Section 8. Participant Retention

This section presents information related to definitions, requirements, and procedures for participant retention in HPTN 059.

8.1 Retention Definition

The term "retention" generally refers to completion of follow-up visits 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 for scheduled follow-up visits will be defined based on whether participants complete scheduled visits within the allowable visit window. Participants who complete their scheduled visits within the allowable visit window will be considered "retained" for those visits.

As indicated above, participants who do not complete a particular scheduled visit within the allowable window, 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 visit. Thus retention rates can fluctuate over time and across visits. Importantly, retention shortfalls can be made up by ensuring that participants return for their next scheduled visit after missing a visit.

The HPTN Statistical and Data Management Center (SDMC) will generate reports during the study presenting retention rates for key study visits designated by the Protocol Team. The SDMC also will generate a final end-of-study retention rate for each site after the study is completed. For purposes of monitoring and ongoing retention efforts at each site, retention will be defined in SCHARP reports as described below:

Retained On-Time: Participant completed visit within the allowable visit window and thus meets the protocol definition of "retained" for that visit.

Retained Early or Late: Participant completed a visit, but was outside the allowable visit window. All visit procedures should be conducted for the given visit. The visit will not meet the protocol definition of "retained," as the visit occurs outside the visit window; however, the visit will be counted as "early" or "late" retained and will contribute to the site's overall retention as reflected in the SCHARP reports. Below are some examples of "early" and "late" retained visits:

- A participant missed her visit 3.0 and the visit window has passed. The participant then shows up for the visit two days after her visit 3.0 visit window has closed. All visit 3.0 procedures should be done at this time, and the visit should be assigned the same visit code 3.0. The visit will be counted as a "late retained visit" based on the visit date recorded on the CRFs.

- A participant knows in advance that she will be unable to complete her visit 4.0 visit within the visit window, but is available for a visit one day before the window opens. In this case, the participant should be asked to complete the visit early, before the visit window opens; the visit should be assigned the same visit code 4.0. This visit will count as an "early retained visit" based on the visit date recorded on the CRFs.

See section 13 of this SSP manual for more details on assigning interim visit codes.

8.2 Retention Requirements

Each study site will target retention of at least 95 percent of enrolled study participants at 24 weeks of follow up.

The purpose of the 95 percent annual retention target is to ensure the accuracy of study results. Low retention rates can have a serious impact on the accuracy of study outcomes. In each group, the observed safety/toxicity and adherence/acceptability rates 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, and thereby avoid bias in the study results, high participant retention rates must be maintained throughout the study.

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 95 percent at 24 weeks of follow up. 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 reminder methods and 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, 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
- 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 process, and to continually review/update this information during follow-up. 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. 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 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 Participant Tracking Database for the Pune, India site:

The HPTN Coordinating and Operations Center (CORE) will provide the Pune site with a Participant Tracking Database to support participant retention efforts in HPTN 059. Among other features and functions, the database will be pre-programmed to generate lists of participants who are due for visits and who have missed visits within specified timeframes. To facilitate off-site participant outreach and tracing activities, lists may be sorted by assigned outreach worker and geographic location. Lists also may be prioritized by the number of days remaining in the current visit window.

When using the database, the site must follow user instructions provided by the CORE, and take part in database training, validation, and quality assurance activities specified by the CORE. The database may not be used to record source data or to generate source documents. All information entered into the database must be based on other source documents contained in participants' study charts.

The US sites will not use the Participant Tracking database as a retention tool, but will develop alternative tools for participant tracking. These tools will be reviewed by CORE prior to study initiation.

8.6 Retention Tips

Some general strategies for maximizing participant retention are presented in protocol Section 3.5. Additional tips for successful retention are as follows:

- 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.
- Host gatherings, parties and/or other social events for participants.
- Host social, educational, and/or other "male involvement" events for participants' partners.
- Use tracking tools to identify when participants' scheduled visits are due and/or overdue. Establish routine mechanisms to remind both study staff and participants of upcoming scheduled visits.
- Schedule all follow up visits at four week intervals from the participant's 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 visit date and time noted.
- Prepare a calendar of scheduled visits (and anticipated time of menses) for each enrolled participant, based on her enrollment date, or offer a planner/calendar as an incentive and note all study appointments in the planner/calendar. Note the dates of all scheduled visits in the participant's file for easy reference

- Contact participant or ask participant to contact the site around the time of participant's menses to confirm next appointment and verify date of the visit will not occur during menses.

- 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 one week 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. 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 SOP 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 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.

- 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 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.