 weeks after a missed appointment.
- Methods for timely evaluation of the utility of retention methods.
- 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.

For each participant, clinic staff will obtain confidential contact information. In the event that a participant misses a scheduled appointment, clinic staff will try to establish communication with the participant through all possible means (*e.g.*, telephone, e-mail, mail contact, and visits to home, workplace or other locations).

At each visit, site staff should emphasize to study participants the importance of attending all scheduled follow-up visits.

7.5 Retention Strategies

Some general strategies for maximizing participant retention are presented below.

- Dedicate adequate staff time and effort to retention efforts.
- Use of a dedicated, toll-free study line for participants to contact study staff.
- Ensure availability of childcare and/or transportation services.
- 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 during 26 week follow-up visits.
- Implement a tracking system 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 participant's next contact and/ or visit before 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 participant's enrollment date (or offer a planner/calendar as an incentive and note all study appointments). As noted in Section 3, SCHARP will provide an on-line visit scheduler to facilitate follow-up visit date calculation. Note the dates of all scheduled visits in the participant's file for easy reference. Given that scheduled visits are 6 months apart, try to provide a reference point for the participant such as a holiday or time of year.
- Pay close attention to the target visit window and prioritize retention efforts for participants nearing the end of the window Organize daily caseloads and work assignments based on these priorities.

- 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 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.
- 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, newspapers, e-mail/internet). Also make use of other available locator information sources, such as phone and post office directories, other public registries and web-based resources.
- 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. Be sure the caller ID on the phone you are using will not inadvertently compromise the participant's confidentiality.
- Assist participants in making transportation arrangements if necessary. This may be done with public transportation or cab vouchers, site-owned vehicles, or instructions about other modes of transportation.
- Make use of off-site visits if allowed at your site, if the participant cannot make it to the clinic.
- If a participant reports that he wishes to discontinue participation in the study, ask if he would be willing/interested in having at least a final assessment.

7.6 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 Enrollment 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. Potential locator items include:

- Participant's 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 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 at least two 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, social service case worker, counselor, rehabilitation provider, participant's child's health care provider, *etc.*
- Name, address, telephone number, and/or other contact information for support groups, shelters, food pantries, *etc.*, frequented 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.

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.

Peer health navigators should try to verify contact information during health navigation visits. However, locator information should be removed from the site. Each site should identify procedures for facilitating updated information while ensuring that participant confidentiality is protected.