Section 1.Data Management

1.1. Overview of Section 1

The purpose of this document is to provide site staff with the information needed to complete and submit HPTN111 case report forms.

The SDMC (Statistical and Data Management Center) for this study is SCHARP (the Statistical Center for HIV/AIDS Research and Prevention). SCHARP is located in Seattle, USA, and is in the US Pacific Time (PT) time zone.

SDMC Contact Information
For information about this section of the SSP or about data management procedures for HPTN111, please contact the SCHARP Clinical Data Managers:

Paul Butler
Email: pbutler@scharp.org
Phone: 206.667.7928

Ian Bell
Email: ibell@scharp.org
Phone: 206.667.7061

For questions about clinical queries, please contact the SDMC Clinical Safety group: sc.clinsafety@scharp.org

1.2. REDCap Cloud Overview

REDCap Cloud (RCC) is the platform used by SCHARP to receive and manage study data collected for the HPTN111 study. The site completes study electronic case report forms (eCRFs) by entering data into the RCC study database. Per the site's required HPTN 111 Source Documentation table, data may be entered directly into the study database (i.e., electronic CRF is source), collected first on paper CRFs and then entered into the study database, and/or entered into the study database based on other non-CRF source documents (e.g., lab reports, testing logs, chart notes, etc.)

The HPTN111 study database in RCC may be accessed at https://login.redcapcloud.com/.

When using RCC, the internet browser chosen and connectivity quality will be the most critical factors affecting functionality, as RCC is accessed via a URL using a web browser.
The following list of web browsers can be used access the website.

- Safari for macOS
- Microsoft Edge
- Google Chrome for Windows, macOS, and Linux desktops
- Mozilla Firefox for Windows, macOS, and Linux desktops

Make sure to always use the most current version of each browser to optimize the full capacity of the product's features and functionality.

Each site's Data Management SOP designates the site staff members responsible for entering data into the study database. SCHARP grants designated site staff access with specific user permissions to the study database.

Site staff should contact the study Clinical Data Manager(s) with any questions related to study data collection and management.

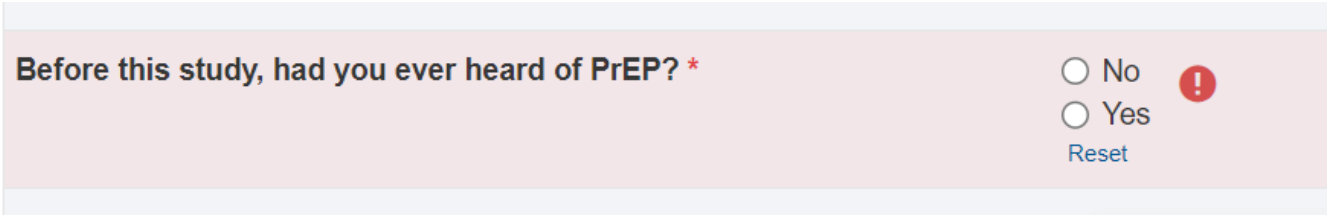
To request new access or to revise access to the study for any of site staff, please send an email sc.access.medidata@scharp.org.

1.3. Data Entry/Quality Control

- All text entries in RCC must be made in English.
- Once data for an eCRF is completed and saved in the study database, the following may occur:
    - A system query may be automatically triggered in RCC (e.g., denoting incomplete or inconsistent data).
    - Manual data queries may be placed by the SCHARP Clinical Data Manager (CDM) or Clinical Safety Associate (CSA) after review of entered forms.
    - Data queries may be placed by the site monitor after required review for certain forms and/or fields.

Query Management and Resolution

- If a site utilizes paper CRFs as source documents, any changes to the data recorded on paper CRFs **must** be entered into the study database.
- If a query is auto-generated it must be answered before proceeding to another form.



When data is entered into the empty field, the auto query will be removed.

Electronic Signatures by Investigators

Signatures are not required for surveys or interview-administered surveys as they are entered by the participants. This fact will also be added to the DMP.

1.4. eCRF Completion

1.4.1 PTID Creation and Screening

Each participant who provides written informed consent to be screened in HPTN111 will be assigned a Participant Identifier, or PTID. The PTID is created when site staff add a subject within the HPTN111 RCC study. Refer to the "Creating Subjects" section of the CRF Completion Guidelines (CCG) for specific instructions.

Each PTID is unique within the site and study it is generated for. It is assigned to a single participant and remains assigned to them even if they transfer to another site during the course of the study.

PTIDs are generated using a custom ID generation with a 3 sequence, starting with 001.

If the participant does not enroll, site staff must complete the Informed Consent CRF, the Inclusion Exclusion Criteria CRF with the reasons for screening out andstating that the participant did not enroll, and the Demographics form.

If a participant returns at a later date to re-screen a new, unique PTID must be assigned and treated as a new participant in the data management system. If they are a re-screen will be asked and recorded in EDC.

1.4.2 Enrollment

Prior to enrollment, eligibility must be confirmed, which includes negative rapid HIV tests on a sample drawn at the screening visit per LC guidelines. The Inclusion Exclusion Criteria form in the participant's enrollment folder must be completed before the Enrollment CRF.

To enroll a participant, site staff mark 'Yes' to the question, "Was the participant enrolled in the study?" on the Enrollment eCRF. **A participant is considered enrolled in the study once this step takes place and the eligibility checklist is completed**; please confirm that the PTID is correct and that all screening procedures are complete prior to enrolling the participant.

1.4.3 General Guidelines for eCRF Completion

- When completing an eCRF, refer to the CRF Completion Guidelines (CCG) document, posted on ATLAS, for detailed instructions on data collection pertaining to the given form and fields on that form.
- REDCap Cloud allows data to be entered directly into the study database (i.e., electronic CRF as source). Any data that is either collected first on paper CRFs or derived from non-CRF source documents (e.g., lab reports) should ideally be entered into RCC within 1-2 business days of the visit, though up to 7 (calendar) days is acceptable.
- If some or all of the eCRFs will be completed first as paper CRFs, write the participant's PTID and Visit Week (e.g., Week 26) or Visit code on the paper form**.**

1.4.4 Visit Codes

Most eCRFs in the study database are set up within pre-defined study visit folders, so the visit name and code automatically appear (and do not need to be entered for required study visits).

Visit names for required visits are listed in table 1-1.

1.5. Visit Scheduling: Target Days and Visit Windows

Whenever possible, visits should be completed on the target day (based on the enrollment date for regular schedule visits) or within the target visit window.

Allowable visit windows are an extension of the target windows and are contiguous. When necessary, visits may be completed inside the allowable window. Visits completed within the allowable window but outside the target window are considered (early/late) for the purpose of assessing on time retention.

The following table lists the HPTN111 visit names, target days and visit windows for each study visit. All windows are listed in days.

Visit	Target Visit Day	Target Visit Window	Allowable Visit Window
Screening	Up to 14 days before enrollment		
Enrollment	Day 0	-	-
Week 26	Day 182	Day 168-196	Day 154-336
Week 52	Day 365	Day 351-379	Day 337-427

Table 1-1: HPTN111 Visit Codes, Target Days, and Visit Windows

1.6. Types of Visits

Please refer to Section 1 of the Accrual, Follow-up, and Retention SSP for additional information on visit types and procedures.

1.6.1 Scheduled Visits

A scheduled visit is a required visit as dictated by the protocol.

1.6.2 Missed Visits

A scheduled visit is considered missed only if it is not completed within its allowable visit window AND the required procedures for that visit are not completed. If a participant is available to complete visit procedures outside of the target window consult with the Clinical Data Manager as appropriate to confirm the best approach for documentation.

1.6.3 Split Visits

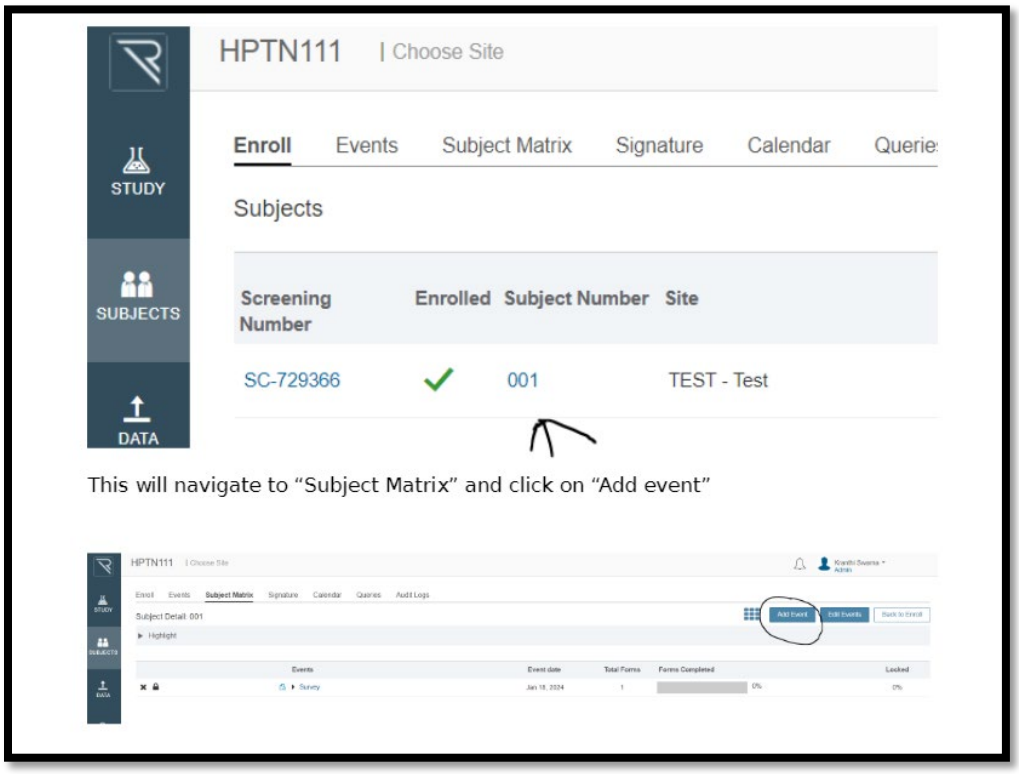
When a participant is not able to complete all required visit evaluations on the same day, the participant may return and complete the remaining evaluations on another day. When such a split visit occurs, case report forms completed for the visit are all assigned the same visit code (even though some forms and evaluations will have different visit dates).

1.6.4 Interim Visits

An interim visit is an 'extra' visit that occurs after procedures for a required visit are completed. For example, a participant comes to clinic for additional STI testing.

All interim visits/contacts with the participant should be documented in a chart note. Additionally, if the interim contact results in at least one newly completed or updated RCC CRF, the interim visit is assigned an interim visit code (visit number ending in something other than ".0"). All phone contacts that meet interim visit criteria as specified above are also assigned interim visit codes.

To add an interim visit in RCC, click on 'Add Event' while in the participant's folder and select 'interim':



An interim visit folder that contains the Interim Visit Summary CRF is then added to the participant's casebook or set of folders.

1.6.5 Interim Visit Codes

Visit Codes will not be used in the HPTN 111 study. The case report forms are summarized in the HPTN111 Schedule of Forms found at the end of this section. A link to the ACASI survey can be found in section 4 of the DM SSP Manual.

1.7.1 Completing Interviewer-administered Forms

In order to standardize interviewer-administered data collection from site to site and to maximize quality, it is important that participant interviews be conducted with a non-biased, non-judgmental approach. Study staff should help a participant feel comfortable sharing personal information and opinions while asking the study questions in a consistent manner from participant to participant.

1.7.2 Site Review (Quality Control) of CRFs

As described in the site's Data Management SOP, each site must perform Quality Control (QC) review steps, especially for paper CRFs prior to their data entry into the study database. (If a site is entering all data directly into REDCap Cloud then this section does not apply.) While paper CRFs are being reviewed, it is important that they are stored and tracked systematically.

Below are specific review guidelines that should be followed for these QC review steps.

QC Review Step #1

- Review visit checklist to ensure all required procedures were completed.
- Review completed paper CRFs and eCRFs based on participant responses to ensure completeness.

QC Review Step #2 procedures for all visits:

- Review visit checklist to ensure all required procedures were completed.
- Ensure the PTID is correct, is recorded correctly on all paper source documents (including paper CRFs) and is the same on the paper source documents and the eCRFs for a given participant.
- Confirm that no participant identifiers other than the PTID are present on paper source documents, including paper CRFs.
- Ensure that the assigned visit code is correct, and is consistent between the paper source documents, including paper CRFs, and the eCRFs.

Additional QC Steps for Paper CRFs

If some or all CRFs will first be completed on paper, the following review step should occur before forms are data-entered into the study database. Ideally, this review will happen once all lab results are available, so that all forms for a particular visit can be reviewed for consistency across documents. The goal is to correct data inconsistencies/errors prior to entering data into the study database, so that data is accurate, complete, and available at the time of data entry, thus minimizing the likelihood of data queries.

- Make sure a response has been recorded for each item, as required per instructions in the CRF Completion Guidelines (CCG) document.
- If a response box with "other" or "specify" line is present, make sure there is text responding to that item.
- Make sure text responses are clearly recorded.

- For paper CRFs that are not source documents, make sure the data recorded on the paper CRFs matches or is consistent with the source documents.

Additional QC Steps for Electronic CRFs (eCRF)

When data is entered into the study database, and an eCRF is saved, system queries are automatically generated in response to inconsistent or incomplete data. Unlike the paper CRFs, which require manual review, eCRFs have the advantage of having the study database itself provide a real-time QC review to ensure data completeness.

No additional review steps are required for eCRFs that are source (i.e., the data is directly entered into the study database, rather than entered based on a separate paper CRF or other paper source document).

Electronic CRFs that are completed based on other paper source documents (e.g., data entry of paper CRFs or lab reports) should be reviewed to ensure that the data entered matches or is consistent with the source documents. The site's Data Management SOP provides additional details and specifies which staff members will perform the review.

1.7.3 CRF Completion Instructions

Detailed form completion instructions for each form are provided in the CRF Completion Guidelines (CCG) document. The instructions document skip patterns, form completion of paper CRFs, and include guidance on completion of the eCRF in the study database. Some items on forms are straightforward and do not require specific instructions. Therefore, you will not see all forms or form items listed in the CCG, but rather only those items needing detailed explanation.

1.7.4 Case Report Forms

The current version of the eCRFs can be found on the HPTN111 Atlas web page: https://atlas.scharp.org/cpas/project/HPTN/111/begin.view?

1.7.5 Schedule of Forms

Participant CRFs

Form Name	*Screening*	*Enrollment*	*Week 26*	*Week 52*
Demographics	X			
Inclusion Exclusion Criteria	X			
Informed Consent Log	X			
Enrollment	X	X		
Physical Exam		(X)	(X)	(X)
HIV Lab Test Results	X		X	X
Interim HIV Testing log			(X)	(X)
STI Test Results	X	X	X	X
Social Impact Log		(X)	(X)	(X)
Protocol Deviation Log	(X)	(X)	(X)	(X)
Alcohol and Drug Use (Enrollment)*		X		
Alcohol and Drug Use (Follow-up)*			X	X
Barbershop Services Received			X	X

Barbershop Transfer Form_Participant			(X)	(X)
Gender Equitable Men Scale*		X	X	X
Barbershop Services Acceptability (Enrollment)*		X		
Barbershop Services Acceptability (Follow-up)*			X[1]	X[1]
HIV prevention Services (Enrollment)*		X		
HIV prevention Services (Follow-up)*			X	X
Self-Efficacy*		X	X	X
Sexual Behavior (ACASI)*		X	X	X
Seroconversion Follow-up			(X)	(X)
Study Termination			(X)	(X)

(X) as needed

*Requires translation

[1] Intervention group only

Barber CRFs

Form Name	*Study Initiation*	*Weeks 13/39/65*	*Weeks 26/52*
Demographics_Barber	X		
Enrollment/Informed Consent_Barber	X		
Inclusion Exclusion Criteria_Barber	X		
Barbershop Intervention Acceptability_Barber (Enrollment)*	X		
Barbershop Intervention Acceptability_Barber (Follow-up)*		X[1]	X[1]
Group Session Log_Barber		X[1]	X[1]
Social Impact Log_Barber		(X)	(X)
Protocol Deviation Log _Barber		(X)	(X)
Barbershop Transfer Form_Barber		(X)	(X)

(X) as needed

*Requires translation

[1] Intervention group only

Barbershop Data Instruments

Form Name	*During client-visits to the barbers*
Pre-baseline Information	X
Services Provided (Log Form)[1]	X
Recruitment (Log Form)	X

[1] Intervention group only

Section 2. Reporting Plan

2.1 Purpose of Reporting Plan

The purpose of this reporting plan is to:

- identify the content of each HPTN111 report;
- identify those responsible for production and distribution of each report;
- identify who should receive and review the reports so corrective action (if necessary) is taken.

The reporting plan is prepared by the HPTN111 Clinical Data Manager at SCHARP in conjunction with SDMC HPTN111 statisticians and programmers.

2.2 Reports

The table below provides detailed information about each report that will be produced for HPTN111, including the distribution frequency and distribution list.

Reports may be developed during the course of the study and added to the table.

Report Name	Purpose	Components	Distribution Frequency	Responsibility for Preparation	Distribution Platform	Distribution List
Screening	Summarizes screening at each site as reflected by case report form data	The number of participants screened, number enrolled, and reasons not enrolled for all sites individually as well as all sites combined.	Daily	SDMC Protocol Programmer and/or Statistical Programmer	Atlas	Open to all
Enrollment	To monitor participant accrual as reflected by case report form data	Enrollment data are presented for all sites individually a well as all sites combined. Includes site activation date, dates of first enrollments, duration of accrual, and the number of participants enrolled each week compared with weekly enrollment targets, and average number enrolled per week.	Daily	SDMC Protocol Programmer and/or Statistical Programmer	Atlas	Open to all
Retention	To monitor participant retention as	Retention data are presented for all sites	Daily	SDMC Statistical Programmer	Atlas	Open to all

Report Name	Purpose	Components	Distribution Frequency	Responsibility for Preparation	Distribution Platform	Distribution List
	reflected by case report form data	individually as well as all sites combined. Includes the total number participants enrolled who 1) completed a visit (on time, early or late) and 2) did not complete a visit (visit was missed or participant was terminated early). Total retention is calculated as the number of enrolled participants who completed follow-up visits divided by the total number of participants expected for a visit.				
Data Management Quality	To provide information on site performance with regard to key data management and data quality metrics	Data are presented for all sites individually as well as all sites combined. Cumulative and previous-month statistics including: • Percentage of CRFs entered	Monthly	SDMC	Atlas	Open to all

Report Name	Purpose	Components	Distribution Frequency	Responsibility for Preparation	Distribution Platform	Distribution List
		within 7 calendar days of study visits • Total number of data queries (i.e. QCs) that have been manually placed by SDMC staff • Number and percentage of queries that have been answered within 7 calendar days after query was opened				
Study Monitoring Committee (SMC)	To monitor the overall progress of the study and study conduct at each site	Summary by site and overall. Report includes in-formation on trial design and SMC history, accrual, baseline characteristics of participants, enrollment, and retention of participants, social harms/impacts, protocol deviations, completion of Computer-Assisted Self	Will occur every 6 months during study implementation.	SDMC Statistical Research Associates (SRAs) and Protocol Statistician, with assistance from SCHARP study team	Atlas	SMC (open and closed reports), Protocol Chairs (open report only), Selected members of HPTN LOC, SDMC, LC, DAIDS and Site IoRs, (open report only)

Report Name	Purpose	Components	Distribution Frequency	Responsibility for Preparation	Distribution Platform	Distribution List
		Interviewing (CASI) data, termination, and other study conduct information, as required by the SMC.				

Section 03. Audio Computer Assisted Self-Interview (ACASI)

3.1 Background

Audio Computer Assisted Self-Interview (ACASI) is a method for collecting information where a person reads questions on a computer screen and enters his or her answers directly into the computer. Many different types of electronic equipment (such as laptops, desktops, touch-screen computers or handheld devices) can be used to administer the ACASI and various types of software can be used to design the data collection tool. For HPTN111, the software used to design the survey is called REDCap Cloud (RCC).

3.2 Technical Requirements

Device

The HPTN 111 ACASI questionnaires are web-based (using RCC software) and can be taken from almost any device with a strong internet connection and a web browser. **Please review RCC's hardware and software requirements web page for more information**:

https://portal.redcapcloud.com/Documentation/article/KA-01028/en-us

In the room where the computer/other device is located, there should be an electrical outlet and a jack for broadband connection unless a reliable wireless connection is used. If possible, the computer should be plugged into an AC power source. If a laptop is used, it is recommended that an external mouse be connected to the laptop. To minimize problems with computers, sites should avoid having food or drink nearby and keep the area where the computer is used clutter-free. An antivirus program should also be installed on the computer.

Each site is responsible for addressing issues of computer security and privacy as well as general issues such as lighting, ergonomics, and overall participant comfort. For questions about how to use a computer, sites should refer to the operations manual of the desktop or laptop. Issues such as where the computer(s) will be located and who is in charge of addressing computer-related issues should be addressed in each site's study specific Data Management Standard Operating Procedure (SOP).

Web Browser

The following list of web browsers can be used to administer the ACASI in RCC.

- Safari for macOS
- Microsoft Edge
- Google Chrome for Windows, macOS, and Linux desktops
- Mozilla Firefox for Windows, macOS, and Linux desktops

Make sure to always use the most current version of each browser to optimize the full capacity of the product's features and functionality.

3.3 ACASI Administration

The ACASI will be administered to participants at many different visits. Participants are expected to complete each of the surveys.

Ideally, the questionnaire should **be administered before any HIV/STD risk reduction counseling occurs** and the participant should complete the questionnaire in one sitting whenever possible. However, if a participant starts the survey at a regularly scheduled visit and must temporarily stop, the participant can resume taking the survey (see section 14.3.8) at a later time.

3.3.1 ACASI Practice for Site Staff

Staff members should be familiar with the content of the questionnaire in order to respond to participant questions. Staff members who will administer the survey should practice taking, and demonstrating how to use, the survey using test ACASI Identification numbers (ACASI IDs) provided by SCHARP. The staff member responsible for administering the ACASI should be able to explain to the participant how to complete the survey, including how to use a computer and how to click through the questions using a mouse or touchpad.

3.3.2 Logging in to the ACASI

When the participant is ready to begin the ACASI, the staff member responsible for administering the survey will click on the appropriate URL. To find the surveys easily it is helpful to bookmark the URL you will be using in this study in your preferred web browser.

Once the survey is opened, the staff member will enter a "ACASI ID" and the appropriate language (if applicable) and visit is selected. You will then be prompted to enter the PTID that is linked to the ACASI ID.

Site staff will then answer one or more questions based on the visit; the answers to these questions will determine whether certain survey items will be included or excluded from the questionnaire.

Once these questions are answered, the participant is ready to take the survey on his or her own.

3.3.3 Navigating the Survey

Participants should navigate through the survey using the "< Prev" and "Next >" buttons that are part of the RCC software (**Figure 1**); they **should not** use the browser navigation buttons, which are the forward and back arrows usually located in the top left-hand corner of the browser (**Figure 2**). If the browser navigation buttons are mistakenly used, proper functioning of the survey can be disrupted, and data may be lost.

If a participant asks for help while taking the survey it is OK for a staff member to assist the participant. For example, if the Internet crashes, the survey freezes or the participant does not understand a question, it is OK for the site staff to help. For technical problems with RCC see Section 9.6.12.

This survey has an optional audio component. There is a "click-to-play" feature to have the audio of the text (descriptions, questions, or response options) play if the participant prefers.

Figure 1: Use the "< Prev" and "Next >" Buttons to Navigate Through the Survey

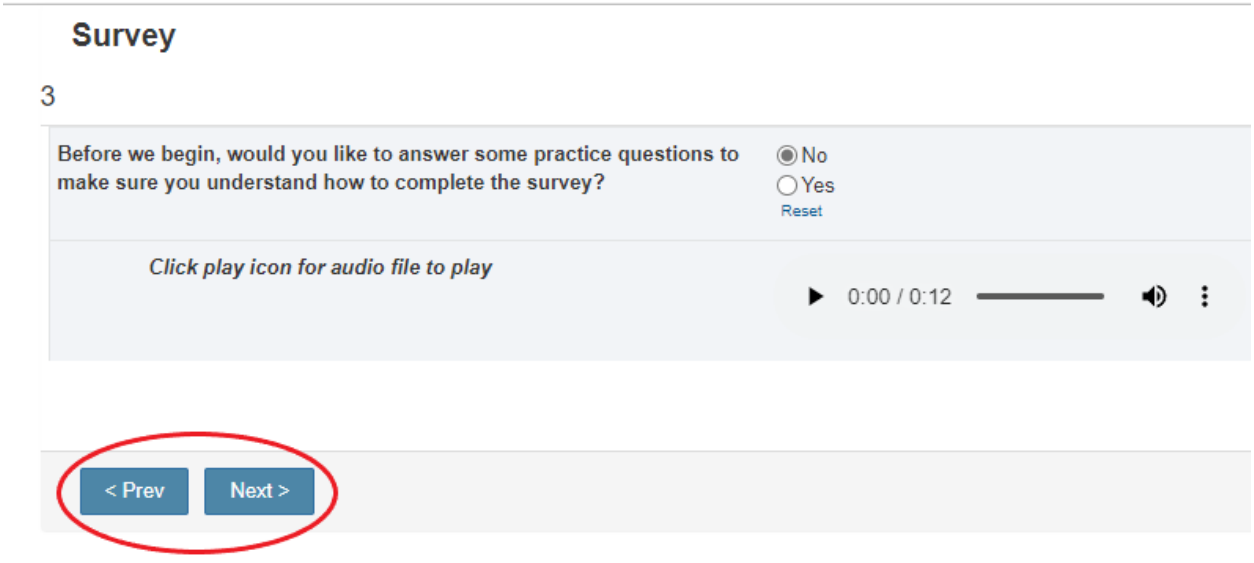
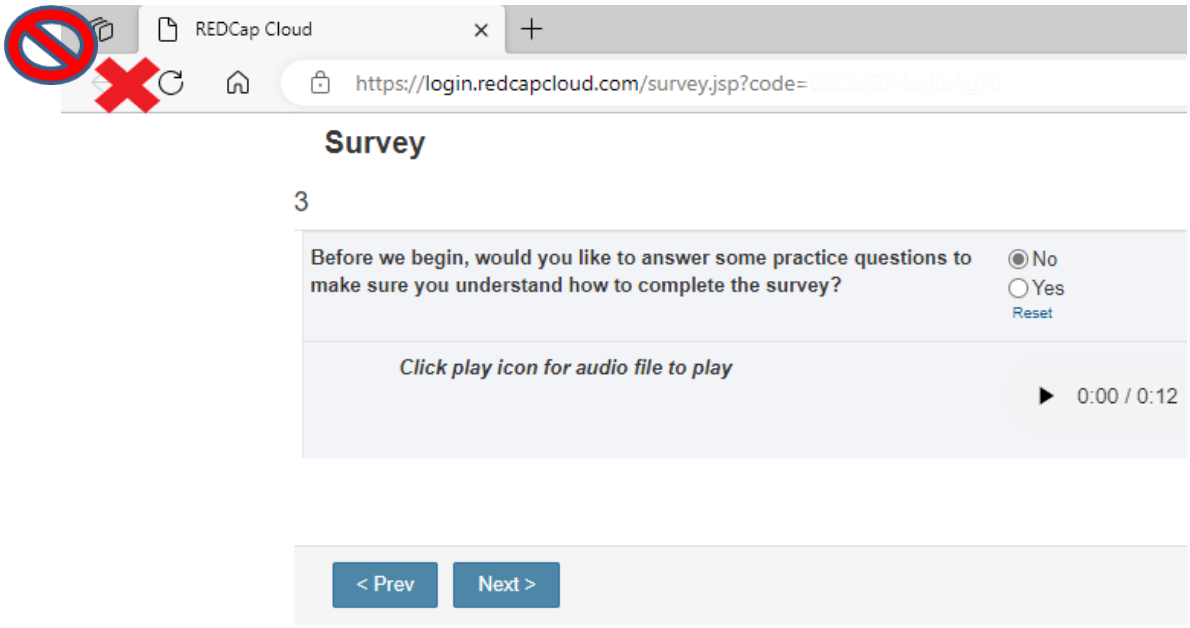


Figure 2: Do Not Use the Browser Navigation Buttons During The Survey



3.3.4 Graphical Interface of the ACASI

Most of the questions in the survey are answered by clicking on radio buttons (**Figure 3**), which consist of a group of circular white dots. When the participant selects one of the circles, a grey dot appears in the middle of the circle. Some of the questions in the survey are answered by clicking on check boxes (**Figure 4**). When the participant clicks on the check box, a blue check appears in the box. For some questions, instructions will indicate whether more than one check box may be selected.

Some questions require participants to type in a number (**Figure 5**). Sometimes an "other, specify" box is included as one of the response categories to capture participant responses that do not fit into one of the categories listed. When a participant's response does not match or fit into one of the listed response categories, the participant may select "other" and type in their answer in the space provided (**Figure 6**).

When training the participant how to complete the survey on the computer, it can be helpful to point out the different ways they will be required to answer questions. There is also a brief (1-page) non-required section at the beginning of the survey for participants to practice entering responses, if desired.

3.3.5 Figure 3: Graphical Interface – Radio Buttons

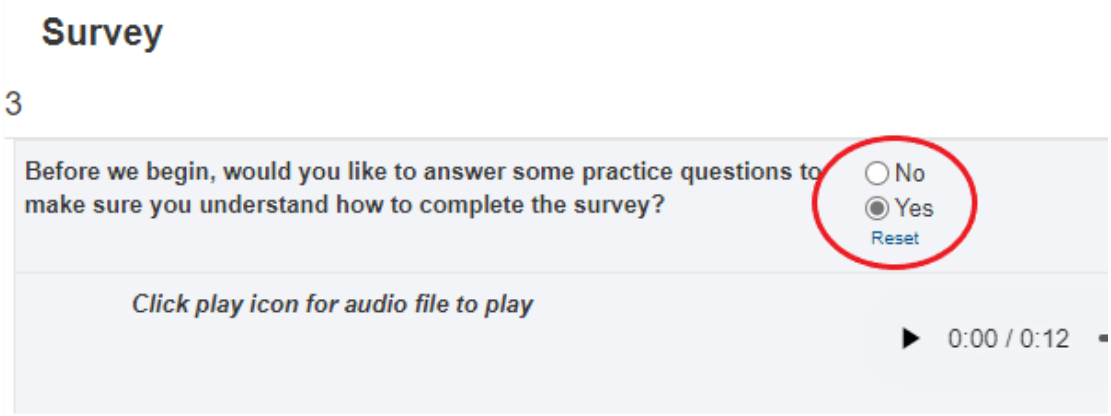


Figure 4: Graphical Interface – Check Boxes

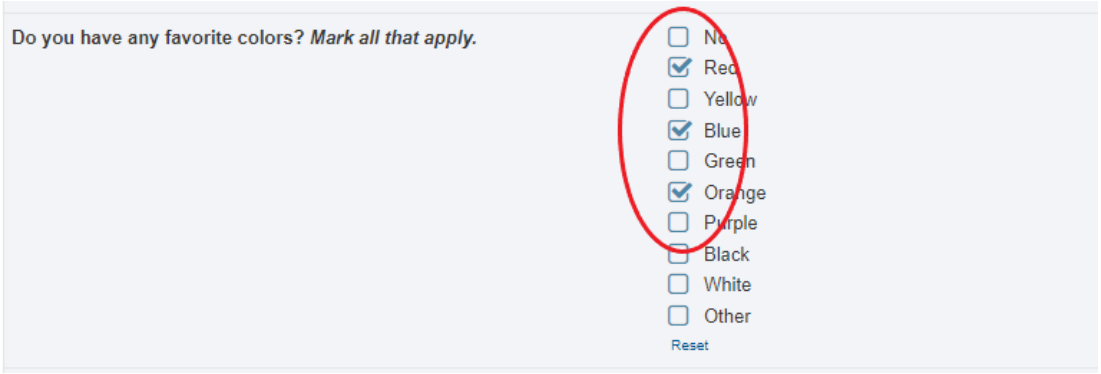


Figure 5: Graphical Interface – Entering Numbers

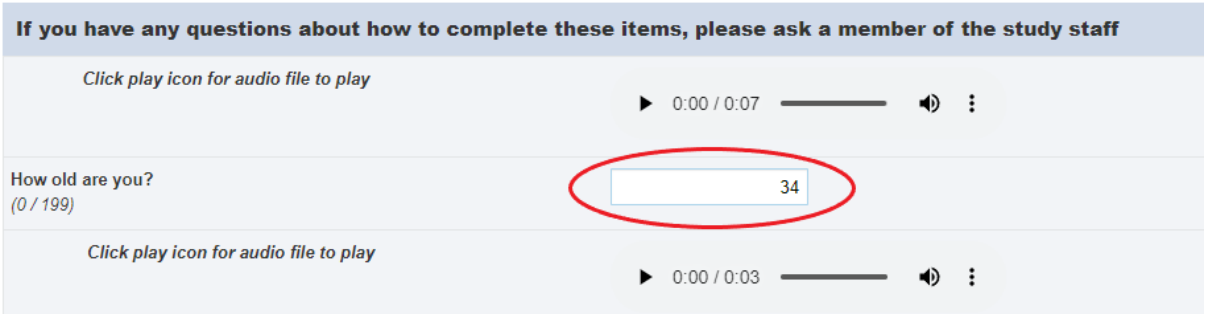
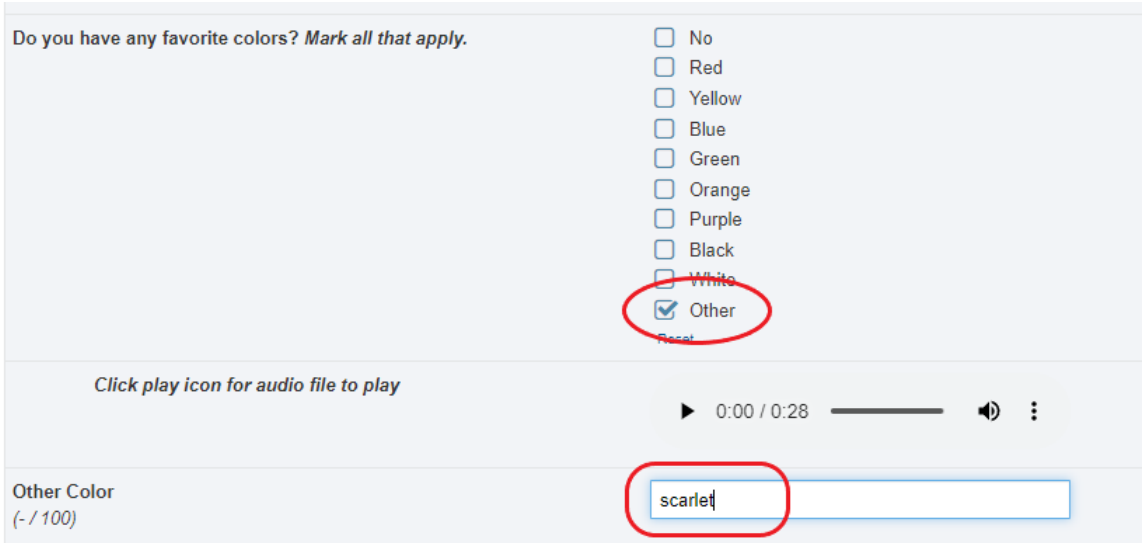


Figure 6: Graphical Interface – Entering Text



3.3.6 Submitting the Survey

Once the participant has answered the last question and clicked the "Submit" button, there will be a "thank you" message on the screen, which indicates the survey is complete.

It is important that the staff member responsible for administering the ACASI survey double check that the participant has completed the survey before closing the browser.

3.3.7 What Happens to the Data?

It is **important** to understand, and to tell the participant, that the data the participant enters into the computer will never be stored on that computer. Each time the "next" button is clicked and the participant moves to the next question, the answer to the previous question will automatically be transmitted to the SCHARP-specific server. Site staff cannot access these data.

3.3.8 How to Resume a Partially Completed RCC Survey

If there is an intentional or accidental closure of the browser, if internet connection is lost, if the computer crashes, or if the participant needs to pause survey completion mid-visit for any reason, site staff will need to log the participant back in to the survey – once available - to allow completion.

Re-open the survey in a web browser and re-enter the participant ID. Open the relevant incomplete section of the survey.

3.3.9 Making Up a Missed ACASI

If a participant misses taking the ACASI at a required visit, or if there is a technical problem that cannot be resolved, the participant can take the ACASI at a later time, but no later than the next required visit. If the survey was not done for Week 13 visit, it can be made up no later than the Week 26 visit. *The original ACASI ID/visit code combination for the missed survey is entered into the ACASI*. For example, the Week 13 visit took place on 1 July 2022 but the survey was not done; the participant returned on 8 July 2022 and completed the survey. Week 13 would be entered into the survey.

3.3.10 Reminders

Before the participants take the survey, the site should remember to do the following:

- Explain the purpose of the survey and provide general instructions regarding how to use the computer, if necessary, such as how to use a mouse and how to "click" a button.
- Emphasize that the browser navigation buttons should never be used; only the buttons that say "Previous" and "Next" in the actual RCC survey should be used when navigating the survey.
- Remind the participants that their answers are completely confidential. The answers provided by the participants will never be permanently stored on the computer (they are sent to a server that is only accessed by the Statistical and Data Management Center); therefore, none of the site staff will ever see their answers.
- Tell the participants that at the end of the survey they will see a "thank you" message on the screen. This indicates that the participants have completed the survey and they do not have to do anything else.
- Let the participants know that they can ask a site staff member for help, if needed.

3.4 Problems and Questions

If a problem with the ACASI occurs, or for all other questions about the ACASI including technical questions regarding RCC, contact the SCHARP Clinical Data Manager:

Paul Butler
Email: pbutler@scharp.org
Phone: 206.667.7928

Ian Bell
Email: ibell@scharp.org
Phone: 206.667.7061

Please remember that the SCHARP office is located in the Pacific Time Zone (GMT – 7:00). Therefore, "real time" responses to emails and phone calls may not always be possible. A response can be expected, however, within 24 hours.

Section 4: Data Communiqués

For HPTN111, SCHARP will use "Data Communiqués" to document and communicate data decisions and procedures that are made or revised during the study. By using Data Communiqués, SCHARP avoids having to re-distribute a revised version of the Data Collection section of this SSP every time a form completion clarification or revision is made.

Data Communiqués are considered official study documentation. As such, each time a Data Communiqué is sent (via email), please circulate it among relevant staff for their review, print the Data Communiqué, and place it in this section of each HPTN111 SSP binder in your possession. Consider each Data Communiqué an official part of the SSP.

Each Data Communiqué sent will consist of three sections: a Reminders section, used to remind sites of specific data collection or forms completion procedures; a Clarification section, used to clarify data collection or form completion procedures; and an Updates section, used to communicate when an updated version of a form is being issued or to notify the sites that an updated version of the forms instructions is about to be distributed (for example).

Note that a "Data Communiqué" does not request specific actions or corrections to a particular participant's data - it is just a listing of general items to keep in mind when performing data collection for the study.

HPTN
HIV Prevention Trials Network

Study Document Approval Sheet

Protocol Number & Name	**HPTN 111: Feasibility and Acceptability of a Barbershop Based HIV Prevention Initiative Among Heterosexual Men in Kalangala Islands, Uganda: A Cluster Randomized Trial**
Document Name	**HPTN 111 SSP Manual (SDMC Manual Sections)**
Document Version Number	1.0
Document Version Date	06 February 2024
New Document?	YES ☒ NO ☐
If no, reason for revision	

Signatures

Entity	Name, Signature and Date
Document author/ manager	Ian Bell Ian Bell Ian Bell (Feb 6, 2024 12:44 PST)
Protocol chair(s)	Zubair Lukyamuzi 06 Feb 2024 Brenda Gati Mirembe 06 Feb 2024

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