7. Participant Retention

7.1 Overview of Section 7

This section presents information related to participant retention definitions, requirements, and procedures. Once a participant enrolls in HPTN 083, the study site will make every effort to retain him/her for their full follow-up in order to minimize possible bias associated with loss-to-follow-up. 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 the completion of study follow-up visits and procedures as specified in the study protocol. Participants who do not complete a particular scheduled visit, 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, during the study 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.

7.3 Retention Targets

Ideally, each site should strive for 100% retention. However, recognizing that this ideal may not always be attainable, per the protocol, each study site will target an average annual retention rate of at least 92.5%, measured from Week 0 enrollment. Routine retention reports for all sites will be available on the Atlas portal maintained by the HPTN SDMC. The HPTN SDMC will also generate a final end-of-study retention rate for each site after the study is completed. See SSP Section 14 for more information about Retention Reports.

7.4 Retention Plan

The site staff is responsible for establishing a community engagement work plan and/or participant retention SOP 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 the relevant Institutional Review Board (IRB)/Ethics Committee (EC), as well as the Community Advisory Board (CAB) before implementing the plan. However, IRB/EC approval is not required for the retention plan. The retention plan should be re-evaluated and modified in response to lower than anticipated retention rates, or at any other time when retention strategies are modified.

It is recommended that the community engagement work plan and/or retention plan or SOP should minimally contain:

- Site-specific retention goals.
- Methods for tracking actual retention versus retention goals.
- Procedures for collecting detailed locator information (see sample locator information sheet in Table 7-1) at the study Screening Visit, and active review and update of this information during subsequent visits.
- Acknowledgement that retention begins with screening and enrolling "good candidates" (as described in Section 4.4 of the SSP manual). 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 the two 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 personalized calendars or post cards, electronic reminders, and phone calls.
- Plans for mobilization of trained outreach staff to complete in-person contact with participants at their homes or other community locations to remind them of study visits or to deliver important study-related information. **No study specific assessments or evaluations can be conducted 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).
- QA/QC procedures related to the above (if not specified elsewhere).

7.5 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 continually review/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 in Section Appendix I). Potential locator items include:

- Participant's full name, alias, and/or nickname; government-issued identification number; home address; home phone number; mobile phone number(s); 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.
- Electronic/social media contact information (e.g. Facebook, Twitter, Instagram, Tumblr, WhatsApp).
- Name, address, telephone number, and/or other contact information for stable community contacts (i.e., participant's family members and friends) who typically know the whereabouts of the participant.

  Note: Although contact information for a participant's current primary partner will likely be useful, contact information for other contacts also should 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, or case workers.
- Name, address, and/or other contact information for other locations frequented by the participant, such as bars, sports venues, or coffee shops.

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 discuss with the participant how they will identify themselves when locator sources are contacted. These arrangements, agreed upon with the participant, should be documented on the locator form and reviewed before each participant contact.

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 locator information that the participant was not able or willing to provide at previous visits.

Study staff should document in their source documentation (e.g. chart notes, visit checklist) that they reviewed the locator information with the participant at every visit. Any updates to the locator form should use standard GCP corrections with initials and date of the staff member making the changes.

7.6 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 or database. 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.

7.7 Retention Strategies

Some general strategies for maximizing participant retention are presented below:

- Dedicate adequate staff time and effort to retention efforts.
- Participants will be followed between 1.5 to 4.5 years once they are enrolled in the study. At screening, it is important that the staff assess the likelihood that a particular participant will be able to meet the visit schedule for the full length of the study.
- Be judicious about participant enrollment. Do not enroll participants who seem ambivalent about study participation. Be sure that volunteers fully understand what is involved in study participation before they are enrolled.
- Treat every participant with respect. Keep their information confidential.
- Make the visits as pleasant and short as possible for participants. Do not keep participants waiting unnecessarily.
- 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 compliment their commitment, time, and effort devoted to the study.
- Whenever possible, make appointments to fit participants' 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 related to the study. 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 participants' scheduled visits are due. Establish routine mechanisms to remind both study staff and participants of upcoming scheduled visits.

- Always schedule the participants' next visit before she/he completes the prior 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 follow-up visits for participants at the **beginning** of the allowable visit window (see Section 13.5 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 reports that she/he wishes to discontinue participation in the study, ask if she/he would be willing to return for Annual Visits until three years from the Enrollment date.
- 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 (e.g., a death certificate) to verify this information and ascertain the cause of death.

7.8 Participant Withdrawal

Regardless of the participant retention methods described above, participants may voluntarily withdraw from the study for any reason at any time. The IoR or designee also may withdraw participants from the study in order to protect their safety and/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, Statistical and Data Management Center (SDMC) Protocol Statistician, and the HPTN Leadership and Operations Center (LOC) Clinical Research Managers (CRMs). However, in cases when continued participation on the study may not be in the best interest of the participant; sites are encouraged to discuss with participants and if possible ask participant to attend yearly visits. As a general rule, participants should not be permanently discontinued from the study unless they have formally withdrawn consent, they died, or they experienced a major safety issue that warrants discontinuation per the IoR.

Participants who are unable to receive the first injection for any reason will be followed annually until three years from the date of Enrollment (see Section 5.3.1 in the SSP for required procedures for participants who did not transition to Step 2). If the reason is due to HIV infection, refer to the HPTN 083 protocol Section 5.13.2. Participants who do not complete the full course of injections for any reason, other than HIV infection, will move to Step 3 of the study and receive up to 48 weeks of open label TDF/FTC, followed by annual follow-up until three years from the date of Enrollment. The timepoint during Step 2 that a participant transitions to Step 3 will determine whether they will be asked to attend annual visits following the completion of Step 3. If the completion of open label TDF/FTC for Step 3 post-dates three years from the date of Enrollment, no further annual follow-up is required. Once a participant has completed three years of follow-up, they will then be transitioned to local prevention services.

Participants may voluntarily withdraw from the study for any reason at any time. In general, participants should not be withdrawn from the study during the blinded, randomized portion of the study except in the case of a) withdrawal of consent; b) death; c) extreme/unusual circumstances to protect participant safety; or d) if they are unwilling or unable to comply with required study procedures. 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. Participants may be withdrawn if the study sponsor, government or regulatory authorities (including Office for Human Research Protections [OHRP] and the FDA), or site IRBs/Ethics Committees (ECs) 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 general, for participants who withdraw consent from the study prematurely during a study visit, the requirements for that visit should be completed to the extent possible **except for provision of study product** and will be considered their final visit. When possible, a plan should be made to give final laboratory results to the participant. For participants who inform the site in between visits that they wish to withdraw consent from the study, sites should make every effort to have the participant return any unused study product.

Table 7-1

PARTICIPANT LOCATOR INFORMATION SHEET--SAMPLE

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

1. Personal Details

Full legal name: _____

Name commonly used in the community: _____

ID number:_____

Home Address: _____

_____

Address Change #1: (date and initial)

_____

_____

Address Change #2: (date and initial)

_____

_____

Please describe the route 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

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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? _____

_____

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3. Workplace or School Details

Workplace or School Name _____

Workplace or School Address _____

Work or School Phone Number: _____

When are you usually at work or school? _____

_____

Can we VISIT you at work or school? ☐ Yes ☐ No

Can we PHONE you at work? ☐ Yes ☐ No

Workplace Change #1 (date and initial):

Workplace Name: _____

Workplace Address:_____

Workplace Phone: _____

Workplace Change #2 (date and initial):

Workplace Name: _____

Workplace Address:_____

Workplace Phone: _____

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4. Places frequently visited in the community

Please tell us the names and addresses of other places that you like to visit or where you often can be found such as bars, coffee shops, or sports venues.

_____

_____

_____

_____

_____

_____

5. Electronic/social media contact information (e.g. Facebook, Twitter, Instagram, Tumblr, WhatsApp)

_____

_____

_____

_____

_____

6. Other details regarding how to contact you

Document how staff should identify themselves and why they are looking for you when trying to locate you for study purposes.

_____

_____

_____

_____