4. Recruitment, Screening and Enrollment

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4.1 Overview of Section 4

This section provides an overview of requirements and procedures for recruiting, screening, and enrolling participants in the study. Additional procedure-specific details can be found in the visit checklists in Section 6, and Protocol Sections 5.1 – 5.2.

4.2 Target Enrollment

A total of approximately 5000 HIV-uninfected men who have sex with men and transgender women who have sex with men, ages 18 and older, at high risk for acquiring HIV infection will be enrolled in to the HPTN 083 study. Participants will be selected for the study according to the criteria in Sections 3.1 and 3.2 of the HPTN 083 Protocol. Due to staggered timelines of study activation at the participating sites, each site-specific accrual period may vary as this period is considered to begin on the first day of participant enrollment at each individual site.

Enrollment will be monitored closely, and enrollment slots may be shifted between sites in order to ensure that the overall study is enrolled as expeditiously as possible. Additionally, the study aims to do the following: 1) enroll the majority of participants 30 years of age and younger; 2) enroll at minimum 50% of the US-based recruitment with Black MSM, and 3) enroll at minimum 10% TGW overall.

For each site, accrual will begin after all applicable approvals are obtained and a Site-Specific Study Activation Notice is issued by the LOC.

Screening and enrollment data will be captured on electronic case report forms (e-CRFs) within the electronic data capture system.

The SDMC will provide screening and enrollment reports available on their portal based on data received and entered into the study database.

4.3 Recruitment Plan

Each site is responsible for establishing a community engagement work plan and/or a recruitment plan/SOP for this study, and for updating the plan if needed to meet the targeted enrollment goals. The work plan/SOP should contain the following elements as necessary and as applicable to the study:

- Site-specific accrual goals
- Methods for tracking actual accrual versus accrual goals
- Recruitment methods and venues
- Methods for ensuring participants are not co-enrolled in another HIV prevention study
- Methods for identifying the recruitment source of participants who present to the site for screening
- Methods for timely evaluation of the utility of recruitment methods and venues
- Pre-screening activities
- Recruitment timelines
- Ethical and human subjects considerations
- Staff responsibilities for all of the above (direct and supervisory)
- Staff training requirements
- QA/QC procedures related to the above (if not specified elsewhere)

- Attached copies of recruitment worksheets, scripts, and other operational tools

4.4 Accrual Tips and Reminders

Recruitment can be more challenging than expected. Therefore, it is important to plan ahead, closely monitor recruitment data throughout the accrual period, and make adjustments as needed.

Recruitment methods and venues should be assessed on an ongoing basis. The usefulness or "yield" of various recruitment sources should be tracked over time. Sites should identify recruitment sources of participants who screen and enroll and track methods for timely evaluation of the usefulness of recruitment methods and venues. The following point should be considered:

- Of all participants contacted through a particular method or at a particular venue, how many eventually enroll in the study?
    - If this number (percentage) is high, keep using that method or venue.
    - If not, try different recruitment methods or identify new venues.
- Designate a Recruitment Coordinator who is responsible for tracking accrual rates and managing recruitment efforts over time.
- Engage community representatives on accrual issues and strategies throughout the accrual period.
- Consider characteristics of a "good candidate", e.g., is a prospective participant at high risk for HIV acquisition, likely to be retained for the duration of the study, and willing to attend all clinic visits?

4.5 Eligibility Determination

It is the responsibility of the site IoR and other designated staff, to ensure that only participants who meet the study eligibility criteria are enrolled in the study. As a condition for study activation, study sites must establish an SOP that describes how study staff will fulfill this responsibility. It is recommended that this SOP contain the following elements:

- Eligibility determination procedures, including:
    - Screening visit eligibility assessment procedures
    - Post-screening visit eligibility assessment, confirming procedures and timelines
    - Final confirmation and sign-off procedures prior to enrollment
    - Documentation
- Ethical and human subjects considerations
- Staff responsibilities for all of the above (direct and supervisory)
- Staff training requirements
- QC/QA procedures related to the above (if not specified elsewhere)

Sites may choose to conduct pre-screening activities, as determined by relevant local IRB/EC policies, SOPs and standard of care practices.

Section 3 (Documentation Requirements) includes a table that sites may wish to use as a template to adapt to a site-specific format for source documents that can be used to demonstrate participant eligibility. Sites may choose to develop their own site-specific documentation to specify the source for each eligibility criteria.

Sites are required to use an Eligibility Checklist to document participant's eligibility to join the study. A template checklist is found in Section 6 of the SSP and further information on the process for completing the checklist is found in Section 3 of the SSP. The template checklist requires four signatures, two signatures are required prior to randomization and two signatures are required prior to the provision of study product - - this latter requirement is mainly to accommodate sites that may need to conduct "split" Enrollment visits (mainly due to off-site pharmacies where randomization needs to occur prior to the participant reporting for the enrollment visit). Sites that are able to randomize and provide study product on the same day will still complete these reviews and signature lines as instructed. Each completed checklist will be emailed within five working days to Marybeth McCauley, Kaila Gomez-Feliciano, Andrea Jennings and Leah Schrumpf at: mmccauley@fhi360.org; kgomez@fhi360.org; ajennings@fhi360.org; lschrumpf@fhi360.org. The completed checklist does NOT need to be emailed prior to randomization (or enrollment, if visit is "split"). Once Marybeth, Kaila, Andrea and Leah receive the completed checklist, they will send an email acknowledging receipt; this acknowledgment should be filed in the research record of the participant with other eligibility and enrollment documentation.

Please note, the Eligibility eCRF in MediData Rave does not substitute the Eligibility Checklist. Both documents must be completed as part of the enrollment process.

4.5.1 Informed Consent Process

Informed consent is a process by which an individual voluntarily expresses his/her willingness to participate in research, after having been informed of all aspects of the research that are relevant to his/her decision. Informed consent is rooted in the ethical principle of respect for persons. It is not merely a form or a signature, but a process, with four key considerations — information exchange, comprehension, voluntariness, and documentation — each of which is described below. See Section 4.8 of the ICH GCP guideline and the informed consent section of the *DAIDS Policy for Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials (DWD-POL-CL-04.00)* for detailed guidance on the informed consent process and documentation requirements.

During the screening process, participants will be administered the IRB/EC locally-approved informed consent form prior to the administration of any study procedures. If a participant meets the eligibility criteria for the study and the study staff agree that the participant can fulfill the study requirements, they will be asked to enroll. For enrolled participants, informed consent should be considered as an ongoing process that continues throughout the duration of the study.

U.S. regulations specify the elements of informed consent that must be conveyed to research participants through the informed consent process (45 CFR 46 and 21 CFR 50). It is the responsibility of the IoR, and his/her delegated staff, to deliver all required information to potential research participants.

Based on the technical and regulatory reviews that are completed as part of the HPTN protocol development and study activation processes, there is adequate assurance that once the HPTN LOC has "activated" a site for study implementation, the site-specific informed consent form specifies all information required by the regulations. However, responsibility for informed consent does not end with preparation of an adequate informed consent form. It also is the responsibility of the IoR and designated study staff to perform the activities described in these sections.

4.5.1.1. Deliver All Required Information in a Manner that is Understandable to Potential Participants

If the participant is literate, give them a copy of the informed consent form to read during the screening/enrollment visits. Also provide the participant with other (IRB/EC-approved) informational materials developed to complement the informed consent form, if any**.** If the participant is not literate, the materials may be read to him/her verbatim. After the participant has read the written material (or had it read to him/her), verbally review the information provided. A checklist or the informed consent form itself may serve as a useful guide for this. For example, you may note the main points described in each paragraph of the informed consent form and ask if the participant has questions or concerns about each point. Listen carefully to the questions or concerns expressed by the participant and discuss these thoroughly. Take as much time as needed to address each question and concern.

If the participant is illiterate, **an impartial witness must be present during the entire informed consent discussion**. The witness will be asked to sign and date the informed consent form to attest that the information in the consent form was accurately explained to, and apparently understood by, the participant, and that informed consent was freely given by the participant. The ICH GCP guideline identifies an "impartial" witness as a person who is independent of the study, who cannot be unfairly influenced by people involved with the study. Each site must specify its procedures for obtaining informed consent from illiterate persons in its SOP for obtaining informed consent. The SOP should define who may serve as an impartial witness to the informed consent process. It is recommended that each site seek IRB/EC review and approval of these procedures.

4.5.1.2. Assure That Informed Consent Is Obtained In A Setting Free Of Coercion And Undue Influence.

During the informed consent discussion, take care to not overstate the possible benefits of the study, nor to understate the risks. Also emphasize to the participant that medical care and other services routinely available from the clinic or hospital associated with the site will not be affected by their decision whether or not to take part in the study. Encourage the participant to take as much time as he/she needs — and to talk about his/her potential participation with others, if he/she chooses — before making a decision.

4.5.1.3. Confirm That the Participant Comprehends the Information

The participant must not be asked to agree to take part in the screening/study, or to sign the informed consent form, until he/she fully understands the screening process/study. Study staff are responsible for implementing procedures to ensure that each participant understands the screening process and the study prior to signing the screening and enrollment informed consent forms, respectively, and undertaking any screening or study procedures.

One approach to assessing comprehension is to use a "quiz" (either oral or written) or other assessment tool that participants complete as part of the consent process. Another approach is to use open-ended questions to ascertain participant understanding during the informed consent discussion. It is possible to incorporate a scoring system into these assessment tools and to re-review the contents of the informed consent until the potential participant can answer a certain percentage of the questions correctly. Table 4-1 includes a sample informed consent assessment tool that sites may choose to adapt for their local use. For sites that choose to adopt tools such as those included in this section, detailed instructions for their use must be specified in the site SOP for obtaining informed consent.

Regardless of the method used to assess comprehension, if the assessment results indicate misunderstanding of certain aspects of the study, review those aspects again until the participant fully understands them. If after all possible efforts are exhausted, the participant is not able to demonstrate adequate understanding of the study, do not ask him/her to sign the informed consent form or screen /enroll in the study. Similarly, if the participant has concerns about possible adverse impacts on him/her if he/she were to take part in the study, or indicates that he/she may have difficulty adhering to the study requirements, do not ask him/her to sign the informed consent form to screen/enroll in the study.

4.5.1.4. Document the Process

U.S. regulations require that informed consent be documented by "the use of a written informed consent form approved by the IRB/EC and signed and dated by the subject or the subject's legally authorized representative at the time of consent."

To fulfill this requirement, complete all signature and date blocks on the informed consent form per local IRB/EC requirements. Per the *DAIDS Policy for Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials (DWD-POL-CL-04.00)*, participants must sign the informed consent form using their complete last name (not just initials); the policy also recommends, but does not require, that the participant's complete first name (not just an initial or nickname) be used as well. It is essential that the date documented on the form either precedes or coincides with the (first) study screening date. In addition, enter a note in the participant chart documenting that informed consent was obtained prior to the initiation of any study procedures. Some sites find it helpful to use a cover sheet attached to the Informed Consent Forms to document all items in this process. See Table 4.2 for a sample coversheet that sites may wish to adapt and use. Finally, regulations require that participants be offered a signed copy of the informed consent forms. If a participant opts not to receive a copy, document this in the research record.

The *DAIDS Policy for Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials (DWD-POL-CL-04.00)* provides detailed requirements and suggestions for documenting the informed consent process. All requirements listed in the *DAIDS Policy* must be met. In order to also meet some of the suggestions listed in the DAIDS Policy, site staff may consider the use of an informed consent "coversheet" similar to the example included in this section.

4.5.1.5. Continue the Informed Consent Process throughout the Study

The previous sections describe aspects of obtaining informed consent from study participants prior to initiating their involvement in the study. Given the ongoing nature of informed consent, key elements of informed consent should also be reviewed at study follow-up visits. At these visits, study staff should review key elements of informed consent with the participant, focusing on the remainder of their study participation. For example, participants should be encouraged to ask questions as they arise and recognize that poor adherence to their study drug regimen will not affect their continued participation in the trial.

4.5.1.6. ICF Requirements for Protocol Amendments

According to DAIDS policy (Protocol Registration Policy and Procedure Manual), the site's IRB/EC is/are ultimately responsible for determining whether study participants need to be re-consented for a protocol amendment. The details of re-consent for a protocol amendment will be determined based on the extent and content of the amendment, and instructions will be provided to sites in this regard, after consultation with DAIDS.

4.5.1.7. Informed Consent SOP

As a condition for study activation, each study site must establish an SOP for obtaining informed consent from potential study participants. This SOP should reflect all of the information provided in this section and minimally should contain the following elements:

- The minimum legal age to provide independent informed consent in the study site locale
- Procedures for ascertaining participant identity and age
- Procedures for ascertaining participant literacy (if applicable – some sites may choose to enroll only literate participants. The study allows illiterate participants.)
- Procedures for providing all information required for informed consent to the participant
- Procedures for ascertaining participant comprehension of the required information
- Procedures to ensure that informed consent is obtained in a setting free of coercion and undue influence
- Procedures for documenting the informed consent process
- Storage locations for blank informed consent forms
- Storage locations for completed informed consent forms

- Procedures for implementing a change in the version of the informed consent form used
- Staff responsibilities for all of the above (direct and supervisory)
- Staff training requirements
- QA/QC procedures related to the above (if not specified elsewhere)
- Attached copies and instructions for use of all forms, worksheets, or checklists to be used during the informed consent process

4.6 Screening and Enrollment

The study screening and enrollment procedures are described in detail in the HPTN 083 Protocol Sections 5.1 and 5.2 and are outlined in the checklists in the SSP Section 6.

4.6.1 Assignment of Participant ID Numbers (PTID) for Screening and Enrollment

Each time a participant screens for the study, she/he will receive a new PTID; therefore, if the participant screens out and re-screens at a later time, a new PTID will be provided. Refer to Section 13 of the SSP for further details related to PTIDs.

4.6.2 Screening and Enrollment Logs

The *DAIDS Policy for Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials (DWD-POL-RA-03.00)* requires study sites to document screening and enrollment activity on screening and enrollment logs. Screening and enrollment logs may be maintained separately or combined into one document. Table 4-3 includes a sample screening and enrollment log that sites may choose to adapt for local use. This may also be used as a link log, if sites plan to separate participant identifying information files.

The *DAIDS Policy for Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials (DWD-POL-RA-03.00)* specifies that participant initials be recorded on screening and enrollment logs, in addition to PTID numbers. However, per HPTN policy and in agreement with DAIDS, participant initials need not be recorded on screening and enrollment logs if doing so presents a potential threat to participant confidentiality. In such cases, a separate document must be available to document the link between a participant's name and PTID.

Note: There is a case report form that will be used to collect screening information for individuals that did NOT enroll in the study. This form is not a replacement for the screening and enrollment log as specified above.

4.6.3 Screening and Enrollment Tracking

Sites will use the electronic data capture system to document screening outcomes for all participants. For ineligible participants, this will include the exclusion criteria included in the protocol as reasons for the screening failure, including an "other" option. The HPTN SDMC will include a real-time, by-site randomization report on the Atlas website (atlas.scharp.org).

4.7 Screening Visit Procedures

A full list of screening procedures is included in the HPTN 083 protocol Sections 5.1 and Appendix Ia. Section 9 of the SSP includes details on clinical considerations for screening. Here are some other important considerations for screening:

- Potential participants may be screened for eligibility only after providing written informed consent.

- Screening may occur over one or more visits depending on availability of the participant and clinic staff.

- Otherwise eligible participants with an exclusionary test result (other than reactive HIV tests and Hepatitis testing (HBsAG and HCVAb)) can be re-tested once during the screening process. If a participant is re-tested and a non-exclusionary result is documented within 45 days of specimen collection, the participant may continue with enrollment. If after re-testing the laboratory test results continue to be exclusionary, the participant is considered to have failed screening. At the discretion of the IoR or designee, an additional screening attempt may be done as per information on next bullet.

- Per Section 5.1 of the HPTN 083 protocol, participants who fail screening for any reason may rescreen one additional time, at the discretion of the IoR or their designee. However, potential participants with clinically-significant cardiovascular disease as outlined in the exclusion criteria in Section 3.2 of the protocol, or any reactive HIV test, may not be re-screened. Participants with symptoms indicative of acute HIV infection (per IoR or designee) may be re-screened in consultation with the CMC once appropriate testing has ruled out acute HIV infection.

- Sites will follow the HIV testing algorithm for screening found in Appendix IE of the protocol and in Section 11 of the SSP manual, which require:

    - FDA-cleared HIV rapid test
    - 4^{th} or 5^{th} generation HIV immunoassay
    - HIV RNA performed within 14 days of Enrollment
      NOTE: 14-day window starts on the day the sample for HIV RNA is collected, which is considered Day 0.

  If a reactive result is obtained for any of the HIV tests, the person is not eligible for the study. Additional testing to confirm HIV infection will be performed in accordance with local guidelines. If HIV infection is confirmed, participants will receive counseling and be referred for appropriate care.

- During the screening process, inform participants that if she/he receives a buttock implant or fillers during the study, they will no longer be able to receive the study injections.

- North and South American sites only: click on the following link to access the SexPro questionnaire: www.mysexpro.org. As a reminder, for US sites, SexPro score will be used for eligibility determination; for South American sites will be

used for data collection purposes. After the participant completes the SexPro questionnaire, sites should print the outcome page, write the PTID on the page, and file it in participant's file as source documentation. If issues arise printing this page, sites may opt to email the page and print the email; take a screenshot of the page and print; or as last resource take a picture of the screen and then print the picture. The SexPro questionnaire must be reviewed and approved by all applicable IRB/EC/other regulatory approving bodies prior to administration (as is the case for any materials that are provided or administered to a participant, e.g., interviewer or self-administered questionnaires, informed consent forms, etc.).

- Participants screening for the study that are currently using daily oral Truvada as PrEP will be able to take it up until the point of enrollment. The stop date should be documented in the participant's file. However, participants need to fully understand that they will be randomized to either injectable cabotegravir or daily oral Truvada, and that neither they nor the study staff will know which arm of the study they will be assigned to. As such, it will be important for the participant not to use PrEP outside the study. Additionally, and equally as important, if the use of daily oral Truvada for PrEP is currently working in the context of their life, they should take this strongly into consideration when deciding if HPTN 083 is the appropriate study for them.

- If a participant reports the use of post-exposure prophylaxis (PEP) during the screening period, the 28-day course of PEP must be completed prior to enrollment in the study. The CMC should be consulted on timing of the enrollment date in relationship to the 28-day PEP completion date.

- A participant that reports <u>any</u> episode of seizure, independent of frequency or timeframe, is not eligible for the study. For example, if a participant reports one episode of seizure as a baby, the participant is ineligible.

In addition to above, there are other criteria that have specific time periods for the participant that must be adhered to, which are:

- Enrollment must occur within 45 days of specimen collection (except for HIV RNA, see bullet below) for the clinical and laboratory evaluation and procedures outlined in the protocol and visit checklists.

- The screening to enrollment window (45 days) starts as soon as the specimens are collected. If all screening and enrollment procedures are not completed up to 45 days of specimen collection, the participant must repeat the entire screening process. It is strongly recommended that when rescreening a participant, to start the process with administering the ICF to document participant's understanding and agreement to undergo a new screening process; however, sites should follow their local IRB/EC guidelines regarding this process. Some IRBs/ECs may not require re-consenting under these circumstances. For sites that choose not to administer the ICF during rescreening, they must obtain documentation from their IRB/EC that re-consenting is not required and include this documentation in the essential documents file. Additionally, sites should include in their ICF information about the process if a second screening attempt is needed. The term "screening attempt" is used to describe each time a participant screens for the study (i.e., each time s/he

provides written informed consent for participation in the study).

- A negative HIV RNA assay must be documented within 14 days prior to **enrollment**. The blood draw, not the test results, must be performed within 14 days of **enrollment**. Counting is by calendar day and not by hour. That is, if a participant has their blood drawn on January 1 – which is considered Day 0, then this draw is valid through January 15. The time of the day does not matter; only the calendar day is important.

- The target visit window for the procedures associated with the DXA subset visit at enrollment is -30 days/+7 days of enrollment.

4.7.1 Participants Found to be Ineligible (Screen Failures)

Screening procedures should be discontinued when the participant is determined to be ineligible. If the participant is found to be ineligible at the beginning of the screening visit, sites may choose to continue with clinical and laboratory evaluations as a service to the participant, per their site SOPs. If a participant fails screening due to a clinical condition requiring follow-up, appropriate referrals should be provided to ensure the well-being of the participant. Documentation of all referrals should be included in the participant chart. All lab results should be provided and explained to participants within a reasonable timeframe, regardless of eligibility determination. For all screened out participants, the following documentation should be in place:

- Completed ICF
- Reason(s) for ineligibility, with date of determination
- Necessary referrals on file (as appropriate) and documentation that any clinically significant abnormalities (labs, etc.) were communicated to the participant (even if referral is not necessary)
- All source documentation completed up until the time that ineligibility was determined
- Chart notes completed up until the time ineligibility was determined
- Indication of what visit procedures were conducted (on visit checklists)

4.8 Enrollment Visit Procedures

A full list of enrollment visit procedures can be found in Section 5.2 and Appendix Ia of the protocol. Section 6 of this SSP also includes sample visit checklists and an eligibility checklist which can be modified by sites for their use. Section 9 of this SSP includes clinical considerations for Enrollment.

Other important considerations for the Enrollment visit include:

- IoR or designee must confirm eligibility prior to randomization.

  Note: Sites that do split enrollment visits due to physical location constraints (e.g., an off-site pharmacy), can randomize prior to completing the rapid HIV testing required at the Enrollment visit; however, these results must be available and

confirmed to be negative/non-reactive prior to the administration of study product.

- The definition of enrollment is the point of randomization. That is, if a site successfully randomizes a participant in the randomization system, that participant is considered enrolled. In the event of a mistaken randomization, or if the participant changes his or her mind once randomization has occurred, that participant will still be considered enrolled. Mistaken randomizations (e.g., the site mistakenly enters the wrong PTID or randomizes prematurely) are considered reportable deviations. Contact Leslie Cottle (leslie@scharp.org), Marybeth McCauley (mmccauley@fhi360.org), and Kaila Gomez-Feliciano (kgomez@fhi360.org) in the event that a mistaken randomization occurs or if a participant changes his or her mind directly or soon after randomization for further guidance.

- HIV test results, including testing for acute HIV testing from Screening and at least one HIV test result conducted at the Enrollment visit, must available and confirmed to be negative/non-reactive prior to provision of study product.

- A complete medical history and physical exam, including concomitant medications, as well as height, weight, blood pressure, and pulse data entry to Medidata Rave, must be performed as part of the Enrollment visit. The collection of height is a one-time collection at Enrollment only. The complete medical history and physical exam may be performed during Screening at the discretion of the IoR or designee.

Table 4-1: HPTN 083 Sample Informed Consent Assessment Tool

	Date: Participant ID:			Staff name/initials
		Participant's Response	Correct Answer	Notes
1	Participation in this research study is voluntary	□ True □ False	☒ True □ False	
2	The purpose of this research study is to find out whether a drug is safe and prevents HIV infection.	□ True □ False	☒ True □ False	
3	This research study is part of the regular medical care offered here at [clinic name].	□ True □ False	□True ☒ False	
4	We will test your blood for HIV.	□ True □ False	☒ True □ False	
5	You can choose which arm you will be assigned to.	□ True □ False	□True ☒ False	
6	You will be asked to come back to the clinic every 2 weeks for the first 4 weeks after enrollment.	□ True □ False	☒ True □ False	
7	If you join this research study, you must stay in the study for as long as the study staff says.	□ True □ False	□True ☒ False	
8	Beginning at week 5, you will be given an injection of either study drug or placebo. You will receive a monthly injection for the first two months and bimonthly thereafter.	□ True □ False	☒ True □ False	
9	Your participation in the study will last up to 4 ½ years.	□ True □ False	☒ True □ False	
10	The study injection is a drug already approved to treat people with HIV and AIDS.	□ True □ False	□True ☒ False	
11	There are no risks in taking part in this research study.	□ True □ False	□True ☒ False	
12	If I have questions between study visits, I need to write them down and bring them with me at my next appointment.	□ True □ False	□True ☒ False	

Table 4-2: Sample Informed Consent Coversheet for HPTN 083

Participant name:	
Date of informed consent discussion:	
Start time of informed consent discussion	
Version number/date of informed consent form used during informed consent process/discussion:	
Name of study staff person completing informed consent discussion (and this coversheet):	
In what language was informed consent obtained?	[*insert local language*] (note whether this was written and/ or verbal)
Was this a re-consent of a participant who had previously consented?	☐ Yes ☐ No
Were all participant questions answered?	☐ Yes ☐ No ⇒ Explain in Notes/Comments. ☐ NA (participant had no questions)
Did the participant accept a copy of the informed consent form (circle one option)?	☐ Yes ☐ No
End time of informed consent process/discussion:	
Notes/Comments (not documented elsewhere):	

Table 4-3: Sample HPTN 083 Screening and Enrollment Log

(May be adapted as needed for local use)

	Participant ID	**Participant Name**	**Date Screened**	**Eligible**	**Date of enrollment (if not enrolled, note N/A)**	**If not enrolled, specify reason (include all applicable codes).**	**Staff name/ Initials**
1				Y N			
2				Y N			
3				Y N			
4				Y N			
5				Y N			
6				Y N			
7				Y N			
8				Y N			
9				Y N			
10				Y N			