

Section 7. Participant Retention

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7.1 Overview of Section 7

This section presents information related to participant retention definitions, requirements, and procedures. Once a participant consents for HPTN 084 OLE 1/Amendment 3 or OLE 2/Amendment 4, the study site will make every effort to retain her for the full study in order to minimize possible bias associated with loss-to-follow-up (LTFU). 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.

7.2 Retention Definition

The term “retention” refers, in general, to participant attendance and completion of study visits/procedures as specified in the protocol. Participants who do not complete a particular scheduled visit within the allowable visit window, but do complete the next scheduled visit, will not be considered retained for the missed visit, but will be considered retained for the attended visit. Thus, retention rates can fluctuate over time and across study visits. Importantly, retention can be improved by ensuring that any participants who miss a visit return for the next scheduled visit.

7.3 Retention Targets

Ideally, each site should strive for 100% retention of those in Protocol Version 3.0. Routine retention reports for all sites are available on the Atlas portal maintained by the HPTN Statistics and Data Management Center (SDMC). The HPTN SDMC will also generate a final end-of-study retention rate for each site at study end. See SSP Section 15 for more information about Retention Reports.

7.4 Retention Plan

As with HPTN 084 pre OLE (Version 3.0), sites are expected to retain participants with no more than 5% annual loss to follow-up. A new SOP is not required for OLE 1 or 2, but sites may wish to modify their existing plan if necessary.

7.5 Participant Tracking Database

Due to the potential complexities that may be encountered when scheduling and completing visits, it is recommended that sites use a participant visit tracking sheet or database. This will most likely be a separate database created at your site for the OLE. 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 participant study charts.

7.6 Retention Strategies

Some general strategies for maximizing participant retention are presented below:

- Dedicate adequate staff time and effort to retention efforts.
- Discuss the length of the study (48 weeks typically) and whether she will be able to meet the visit schedule during the consent process.
- Treat every participant with respect. **Keep information confidential.**
- Make visits as pleasant and short as possible. Do not keep participants waiting unnecessarily.
- Emphasize the value of the participant involvement in the study during the informed consent process and at subsequently visits. When participants complete scheduled visits, acknowledge and compliment their commitment, time, and effort devoted to the study.
- Whenever possible, make appointments to fit participant needs, such as offering clinic hours during the evening, weekend, or early in the morning.
- Work with Community Advisory Board members and key stakeholders to identify the most applicable contact and retention strategies for the local study population, including the type and amount of participant incentives.
- Keep participants, Community Advisory Board members, and key stakeholders 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 and address any questions or concerns they have. Encourage them to express their support for the study and inform potential participants and key stakeholders about the study.

- Use a Tracking Database to easily identify when participant visit schedules. Establish routine mechanisms to remind both study staff and participants of upcoming scheduled visits.
- Always schedule the participant's next visit before she completes the current contact or visit. During clinic visits give the participant an appointment card with the next scheduled visit date and time noted.
- Prepare a calendar of scheduled visits or input scheduled visit dates on participant's cell phone 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.
- Consider scheduling study visits for participants at the **beginning** of the allowable visit window (see Section 13 of the SSP for allowable visit windows) to allow maximum time for re-contact and rescheduling 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 contact and 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 contact efforts when necessary.
- Use all information collected on the participant's locator form while being careful to protect the participant's privacy. Even if a locator source is not useful/ successful on one occasion, try it again later unless it is proven to be incorrect.
- Use all available contact methods the participant agreed to (e.g., phone, mail, home visits, street outreach, cell phone texts, e-mail, and social media). Also make use of other available locator information sources, such as phone and post office directories and other public registries.
- Post outreach staff at other local service organizations used by the study population, such as health care clinics. Be sure to maintain participant confidentiality in these public situations.
- 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 mass transit vouchers, site-owned vehicles, or assistance with other modes of transportation.
- If a participant dies during the study (even if that participant is LTFU), every effort should be made to locate copies of official paperwork if it exists (e.g., a death certificate) to verify this information and ascertain the cause of death.

7.7 Participant Withdrawal

Regardless of the participant retention methods described above, participants may voluntarily withdraw from the study for any reason at any time.

The Investigator of Record (IoR) or designee also may withdraw participants from the study in order to protect their safety or if they are unwilling or unable to comply with required study procedures after consultation with the Protocol Chair, Division of AIDS (DAIDS) Medical Officer, SDMC Protocol Statistician, and the HPTN Leadership and Operations Center (LOC) Clinical Research Managers (CRMs). In general, participants should not be withdrawn from the study except in the case of a) withdrawal of consent b) death; or c) extreme/unusual circumstances to protect participant safety. Any such safety-related participant terminations should only be implemented after consultation with the Protocol Chair, Division of AIDS (DAIDS) Medical Officer, Statistical and Data Management Center (SDMC) Protocol Statistician, representatives from the Laboratory Center (LC), the Leadership and Operations Center (LOC) Clinical Research Manager (CRM), and others. Consultation is conducted through the CMC alias.

Participants may be withdrawn if the study sponsor, government or regulatory authorities, or site IRBs/Ethics Committees terminate the study prior to its planned end date.

Every reasonable effort will be made to complete a final evaluation of participants who terminate from the study early, and study staff will record the reason(s) for all withdrawals from the study in participants' study records. In such cases, the IoR or designee must contact the Clinical Management Committee (CMC) for guidance regarding final evaluation procedures.