

Section 14. Computer Assisted Self-Interview (CASI)

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14.1 Background

Computer Assisted Self-Interview (CASI) is a method for collecting information where a person reads questions off of 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 CASI and various types of software can be used to design the data collection tool. For HPTN 084, the software used to design the survey is called Illume (by DatStat, Inc.). The HPTN084 Questionnaire is attached in **Appendix 14A**.

14.2 Technical Requirements

Device

The HPTN 084 CASI questionnaires are web-based (using Illume software, supported by DatStat, Inc.) and can be taken from almost any device with a strong internet connection and a web browser. **Please review DatStat's hardware and software requirements web page for more information:**

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

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. A virus 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 CASI in DatStat 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.**

Remote Data Collection

While the CASI was designed to be administered over the web, if necessary it can be administered to participants "locally" (or "remotely") without an Internet connection using the Remote Data Collection (RDC) version of Illume. The HPTN 084 questionnaires can be administered using this method only if there is no reliable internet connection or if the internet connection is temporarily interrupted. Please see DatStat's website for more information: <http://academy.datstat.com/illume/remote-data-collection>

14.3 CASI Administration

The CASI will be administered to participants at many 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 14.3.8) at a later time.

14.3.1 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 over time that the surveys will need to be updated; using a desktop link or shortcut will result in the old version of the survey being administered.

14.3.2 CASI 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 CASI Identification numbers (CASI IDs) provided by SCHARP. The staff member responsible for administering the CASI 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.

14.3.3 Logging in to the CASI

When the participant is ready to begin the CASI, 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.

SCHARP will provide each site a list of live CASI IDs in a link log designed to capture and document the HPTN 084 PTID assigned to each CASI ID.

Once the survey is opened, the staff member will enter a “CASI 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 CASI 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.

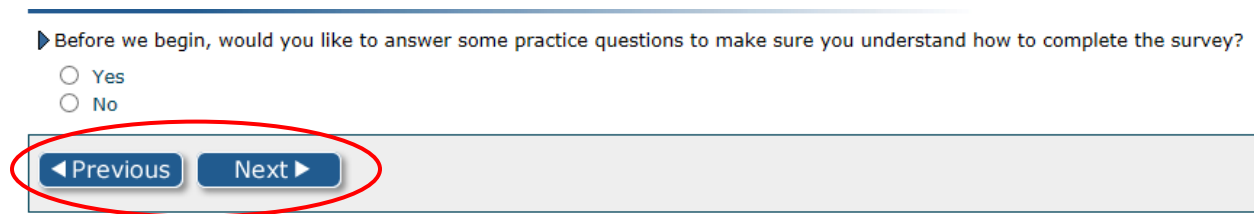
Once these questions are answered, the participant is ready to take the survey on her own.

14.3.4 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 14.4.

Figure 1: Use the “Previous” and “Next” Buttons to Navigate Through the Survey



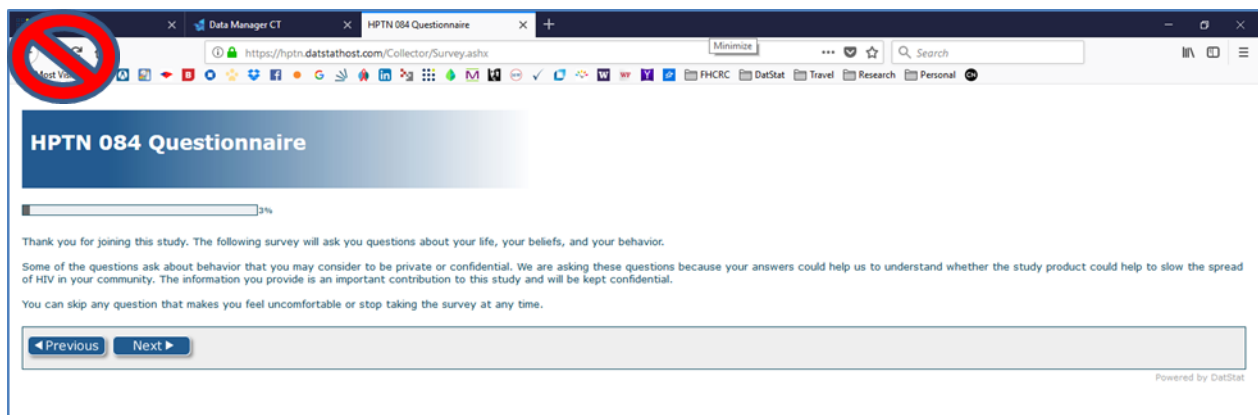
▶ Before we begin, would you like to answer some practice questions to make sure you understand how to complete the survey?

☐ Yes

☐ No

◀ Previous Next ▶

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



The screenshot shows a web browser window with the title "HPTN 084 Questionnaire". The address bar shows the URL "https://hptn.datstathost.com/Collector/Survey.aspx". The page content includes a progress bar at 3%, a thank you message, and a disclaimer. At the bottom, there are "Previous" and "Next" buttons. A red 'X' is placed over the browser's navigation buttons (back, forward, etc.) to indicate that they should not be used during the survey.

14.3.5 Graphical Interface of the CASI

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 use a computer and how to complete the survey, it can be helpful to point out the different ways they will be required to answer questions.

Figure 3: Graphical Interface – Radio Buttons

The screenshot displays the 'HPTN 084 Questionnaire' title in a blue header. Below the header is a progress bar showing 5% completion. The main question is: 'Before we begin, would you like to answer some practice questions to make sure you understand how to complete the survey?'. There are two radio button options: 'Yes' and 'No'. A red arrow points to the 'No' radio button. At the bottom, there are two buttons: 'Previous' and 'Next'.

HPTN 084 Questionnaire

5%

► 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 ▶

Figure 4: Graphical Interface – Check Boxes

The screenshot displays the 'HPTN 084 Questionnaire' title in a blue header. Below the header is a progress bar showing 9% completion. The main question is: 'With whom do you live? Mark all that apply.'. There are seven check box options: 'Alone', 'Partner', 'Parent(s)', 'Sibling(s)', 'With own children', 'Roommate(s)', and 'Other, specify:'. A red arrow points to the 'Parent(s)' check box. Below 'Other, specify:' is a text input field. At the bottom, there are two buttons: 'Previous' and 'Next'.

HPTN 084 Questionnaire

9%

► With whom do you live? *Mark all that apply.*

☐ Alone

☐ Partner

☐ Parent(s)

☐ Sibling(s)

☐ With own children

☐ Roommate(s)

☐ Other, specify:

☐ Prefer not to answer

◀ Previous Next ▶

Figure 5: Graphical Interface – Entering Numbers

The screenshot shows the 'HPTN 084 Questionnaire' title at the top. Below it is a progress bar indicating 48% completion. The main text reads: 'Now we will shift to the number of times you had sex. If you can't recall exact numbers, please give your best estimate.' The question is: 'In the past month, approximately how many times did you have vaginal sex?'. There are two radio button options: 'Number of times' followed by a text input field, and 'Prefer not to answer'. A red arrow points to the text input field. At the bottom are 'Previous' and 'Next' navigation buttons.

Figure 6: Graphical Interface – Entering Text

The screenshot shows the 'HPTN 084 Questionnaire' title at the top. Below it is a progress bar indicating 86% completion. The main text reads: 'You will now be asked to think about the different characteristics of injectable and oral HIV prevention methods that you might like or dislike. For each question, you may give multiple answers.' The question is: 'What do you think you might like about an injectable method? Mark all that apply.' There are several checkbox options: 'Nothing', 'May protect against HIV', 'Easier to use than other methods (i.e., don't have to remember to take pills; easier than condoms)', 'May provide longer-term protection than other methods', 'Can be used discreetly, without a partner's knowledge', 'Is administered by a healthcare provider', 'Does not interrupt sex', 'Other, specify:' followed by a text input field, and 'Prefer not to answer'. A red arrow points to the 'Other, specify:' text input field. At the bottom are 'Previous' and 'Next' navigation buttons.

14.3.6 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 CASI survey double check that the participant has completed the survey before closing the browser.

14.3.7 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.

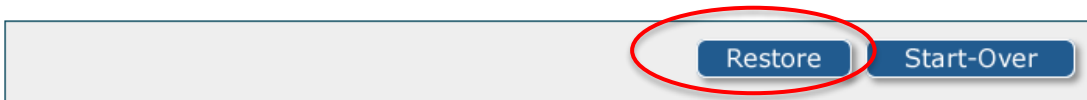
14.3.8 How to Resume a Partially Completed Illume Survey

If there is an intentional or accidental closure of the browser, if Internet connection is lost, or if the computer crashes, etc., site staff will need to log the participant back in to the survey in order for the participant to complete the survey. For a survey administered via the Internet, re-open the survey in a web browser and re-enter the participant ID. For a survey administered locally, select the survey from the list of available surveys and select the “Collect Data” button. 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. Please note that unless there are technical issues, the participant must complete the survey using the same administration method (Internet or local) they used to start the survey.

14.3.9 Missed CASI and Visit Codes

If a participant misses taking the CASI at a required visit, or if there is a technical problem that cannot be resolved, the participant can take the CASI at the next visit. In the event of a split visit, blood specimens must be taken on the same day as the CASI. Further, the survey must be completed before HIV counseling occurs.

If a participant is on an alternative schedule (for example, the Pregnancy Schedule or Open Label Truvada Schedule), then she should be given the survey that would correspond to the date (and window) of where she would be in the main visit schedule. Therefore, if according to the main visit schedule, if a PTID would be in the week 49 visit window but falls pregnant and is in the clinic for Pregnancy visit week 12, then the PTID should take the week 49 CASI. As there are no special surveys or visit codes for the alternative schedules. Note, not all questions may apply.

14.3.10 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 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.

14.4 Problems and Questions

If a problem with the CASI occurs, please document the problem on the HPTN 084 CASI Problems Log (see Appendix 14B) and email the document to the SCHARP Clinical Data Manager.

For all other questions about the CASI, including technical questions regarding Illume, contact the SCHARP Clinical Data Manager alias: sc.084cdm@scharp.org.

Stephanie Beigel-Orme
Phone: +1.206.667.7109

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.