

Section 9: Counseling and Behavioral Considerations

9.1	Overview of Section 9.....	9-1
9.2	Overview of Counseling Considerations	9-1
9.3	HIV Pre-/Post-Test and Prevention Counseling	9-2
9.4	Gender Affirming Hormone Therapy Counseling and Support.....	9-3
9.5	Overview of Behavioral Measures.....	9-3
9.6	Audio Computer Assisted Self-Interview (ACASI)	9-3
9.6.1	Technical Requirements	9-3
9.6.2	ACASI Administration.....	9-4
9.6.3	Survey URL.....	9-4
9.6.4	ACASI Practice for Site Staff.....	9-4
9.6.5	Logging in to the ACASI	9-4
9.6.6	Navigating the Survey.....	9-5
9.6.7	Graphical Interface of the ACASI.....	9-6
9.6.8	Submitting the Survey	9-9
9.6.9	What Happens to the Data?.....	9-9
9.6.10	How to Resume a Partially Completed Illume Survey	9-9
9.6.11	Making Up a Missed ACASI	9-10
9.6.12	Reminders	9-10
9.6.13	Problems and Questions.....	9-10

9.1 Overview of Section 9

This section provides guidance on counseling and behavioral considerations for conducting the HPTN 091 protocol.

9.2 Overview of Counseling Considerations

This section contains guidance on HIV Pre -/ Post-Test counseling and GAHT counseling and support provided in HPTN 091:

All counseling should be documented in participant study records. Proper documentation may be achieved by using counseling checklists, worksheets, and other tools, as well as counselors' chart notes. To support ongoing participant-centered counseling over time, documentation of each counseling session should include sufficient information and detail to inform and guide the participant's next counseling session.

During counseling, a site-specific tool may be used to guide any of the counseling sessions. During the session, counselors should engage in the discussion rather than focusing on taking notes. A summary of the counseling session should be written once the session is completed.

9.3 HIV Pre-/Post-Test and Prevention Counseling

HIV testing is required at each scheduled HPTN 091 study visit for as long as the participant is not found to be HIV infected. All counseling should be provided in a non-judgmental participant-centered manner that responds to current participant needs for information, education, support, skills building, and/or referrals. Participants' needs are likely to change over time; counseling provided should also change over time accordingly.

Each site is encouraged to develop an SOP for this counseling. It is suggested that the SOP be site-specific, and the following elements be incorporated:

- Each participant should be provided with information that allows them to decide whether to be tested (informed decision with informed consent).
- The HIV testing procedure should be organized to maximize confidentiality.
- HIV antibody testing should be linked with the provision of information and recommendations regarding HIV.
- Adequate pre- and post-test counseling should be provided to all individuals being tested.
- Disclosing HIV status to others should be discussed with all participants.
- The need for additional and appropriate referrals should be addressed where possible.

All HIV counseling should be provided in accordance with local counseling standards. Study staff who provide HIV counseling should be trained to do so per local practice standards. Counseling staff should also be trained on study-specific HIV testing methods and interpretation of test results.

Given that HIV counseling will be provided at all HPTN 091 study visits, when providing pre-test and post-test counseling, it is especially important to avoid repetition of the same information at each counseling session. Participant-centered approaches should be used to assess participant knowledge of relevant information, dispel any misconceptions, ensure participant readiness for HIV testing, and ensure participant understanding of test results.

HIV test results should be provided in the context of post-test counseling, which should begin when the first test results (rapid test results) are available the day of testing, and continued, as results become available. If it is convenient for the participant, or it is part of a site's standard of care, interim visits may be scheduled to give HIV test results and conduct post-test counseling.

An addition, a specific SOP detailing the mechanisms for linking individuals who acquire HIV infection during study participation to appropriate HIV specialty care is required for each site. "Appropriate care" should be locally defined and include consideration of language, geography, insurance status and type, provider cultural sensitivity, and resource availability.

Risk reduction counseling should be incorporated into the HIV counseling approach noted above. Participant-centered approaches should be used when providing risk reduction counseling. For HPTN 091, risk reduction counseling will include condom use, data on the known effectiveness of TDF/FTC as PrEP, data on the known effectiveness of TAF/FTC (for US Sites only), and the unknown effects of hormonal therapy on PrEP concentrations. The counselor should ask open-ended questions, actively listen to participant responses, probe as needed for further information, and guide the participant in identifying his/her risk factors and barriers to risk reduction, as well as strategies and action plans to try to address these.

9.4 Gender Affirming Hormone Therapy Counseling and Support

All counseling should be provided in a non-judgmental, participant-centered manner that responds to current participant needs for information, education, support, skills building, and/or referrals. Participants' needs are likely to change over time; counseling provided should also change over time accordingly.

Each site is encouraged to develop an SOP for this counseling. It is suggested that the SOP be site-specific and follow the guidance provided in Appendix II.

9.5 Overview of Behavioral Measures

HPTN 091 behavioral assessments will be collected via web-based Audio Computer Assisted Self-Interviews (ACASI) and In-Depth Interviews (IDI). This section contains information about the necessary preparation, equipment, and process for participant completion of ACASI. Information about IDI administration can be found in Appendix I of the SSP manual.

Information on the timing of the ACASI and IDIs can be found in Section 6.6, Section 6.8, Appendix 1a, and Appendix 1b of the HPTN 091 protocol.

9.6 Audio Computer Assisted Self-Interview (ACASI)

Audio Computer Assisted Self-Interview (ACASI) is a method for collecting information where a person listens to questions through a computer and enters their answers directly on a computer screen. 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 HPTN 091, the software used to design the survey is called Illume (by Frontier Science Foundation, Inc.).

9.6.1 Technical Requirements

Device

The HPTN 091 ACASI questionnaires are web-based (using Illume software, supported by Frontier Science Foundation, Inc.) and can be taken from almost any device with a strong internet connection and a web browser. **Please review Frontier Science Foundation's hardware and software requirements web page for more information:**

<http://academy.datstat.com/developer/illume-hardware-software-requirements/>

Sites should select a location in the research offices for the computer that is private (i.e., the screen should be out of sight to staff members or other participants while answers are being entered), but allows study staff to be nearby to answer questions or assess whether the participant is having computer problems. In the room where the computer 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 Frontier Science, Illume.

- Google Chrome
- Mozilla Firefox
- Microsoft Edge
- Internet Explorer 10 or higher
- Safari

Make sure to always use the most current version of each browser to optimize the full capacity of the product's features and functionality. Please note: **JavaScript is required to be enabled on any browser that is used to access the platform's web interface.**

9.6.2 ACASI Administration

The ACASI will be administered to participants at different visits. Participants are expected to complete each of the surveys. However, if the participant does not complete the survey (e.g., decides not to take it), this must be noted on the Enrollment Visit or Date of Visit electronic Case Report Form (eCRF) as appropriate.

The questionnaire should **always 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 has to temporarily stop, the participant can resume taking the survey (see section 9.6.10) at a later time.

9.6.3 Survey URL

All surveys are accessed via a single URL provided by SCHARP to sites over email. The link can be bookmarked in a web browser; however, ***desktop shortcuts to the survey should not be created***: using a desktop link to connect to the survey will result in the site always connecting to the version of the survey that was running when they originally created the link rather than the most current version of the survey. It is likely that the survey will need to be updated over time; using a desktop link or shortcut will result in the old version of the survey being administered.

9.6.4 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.

9.6.5 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.

SCHARP will provide each site a list of ACASI IDs in a link log to document the HPTN 091 PTIDs linked to each ACASI ID.

Once the survey is opened, the staff member will enter an “ACASI ID” from the list provided by SCHARP and the appropriate language and visit is selected. You will then be prompted to enter the PTID that is linked to the ACASI ID. Each PTID may only be used one time for each ACASI questionnaire.

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 their own.

9.6.6 Navigating the Survey

Participants should navigate through the survey using the “previous” and “next” buttons that are part of the Illume 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 Illume see Section 14.6.12.

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 “Previous” and “Next” Buttons to Navigate Through the Survey

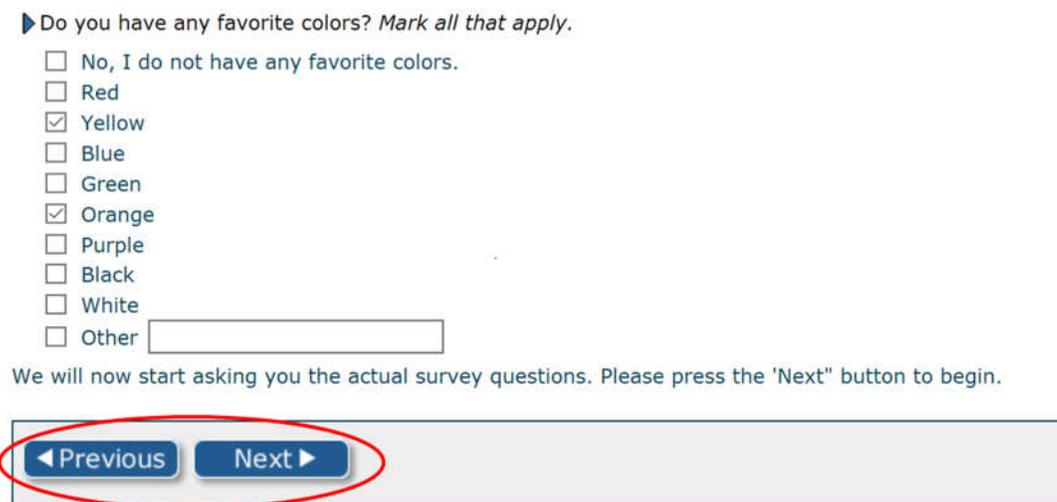
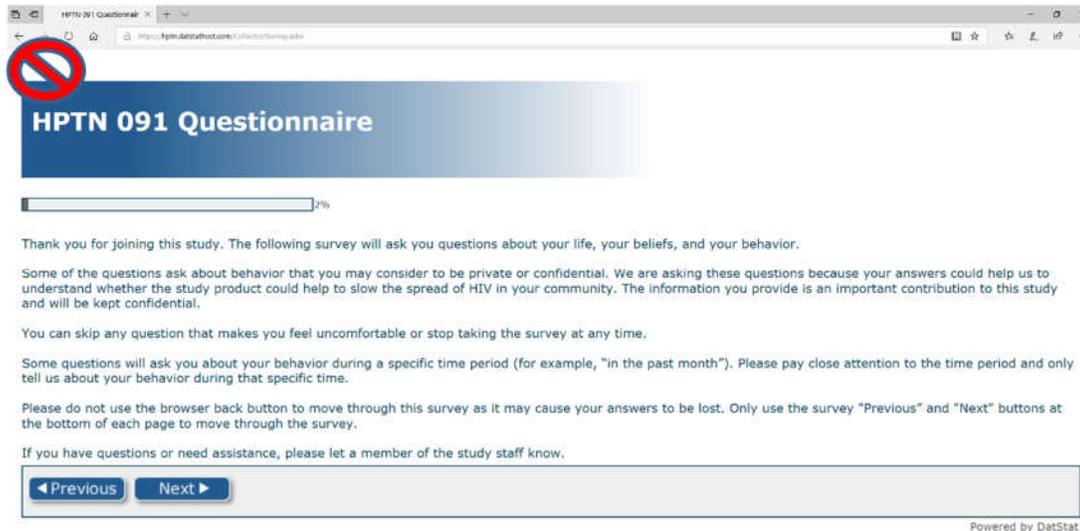


Figure 2: Do Not Use the Browser Navigation Buttons During the Survey



9.6.7 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 green 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 green 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 in order 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.

Figure 3: Graphical Interface – Radio Buttons

The figure consists of two screenshots of the HPTN 091 Questionnaire interface. The top screenshot shows a progress bar at 4% and a question: "Before we begin, would you like to answer some practice questions to make sure you understand how to complete the survey?". The "Yes" radio button is selected, indicated by a red arrow. Below the question are "Previous" and "Next" navigation buttons. The bottom screenshot shows a progress bar at 12% and a question: "Please click on the line below at the point showing your best guess about how much of PrEP medication you took every day over the past month. 0% means that you have taken no pills, 50% means you have taken half of your pills, and 100% means you have taken every single pill." Below this is a horizontal scale with radio buttons at 0%, 10%, 20%, 30%, 40%, 50%, 60%, 70%, 80%, 90%, and 100%. The 80% radio button is selected, indicated by a red arrow. Below the scale is the question "Are you currently on PrEP?" with "No" and "Yes" radio buttons. Both screenshots include "Previous" and "Next" navigation buttons and a "Powered by DatStat" watermark.

HPTN 091 Questionnaire

4%

▶ Before we begin, would you like to answer some practice questions to make sure you understand how to complete the survey?

Yes
 No

◀ Previous Next ▶

Powered by DatStat

HPTN 091 Questionnaire

12%

▶ Please click on the line below at the point showing your best guess about how much of PrEP medication you took every day over the past month. 0% means that you have taken no pills, 50% means you have taken half of your pills, and 100% means you have taken every single pill.

0%	10 %	20 %	30 %	40 %	50 %	60 %	70 %	80 %	90 %	100%
<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>							

▶ Are you currently on PrEP?

No
 Yes

◀ Previous Next ▶

Powered by DatStat

Figure 4: Graphical Interface – Check Boxes

▶ Do you have any favorite colors? *Mark all that apply.*

- No, I do not have any favorite colors.
- Red
- Yellow
- Blue
- Green
- Orange
- Purple
- Black
- White
- Other

We will now start asking you the actual survey questions. Please press the 'Next' button to begin.

◀ Previous Next ▶

Figure 5: Graphical Interface – Entering Numbers

HPTN 091 Questionnaire

4%

If you have any questions about how to complete these items, please ask a member of the study staff.

▶ How old are you?

34

▶ How many brothers and sisters do you have?

Figure 6: Graphical Interface – Entering Text

▶ Do you have any favorite colors? *Mark all that apply.*

- No, I do not have any favorite colors.
- Red
- Yellow
- Blue
- Green
- Orange
- Purple
- Black
- White
- Other

We will now start asking you the actual survey questions. Please press the 'Next' button to begin.



9.6.8 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.

9.6.9 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.

9.6.10 How to Resume a Partially Completed Illume 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. A page will appear with the following message: “We have located a survey in-progress. Would you like to continue where you last left off or start over?” (Figure 7).

Figure 7: Resuming a Partially Completed Survey

We have located a survey in-progress.

Would you like to continue where you last left off or start over?



Select the “restore” button to open the survey to where the participant stopped. Selecting the “start over” button will start the survey over from the very beginning.

9.6.11 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. *The original ACASI ID/visit code combination for the missed survey is entered into the ACASI.* For example, the Week 26 visit (code 4.0) took place on 1 July 2021, but the survey was not done; the participant returned on 8 July and completed the survey. Visit code 4.0 would be entered into the survey, not an interim visit code.

9.6.12 Reminders

Before the participant takes 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 Illume 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.

9.6.13 Problems and Questions

If a problem with the ACASI occurs, or for all other questions about the ACASI including technical questions regarding Illume, contact the [SCHARP Clinical Data Manager](#):

Ian Bell
Email: ibell@scharp.org
Phone: +1.206.667.7061

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.