1. Participant Accrual

1.1 Overview of Section 1

This section provides an overview of requirements for recruiting, screening, and enrolling participants in the study. Additional procedure-specific details can be found in the visit checklists in section 6 of the Accrual, Follow-up, and Retention Manual, Protocol Sections 5.2, and Protocol Appendix IA.

1.2 Accrual plans and targets

This study will recruit up to 250 men, as the budget allows. Each of the 18 barbershops has a minimum recruitment target of 10 men. If recruitment rates are similar across shops, we would expect each shop to recruit around 13 men. Recruitment will be monitored daily by the coordinating site and communicated to the HPTN LOC CRMs on a weekly basis. If recruitment rates differ significantly between shops, the HPTN LOC/SDMC will request to pause recruitment in shops that have already met their recruitment target to ensure that budget is reserved to allow all shops to meet the recruitment target. For example, once a shop reaches 13 enrollments, the HPTN LOC/SDMC may request a pause in enrollments from that shop and that any clients that have been referred but not yet enrolled be included on a waitlist for enrollment.

Accrual of barbers will occur primarily prior to randomization. All eligible barbers from participating shops will be invited to join the study. After randomization, if new barbers join a participating shop, the protocol team will determine whether they will be invited to join the study. Changes in shop barbers will be identified by study staff during their weekly visits to the

shop. Barbers who join the study after randomization will complete all training and CRFs associated with study activation (e.g., demographics, baseline surveys) and then be integrated into a schedule of events aligned with other barbers in the study. Additional details about barbers joining the study can be found in SSP Section 4.3 of the Accrual, Follow-up, and Retention Manual.

1.3 Screening and Enrollment

The study screening and enrollment procedures are described in detail in the HPTN 111 Protocol Section 5.2 and are outlined in the checklists in SSP Section 6 of the Accrual, Follow, and Retention Manual.

1.3.1.1 Definition of screening

The term "screening" refers to all procedures undertaken to determine whether a potential participant is eligible to take part in HPTN 111. The study eligibility criteria for the study are listed in protocol Section 4.1.1. Information on screening procedures is found in Section 5.2 of the Protocol. The HPTN 111 Informed Consent Form (ICF) must be administered before any study procedures are performed. As part of the informed consent process, staff should assess participant's understanding of the information. Once understanding is confirmed, participants can sign the ICF. It is the responsibility of the IoR and designated study staff to ensure that all individuals that are to be considered for participation in HPTN 111 undergo all screening procedures as needed.

1.3.1.2 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. Eligibility determination includes the following procedures:

- Complete pre-screening procedures
    - Determining presumptive eligibility for volunteers who show interest in the study using a pre-screening checklist.
- Confirm eligibility during screening and complete eligibility checklist. Information pertaining to inclusion and exclusion criteria can be found in Protocol Sections 4.1.1 and 4.1.2.
- Post-screening visit eligibility assessment, confirming procedures and timelines.
- Final confirmation and sign off procedures prior to enrollment.
- Documentation

Eligibility determination should also follow all requirements of the site-specific SOP.

1.3.1.3 Definition of a Regular Client

Per the inclusion criteria for HPTN 111, the term "regular client" refers to a resident of the Kalangala district of Uganda who has visited a specific participating barbershop for a haircut at least three times.

1.3.1.4 Definition of enrollment

The term "enrollment" refers to the stage in which an individual has signed the ICF, completed screening and confirmation of eligibility, and completed enrollment checklist and CRF. All enrolled participants will return for a required protocol visits at Week 26 and Week 52. Participants should not be informed of study group until they are confirmed to be enrolled (i.e., eligibility confirmed on checklist). Information on enrollment procedures is found in Protocol Section 5.2.

1.4 Screening - enrollment timeframe

Ideally, participants will continue with enrollment on the same day as they have completed screening, or as soon as possible following screening. All participants have a maximum of 14 days from the start of the screening visit to enroll in the study. If the participant screens-out or does not return for enrollment, the participant can be re-screened up to two times. However, a participant cannot be re-screened if the participant has a reactive HIV test at screening.

1.5 Re-screening procedures

There may be an instance in which a participant will need to rescreen before moving on to enrollment. If a participant has not completed all enrollment procedures within the 14 days from the start of screening, the entire screening process must be repeated during re-screening. All participants can be re-screened up to two times at the discretion of the IoR/designee. Please consider the following when re-screening a participant:

- A rescreened participant must be re-consented, including the signing of a new ICF to document the participant's understanding and agreement to undergo a new screening process. The term "screening attempt" is used to describe each time a participant screens for the study (i.e., each time a participant provides written informed consent for participation in the study).

1.6 Participant Found to be Ineligible (Screen Failures)

Screening procedures should be discontinued when the participant is determined to be ineligible. Study staff should not provide the participant with the exact reason they have screened out of the study but can generally notify them that they cannot join the study at this time.

If the participant is found to be ineligible at the beginning of the screening visit, sites may choose to continue with HIV testing as a service to the participant, per their site SOPs. HIV test results should be provided and explained to participants within a reasonable timeframe per local standards, regardless of eligibility determination, and a referral provided to participants for ART or HIV prevention services, as indicated. For all screened-out participants, the following documentation should be in place:

- Completed ICF
- Completed Demographics CRF
- Completed Inclusion Exclusion Criteria CRF
- Completed Screening and Enrollment log noting reason(s) for ineligibility, with date of determination.
- Documentation that results were communicated to the participant if HIV and syphilis testing were performed and record on file any referrals made.
- All source documentation completed up until the time that ineligibility was determined.
- Chart notes and CRFs completed up until the time ineligibility was determined.
- Indication of what visit procedures were conducted (on visit checklists)

1.7 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 3.2 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.

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 real-time, reports necessary to track enrollments across barbershops on the Atlas website (atlas.scharp.org).

1.8 Assignment of participant ID numbers

Each time a participant screens for the study, 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. Per Protocol Section 5.2, all participants can be re-screened up to two times at the discretion of the IoR/designee. Refer to Data Management Manual for further details related to PTIDs.

Table 5-1: HPTN 111 Screening and Enrollment Log

Table 5-1: Sample HPTN 111 Screening and Enrollment Log *(May be adapted as needed for local use)*

*Note: The Inclusion Exclusion Criteria CRF will be completed for all participants, including individuals who did NOT enroll in the study. This form is **not** a replacement for the screening and enrollment log as specified above.*

	Participant ID	**Participant Name**	**Date Screened**	**Eligible**	**Date of enrollment (if not enrolled, note N/A)**	**If not enrolled, specify reason(s) (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			

2. Informed Consent

2.1 Overview of Section 2

This section includes an overview of the informed consent process with attention to HPTN 111 specific considerations. The site will have further details about the informed consent process included in a site SOP.

2.2 Informed Consent Process

Informed consent is a process by which an individual voluntarily expresses their willingness to participate in research, after having been informed of all aspects of the research that are relevant to their 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. See Section 4.8 of the ICH GCP guidelines and the informed consent section of the DAIDS Site Clinical Operations and Research Essentials (SCORE) Manual 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 conduct of any study procedures. Prior to signature of the informed consent form, participants should be encouraged to ask any questions they have, and staff should assess their understanding of the study. Documentation of informed consent at screening must be completed per all local IRB/EC requirements and the DAIDS SCORE manual. The site will detail assessment of understanding and documentation in the site SOP.

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 their delegated staff, to deliver all required

information.

2.3 Considerations for participants who cannot read/write

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. The 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.

2.4 Considerations for Minors

Participants aged 16 or 17 years old may be enrolled in the study, following local guidelines for enrollment of mature and emancipated minors. The site SOP must define how mature or emancipated minor status will be confirmed and documented.

2.5 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 site in this regard, after consultation with DAIDS.

2.6 Informed Consent SOP

As a condition for study activation, the site must have an SOP for the informed consent process. The SOP may be site-specific or study specific, depending on the needs of the site. The SOP must contain, at a minimum, the following elements:

- The minimum legal age for independent informed consent
- Procedures for determining participant identity and age
- Procedures for determining participant literacy
- Procedures for providing all information required for informed consent
- Procedures for determining participant comprehension
- Procedures to ensure that informed consent is obtained without coercion or undue influence
- Procedures for documentation of the process
- Storage locations for blank and completed informed consent forms
- Procedures for implementing a change in the version of the informed consent form
- Staff responsibilities for all of the above
- Staff training requirements
- QA/QC procedures related to the above

3. Participant follow-up

3.1 Overview of Section 3

This section provides a brief overview of requirements and procedures during follow-up (i.e., once a participant is enrolled in the study). Additional procedure-specific details can be found in the HPTN 111 protocol and relevant SSP manual sections.

3.2 Study follow-up plan and retention targets

After participants enroll in the study, they are expected to complete protocol-required follow-up visits at Weeks 26 and 52. Participants that enroll after the first three months of study accrual will only be required to have a follow-up visit at 26 weeks. Required follow-up visit procedures are listed in protocol Section 5.2 and Appendix IA.

The Schedule of Events found in Appendix IA of the protocol lists all the administrative, behavioral, clinical, and laboratory procedures required in HPTN 111 at follow-up visits. Most of the procedures are required at all visits, except for the ones marked with a numbered superscript that should be performed only if clinically indicated, based on clinician discretion.

3.2.1 Types of follow-up visits

Protocol-required visits: It includes all visits required by the protocol, as described in Sections 5.2, 5.3, & 5.10 of the protocol: Screening and Enrollment. Please note, there are other protocol-required visits for participants with Suspected or Confirmed HIV Infection, which is described in Section 5.4 of the protocol.

Visit windows for each required study visit are found in Section 5.10 of the protocol. For each required study visit, there is an allowable visit window specifying on which study days (post-enrollment) the visit is "allowed" to be completed. The allowable visit windows are contiguous from visit to visit, and do not overlap. Within each allowable visit window, there is a target visit window when study visits should ideally be conducted. Missed visits are only those that are not conducted within the allowable window.

Interim visits: Interim contacts and visits may take place between regularly scheduled visits. These contacts/visits may be done at participant request (e.g., to receive further counseling about HIVST or clarify any questions) or as deemed necessary by the investigator or designee at any time during the study (e.g., to follow-up on an adverse event or social impact). Procedures to be performed during these contacts/visits will be based on the reason for it.

Split visits: A split visit is defined as a visit conducted over multiple days within a visit window. Ideally, all procedures specified by the protocol to be performed at a visit will be completed at a single visit on a single day. If all required procedures cannot be completed on a single day (e.g., because the participant must leave the study site before all required procedures are performed), the remaining procedures may be completed on subsequent day(s), within the target visit window. When this occurs, the visit is considered a split visit. All case report forms completed for a split visit are assigned the same visit code (even though the dates recorded on the case report forms may be different).

Missed Visits: Even though study visits are “allowed” anytime during the study, for data management purposes, if a visit is not conducted within the allowable window, per the Data Management Manual, a Missed Visit e-CRF should be completed if a visit is missed and cannot be made up.

In general, when a visit is missed altogether and a participant report to the site for the next scheduled visit, the procedures from the missed visit that are not also required for the current visit should be performed. If a participant misses their Week 26 and/or Week 52, every effort should be made to contact the participant and complete the visit, even if the allowable window has closed. In this case, contact the protocol team for further guidance.

3.2.2 Follow-up visit scheduling

The site should maintain a process for tracking required follow-up visits for enrolled participants (i.e., follow-up visit schedule log).

3.3 Follow-up visit procedures

After participants enroll in the study, they are expected to complete two protocol required visits at Week 26 and Week 52. Required follow-up visit procedures are listed in protocol section 5.3 and Appendix IA.

- Refer to Protocol Appendices for the Schedule of Evaluations
- Assessment of HIV status must be completed at every follow-up visit. HIV Testing should follow the testing algorithm in SSP Section 1 of the Lab Considerations Manual. Counseling should be provided in accordance with SSP Section 1 of the Clinical, Safety, and AE Management Manual.
    - Study staff should review any interim testing logs completed between study visits in order to counsel the participant appropriately.
- If a participant has difficulty completing the ACASI questionnaire, the staff may read it to the participant and enter information on their behalf. However, the participant must agree to allow staff to enter information given the sensitive nature of the questions. If the participant does not agree to have staff enter the information on their behalf, then document that the questionnaire will be missed.
- Participants may withdraw from the study for any reason at any time. The IoR may, in consultation with the HPTN 111 protocol team, withdraw participants before their scheduled termination visit to protect their safety, and/or if participants are unable or unwilling to comply with study procedures. The protocol team should also be consulted regarding procedures to be performed in the case of early termination, if a participant is willing to undergo such procedures.

3.4 Follow-up visit locations

Screening, Enrollment, and Follow-up visits will ideally occur at the clinic. However, to relieve the burden of travel for participants, screening, enrollment, and follow-up visits (Week 26 and 52) may occur at off-site locations that the participant and designated study staff member has agreed upon. **Additional information about off-site visits is included in SSP Section 5 of the Accrual, Follow-up, and Retention Manual.**

3.5 Procedures for participants who transfer barbershops

During the study, participants may leave the area where they were enrolled or request a different barbershop. To accomplish this transfer study staff will complete the Barbershop Transfer Form CRF to confirm the following:

- The participant has stopped getting haircuts from the barbershop they were previously assigned to (i.e., the barbershop they were recruited from).
- The participant does not intend to return to the shop they were previously assigned (i.e., the barbershop they were recruited from) within the next six months.

Study staff should also work with the barbershops to coordinate the transfer of any on-site documentation to the new barbershop. For further guidance about participant transfers email the HPTN 111 reporting email alias list 111reporting@hptn.org.

3.6 Procedures for participants who acquire HIV

Information on procedures for participants who have acquired HIV is found in Section 5.4 of the protocol. A few important considerations:

- Participants should continue participation if willing.
- HIV testing will not be completed at the next scheduled visit.
- Complete Seroconverter form and follow-up on any linkage to care.
- If the participant is in the intervention group, work with them to determine how they would like to continue receiving information (i.e., from study staff, barber, provider, etc.)

3.7 Resumption of study participation after voluntary withdrawal

If a participant withdraws from the study and then indicates the desire to resume participation, please contact the reporting team alias (111reporting@hptn.org) for further guidance.

4 Barber Procedures and Barbershop-based interventions

4.1 Overview of Section 4

This section includes specifics on the procedures required for barber study participation and the barbershop-based intervention components.

4.2 Initial Barber Sensitization

Following engagement with local stakeholders and community members, barbers who work at the shops that have been selected for study participation will have an initial meeting(s) with study staff to orient them to the study. Ongoing sensitization with shop owners, barbers, and community leaders will also take place prior to study activation.

Study staff will also be available to engage with barbers 1:1 and visit the barbershops to discuss the study prior to barber training. Each participating barbershop will be visited by the study team at least once prior to the training, to ensure that the barber is comfortable with participation, assess the needs of the barber and the shop, and build rapport.

4.3 Barber enrollment into the study

Following the initial sensitization and orientation to HPTN 111, barbers who meet all eligibility criteria will be asked to sign the memorandum of understanding (MOU) so that they understand what is involved with engagement in the study (see SSP Section 2 of the Accrual, Follow-up, and Retention manual). After signing the MOU, the barber can attend the overview study training. The barber will need to sign the ICF prior to study procedures (i.e., questionnaires), randomization, and intervention-specific training (as applicable). The barber will be considered enrolled in HPTN 111 once they have signed both the MOU and the ICF.

Following enrollment in the study but before randomization, all barbers will have baseline questionnaires administered to record demographics and baseline measures of acceptability of the intervention. Locator information should be collected to assist with retention and ease of contact with barbers through the course of the study.

4.4 Barber training

Barber training will occur after barbers have signed the MOU (for overview training) and after ICF and completed baseline questionnaires (for intervention-specific training). The training will comprise of two components:

1) Overview training for all participating barbers (from both intervention and control shops)
2) Intervention training for participating barbers from shops randomized to the intervention group

Training content and materials will be developed by the protocol team and the coordinating site will lead all barber trainings in person in a location that accommodates barbers and study staff. All barbers will be provided with training materials that will include information from the trainings that they can reference as needed outside of the trainings.

4.4.1 Overview barber training

The overview training will focus on general understanding of the study, expectations for barbers, confidentiality, and client recruitment. Training will last a minimum of 1-2 days, or the equivalent time will be split across more days, to

accommodate the work schedules of the barbers. The full curriculum/sample training agenda is in Appendix A.

The overview training will take place at a central location so that all barbers can attend. It may be necessary to conduct more than one overview training, to accommodate all barbers. At the conclusion of the overview training(s), barbers will participate in the public randomization event, as described in SSP Section 4.2.2.3 of the Study Management Overview Manual.

4.4.2 Intervention Barber training

Barbers from the intervention group will have additional training that will take place over the course of approximately one week. The intervention training will focus on the intervention components content and delivery (see Sections 4.7.1–4.7.5 below), counseling and peer support skills, expectations of study documentation, and support that can be expected from the protocol team. The full curriculum/sample training agenda is in Appendix B.

4.4.3 Refresher training

Refresher training may take place at any time during the study. Topics may be requested by barbers or identified by study staff as an ongoing need. The study team will accommodate refresher trainings with ad-hoc or formal training sessions. If the topic is something that could benefit all barbers, the study team may convene a central training session for all barbers to attend. Alternatively, the study team may provide individual trainings at barbershops to accommodate work schedules for the barbers and target barbers who most directly require the refresher training. Topics for refresher training may include documentation of services delivered to clients, HIV care and prevention services in the community, how to use the self-test kit, or any other topic identified by the barbers or study team that would benefit the delivery and execution of the study and intervention.

4.4.4 New barbers while the study is ongoing

If a barber joins a participating barbershop during the study, or previously declined participation but changes their mind, study staff will provide sensitization and the barber may have the opportunity to join the study. New barbers from control barbershops will only be able to join the study during the period of participant accrual. Once participant accrual has ended for the study, new barbers at the control barbershops will be sensitized but not have the opportunity to join the study or recruit clients. At intervention barbershops, new barbers may join the study during the accrual or follow-up phase of the study.

During the participant accrual phase of the study, new barbers may refer clients for enrollment after they have completed the memorandum of understanding, informed consent, baseline questionnaires, and barber training as described in the

SSP Section 04 of the Study Management Overview Manual. For new barbers working at intervention barbershops, they can refer clients and begin delivering the intervention as per the protocol and SSP requirements. If the new barber from an intervention shop joins the study during the follow-up only phase (after accrual has ended), they can provide the intervention to existing participants from that shop but will not recruit new clients.

4.4.5 Barber transfer to a different barbershop

It is possible that a barber may move their employment to a different barbershop. In such cases, the study staff should record this information on the relevant CRF and document whether the new barbershop is one already participating in HPTN 111. The study team should contact the HPTN LOC CRM and Protocol Statistician for consideration of ongoing intervention delivery by the barber at the new shop, if applicable.

4.5 Recruitment of clients into the study

Barbers from both the control and intervention shops will be responsible for recruiting potential participants for screening with study staff.

Barbershops will be activated individually once the shop has completed all requirements for activation. This includes barber(s) enrollment in the study (i.e., completion of informed consent and MOU), readiness of the barbershop, completion of training, and baseline study questionnaires. Once the barbershop is activated for study procedures, barbers will be able to talk with their clients about the study, hang recruitment fliers, and/or hand out palm cards with study information. Barbers will be asked to refer as many clients as is needed to enroll a minimum of 10 clients into the study from that shop. If the shop has multiple participating barbers, the number of enrolled men is counted per shop, not per barber.

During routine visits to the barbershops, study staff will check-in with barbers about successes and challenges with recruitment. Study staff will share recruitment numbers across the study and by barbershop (without identifying specific location/names of other shops). Barbers will be required to document the number of men to which they have provided information about the study and the number of men they have directly referred to study staff for screening. The simple checklist (Appendix C) will be kept for each shop (one checklist for all barbers within the shop) and stored within the lockable cabinet at the shop. Study staff will collect the recruitment log from the shop weekly and enter it into the database for central tracking.

During the recruitment contact with clients, barbers will be asked <u>not</u> to disclose which study group their shop was randomized to, with the goal of reducing potential biases in recruitment between intervention and control shops.

4.6 Tracking clients/participants

Once a participant has been screened and enrolled in the study, study staff will notify the intervention barber that referred the client, that he has been enrolled. In the case that there is more than one barber involved with the study at any one participating shop, the study staff will contact the referring barber. Study staff will contact the barber via a phone call or in-person visit but will not use SMS or WhatsApp to provide the participant information to the barber. Study staff will be required to document that the barber has been successfully notified in the participant chart.

Barbers will track their clients enrolled in the study in a way that best suits their needs. This may be as simple as a list of names of the clients that are enrolled participants in the study. The goal is that barbers will know which clients are enrolled and should be provided with the intervention. However, barbers will be trained not to identify clients directly as study participants (e.g. do not write name of client on TRIM/HPTN 111 branded materials). Study staff will check-in with the barber about their process for tracking clients enrolled in the study on an ongoing basis to ensure that confidentiality is being maintained.

4.7 Delivery of the Intervention

Barbers at the intervention shops will deliver the intervention to each enrolled client. As described above, barbers will be notified when one of their clients is enrolled in the study and should begin receiving the intervention. Participants will also be counseled by study staff to let their barber know they are in the study in order to receive the intervention at their next haircut. Participants will be provided with a study appointment card that they can also show their barber to indicate they are enrolled and should receive the intervention.

If additional clients are in the barbershop at the same time as a study participant, the barber may provide the HIV education and self-test kits to all patrons of the shop. The barber should not disclose to other patrons who is enrolled in the study but can generally tell clients that the HIV education and information is part of a study, and they can learn more about it if they'd like.

Details of each component of the intervention are provided below.

4.7.1 Status Neutral HIV education

Intervention barbers will provide status neutral HIV education to each enrolled participant when they come for a haircut. If the client declines to receive the education at the visit, the barber can document this on the services provided checklist. HIV education will align with key principles of the Ugandan Ministry of Health (MOH) information and include the following key topics:

- What is HIV?

- How HIV is transmitted
- HIV testing, including HIV self-testing
- HIV treatment for people living with HIV
- HIV prevention for people vulnerable to HIV
- Where to access HIV prevention and care services (see also SSP Section 4.7.3)

Materials to support HIV education discussions

Each barbershop will be provided with laminated HIV Education Job Aids that were developed centrally by the LOC communications team and approved by the IRB before use. The laminated sheet can be reviewed during a haircut/education session or at any time the barber needs a refresher on the basic HIV education content. Non-laminated paper versions will also be available at the shop in case participants or other clients would like to take the information with them.

4.7.2 HIV self-test kit distribution

Intervention barbers will provide enrolled participants with information about HIV testing, including information about HIV self-test kits and how they can be used to test for HIV on a schedule consistent with recommendations from the Ugandan MOH. Men who are behaviorally vulnerable to HIV are recommended to test every three months. Barbers will be able to show participants how to use the test kit and will be provided with extra kits that can be used to show participants the components of the test and any relevant 'pointers' on how to use the kit.

Barbers will advise participants on what to do following HIV self-testing: if the result is positive, the result is not considered final until a confirmatory test is completed. The participant may contact study staff for further direction and testing and/or they may go to the nearest facility that offers HIV testing.

HIV self-test kits provided to enrolled participants will be purchased centrally by the HPTN 111 coordinating site. Stock of study purchased kits will be tracked by the study staff (e.g. amount distributed to each barbershop). During regular check-ins with the barbers at the shops, study staff will check the stock of HIV self-test kits and resupply as needed. Barbers will also be trained to communicate with study staff in case they run low on HIV self-test kits so that they can be re-stocked. All HIV self-test kits will be marked with a simple sticker (not identifiable as TRIM/HPTN 111) such that any return test kits can be identified as a study provided kit.

Kits for clients not enrolled in the study

HIV self-test kits may be provided to clients that are not enrolled in the study in order to protect confidentiality of enrolled participants who may otherwise be identified as a

research participant if they are taking HIV self-test kits from the barber. These kits will be donated by the local health center and not purchased centrally through HPTN 111. The study team will help manage the stock of these kits, as they do for the study purchased kits. If a client that is not enrolled in the study would like to take an HIV self-test kit after hearing about the kits and HIV information, the barber can provide them with an HIV self-test kit(s). As part of the requirement for providing health center kits, the barber and study team must follow the standard-of-care. Standard-of-care for HIV self-testing requires that the person who takes the kit provides a phone number so that health facility staff can contact them to determine if they used the kit and the results. The barber will collect the client's phone number on a simple log form (Appendix D) and keep it in the lockable cabinet for confidentiality purposes. The study team will collect the log and follow up on the use of kits and results. The study team will work with the local health facility (HIV testing center) to ensure that any person who obtained a kit from the barbershop is reached to complete the Ugandan ministry of health recommended HIV self-testing form (per local standard of care). At the barbershop, all clients who have obtained an HIVST will have their contacts and names recorded on the log (Appendix D), including study participants. Once the study team receives the completed log from the barbershop, the team will exclude the phone contacts/names that belong to study participants, and the remaining contacts will be followed up with the local HIV testing center to complete the standard-of-care processes in documentation and contact.

Materials to support HIV self-test discussions

Each barbershop will be provided with laminated HIV Self-testing Job Aids that were developed centrally by the LOC communications team and approved by the IRB before use. The laminated sheet can be reviewed during a haircut/education session or at any time the barber needs a refresher on HIV testing information. Non-laminated paper versions will also be available at the shop in case participants or other clients would like to take the information with them. The barber should also notify participants that the HIV self-test kit has a package insert with detailed instructions on how to conduct the test.

4.7.3 Referral information for HIV services

As part of the HIV education provided to participants, intervention barbers will be knowledgeable about established venues for receiving HIV testing, prevention services (PrEP, PEP, and circumcision), and treatment/care. Services may vary depending on shop and geographic location. Study staff will assist barbers in compiling the local service providers near the shop that can be provided to participants interested in receiving any available services. Study staff should review services/resources periodically during the course of the study to ensure that clients are receiving accurate information about where to access services.

Materials to support referrals to HIV services

Barbers will be provided with a list of local resources for HIV testing, PrEP, PEP, circumcision, and HIV treatment.

4.7.4 Peer group sessions

Intervention barbers will offer all enrolled clients the opportunity to join group sessions every two months. Barbers will notify and remind clients of the session during their haircut. Study staff will assist barbers in identifying the best location for the sessions and ensuring that the space is adequate to accommodate the group.

Peer group sessions will focus on similar status-neutral HIV education content but within an environment of peer support and shared experience among men. Barbers will be trained on peer support during the intervention training and will utilize these skills during the group sessions.

Study staff will attend each group session but will not be responsible for leading the session. If the barber feels they need support or clarification, study staff can assist but should encourage the barber to maintain leadership and be the primary facilitator of the session.

At each session, staff will document which topics were covered during the session, key questions and discussion points, the number of men in attendance, and the accuracy and quality of the information provided by the barber. A standard form will be utilized to document this information for each session, as shown in Appendix E.

4.7.5 Tracking delivery of the intervention

It is important to understand barbers' fidelity to the intervention – i.e. is the barber delivering all components of the intervention to enrolled clients? Fidelity will be assessed in two main ways: 1) participants will be asked at each follow-up visit what information they received from the barber at their haircuts, and 2) barbers will be asked to complete a checklist of the intervention components provided to enrolled clients (Appendix F).

The checklist of intervention components provided to enrolled clients should be documented for every enrolled participant and at each haircut. For barbershops with multiple participating barbers, only one checklist will be completed for the shop. The checklist must be stored in the lockable cabinet at the barbershop when the barber is not at the shop. Study staff will review the checklist every week when they visit the barbershop and will discuss any barriers to completion; staff will take the checklist with them each week to enter the data into a central database for tracking purposes.

Information about checklist completion, by item, is listed here:

- *Date*: the date the services were provided to an enrolled client
- *#:* listed in numerical order for each day. This is not an identifying number or participant number; it is a simple numerical order listing for ease of tracking.

- *HIV education*: If the barber provided the client with any HIV education, the barber should mark this column with an X (if services were NOT provided) or a ✓ check mark (if services were provided).
- *HIV prevention/care referral info:* If the barber provided the client with any HIV prevention or care referral information, the barber should mark this column with an X (if services were NOT provided) or a ✓check mark (if services were provided).
- *HIV self-test info:* If the barber provided the client with any HIV self-testing information, even if the client did not take a self-test kit with them, the barber should mark this column with an X (if services were NOT provided) or a ✓ check mark (if services were provided).
- *# HIVST kits given to enrolled client:* The barber should record the total number of HIV self-test kits the enrolled participant took with them at this visit. Do not include any test kits provided to other clients that were in attendance at the same time.
- *Client declined any information:* If an enrolled client attends the shop for a haircut but does not want to receive any information about HIV prevention or services, or self-test kits, then the barber should mark this column with a ✓ If this column is marked, then no other column should also be marked *(i.*e. if a client declines all information, then we would not expect the barber to mark that HIV services were provided).
- *# other clients in attendance:* The barber should indicate the number of other clients in the shop that received the information when it was provided to the enrolled client.
    - If there are two or more enrolled clients in the shop at the same time, then each enrolled client should be entered separately on a different row.

4.8 Barber research questionnaires

In addition to the baseline questionnaires administered to all barbers prior to randomization, barbers will also be asked to complete interviewer administered forms during the course of the study. The questionnaires must be completed in a private space, agreeable to the barber and study staff, but do not need to be completed at the satellite study clinic.

Barbers in the control group will complete questionnaires at baseline and approximately three months after activation. The follow-up questionnaire will focus on their experience recruiting clients to enroll in the study and will document any social impacts reported.

Barbers in the intervention group will complete questionnaires at baseline and quarterly thereafter, until the end of the participant follow-up. Barber visit windows are listed below in Table 1.

Table 1. Visit windows for barbers at Intervention Barbershops

Visit Week	Target Day	Window Opens	Target Window Closes	Allowable Window Closes
0	Enrollment (day ICF signed)			
13	91	84	98	174
26	182	175	189	265
39	273	266	280	356
52	364	357	371	385

The follow-up questionnaires will focus on their experience recruiting clients to enroll in the study and delivering the intervention. Barbers will also be asked about any social impacts due to their participation in the study.

4.9 Protecting client confidentiality

All barbers will be trained on confidentiality and potential consequences of breaching confidentiality of their clients or enrolled participants. For example, breaches of confidentiality may impact their ability to retain clients, maintain respect within the community, or jeopardize their participation in the study, etc.

Each barbershop will be supplied with a small lockable cabinet that will be used to store all study related documentation. Only the participating barber(s) and the study team will have access to the key for the cabinet. The study team will check that the cabinet is being used appropriately during their regular check-in visits and that no participant information is being kept in a way that could breach confidentiality.

Any breaches of confidentiality will be reported to the Protocol Team and local regulatory authorities, as per their requirements. In such cases, the barber(s) involved would be retrained on confidentiality and key study procedures and study staff would increase engagement to ensure that the barber is correctly implementing protections for participants.

Appendices

Appendix A: Overview Training agenda

Time	Topic	Content Covered
8:30 am	**Welcome and Introductions (60 min total)** • **Introductions** • **Ice Breaker**	• Introductions & ice breaker • Ground Rules • Pre-assessment
	Overview of HPTN 111 (xx min)	• Importance & impact of HPTN 111 – what could come next? • Randomization – what does it mean and how will it work?
	Overview of Barber Role in HPTN 111 (xx min)	• Recruitment – linking clients to study staff • Intervention – HIV education, HIV self-test kits, group sessions • Their study participation (questionnaires/interviews)
	Overview of HIV Education (total min) • **What is HIV? (xx min)** • **HIV prevention (xx min)** • **HIV treatment (xx min)**	• Basic knowledge of HIV (What is HIV, how it is spread, prevention, treatment) • What barber needs to know about HIV in the context of HPTN 111 and recruiting their clients • Define status-neutral HIV education
10:15 am	**Break (15 min)**	
10:30 am	**Confidentiality (xx min)**	• What information is to be kept confidential? • Importance of confidentiality. They are a part of study team and confidentiality is important. • How much they can share with the clients and what the study staff manages. • What are consequences of breaking confidentiality?
	Study Logistics (xx min)	• What information barbers will need to record. • How barbers will record information • Storage of documents • Visits with study staff • How to contact study staff with questions/updates
	Communication Skills (xx min)	• Explain why communication is important for ALL barbers (related to recruitment and talking about the study) • Types of communication • Review challenges in communication • Review basic qualities of a good communicator
	Recruitment (xx min)	• Describe how barbers will recruit clients

	• **Role play**	• Describe who the study is interested in recruiting. • Explain how they will link clients to study staff? • Explain expectations of recruitment for each shop (number of men to be recruited)
	Next Steps (xx min)	• Randomization Event • Starting Recruitment
	Review Parking Lot & Adjourn (xx min)	

Appendix B: Intervention Training agenda

Time	Topic	Content Covered
8:30 am	**Welcome and Introductions (xx min total)** • **Introductions** • **Ice Breaker**	• Introductions & ice breaker • Reminder about ground rules
	HPTN 111 Refresher (xx min)	• Re-review basic information about HPTN 111 that was covered in the all-barber training
	The HPTN 111 HIV Prevention Initiative (xx min)	• Status neutral HIV education • HIV self-test kits & how to use them • HIV prevention and care services information • Group sessions
	HIV Education (X min)	• HIV information that can be provided to clients, including: what is HIV, how it is spread, prevention, treatment • HIV counseling basics – the five C's
10:15 am	**Break (15 min)**	
10:30 am	**Peer Support Group Sessions (X min)**	• Defining peer support • Ground rules and best practices for facilitating group sessions • Content to be covered in the group sessions
	Communication Skills (xx min)	• Explain why communication is important for ALL barbers (related to recruitment and talking about the study) • Types of communication • Review challenges in communication • Review basic qualities of a good communicator
	Study Logistics (xx min)	• What information barbers will need to record – recruitment, services provided, HIVST kit distribution • How barbers will record information • Storage of documents • Visits with study staff • How to contact study staff with questions/updates
	Mock Sessions (xx min) • **Scenarios** • **Role play**	• Describe how barbers will recruit clients • Describe who the study is interested in recruiting. • Explain how they will link clients to study staff? • Explain expectations of recruitment for each shop (number of men to be recruited)

	Next Steps (xx min)	• Starting Recruitment • Delivering the intervention
	Review Parking Lot & Adjourn (xx min)	

Appendix C: Barbershop Recruitment Log

Date	# Clients talked to about study	# clients referred/linked to study staff

8.10.6 Appendix D: HIV Self-test kit distribution Log

Date	Client Name	Phone contact

Appendix E: Peer Group Session tracking and scoring

1.	Date of form completion:	
2.	Date of group session:	
3.	Number of men in attendance:	
4.	Length of session (# minutes):	# minutes
5.	Mark all topics discussed during session:	☐ What is HIV ☐ How HIV is spread ☐ Condom use ☐ HIV PrEP ☐ HIV PEP ☐ HIV testing ☐ HIV self-testing ☐ STI management ☐ Circumcision ☐ Referral/community resources ☐ Other, specify:
Rank the barber's skills at this session as Excellent, Good, Adequate, or Needs Improvement.		
6.	The barber provided accurate information about HIV and prevention.	1 – Excellent 2 - Good 3 - Adequate 4 – Needs improvement
7.	The barber was non-judgmental and practiced active listening skills.	1 – Excellent 2 - Good 3 - Adequate 4 – Needs improvement
8.	The barber engaged their clients and encouraged participation.	1 – Excellent 2 - Good 3 - Adequate 4 – Needs improvement
9.	Overall, the barber led a successful group session.	1 – Excellent 2 - Good 3 - Adequate 4 – Needs improvement
10.	Comments:	
11.	Form Completed By (initials):	

Scoring Rubric for group sessions:

Score	The barber provided accurate information about HIV and prevention.	The barber was non-judgmental and practiced active listening skills.	The barber engaged their clients and encouraged participation.	Overall, the barber led a successful group session.
1 – Excellent	Barber demonstrated exceptional understanding of HIV and prevention information	Consistently demonstrates active listening, showing full engagement, paraphrasing, and asking clarifying questions.	Barber actively encourages and involves all participants, creating an inclusive and supportive environment.	Leads the session with confidence, effectively managing time, content, and interactions.
2 - Good	Barbers shows a solid understanding of HIV information	Generally, practices active listening, showing attentiveness and occasional paraphrasing or questioning.	Effectively engages participants, fostering a positive atmosphere for contributions.	Successfully leads the session, with good time management and effective handling of content and interactions.
3 - Adequate	Barber shows a satisfactory level of understanding but lacks depth or missed some key points	Displays basic active listening skills but may struggle to consistently engage or respond appropriately.	Encourages participation to some extent but may overlook certain individuals or lack enthusiasm.	Leads the session adequately but may face challenges in content delivery or engagement.
4 – Needs improvement	Barber shows a limited understanding of HIV information and/or has significant gaps in knowledge	Demonstrates limited active listening, with minimal engagement and understanding of others' contributions.	Struggles to engage participants, resulting in limited contributions and a less inclusive environment.	Faces significant challenges in leading the session, impacting overall effectiveness and participant engagement.

Appendix F: Intervention Delivery tracking for enrolled participants

**Note: This is a template.*

Intervention Checklist & Tracker

HPTN 111 (TRIM) | SSP Manual Section 8 | Appendix D | Version 0.1 | 18 January 2024

DATE	CLIENT	EDUCATION		PREVENTION OR CARE		SELF-TEST KIT INFO		# SELF-TEST KITS GIVEN	INFO DECLINED		NEARBY CLIENTS
DD MMM YYYY	#	✓	✗	✓	✗	✓	✗	#	✓	✗	#

5. Participant Retention

5.1 Overview of Section 5

This section includes information related to participant retention definition, requirements, and procedures. Once a participant enrolls in HPTN 111, the study site will make every effort to retain a participant for their full follow-up 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. It also relies on development and implementation of a comprehensive retention plan.

5.2 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 within the allowable visit window, 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.

5.3 Retention targets

The study site will target for 90% retention at Week 26 and Week 52 visits. Routine retention reports will be generated by the SDMC during the study and a final end-of-study rate once the study is completed.

5.4 Retention plan and best practices

The site will follow best practices for retaining participants and full details are included in a site-specific SOP.

A key component will be to collect full locator information for participants, including alternate contacts, phone numbers, alternate/preferred name(s), and home location.

In an effort not to unduly influence men in their HIV prevention seeking behaviors, the study team will keep minimum contact with participants between study visits. All participants will be contact approximately 2 weeks after study enrollment to ensure that they are comfortable with participation and answer any questions. The site team will also

contact participants starting two weeks prior to their scheduled follow-up visit as a courtesy reminder.

Some general strategies for retention are included below:

- Dedicate adequate staff time and effort to retention efforts.
- At screening, assess the likelihood that a particular participant will be able to meet the visit schedule for the full length of the study (up to one year).
- 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.
- 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.

Barber Retention Strategies

The site will engage with study barbers on various occasions (i.e., study initiation, weeks 13, 26, 39, 52, and 65, and community events). A key component of retaining study barbers, similar to participants/clients, involves collecting full locator information from barbers. In addition to collecting full locator information from barbers, study staff should conduct weekly check-ins to help barbers troubleshoot and address any issues or concerns (i.e., lacking confidence in providing status-neutral HIV education, need for more HIVST kits or condoms, etc.).

5.5 Off-site visits

Off-site visits may help participants with visit attendance. In order to conduct an off-site visit with a participant, they must consent to off-site visits on the informed consent form.

Visits may occur at the participant's home, place of work, or another place as agreed upon by the participant and study staff. It is possible to complete all study procedures off-site so long as the space allows for the procedures and the delegated study staff are in attendance. Samples collected off-site will need to be maintained and transported as per the SSP Sections 3.10 and 3.11 of the Study Management Overview Manual. It may be necessary to invite the participant to come to the study clinic for some visit procedures (e.g., physical exam if clinically indicated, follow-up HIV testing).

6. Visit Checklists

6.1 Overview of Section 6

This section provides a template checklist for each of the required study visits. The use of visit checklists is strongly recommended but is optional; sites may modify them as needed.

6.2 Visit Checklists as Source Documentation

Checklists are convenient tools, which may serve as source documentation if designed and completed appropriately. These checklists alone may not be sufficient for documenting all procedures but can be used to indicate that the procedure was completed and by whom. Additional information could be documented on the checklist comment sections and/or chart notes. It is up to each site to determine whether and how to use the visit checklists as source documentation.

It also should be noted that the visit checklists outlined below depict the visit schedule for a participant completing all protocol-specified study visits. In what is hoped to be a rare occurrence, there may be cases where a participant may have a modified study visit; in which case, any modifications to the procedures could be noted in in the comment section of the checklists.

6.3 Use of the Checklists

One checklist should be used for each participant. A common way that checklists are used is for the checklist to follow the participant through the visit; as activities are completed, they are checked off the list. The checklists are designed so that there is one for each visit. Sites may modify order of procedures to maximize the efficiency of site-specific study operations, with the following exceptions/considerations:

- Informed consent must be obtained before any study procedures are performed.
- Once informed consent is obtained, the first procedure to be performed should be assignment of PTID.

- During follow-up visits, behavioral assessment and acceptability assessments should be administered prior to the delivery of HIV and adherence counseling.
- Collect blood early in the visit so participants can have something to eat or drink immediately after blood collection.

When using the checklists, it is important that every item is completed - this is done by initialing and dating each step of the checklist (to show that the step was completed), or by entering ND (not done), or NA (not applicable) if a procedure is not performed. See checklist instructions for further information.

The source documentation for the procedure will need to be identified for some items that are in the protocol, but not captured on the CRFs.

A good example of this is locator information. At each visit, the protocol requires that locator information is confirmed and, if necessary, updated. Some of the ways that the "act" of confirming or updating can be documented at each visit include writing a note in the participant's chart, creating a locator information log, or having a review/revision log attached to the locator information itself. The checklist cannot serve as the source for the confirmation of locator information unless it is revised to show who confirmed the information if changes were made to the form.

6.4 Visit Checklist Templates

HPTN 111 Study Eligibility Checklist

Place PTID Label Here

Date of this evaluation

INSTRUCTIONS: Enter staff initials next to each criterion reviewed. Do not initial criteria reviewed and checked by another staff member. If other staff members are not available to initial next to the criterion they checked, add a note on the checklist documenting who checked the criterion. If all criteria listed on the checklist are reviewed and checked on the date entered in the top section of the checklist, it is not necessary to enter the date beside each item. If criteria listed on the checklist are reviewed and checked on multiple dates, enter the date upon which each criterion was evaluated and checked beside each item. The study Principal Investigator/designee must review the eligibility checklist, as well as reports of information pertinent to the study, and initial and date the checklist to document his/her review. **Checklist is considered source for procedures that are grayed out.**

HPTN 111 Eligibility Checklist					
These are inclusion criteria. Any box checked "No" disqualifies the potential participant from enrolment.					
		Eligible	**Not Eligible**	**Initials**	**Date**
1.	Person identifies as a heterosexual male	Yes ☐	No ☐		
2.	At screening, potential participant is ≥ 16 years of age	Yes ☐	No ☐		
3.	Able to provide and has provided written informed consent	Yes ☐	No ☐		
3.	Behaviorally vulnerable to HIV, based on self-report of at least one of the following in the last three months: a. Had condomless sex with a person of unknown HIV status or a person living with HIV b. Had more than one sexual partner	Yes ☐	No ☐		
5.	At screening, HIV negative per Ugandan Ministry of Health guidelines and the SSP Manual	Yes ☐	No ☐		
6.	Is a regular customer at a participating barbershop as defined in the SPP Manual	Yes ☐	No ☐		
These are exclusion criteria. Any box checked "Yes" disqualifies the potential participant from enrolment.					
		Not Eligible	**Eligible**	**Initials and EMPID**	**Date**
7.	Not planning to stay in the study catchment area in the next 12 months	Yes ☐	No ☐		
8.	Any other condition or adverse social situation	Yes	No		

	that, in the opinion of the site investigator, would preclude informed consent, make study participation unsafe, complicate interpretation of study outcome data, or otherwise interfere with achieving the study objectives	☐	☐			

The Principal Investigator OR Designee verifying the information above must review the eligibility checklist, as well as reports of information pertinent to the study, and initial and date the checklist to document his/her review.

Initials of Principal Investigator/designee:

_____

EMPID of Principal Investigator / designee:

_____

Date: _____

dd mmm yy

HPTN 111 HIV Confirmatory Visit Checklist

PTID: _____ Date: _____Visit Type: _____

Instructions: Procedures do not have to be conducted in the order in which they appear in the checklist. When an item is performed, complete "Staff Initials" cell. If not done but required, write "ND" and staff initials in "Staff Initials" cell, and provide more details in the chart notes as needed. Do not initial for other staff members. If other staff members are not available to initial items themselves, write and initial/ date a note documenting who completed the procedure, e.g., "done by {name}" or "done by nurse." If visit procedures are split across more than one date, ensure the date is captured in the comments cell for procedures conducted on a date different than that provided above. **Checklist is source for grayed out items.**

	HIV Confirmatory Visit Procedures	**Staff Initials:**	**Comments:**
1.	Confirm identity and PTID		
2.	Check for co-enrollment in other studies: ❒ NOT enrolled in another study ==> CONTINUE ❒ Enrolled in another study ==> CONTINUE and notify CMC		
3.	Explain today's procedures		
4.	Provide and document counseling as may be needed and refer to HIV care and treatment		
5.	Collect blood for confirmatory HIV (***Collect sample at different time point from initial positive test result)*** and send to lab for required testing: **a) 1x10 mL lavender top (EDTA) tube for:** ❒1x10 mL confirmatory HIV testing ***(per approved HIV testing algorithm. Specimen collection for this testing must occur at a different timepoint from initial positive test result)***		
6.	Provide and explain all available findings and results. Refer for findings as indicated. If positive, encourage participant encouraged to continue to attend study visits and receive HIV risk reduction counseling (e.g., treatment as prevention), STI testing, and complete socio-behavioral questionnaires.		
7.	Collect information on linkage to HIV care and start of treatment		
8.	Does the participant want to receive any further HIV education from the barber or attend the group sessions? ❒ Yes ❒ No		
9.	Does participant want the study staff to notify the barber about the participant's decision regarding the HIV prevention initiative provided by the barber? ❒ Yes ❒ No		

HIV Confirmatory Visit Procedures		Staff Initials:	Comments:
10.	Schedule next visit. ☐☐/☐☐☐/☐☐ dd mmm yy		
11.	Perform QC1 while participant is still present to ensure information is complete and accurate. **Ensure all required Case Report Forms are submitted in Medidata Rave.**		
12.	Provide reimbursement		
13.	Update the Participant Tracking Database (or site-specific tracking documents).		

QC I Initials and date		Empid
QC II Initials and date		Empid

HPTN 111 Participant Screening Visit Checklist

PTID: _____ Date: _____ Visit Type: Screening

Instructions: Complete staff initials next to procedures completed. Do not initial for other staff members. If other staff members are not available to initial checklist items themselves, initial and date a note on the checklist documenting who completed the procedure, e.g., "done by {name}" or "done by nurse." If a procedure listed on the checklist is not performed, enter "ND" for "not done" or "NA" for "not applicable" beside the item and record the reason why (if not self-explanatory); initial and date this entry. If any procedures are not conducted on the date recorded above, ensure the date procedure conducted is included in the comments section. Use a new Screening Visit Checklist if a second screening attempt is needed. **Checklist is considered source for procedures that are grayed out.**

Screening Visit Checklist			
	Procedure	**Staff Initials**	**Comments:**
1.	Confirm identity, age, and prescreening ID per site SOP ***NOTE: If participant presents for screening and does not have a prescreening ID already assigned, complete this process***		
2.	Check for co-enrollment ❒ NOT currently or recently enrolled in another study ==> CONTINUE. ❒ Currently or recently enrolled in another study ==> STOP. Assess eligibility to continue. ***NOTE: In general, participants in this study will not be allowed to take part in other concurrent HIV or interventional research studies during their participation in the study. This is due in part to concerns about participant study burden and to avoid confounding in the interpretation of the study data. The Protocol Team should be consulted for any possible exceptions, including for observational studies.***		
3.	Determine screening attempt number (check if HPTN 111 screening/enrollment ICF has been previously signed) _____(write in)		
4.	Explain procedures to be performed at today's visit		
5.	Explain, conduct, and document the screening and enrollment informed consent process, including comprehension assessment/assessment of understanding: ❒ Willing and able to provide written informed consent ==> CONTINUE. ❒ NOT willing or able to provide written informed consent ==> STOP. NOT ELIGIBLE.		
6.	Participant offered unsigned copy of screening and enrolment ICF to read further at home ❒ Participant accepted unsigned copy for further reading ❒ Participant opted not to take unsigned copy of Enrolment ICF for further reading		
7.	Assign PTID (if not done during a previous screening attempt) by completing a row on the PTID name-linkage log		

Screening Visit Checklist			
	Procedure	**Staff Initials**	**Comments:**
8.	Provide and document counseling: ❒ HIV pre-test counseling		
9.	Study coordinator/designee obtains screening number from the online data capture system		
10.	Enter PTID onto Screening and Enrollment Log if not already assigned during previous screening attempt		
11.	Collect blood and send to lab for required testing: **b) 1x10 mL lavender top (EDTA) tube for:** ❒ HIV Testing ❒ Syphilis Testing		
12.	Provide HIV test results in the context of post-test counseling. Provide referrals if needed/requested. ❒ If rapid test negative ==> UNINFECTED ==> ELIGIBLE ==> CONTINUE. ❒ If rapid test positive ==> INFECTED ==> STOP. NOT ELIGIBLE. ==> Refer for further management		
13.	Collect Demographic information		
14.	Collect socio-behavioral information (ACASI)		
15.	Provide study informational material to include site contact information, and instructions to contact the site for additional information and/or counseling, (and offer condoms) if needed before the next visit.		
16.	If STI/RTI/UTI is diagnosed, provide treatment. ❒ Treatment given ❒ No STI/RTI/UTI diagnosed		
17.	Provide and explain all available findings and results. Refer for other findings as indicated.		
18.	Assess participant's current eligibility status: ❒ ELIGIBLE thus far ==> CONTINUE. ❒ NOT ELIGIBLE but likely to meet eligibility criteria within this screening attempt ==> PAUSE ==> perform and document relevant outcomes of all clinically indicated procedures. Schedule Enrollment Visit when participant is likely to be eligible. ❒ NOT ELIGIBLE and NOT likely to meet eligibility criteria within this screening attempt ==> STOP. Provide clinical management and referrals as needed.		

Screening Visit Checklist			
	Procedure	**Staff Initials**	**Comments:**
19.	Obtain locator information and determine adequacy: ❒ Adequate locator information ==> CONTINUE. ❒ Inadequate locator information ==> PAUSE and re-assess: ❒ Adequate information likely to be available prior to enrollment ==> CONTINUE. ❒ Adequate information NOT likely to be available ==> STOP. NOT ELIGIBLE.		
20.	Determine if participant will continue to enrollment ❒ If participant will not proceed to enrollment, complete Eligibility Checklist, complete and submit Screening Failure CRF. ❒ If participant will proceed to enrollment, CONTINUE.		
21.	Determine last possible enrollment date for this screening attempt (14 days): ☐☐/☐☐☐/☐☐ ☐N/A dd MMM yy		
22.	Schedule enrolment visit (if applicable) and advise him of potential length of next visit. ☐☐/☐☐☐/☐☐ dd MMM yy		
23.	Perform QCI to ensure all screening procedures have been done		
24.	Provide Reimbursement ☐N/A (if enrollment on same day)		
25.	Enter PTID into Participant Tracking Database (or site-specific tracking system/log)		

QC I Initials and date		Empid
QC II Initials and date		Empid

HPTN 111 Enrollment Visit Checklist

PTID: _____ Date: _____Visit Type: Enrollment

Instructions: Complete staff initials next to procedures completed. Do not initial for other staff members. If other staff members are not available to initial checklist items themselves, initial and date a note on the checklist documenting who completed the procedure, e.g., "done by {name}" or "done by nurse." If a procedure listed on the checklist is not performed, enter "ND" for "not done" or "NA" for "not applicable" beside the item and record the reason why (if not self-explanatory); initial and date this entry. **Checklist considered source for grayed out items.**

Enrollment Visit Checklist			
Procedure		**Staff Initials**	**Comments:**
1.	Confirm identity and PTID		
2.	Check for co-enrollment in other studies: ❒ NOT enrolled in another study ==> CONTINUE ❒ Enrolled in another study ==> STOP. Assess eligibility to continue.		
3.	Confirm participant is within 14-day screening window. ❒ WITHIN 14 days from screening visit ==> CONTINUE. ❒ OUTSIDE 14 days from screening visit ==> STOP. Not eligible to enroll during this screening attempt ==> If willing, schedule for rescreening		
4.	Explain today's procedures		
5.	Review/update locator information and re-assess adequacy: ❒ Adequate locator information ==> CONTINUE. ❒ Inadequate locator information ==> STOP. NOT ELIGIBLE.		
6.	Collect demographic information		
7.	Conduct social impacts assessment		
8.	Conduct socio-behavioral assessment (ACASI)		
9.	Collect Urine and send to lab for required testing: **c) 1x5 mL for:** ❒ Gonorrhea and Chlamydia testing		
10.	Provide HIV prevention services or HIV Care and referral. Provide referrals if needed/requested. ❒ If rapid test from screening negative ==> UNINFECTED ==> ELIGIBLE ==> CONTINUE. ❒ If rapid test from screening positive ==> INFECTED ==> STOP. NOT ELIGIBLE. ==> Refer for further management		
11.	Provide contact information and instructions to report symptoms and/or request information, counseling, or condoms before next visit. Also include information about recommended HIV testing schedule		

Enrollment Visit Checklist			
Procedure		**Staff Initials**	**Comments:**
12.	Review screening visit documentation		
13.	Obtain available medical record and collect baseline medical, medications or drug history. Review available medical records.		
14.	Perform complete physical exam. (Complete vital sign CRF)		
15.	Provide and explain all available findings and results. Refer for other findings as indicated.		
16.	If STI/RTI/UTI is diagnosed, provide treatment. Update baseline medical history log and Concomitant Medications Log. ❒ Treatment given ❒ No STI/RTI/UTI diagnosed		
17.	Complete final eligibility determination and confirmation by review/completion of Eligibility Checklist ***(a negative HIV test result must be available at screening prior to enrollment)***, ❒ ELIGIBLE ==> CONTINUE ==> sign the Eligibility Checklist and proceed to eligibility verification ❒ NOT ELIGIBLE ==> STOP. DO NOT ENROLL. ==> Pause and evaluate whether participant is: ❒ NOT ELIGIBLE but likely to meet eligibility criteria within this screening attempt ==> PAUSE ==> perform and document all clinically indicated procedures. Schedule another Enrollment Visit when participant is likely to be eligible. ☐☐/☐☐☐/☐☐ dd mmm yy ❒ NOT ELIGIBLE and NOT likely to meet eligibility criteria within this screening attempt ==> STOP. Provide clinical management as needed. Complete the Screening Failure-Inclusion/Exclusion Log.		
18.	Verify participant eligibility by review of Eligibility Checklist (must be different staff member than step 17): ❒ ELIGIBLE ==> CONTINUE → enter checklist data into SES to enroll the participant, print and file a copy of the confirmation ❒ NOT ELIGIBLE ==> STOP. DO NOT ENROLL. Provide clinical management as needed.		
19.	Disclose study group (intervention or control)		
20.	Conduct Intervention acceptability assessment		

Enrollment Visit Checklist				
Procedure			**Staff Initials**	**Comments:**
21.	Schedule Week 26 visit and advise the potential length of the visit. ☐☐/☐☐☐/☐☐ dd mmm yy			
22.	Schedule Week 2 Post-enrollment call to check on the participant. ☐☐/☐☐☐/☐☐ dd mmm yy			
23.	Perform QC1: while participant is still present to ensure all enrollment procedures have been done accurately. **For enrolled participants, ensure all required CRFs from the Screening and Enrollment visits are complete in REDCAP.** **If participant is not enrolled for this screening attempt, ensure the screening failure eCRF is complete in REDCAP**			
24.	Provide reimbursement			
25.	Update Screening and Enrollment Log			
26.	Perform QCII ensuring that all forms have been completed accurately			
27.	Update participant tracking database (or site-specific tracking documents). Generate participant visit calendar			
	QC I Initials and date		Empid	
	QC II Initials and date		Empid	

HPTN 111 Week 26 Visit Checklist

PTID: _____ Date: _____ Visit Type: Week 26

Instructions: Procedures do not have to be conducted in the order in which they appear in the checklist. When an item is performed, complete "Staff Initials" cell. If not done but required, write "ND" and staff initials in "Staff Initials" cell, and provide more details in the chart notes as needed. Do not initial for other staff members. If other staff members are not available to initial items themselves, write and initial/ date a note documenting who completed the procedure, e.g., "done by {name}" or "done by nurse." If visit procedures are split across more than one date, ensure the date is captured in the comments cell for procedures conducted on a date different than that provided above. **Checklist is source for grayed out items.**

	Week 26 Visit Procedure (Intervention and Control Group)	**Staff Initials:**	**Comments:**
14.	Confirm identity and PTID		
15.	Explain today's procedures		
16.	Check for co-enrollment in other studies: ❒ NOT enrolled in another study ==> CONTINUE ❒ Enrolled in another study ==> CONTINUE and notify Protocol Team		
17.	Review elements of informed consent as needed		
18.	Provide and document counseling: ❒ HIV pre-test counseling		
19.	Collect blood and send to lab for required testing: **a) 1x10 mL lavender top (EDTA) tube for:** ❒ HIV diagnostic testing ❒ Syphilis ❒ Storage for Quality Control		
20.	Collect Urine for: ❒ Gonorrhea and Chlamydia testing		
21.	If applicable, provide HIV test results in the context of post-test counseling. If indicated provide referrals if needed/requested. ❒ If diagnostic test negative ==> UNINFECTED ==> CONTINUE. ❒ If diagnostic test positive ==> o Complete clinical HOLD documentation o Notify the Protocol Team of initial positive result o Document HIV confirmatory visit procedures on the confirmatory visit procedures checklist.		
22.	Conduct social impacts assessment		
23.	Conduct socio-behavioral assessment (ACASI)		

Week 26 Visit Procedure (Intervention and Control Group)		Staff Initials:	Comments:
24.	Conduct Intervention acceptability assessment		
25.	Conduct HIV self-testing assessment		
26.	Qualitative IDI ❒ Qualitative IDI done ❒ Not selected or consented ❒ Already participated in qualitative IDI		
27.	Provide contact information and instructions to report symptoms and/or request information, or condoms before next visit. Also include information about recommended HIV testing schedule		
28.	Collect follow-up medical/medications history: **Review/update Adverse Experience Log, Concomitant Medications Log.**		
29.	Perform targeted physical exam. (Complete vital sign CRF) ❒ Physical Exam done		
30.	Provide and explain all available findings and results. Refer for findings as indicated.		
31.	If STI/RTI/UTI is diagnosed, provide treatment. ❒ Treatment given ❒ No STI/RTI/UTI diagnosed		
32.	Document any Adverse Events: Complete/update AE CRF as needed ❒ AE(s) documented/ updated ❒ Not applicable		
33.	Request for the following tests if clinically indicated ❒ No clinical indication The following tests have been ordered ❒ Liver function tests ❒ Renal function tests ❒ Complete blood count ❒ Other, specify:		
34.	Schedule next visit. ☐☐/☐☐☐/☐☐ dd mmm yy		
35.	Schedule week 2 post-visit call to check on the participant. ☐☐/☐☐☐/☐☐ dd mmm yy		
36.	Review/update locator information		

Week 26 Visit Procedure (Intervention and Control Group)		Staff Initials:	Comments:
37.	Perform QC1 while participant is still present to ensure information is complete and accurate. **Ensure all required Case Report Forms are submitted in REDCAP**		
38.	Provide reimbursement		
39.	Update the Participant Tracking Database (or site-specific tracking documents).		
QC I Initials and date		Empid	
QC II Initials and date		Empid	

HPTN 111 Week 52 Visit Checklist

PTID: _____ Date: _____ Visit Type: Week 52

Instructions: Procedures do not have to be conducted in the order in which they appear in the checklist. When an item is performed, complete "Staff Initials" cell. If not done but required, write "ND" and staff initials in "Staff Initials" cell, and provide more details in the chart notes as needed. Do not initial for other staff members. If other staff members are not available to initial items themselves, write and initial/ date a note documenting who completed the procedure, e.g., "done by {name}" or "done by nurse." If visit procedures are split across more than one date, ensure the date is captured in the comments cell for procedures conducted on a date different than that provided above. **Checklist is source for grayed out items.**

	Week 52 Visit Procedure (Intervention and Control Group)	**Staff Initials:**	**Comments:**
40.	Confirm identity and PTID		
41.	Explain today's procedures		
42.	Check for co-enrollment in other studies: ❒ NOT enrolled in another study ==> CONTINUE ❒ Enrolled in another study ==> CONTINUE and notify Protocol Team		
43.	Review elements of informed consent as needed		
44.	Provide and document counseling: ❒ HIV pre-test counseling		
45.	Collect blood and send to lab for required testing: **b) 1x10 mL lavender top (EDTA) tube for:** ❒ HIV diagnostic testing ❒ Syphilis ❒ Storage for Quality Control		
46.	Collect Urine for: ❒ Gonorrhea and Chlamydia testing		
47.	If applicable, provide HIV test results in the context of post-test counseling. If indicated provide referrals if needed/requested. ❒ If diagnostic test negative ==> UNINFECTED ==> CONTINUE. ❒ If diagnostic test positive ==> o Complete clinical HOLD documentation o Notify the Protocol Team of initial positive result o Document HIV confirmatory visit procedures on the confirmatory visit procedures checklist.		
48.	Conduct social impacts assessment		
49.	Conduct socio-behavioral assessment (ACASI)		
50.	Conduct Intervention acceptability assessment		

Week 52 Visit Procedure (Intervention and Control Group)		Staff Initials:	Comments:
51.	Conduct HIV self-testing assessment		
52.	Conduct long-acting PrEP interest questionnaire		
53.	Qualitative IDI ❒ Qualitative IDI done ❒ Not selected or consented ❒ Already participated in qualitative IDI		
54.	Provide contact information and instructions to report symptoms and/or request information, or condoms before next visit. Also include information about recommended HIV testing schedule		
55.	Collect follow-up medical/medications history: **Review/update Adverse Experience Log, Concomitant Medications Log.**		
56.	Perform targeted physical exam. (Complete vital sign CRF) ❒ Physical Exam done		
57.	Provide and explain all available findings and results. Refer for findings as indicated.		
58.	If STI/RTI/UTI is diagnosed, provide treatment. ❒ Treatment given ❒ No STI/RTI/UTI diagnosed		
59.	Document any Adverse Events: Complete/update AE CRF as needed ❒ AE(s) documented/ updated ❒ Not applicable		
60.	Request for the following tests if clinically indicated ❒ No clinical indication The following tests have been ordered ❒ Liver function tests ❒ Renal function tests ❒ Complete blood count ❒ Other, specify:		
61.	Schedule next visit. ☐☐/☐☐☐/☐☐ dd mmm yy		
62.	Review/update locator information		
63.	Perform QC1 while participant is still present to ensure information is complete and accurate. **Ensure all required Case Report Forms are submitted in REDCAP**		
64.	Provide reimbursement		
65.	Update the Participant Tracking Database (or site-specific tracking documents).		

Week 52 Visit Procedure (Intervention and Control Group)	Staff Initials:	Comments:
QC I Initials and date		Empid
QC II Initials and date		Empid