CRF Completion Guidelines

HPTN 083

CRF Completion Guidelines

Protocol Name:	A Phase 2b/3 Double Blind Safety and Efficacy Study of Injectable Cabotegravir Compared to Daily Oral Tenofovir Disoproxil Fumarate/Emtricitabine (TDF/FTC), For Pre-Exposure Prophylaxis in HIV-Uninfected Cisgender Men and Transgender Women who have Sex with Men
Protocol Number:	HPTN 083
Author:	Julie Ngo
Version:	8.1

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CONFIDENTIAL DOCUMENT
HPTN 083 CRF Completion Guidelines Version 8.1
20MAR2024

TABLE OF CONTENTS

CONFIDENTIAL DOCUMENT
HPTN 083 CRF Completion Guidelines Version 8.1
20MAR2024

CONFIDENTIAL DOCUMENT
HPTN 083 CRF Completion Guidelines Version 8.1
20MAR2024

CRF Completion Guidelines

The following instructions are study-specific data completion instructions intended to assist site staff when completing electronic case report forms (eCRFs) and paper case report forms (CRFs). Detailed guidance on general data collection, entry, navigation and general use of Medidata Rave is provided in the Medidata Rave Electronic Data Capture (EDC) Training Manual, which is found on the HPTN 083 Protocol page: https://atlas.scharp.org/cpas/project/HPTN/083/begin.view

General Guidelines

- The Participant ID is automatically assigned by Rave EDC as a 9-digit field, starting with the 3-digit site number followed by a randomly assigned 5-digit participant number, and 1-digit check number.
- All data entered in Rave must match the data on any source documents/paper CRFs.
- Complete all required data fields. Ensure that all entries are in English and are accurate, consistent, complete and medically logical.
- If “Other” is chosen as a response, further details must be provided by responding to the “If ‘Other’, specify” field.
- Text box fields have character limits. Text exceeding the limit will not be saved and a “Non-conformant” icon will appear.
- Visit dates must be complete and in chronological order according to the protocol.
- Most date fields must be entered as Day/Month/Year (dd/mmm/yyyy) (e.g., 01 NOV 2017). Exceptions are detailed in specific form sections where applicable.
- Drop-down menus are available for many fields. Use these menus, when available, to select the appropriate response.
- Avoid using abbreviations, symbols or special characters.
- Avoid hitting the return or enter key in text fields.
- If a scheduled visit is missed, do not enter data on the forms required for the visit, except for the Date of Visit form. Marking “no” on the Date of Visit form will add the Missed Visit form to the visit folder for completion.
- Log forms allow you to make multiple entries over the course of the study. All entries at the same time in ‘Complete View’ and View individual entries in portrait view.
- The following log forms for this study are available in the Ongoing logs folder at the bottom of the sidebar on the Participant’s home page:
    - Adverse Event
    - Concomitant Medications
    - Social Impact
    - Log Revisions

CONFIDENTIAL DOCUMENT
HPTN 083 CRF Completion Guidelines Version 8.1
20MAR2024

  - Product Hold/Discontinuation
  - Protocol Deviation
  - ART Medication

- Correct/update data fields by clicking the pencil icon at the far right of the field, correct/update the value and give the reason for the change, if applicable. Save the form to apply the changes.
- If an incorrect data entry is made, a system query will fire. Correct the error and save the form.
  - System generated queries with no query response will automatically close with a form correction.
  - System generated queries with a query response will change into a manual query that will need to be closed by the data management team.
- All actions performed on a data field are tracked in the audit trail. If data is modified inadvertently, the change is also shown in the audit trail for that field.
- The Investigator of Record (IoR) will sign all forms after the participant's data has been reviewed. After the signature is applied, no further changes or additions to the forms are expected.
- Any modifications that are made to forms after the IoR has signed off will remove the signature. Once the data has been reviewed, the signature will need to be applied again.
- The SCHARP Clinical Data Manager will provide direction for when the Investigator should perform the final review and sign the eCRF pages.

Add Event

- The **Add Event** drop-down menu can add select forms and visit folders to a participant's casebook.

Interim Visits

- Add an Interim Visit folder to a participant's casebook by clicking on the **Add Event** button on the PTID (Subject)-level page and selecting "Interim Visit", then clicking "Add". An Interim Visit folder will appear in the participant's casebook.
- Open the Interim Visit folder to access the Interim Visit form. On the Interim Visit form, select the forms that were completed at the interim visit. The selected forms will then load in the folder.
- On the Interim Visit form, enter the visit date as the earliest date visit procedures were performed for that interim visit.

Yearly Visits

- After a participant transitions to yearly visits, add a yearly visit folder by clicking on the Add Event button. Select "Yearly Visit". A Yearly Visit folder will appear in the participant's casebook.
- Open the Yearly Visit folder to access the "Yearly Visit Summary" form and select the applicable Yearly visit code from the pull-down menu.

- Select “Yes” for each assessment that was performed. The selected forms will be populated automatically within the applicable Interim Visit folder.

- On the Yearly Visit Summary eCRF, enter the visit date as the earliest date visit procedures performed at the visit began.

- If a participant completely misses a yearly visit, create the expected Yearly visit folder as above and select No to the question “Did the participant complete the visit?” Once the form is saved complete the Missed Visit form that now appears in the folder.

  Note: Step 2 participants who no longer receive injections and do not or cannot take Step 3 open label study product must first complete the Step 3 schedule before moving to yearly visits.

Loading of Forms in Visit Folder

- Medidata Rave will add forms to a visit folder in a participant’s casebook based on specified responses on forms. Below are a few key examples.
  - **Example 1**: Date of Visit form
    - If question “Did the participant complete this visit” is marked “No”, the Missed Visit form will add to the visit folder and the required forms for that visit will not appear in the visit folder.
    - Most forms under “Additional Procedures/Forms” on the Date of Visit form that are checked will be added to the visit folder. If a checked form does not load, please contact the study clinical data manager, who will load the form manually.
  - **Example 2**: Interim Visit form
    - Forms under “Forms Completed at Interim Visit” on the Interim Visit form that are checked will be added to the Interim Visit folder.
    - Any “Procedures completed at Interim Visit” on the Interim Visit form that are marked will be added to the Interim Visit folder.

Loading of Folders in Participant Casebook

- Medidata Rave will dynamically add folders and eCRFs to a visit folder within a participant’s casebook based on specified responses on certain eCRFs. Below are a few examples:
  - Example 1: Enrollment eCRF - Enrollment folder
    - If “Yes” is selected for “Is the participant enrolling in the study?”, all Step 2 and Step 3 folders will be added.
  - Example 2: Date of Visit eCRF
    - If “No” is selected for “Did the participant complete this visit?” the Missed Visit eCRF will be added to the visit folder and required eCRFs for that visit will not appear in the folder.
    - If any additional eCRFs are marked in the “Mark any additional forms or procedures” section, those marked eCRFs will be added to the visit folder. Note: If the eCRF already appears in the folder as a required form do not mark that form on the list.
  - Example 3: Adverse Event Y/N

- Selecting 'Yes' for "Has the participant experienced an Adverse Event during the study?" will dynamically add the Adverse Events Log eCRF to the Ongoing Logs folder.

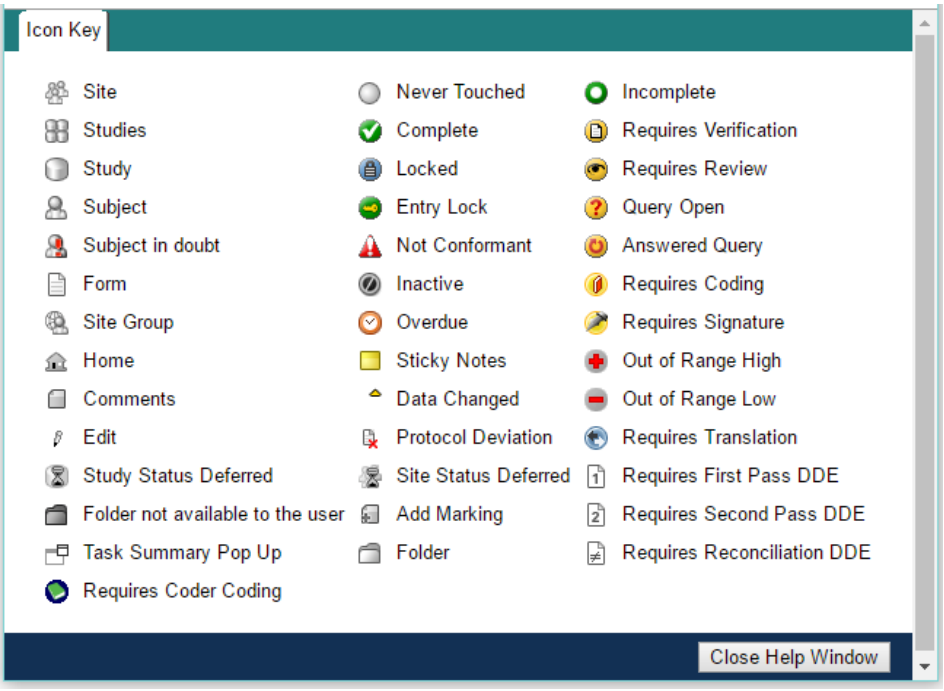
Dynamic Search Lists

- Some forms have data fields with 'dynamic' drop-down lists of available options. Options are populated by corresponding log form entries.
- Dynamic drop-down lists will be blank until entries are made and saved in the corresponding log form.
- Your selection in the dynamic search list can be deleted if entered in error.
- Changing the original log data or inactivating a log form entry that has been selected for a dynamic search list field, will make that field non-conformant and it will need to be updated.
- For Example:
  - An AE of '*FEVER*' started on 05DEC2017 and is reported on the Adverse Events log form
  - On the Concomitant Medications log form, if a listed medication was used for this AE, a dynamic search list can be used to select the applicable AE record from the dropdown list.
  - The start date for AE *'FEVER'* is corrected to 06DEC2017 on the Adverse Events log form.
  - The selection on the Concomitant Medication log form becomes non-conformant.
  - To resolve the non-conformant data, re-select the AE '*FEVER'* from the dynamic search list with the corrected start date.

Icon Key

A link to an Icon Key is available on the PTID (Subject)-level page. The key contains pictures and descriptions of the icons used in Rave. Below is a screen shot of the Icon Key.

Figure 1. Icon Key

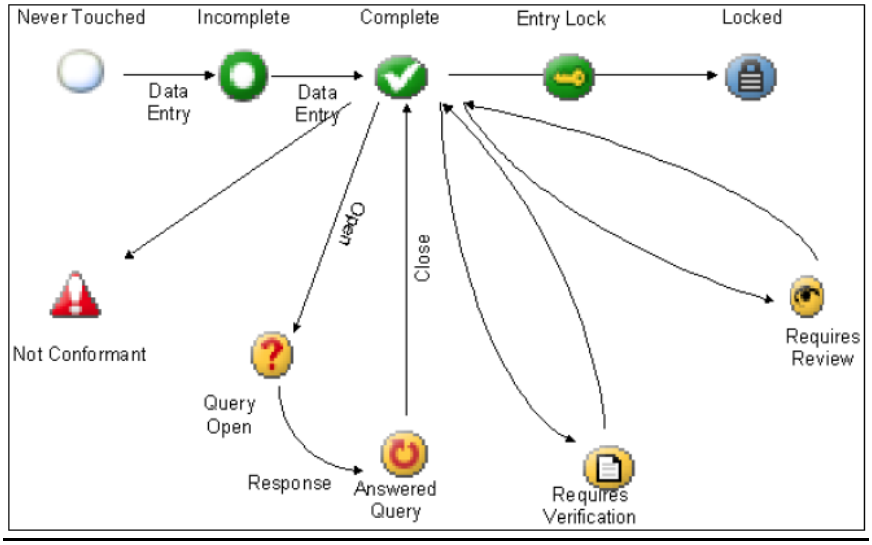


Icon Progression

The life cycle of participants, folders, forms, and fields follows a logical progression starting with “never touched” and moving toward “complete” and “locked”. Graphical icons are used throughout Rave to show status.

The following figure illustrates the status represented by each icon and the progression of icons through the life cycle.

Figure 2. Icon Progression



Task Summary

The Task Summary displays all pending tasks for the study. It displays the number of participants with outstanding tasks that need site review (see Figure 3); for example, open queries. Clicking on the arrow

next to the task expands it to show the specific participants with open queries (see Figure 4). Clicking on a PTID will open the participant's casebook.

Figure 3. Site-Level Task Summary

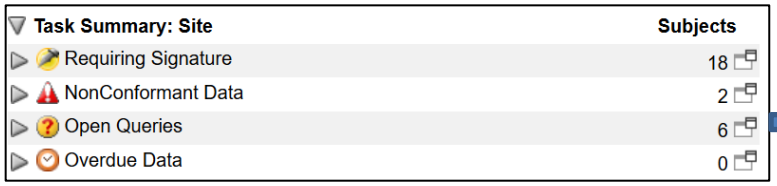
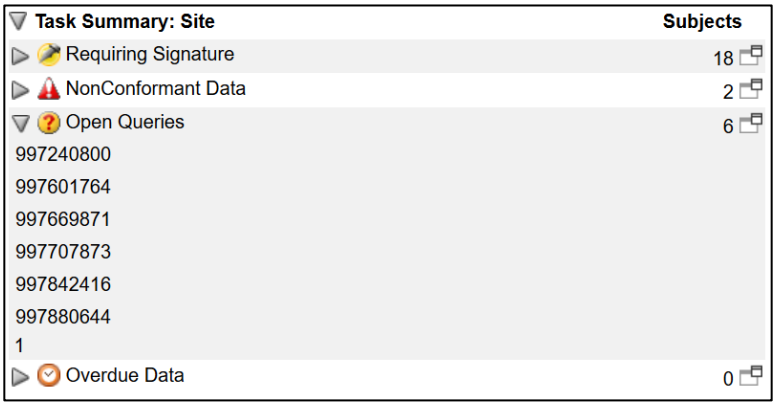
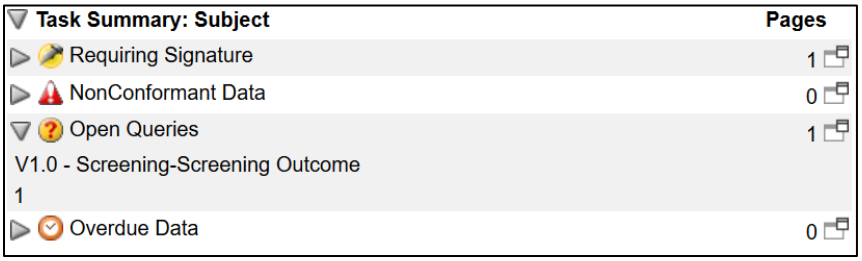


Figure 4. Site-Level Task Summary



At the Subject level, the Task Summary displays the number of pages for that participant that need site review. In Figure 5 below, there is one open query on the Screening Outcome form at V1.0 – Screening. In the expanded task summary view, clicking on this form link will open the form.

Figure 5. Subject-Level Task Summary



General Guidelines – Paper CRF Completion

CRF PDFs are generated from Rave and posted on the protocol webpage. When completing a paper CRF, refer to detailed instructions for data collection pertaining to the specific form and fields on that form in this document.

- Based on Good Clinical Practices (GCPs), refer to the following guidelines to complete paper CRFs:
  - Use a black or dark blue medium ballpoint pen. Do not use any other type of writing tool.
  - Print all data and comments legibly by hand. Do not use cursive/script handwriting.
  - Record data on the front side of the paper only.
  - If the spaces/lines provided for a response are not large enough, continue in another blank area of the paper CRF.
  - Mark only one answer unless instructions state to mark or select all that apply.
  - A response is required for every data field unless skip instructions are provided.
  - Do not use correction fluid (“White-Out”) or correction tape on paper CRFs.

Recording Dates – Rave Form and/or Paper CRF

- Dates are entered using the “dd MMM yyyy” format, where “dd” represents the two-digit day, “MMM” represents the three-letter abbreviation of the month (in capital letters), and “yyyy” represents the four digits of the year.
- Month abbreviations are shown below. In Rave EDC, these abbreviations are in a drop-down list in the month field.

Month	Abbreviation	Month	Abbreviation
January	JAN	July	JUL
February	FEB	August	AUG
March	MAR	September	SEP
April	APR	October	OCT
May	MAY	November	NOV
June	JUN	December	DEC

For example, record September 20, 2016 as:

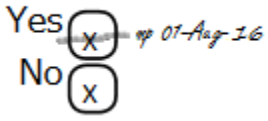
Recording Time - Rave Form and/or Paper CRF

- Use a 24-hour clock (00:00-23:59), where hours are designated from 0–23.
- Midnight is recorded as 00:00, not 24:00.

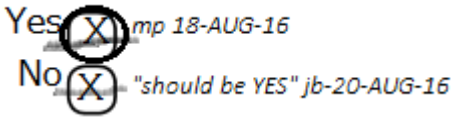
  For example, record 2:25 p.m. as:

Data Corrections and Additions - Rave Form and/or Paper CRF

- Data fields may need to be updated or corrected, such as in response to a query or after site review.
- If the source document is non-CRF in nature (i.e., lab report), it is sufficient to make data updates in the study database itself. If a paper CRF was completed, make changes to the paper CRF first and then enter the updated data into Rave.
- Use the standards below when changing, clarifying, or amending data:
  - Draw a single horizontal line through the incorrect entry. Do not obscure the entry or make it unreadable with multiple cross-outs.
  - Place the correct or clarified answer near the previous response.
  - If an **X** is marked in the wrong response box, correct it by doing the following:
    - draw a single horizontal line through the incorrectly marked box,
    - mark the correct box, and
    - initial and date the correction as shown below:



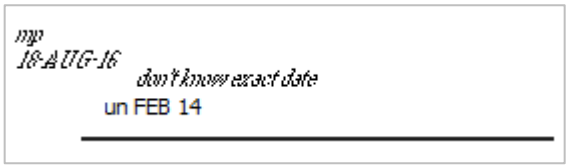
- If the correct answer has previously been crossed out, do the following:
  - circle the correct response,
  - write an explanation in the white space near the response, and
  - initial and date all corrections as shown below:



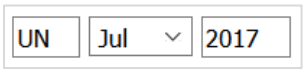
Missing and Unknown Data - Rave Form and/or Paper CRF

On paper CRF, if the answer to a required question is unknown, unavailable, or if the participant refuses to answer, draw a single horizontal line through the applicable question and initial and date. It is helpful to write “don’t know,” “refuses to answer,” “UNK” (unknown), “N/A” (not applicable), or “REF” (refused) near the fields.

- For example, when recording a date, if the exact day is not known, write “un” to designate the “dd” (or date) and write “don’t know” next to the response, as shown below. Initials and date are required for any data that are refused, missing, unknown, or not applicable, regardless of whether they are marked as such during the initial form completion, or as an update to the form.

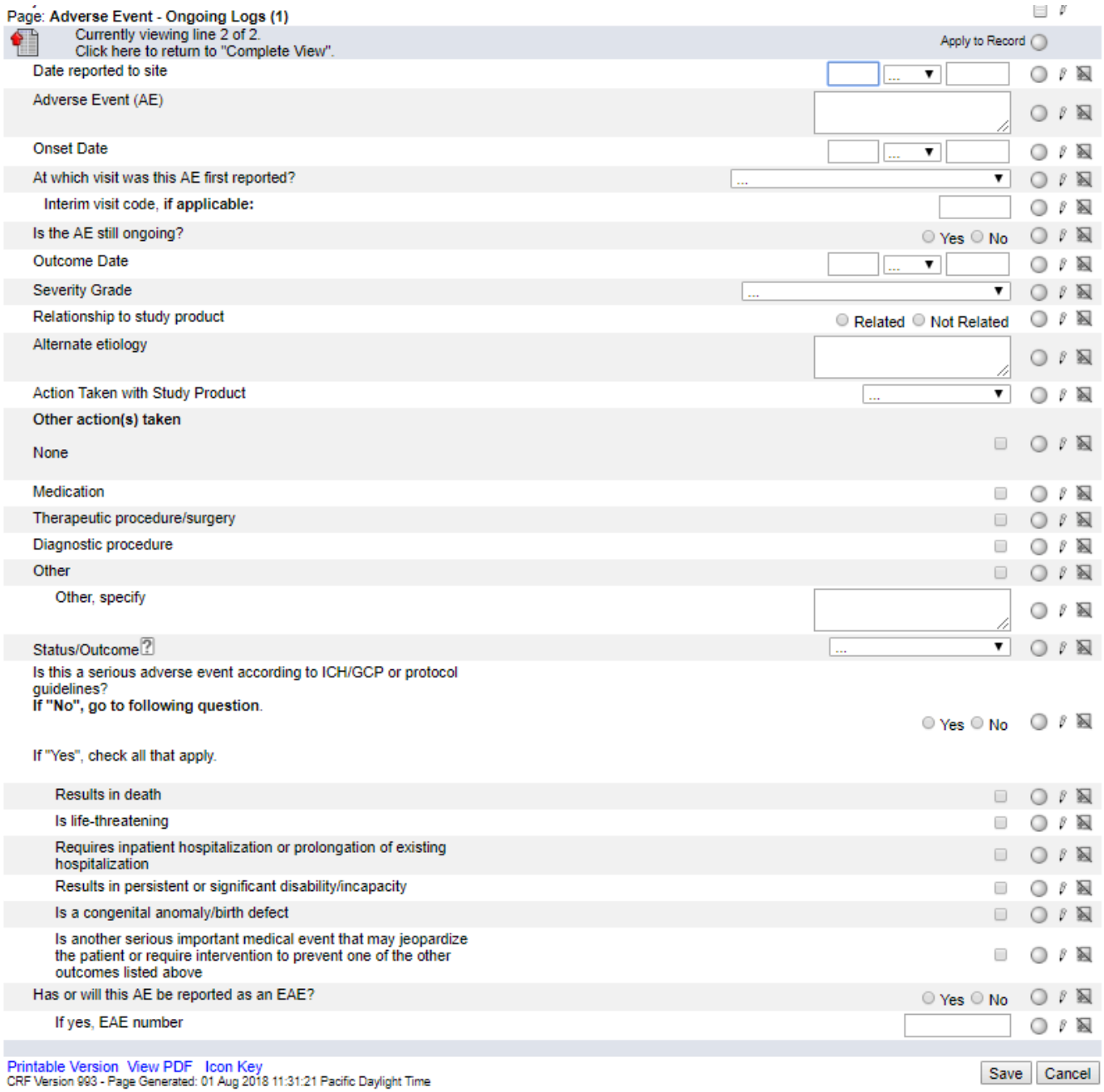


- In Rave, where the data are missing or unknown, enter “UN” for the day and/or select ‘UNK’ from the drop-down list for the month.



Form-Specific Instructions

ADVERSE EVENT


Page: **Adverse Event - Ongoing Logs (1)**

Currently viewing line 2 of 2.
Click here to return to "Complete View".

Apply to Record

Date reported to site

Adverse Event (AE)

Onset Date

At which visit was this AE first reported?

Interim visit code, **if applicable:**

Is the AE still ongoing? Yes No

Outcome Date

Severity Grade

Relationship to study product Related Not Related

Alternate etiology

Action Taken with Study Product

Other action(s) taken

None

Medication

Therapeutic procedure/surgery

Diagnostic procedure

Other

Other, specify

Status/Outcome

Is this a serious adverse event according to ICH/GCP or protocol guidelines?
If "No", go to following question.

Yes No

If "Yes", check all that apply.

Results in death

Is life-threatening

Requires inpatient hospitalization or prolongation of existing hospitalization

Results in persistent or significant disability/incapacity

Is a congenital anomaly/birth defect

Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above

Has or will this AE be reported as an EAE? Yes No

If yes, EAE number

Printable Version View PDF Icon Key
CRF Version 993 - Page Generated: 01 Aug 2018 11:31:21 Pacific Daylight Time

Save Cancel

CONFIDENTIAL DOCUMENT
HPTN 083 CRF Completion Guidelines Version 8.1
20MAR2024

Purpose:
To document any Adverse Event (AE) reported by the participant or clinically observed as defined by the protocol.

General Instructions:
Complete one log line for each adverse event (AE). HIV infection should not be reported on this form.

Only list conditions that start on or after enrollment date, otherwise record conditions as pre-existing. Record increases in severity/frequency as new events with corresponding start/stop dates and add additional log lines by clicking “Add a new Log line”.

Item-specific Instructions:

Field	Instructions
Date Reported to Site	• Record the date the site first became aware of the AE. • For lab AEs, record the date the lab result was received. • If results are received outside of a regular visit, create an interim visit. • This date should correspond to the visit at which AE was first reported (see below).
Adverse Event (AE)	• Describe the AE using medical terminology. Record a diagnosis/anatomical location if available. • Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded on a separate AE log line. • For lab abnormalities, reporting format is “increased/decreased [test name]” – for example, “decreased hematocrit” or “increased ALT”. • If a cluster of symptoms reported on separate Adverse Experience Log lines is later attributed to a single diagnosis, change the earliest reported symptom to the final diagnosis. In addition, inactivate the AE Log lines for the other symptoms with the option “INACT_L – Log line not required.”
Onset Date	• At minimum, a month and year are required. If day is unknown, enter “UN” in the day field. • Record date participant first experienced symptoms, date of abnormal exam findings, or specimen collection date of abnormal test as appropriate • For lab AEs, select the visit the blood draw was done

Field	Instructions
At which visit was this AE first reported?	• Select visit when the site first became aware of the AE from the dropdown list • For lab AEs, select the visit the blood draw was done. • If Interim visit, enter “Interim Visit”, and record visit number in next field.
Interim visit code, if applicable	• Enter interim visit code in space provided
Is the AE still ongoing?	• Select “Yes” if the AE is continuing at the time it is first reported • Select “No” if the condition is no longer present or returned to pre-enrollment severity/frequency. If a participant is taking a medication to control an AE that arose during study participation, it is not considered resolved. • If “Yes”, leave Outcome Date blank
Outcome Date	• Record the outcome date for the AE • At minimum, month and year are required. If day is unknown, enter “UN” in the day field. • Outcome date may be date on which participant reports no longer experiencing the AE, or the date of visit or specimen collection date at which it is first noted the AE has resolved or returned to baseline status.

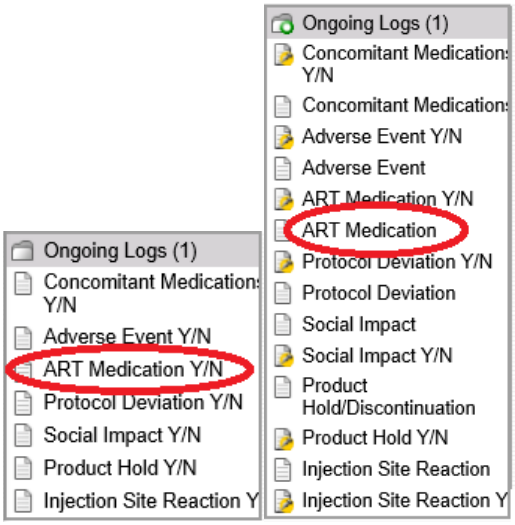
Severity Grade	• Record the severity grade using the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events* (including relevant appendices/addendums)
	  ○ Grade 1 (Mild)
	  ○ Grade 2 (Moderate)
	  ○ Grade 3 (Severe)
	  ○ Grade 4 (Potentially life-threatening)
	  ○ Grade 5 (Death)

Relationship to study product	• Record assessment of the relationship between the AE and the study agent • Mark “Related” if there is a reasonable possibility that the AE may be related to the study agent. • Mark “Not Related” if there is not a reasonable possibility that the AE is related to the study agent.

Field	Instructions
Alternate etiology	• If AE is not related to study agent, record rationale or alternate etiology. • If an alternate etiology is not established, this response should be blank.
Action Taken with Study Product	• Select “dose not changed” if there is no change to the participant’s planned use (dose, frequency, schedule) of study product as a result of the AE. • “Dose reduced” and “dose increased” do not apply and should not be selected in HPTN 083. • Select “drug withdrawn” if the AE results in permanent discontinuation of study product. • Select “drug interrupted” if AE results in a clinician-initiated product hold. • For multiple AEs, mark “drug withdrawn” or “drug interrupted” for each AE contributing to the permanent or temporary discontinuation. Ensure the Product Hold Y/N and Product Hold/Discontinuation forms are completed. • Select “not applicable” if the AE’s onset date is on or after the date the participant permanently discontinues study product use.
Other action(s) taken	• Select “None” or check all that apply. • Select “Medication” only if participant reports taking medication. Report medication(s) on the “Concomitant Medications” log form. • Select “Therapeutic procedure/surgery” only if participant reports a procedure or surgery. • Select “Diagnostic procedure” only if a diagnostic procedure is reported. • If “Other”, specify relevant details in the “Other, specify” text field provided.

Field	Instructions
Status/Outcome	• Select “recovered/resolved” if AE is no longer present, has returned to baseline severity/frequency, or has increased in severity/frequency. Note that if a participant started taking medication once enrolled to control an AE, the AE is not considered resolved while the medication is still indicated. • Select “recovering/resolving” if AE is continuing and has not yet resolved or returned to baseline severity/frequency. • Select “resolved with sequelae” if participant has recovered from the AE, but with remaining effects or impairment. These remaining effects can be temporary but are still present at the time of the report. • Select “not recovered/resolved” if AE is continuing at the time of participant termination from the study. • Select “fatal” only if the severity grade of this AE is Grade 5. Any other AEs continuing at the time of death should be recorded as “not recovered/resolved”.
Is this a Serious Adverse Event according to ICH/GCP or protocol guidelines?	• Select “Yes” or “No” If “Yes”, check all that apply. ○ Results in death ○ Is life-threatening ○ Requires inpatient hospitalization or prolongation of existing hospitalization ○ Results in persistent or significant disability/incapacity ○ Is a congenital anomaly/birth defect ○ Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above
Has or will this AE be reported as an EAE?	• Select “Yes” or “No” • For questions about ICH guidelines and EAE reporting, refer to current *Manual for Expedited Reporting of Adverse Events to DAIDS.* • If reported as an EAE (indicated as “yes”), provide the EAE number and complete any subsequent updates to this form on the applicable EAE form.
If yes, EAE number	• Enter EAE number in text field provided

ART MEDICATION Y/N



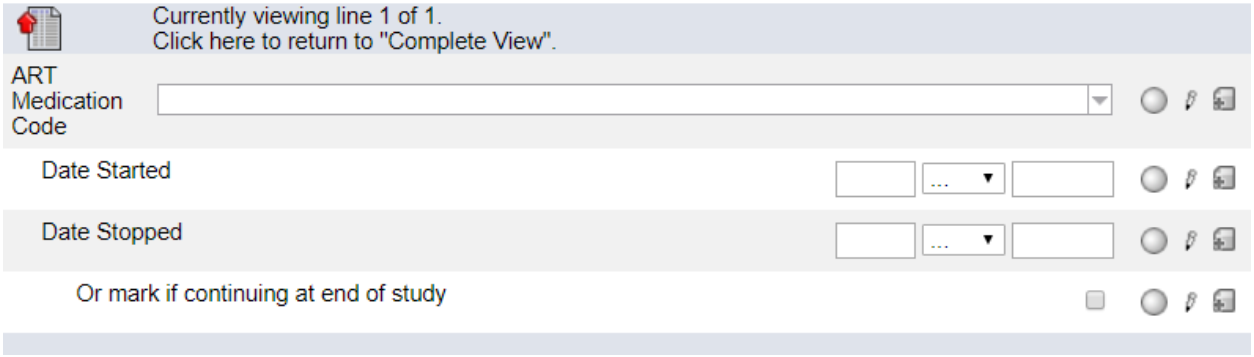
Purpose:
This form documents whether any ART medications were taken by the participant after HIV infection was confirmed.

General Instructions:
This summary form is located within the "Ongoing Logs" folder.

Item-specific Instructions:

Field	Instructions
Has the participant started taking any ART medication?	• Select "Yes" or "No" • If "Yes" is selected and the form is saved, the ART Medication form will appear in the "Ongoing Logs" folder. • If at the time of termination, the participant has not taken any ART medication, mark "No".

ART MEDICATION



Purpose:
To document ART medications taken by the participant after HIV infection is confirmed. These medications should not be documented on the Concomitant Medications form.

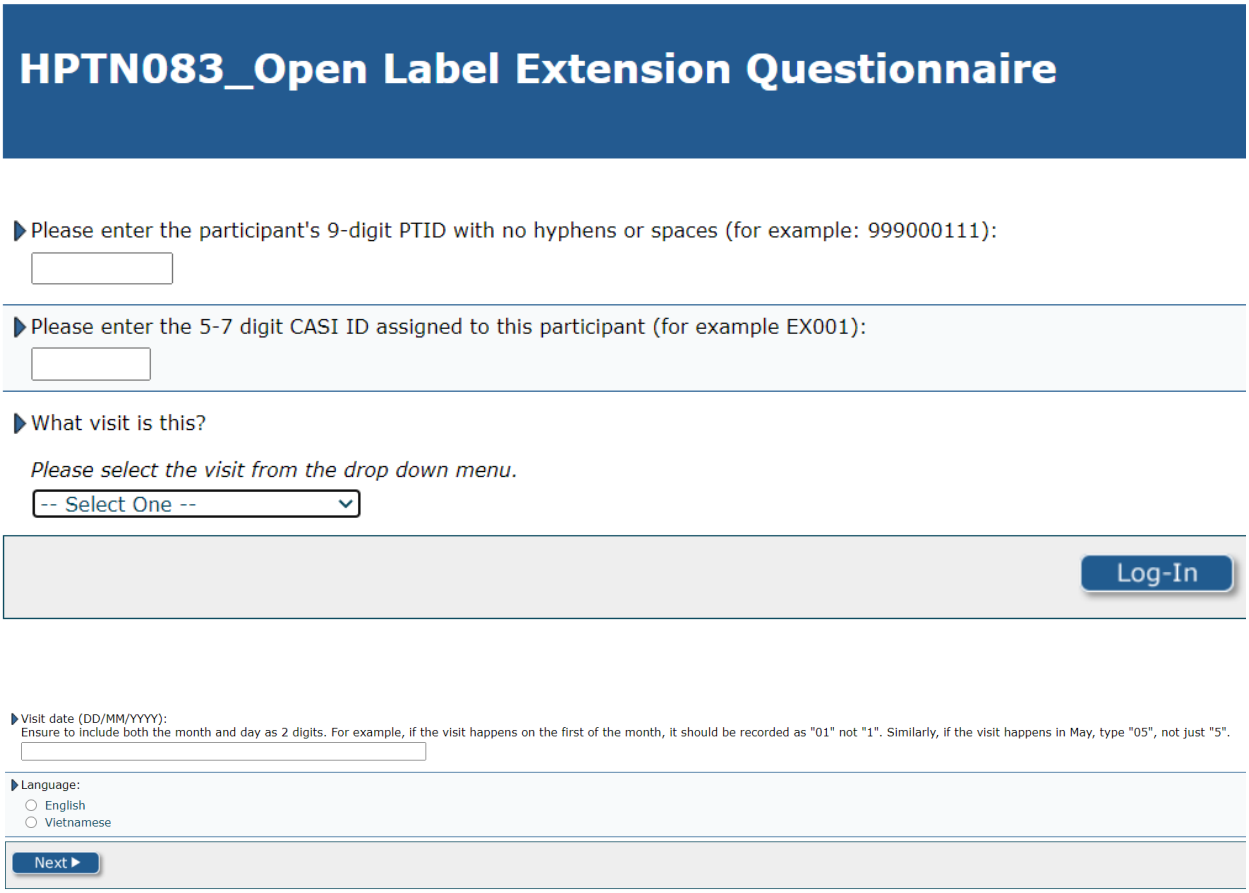
General Instructions:
This form is located within the “Ongoing Logs” folder. Complete one log line for each medication and add additional log lines by clicking “Add a new Log line”.

Item-specific Instructions:

Field	Instructions
ART Medication Code	• Select the appropriate medication from the dropdown list. • To move between pages of medications click on the “<<Back” and “Next>>” buttons at the top of the list. You can also type the first letters of the medication and only medications starting with those letters will appear for selection.
Date Started	• Enter the date the medication started • A complete date is required

Field	Instructions
Date Stopped	• If applicable, enter the date the medication was discontinued • A complete date is required • At the participant's Study Exit/Termination Visit, either "Date Stopped" OR "Mark if continuing at end of study" box must be marked
Or mark if continuing at end of study.	• Mark box if medication was continuing at the time of study completion

CASI - OLE



Purpose:

This survey records participant's sexual behavior throughout the OLE phase of the study.

General Instructions:

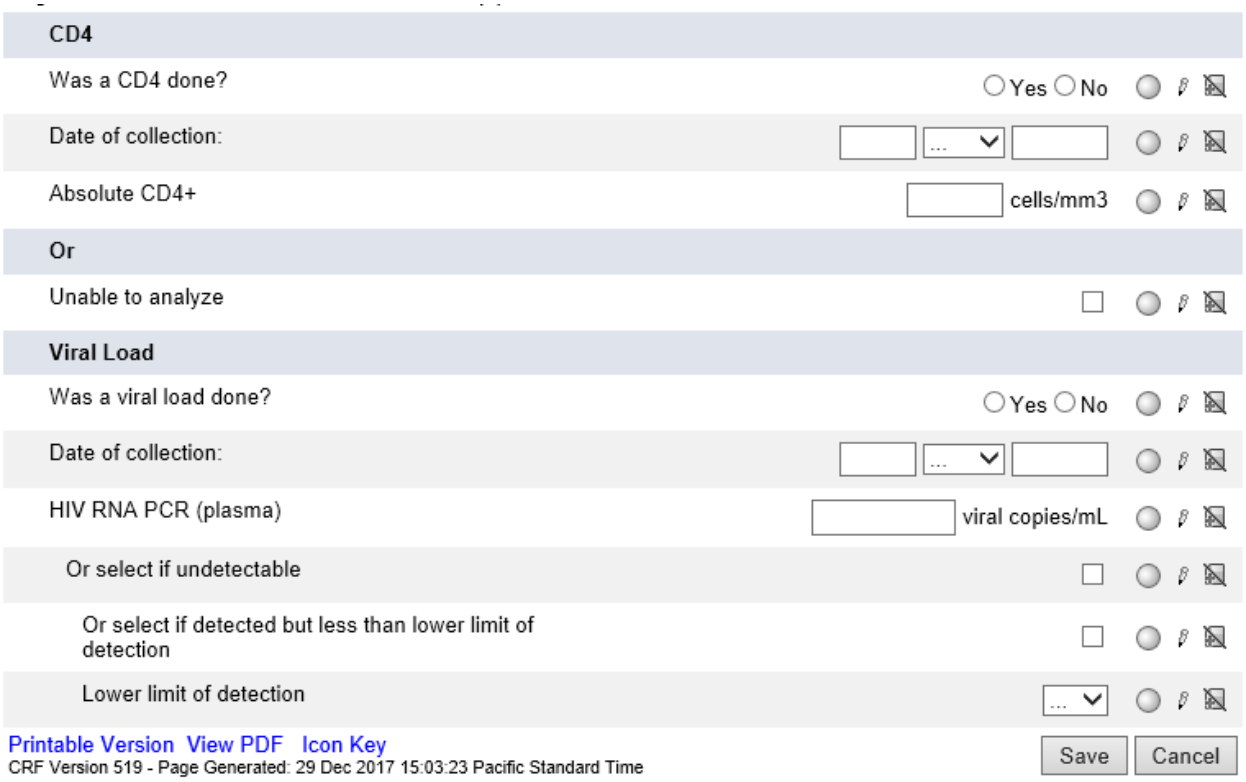
This is a behavioral survey and **SHOULD NOT** be taken retrospectively or for future visits. A drop-down menu allows for the selection of **any visit code** (i.e. including non-CASI visits) in the OLE phase of the study. The survey Visit code must match the Visit code in Rave.

To see what surveys have already been taken, use the CASI listing on Atlas (Communiqué #12). Do not use Illume to find out whether a survey was taken, as this introduces survey entries with no participant's data that must be removed.

Item-specific Instructions:

Field	Instructions
Please enter the participant's 9-digit PTID with no hyphens or spaces (for example: 999000111):	• Enter PTID • CASI ID and PTID must match
Please enter the 5-7 digit CASI ID assigned to this participant (for example: EX001):	• Enter CASI ID • CASI ID and PTID must match
What visit is this? **Please select the visit from the dropdown menu.**	• Select the visit when participant took the survey • Do not select a future visit • Do not select a past visit
Visit date (DD/MM/YYY): **Ensure to include both the month and day as 2 digits. For example, if the visit happens on the first of the month, it should be recorded as "01" not "1". Similarly, if the visit happens in May, type "05", not just "5".**	• Enter today's date • If survey was taken on paper in the past and is transcribed into Illume later, enter the date the survey was taken on paper. This is the only scenario that permits entry of a past date.

CD4/VIRAL LOAD RESULTS



Purpose:
To document CD4 and HIV viral load for HIV infected participants.

General Instructions:
Complete this form at the HIV Confirmation Visit, V55.0 – Week 24, and V57.0 – Week 48, or when clinically indicated during follow-up. To add this form to a participant's visit folder, mark "CD4/Viral Load" on the Date of Visit CRF. Once the Date of Visit form is saved, the form appears in the visit folder.

Item-specific Instructions:

Field	Instructions
Was a CD4 done?	• Select "Yes" or "No"

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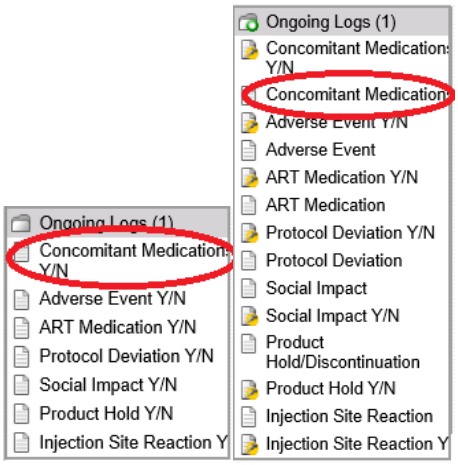
HPTN 083 CRF Completion Guidelines Version 8.1
20MAR2024

Field	Instructions
Date of collection:	• If CD4 was done, enter the date the sample was collected • A complete date is required
Absolute CD4+	• Enter the absolute CD4 in units of “cells/mm3”
Or	
Unable to analyze	• Check if sample was unable to be analyzed
Was a viral load done?	• Select “Yes” or “No” • If viral load was done on the same specimen used to confirm HIV infection (and recorded on the HIV Test form), enter the RNA results on the HIV Test Results form.
Date of collection:	• Enter the date the sample was collected • A complete date is required
HIV RNA PCR (plasma)	• Enter the result in units of “viral copies/mL”
Or select if undetectable	• Select if result is undetectable
Or select if detected but less than lower limit of detection	• Select if test result is below the lower limit of detection
Lower limit of detection	• Select the lower limit of detection from the dropdown list.

CONCOMITANT MEDICATIONS Y/N



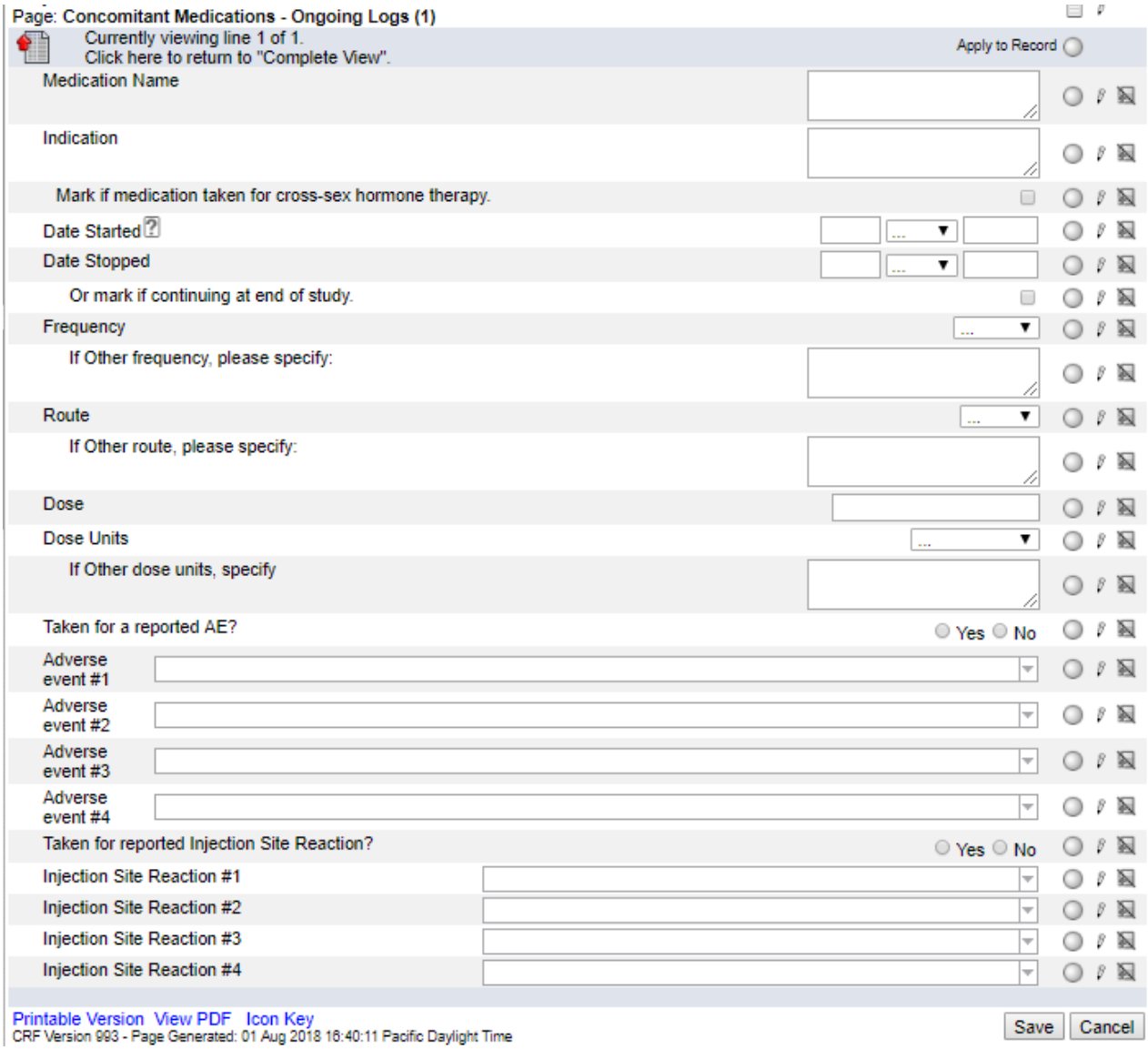
Purpose:
This form documents if any concomitant medications were reported by the participant during the study or within 30 days prior to study enrollment.

General Instructions:
This summary form is located within the “Ongoing Logs” folder.

Item-specific Instructions:

Field	Instructions
Were any concomitant medications taken?	• Select “Yes” or “No” • If “Yes” is selected and the form saved, the Concomitant Medications log form appears within the “Ongoing Logs” folder

CONCOMITANT MEDICATIONS



Purpose:
This log form is used to document all medications taken by the participant, starting up to 30 days prior to the Enrollment Visit. This includes, but is not limited to: prescription medications, non-prescription (i.e., over-the-counter) medications, contraceptive hormonal medications, preventive medications and

treatments (e.g., allergy shorts, flu shots, and other vaccinations), herbal preparations, vitamin supplements, and naturopathic preparations.

General Instructions:
Complete a separate entry in the study database for each reported concomitant medication. Use the "Add a new Log line" button to add an additional concomitant medication.
Item-specific Instructions:

Field	Instructions
Medication Name	• Record the trade or generic name of the medication • A combination medication can be recorded as one entry
Indication	• Record the underlying indication for which the medication was taken. • For health supplements, such as multivitamins, record "general health" • For preventive medications, record "prevention of [insert condition]" (e.g., for flu shot, record "prevention of influenza").
Mark if medication taken for cross-sex hormone therapy.	• Mark box if medication is being taken for cross-sex hormone therapy
Date Started	• Enter the date the medication was initiated • If participant is unable to recall exact date of medication initiation, obtain best estimate • Year is required at minimum
Date Stopped	• Enter the stop date of this medication if known • Month and year are required at minimum • At the participant's Study Exit/Termination Visit, the "Date Stopped" must be recorded for each medication OR the "Or mark if continuing at end of study" box must be checked
Or mark if continuing at end of study.	• Mark box if medication was continuing at the time of study completion

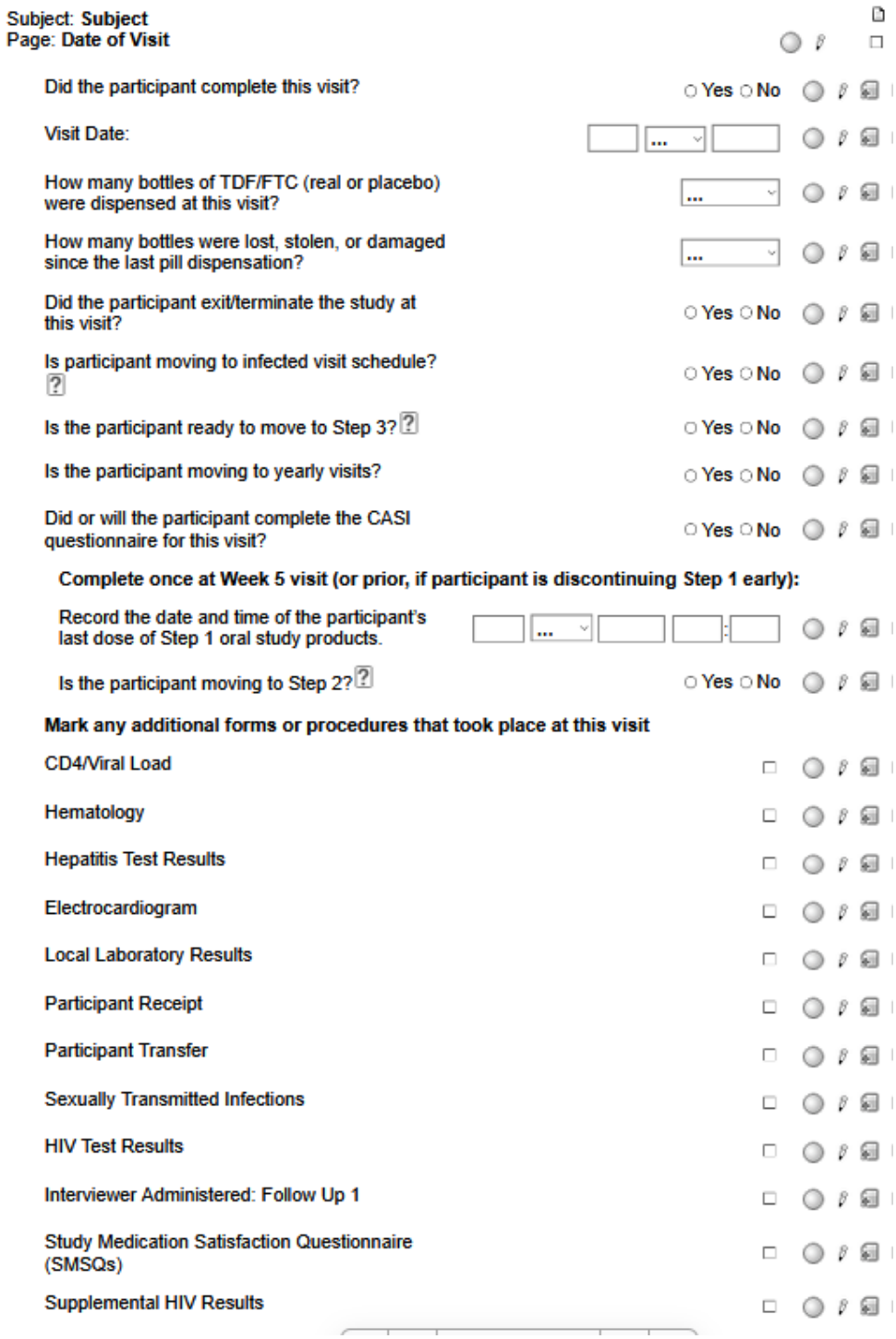
Frequency	• Select the frequency from options provided in the dropdown list
	• *Common frequency abbreviations:*
	  ○ PRN: as needed
	  ○ QD: every day
	  ○ TID: three times daily
	  ○ QID: four times daily
	  ○ QHS: at bedtime
	  ○ ONCE: one time
	  ○ BID: twice daily
	  ○ Other
	• If "Other" is selected, record frequency in the corresponding "If Other frequency, specify" text field provided

Route	• Select the route from options provided in the dropdown list
	• *Common route abbreviations:*
	  ○ PO: oral
	  ○ IM: intramuscular
	  ○ IV: intravenous
	  ○ TOP: topical
	  ○ IHL: inhaled
	  ○ VAG: vaginal
	  ○ REC: rectal
	  ○ SC: subcutaneous
	  ○ Other
	• If "Other" is selected, specify route in the corresponding "If Other route, specify" text field provided

Dose	• Enter the dose in the field provided • For combination drugs, use the "/" or "-" to distinguish the different doses (i.e., hydrocodone/acetaminophen 5/500). • If the dose is unknown, enter "Unknown" in the space provided.
Dose Units	• Select the applicable dose units provided from the dropdown list • If unit of measurement is not known, select the "Unknown" option. • If "Other" is selected, provide a response to the "If Other dose units, specify" text field below
Taken for a reported AE?	• If the medication was taken for a reported AE, select "Yes" • If taken for an AE, the AE must be linked below

Adverse event **(#1, #2, #3, #4)**	• If the medication was taken for a reported AE, select appropriate AE from the dropdown list. • The AE form must be completed before it can be linked on the Concomitant Medications form. • Up to 4 adverse events can be entered for each Medication Name.
Taken for a reported Injection Site Reaction?	• If the medication was taken for a reported ISR, select “Yes” • If taken for an ISR, the ISR must be linked below
Injection Site Reaction **(#1, #2, #3, #4)**	• If the medication was taken for a reported ISR, select ISR from the dropdown list • The ISR form must be completed before it can be linked on the Concomitant Medications form • Up to 4 ISRs can be entered for each Medication Name.

DATE OF VISIT


Subject: **Subject**
Page: **Date of Visit**

Did the participant complete this visit? ○ Yes ○ No

Visit Date:

How many bottles of TDF/FTC (real or placebo) were dispensed at this visit?

How many bottles were lost, stolen, or damaged since the last pill dispensation?

Did the participant exit/terminate the study at this visit? ○ Yes ○ No

Is participant moving to infected visit schedule? ○ Yes ○ No

Is the participant ready to move to Step 3? ○ Yes ○ No

Is the participant moving to yearly visits? ○ Yes ○ No

Did or will the participant complete the CASI questionnaire for this visit? ○ Yes ○ No

Complete once at Week 5 visit (or prior, if participant is discontinuing Step 1 early):

Record the date and time of the participant's last dose of Step 1 oral study products.

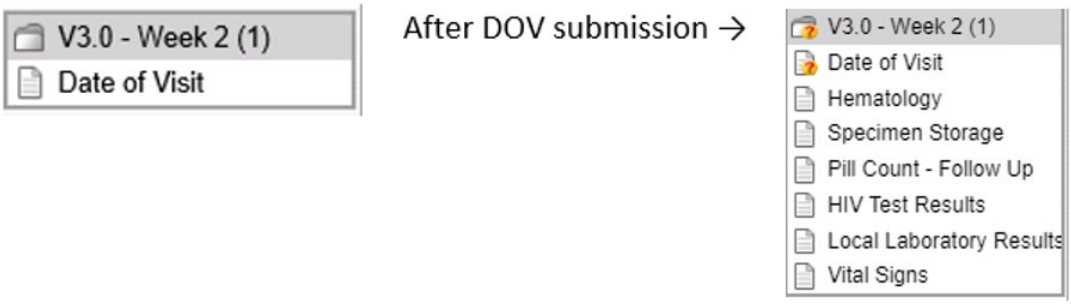
Is the participant moving to Step 2? ○ Yes ○ No

Mark any additional forms or procedures that took place at this visit

- CD4/Viral Load
- Hematology
- Hepatitis Test Results
- Electrocardiogram
- Local Laboratory Results
- Participant Receipt
- Participant Transfer
- Sexually Transmitted Infections
- HIV Test Results
- Interviewer Administered: Follow Up 1
- Study Medication Satisfaction Questionnaire (SMSQs)
- Supplemental HIV Results

Purpose:
This form is filled out at the start of each scheduled follow-up visit to establish form expectations within Rave and to provide pill bottle dispensation information.

General Instructions:
Complete this form in order to generate all other forms related to a specific visit. Additional forms can be added using the checkboxes provided on the Date of Visit form.



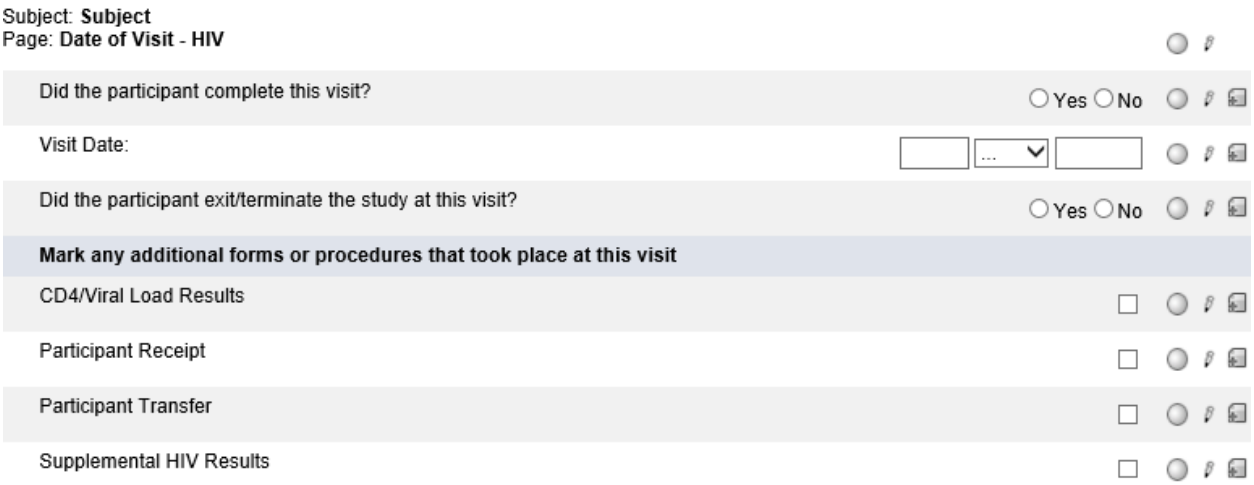
Item-specific Instructions:

Field	Instructions
Did the participant complete this visit?	• Select “Yes” or “No” • If “No” is selected, a Missed Visit form is generated in the same visit folder.
Visit Date:	• A complete date is required • If visit was missed, skip this field
How many bottles of TDF/FTC (real or placebo) were dispensed at this visit?	• Select the number of bottles from the dropdown list • If no bottles were dispensed, select ‘none’
How many bottles were lost, stolen, or damaged since the last pill dispensation?	• Select the number of bottles from the dropdown list • If no bottles were lost, stolen or damaged, select ‘none’
Did the participant exit/terminate the study at this visit?	• Select “Yes” or “No” • If “Yes”, a Termination form will be added to the visit folder and must be submitted.

Field	Instructions
Is participant moving to the infected visit schedule?	• Select “Yes” or “No” • If “Yes”, the remaining Step 2 visit folders are removed from the participant’s casebook.
Is the participant ready to move to Step 3?	• Select “Yes” or “No” • Select “Yes” at last Step 2 visit before participant moves to Step 3. • At Step 3 visits, leave this question blank. • If “Yes”, any Step 3 Day 0 forms not already present in the folder must be added; refer to the schedule of forms. If “Yes”, the remaining Step 2 visit folders are removed from the participant’s casebook.
Is the participant moving to yearly visits?	• Select “Yes” or “No” • Only select “Yes” If participant is in Step 1 and has not had a Week 5 injection OR the participant has completed all Step 3 visits. • If “Yes” is selected during Step 1, the Step 2 and Step 3 visit folders are removed from the participant’s casebook.
Did or will the participant complete the CASI questionnaire for this visit?	• Select “Yes” or “No”
Record the date and time of the participant’s last dose of Step 1 oral study products.	• Record a response to this question only once at or prior to the Week 5 visit • Record the date and time of the participant’s last dose of Step 1 oral study products using a 24-hour clock • If time is not known enter “00:00”
Is the participant moving to Step 2?	• Mark an answer to this question only once at or prior to the Week 5 visit • Select “Yes” or “No” • If “No” is selected the remaining Step 2 visit folders are removed from the participant’s casebook.

Field	Instructions
Mark any additional forms or procedures that took place at this visit	• *Check all additional forms to be completed at this visit*
Mark at Step 3 visits as needed:	• *Check all additional Step 3 forms to be completed at this visit* • *Only mark these items if the participant is currently in Step 3.*

DATE OF VISIT – HIV



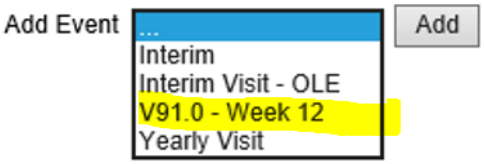
Purpose:

This form is used to record visits for HIV-positive participants done **during the open-label extension (OLE) only**.

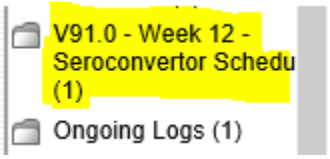
General Instructions:

The first visit on the HIV-infected schedule is coded as **V91.0 – Week 12**. Complete the Date of Visit – HIV form to generate all required and additional CRFs required for a specific visit. Additional forms can be added by marking checkboxes provided under the “Mark any additional forms or procedures that took place at this visit” section on the Date of Visit – HIV.

To generate this form, select "**V91.0 – Week 12**" from the participant's homepage using the "Add Event" dropdown.



Visit 91.0 – Week 12 will appear in the visit menu on the left above "Ongoing logs".



Field	Instructions
Did the participant complete this visit?	• Select "Yes" or "No" • If "No" is selected, a Missed Visit form is generated in the same visit folder.
Visit Date:	• A complete date is required • If visit was missed, skip this field
Did the participant exit/terminate the study at this visit?	• Select "Yes" or "No" • If "Yes", a Termination form will be added to the visit folder and must be submitted.
Mark any additional forms or procedures that took place at this visit	• Check all additional forms to be completed at this visit

DATE OF VISIT – OLE

Subject: **Subject**
Page: **Date of Visit - OLE**

Did the participant complete this visit?	Yes No
Visit Date:	...
How many bottles of study drug (TDF/FTC or oral CAB) were dispensed at this visit?	...
Did the participant exit/terminate the study at this visit?	Yes No
Did or will the participant complete the CASI questionnaire for this visit?	Yes No
Is the participant moving to a new step or visit schedule?	Yes No
If Yes, please indicate which Step or visit schedule?	...
Mark any additional forms or procedures that took place at this visit	
CD4/Viral Load Results	☐
Hepatitis Test Results	☐
Local Laboratory Results	☐
Participant Receipt	☐
Participant Transfer	☐
Sexually Transmitted Infections	☐
Supplemental HIV Results	☐

Purpose:

This form is used to record visits for participants done **during the open-label extension (OLE) only**.

General Instructions

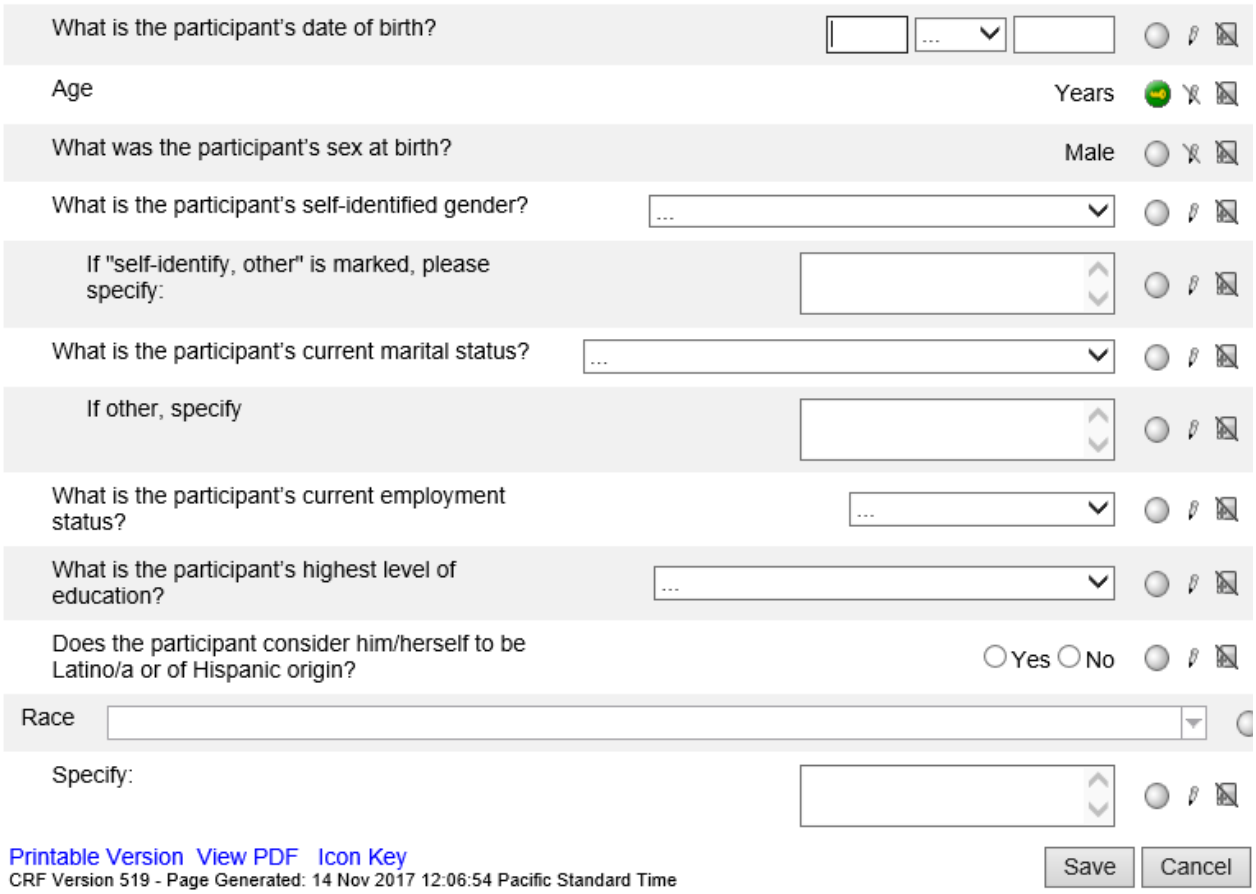
This form will generate once the Product Choice – OLE form is completed. Complete the Date of Visit – OLE from to generate all required CRFs related to a specific visit. Additional forms can be added by marking checkboxes provided under the "Mark any additional forms or procedures that took place at this visit" section on the Date of Visit – OLE.

Item-specific Instructions:

Field	Instructions
Did the participant complete this visit?	• Select "Yes" or "No" • If "No" is selected, a Missed Visit form is generated in the same visit folder.
Visit Date:	• A complete date is required • If visit was missed, skip this field
How many bottles of study drug (TDF/FTC or oral CAB) were dispensed at this visit?	• Select the number of bottles from the dropdown list • If no bottles were dispensed, select '0'.
Did the participant exit/terminate the study at this visit?	• Select "Yes" or "No" • If "Yes", a Termination form will be added to the visit folder and must be submitted.
Did or will the participant complete the CASI questionnaire for this visit?	• Select "Yes" or "No"

Is the participant moving to a new step or visit schedule?	• Select “Yes” or “No” • Select “Yes” only if participant is moving to a new step or visit schedule (e.g. Step 5 to Step 4a) • Select “No” when participant follows the step progression per Schedule of Forms (e.g. Step 4a to Step 4b to Step 4c to Step 5)
If Yes, please indicate which Step or visit schedule?	• Select the Step or visit schedule from drop down menu.
Mark any additional forms or procedures that took place at this visit	• Check all additional forms to be completed at this visit

DEMOGRAPHICS



Purpose:

This form is used to document a participant's demographic and socioeconomic information.

General Instructions:
This form is completed at the V2.0 – Day 0/Enrollment visit. Responses should reflect the participant's status at screening and should not be changed after enrollment unless correction is needed.

Item-specific Instructions:

Field	Instructions
What is the participant's date of birth?	• Provide the date of birth • A complete date is required
Age	*This is an automatically derived field based on the participant's date of birth and the date of initial form completion. No data entry is required.*
What was the participant's sex at birth?	*This field is automatically filled as Male due to the protocol eligibility requirements. No data entry is required.*
What is the participant's self-identified gender?	• Select the applicable response from the dropdown list. • If "Self-identify, other" is selected, provide a response in the text field provided.
What is the participant's current marital status?	• Select the applicable response from the dropdown list based on the participant's response. • If "Other", provide a response in the text field provided.
What is the participant's current employment status?	• Select the applicable response from the dropdown list.
What is the participant's highest level of education?	• Complete this item based on participant self-report.

Field	Instructions
Does the participant consider him/herself to be Latino/a or of Hispanic origin?	• Select “Yes” or “No”
Race	• Select race from the dropdown list. • If “Other, specify” is selected, provide a response in the Specify text field provided below.

DXA SCAN

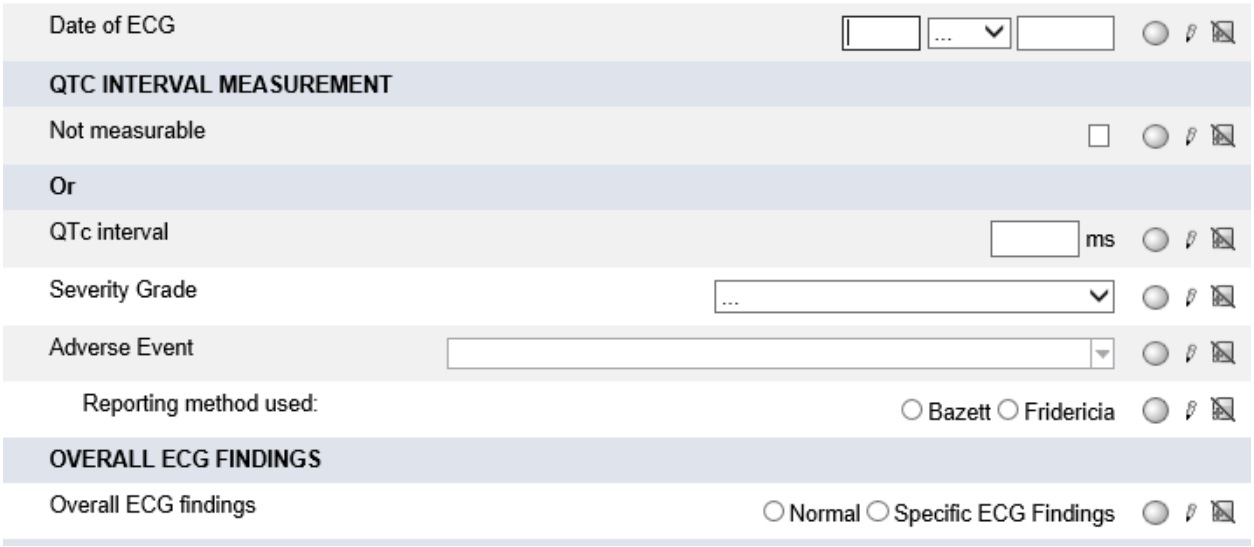
Purpose:
This form is used to document the participant's DXA scan information.

General Instructions:
Complete this form for all participants at specified visits.

Item-specific Instructions:

Field	Instructions
Did the participant have a DXA scan for this visit?	• Select "Yes", "No", or "N/A (slots filled or site not participating)"
Date of DXA scan	• Provide date of the scan • A complete date is required • Leave item blank if scan was not performed.

ELECTROCARDIOGRAM



Purpose:
This form is used to document normal and abnormal findings observed during Lead ECG tests.

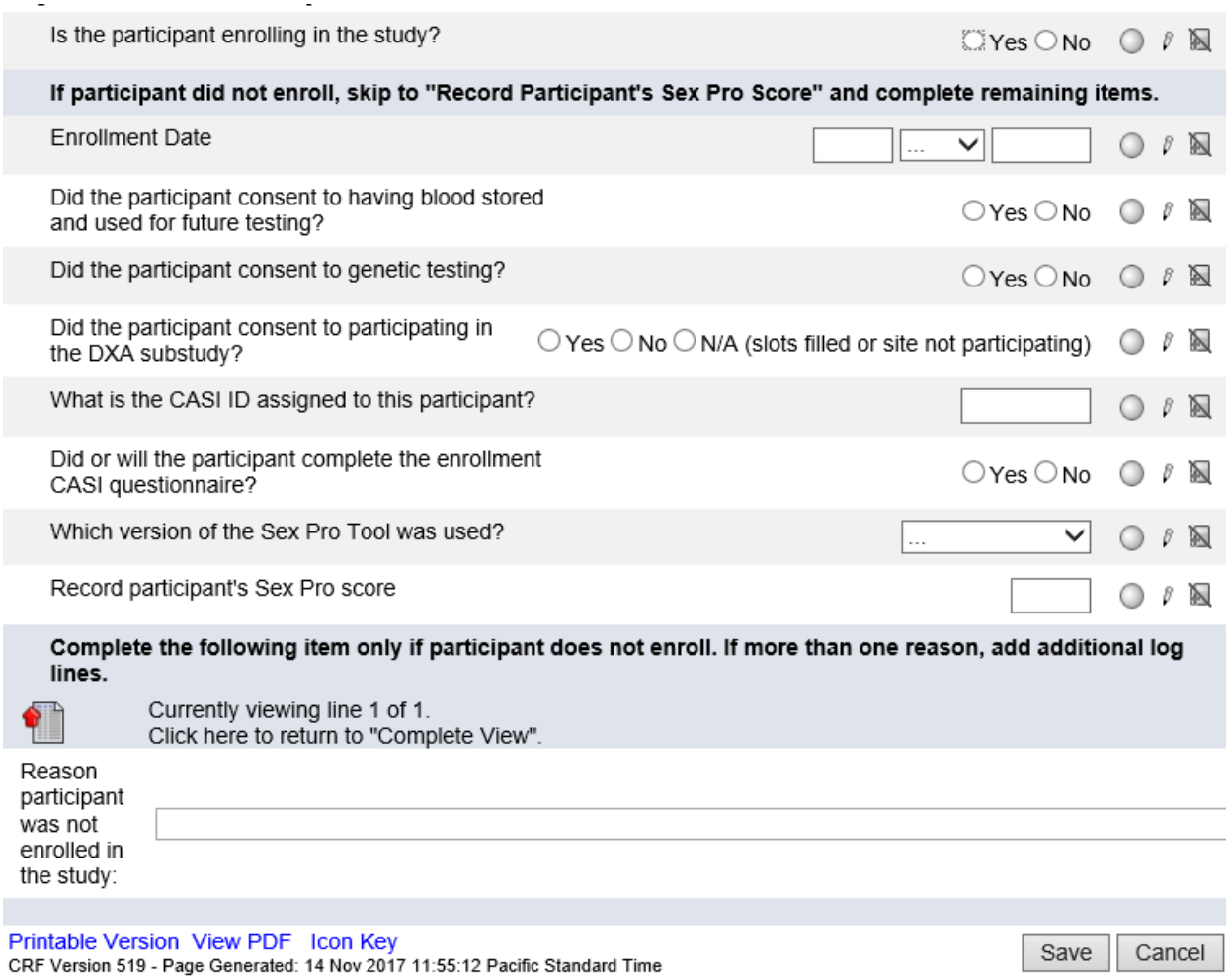
General Information/Instructions:
This form is completed at protocol-specified visits, and as clinically indicated at any other study visits.

Item-specific Instructions:

Field	Instructions
Date of ECG	• Enter the date the ECG was performed • A complete date is required
QTC INTERVAL MEASUREMENT	
Not measurable	• Select if the ECG was not measurable. • If a result was obtained, leave field unchecked and enter results in fields below.
Or	

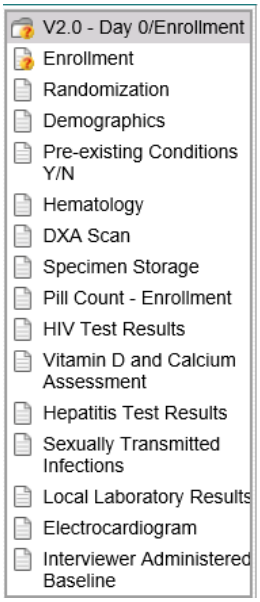
Field	Instructions
QTc interval	• Enter ECG result in units of milliseconds (ms)
Severity Grade	• Select a severity grade (1-4) or “not gradable” from dropdown list • If a severity grade is selected, the test result field must not be blank
Adverse Event	• If test is linked to a reported AE, select the AE in the search list provided • The AE form must be completed before it can be linked on the Electrocardiogram form.
Reporting method used:	• Select which reporting method was used, “Bazett” or “Fridericia”
Overall ECG Findings	
Overall ECG findings	• Select “Normal” or “Specific ECG findings” • If “Specific ECG Findings” is selected, ensure all applicable findings are marked from the items listed below
SPECIFIC ECG FINDINGS	
Specific ECG findings	• If specific findings are noted, indicate by checking all findings as applicable
Other, specify:	• If any finding does not apply to the specific options provided, specify in text field provided

ENROLLMENT



Purpose:
This form is used to document a participant's study enrollment and to set target dates for future visits. This form is completed at enrollment for participants who have provided informed consent and who are eligible to participate in the study. This form is also completed for participants who screen for the study but do not enroll.

General Instructions:
Complete this form for each participant who signed informed consent for HPTN 083.



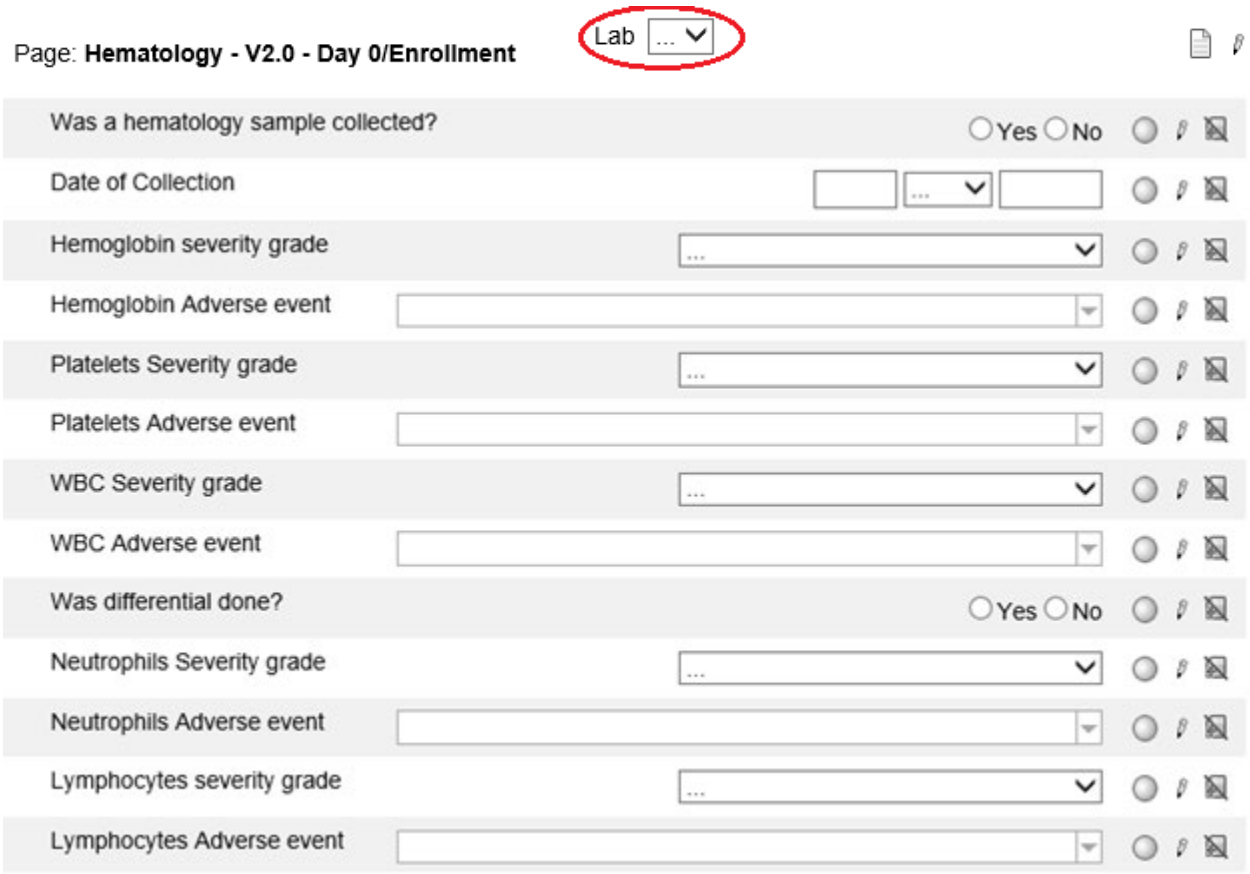
After an Enrollment form is submitted indicating a participant is going to be enrolled in the study, other Enrollment forms will be generated.

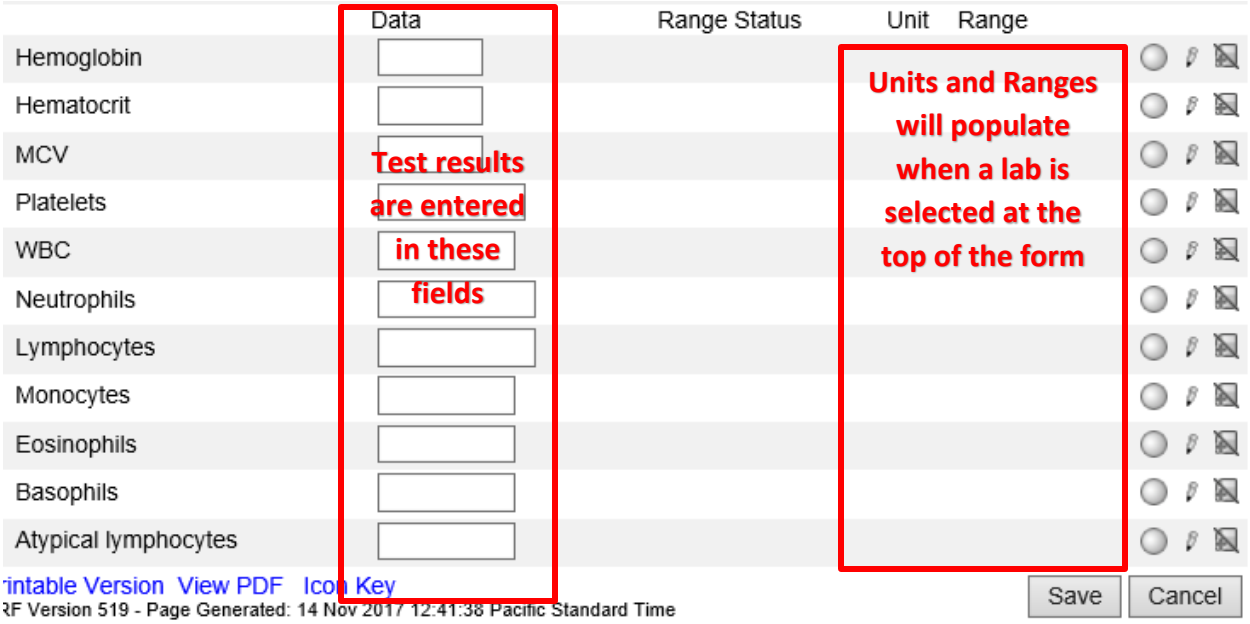
Item-specific Instructions:

Field	Instructions
Is the participant enrolling in the study?	• Select “Yes” or “No” • If participant did not enroll, skip to "Which version of the Sex Pro Tool was used?” and complete remaining items.
Enrollment Date	• A complete date is required
Did the participant consent to having blood stored and used for future testing?	• Select “Yes” or “No” • Update as needed if the participant changes consent during the study.

Field	Instructions
Did the participant consent to genetic testing?	• Select “Yes” or “No”
Did the participant consent to participating in the DXA substudy?	• Select “Yes”, “No”, or “N/A (slots filled or site not participating)”
What is the CASI ID assigned to this participant?	• Enter the CASI ID assigned in the text field provided
Did or will the participant complete the enrollment CASI questionnaire?	• Select “Yes” or “No”
Which version of the Sex Pro Tool was used?	• Select either “South America”, “North America”, or “Not Applicable”
Record participant’s Sex Pro score	• Enter the participant’s Sex Pro score in the field provided • If Sex Pro Tool was not used, leave item blank
Reason participant was not enrolled in the study:	• Select the reason participant was not enrolled from the dropdown list • To move between pages of termination reasons, click on the “< Back” and “Next >” buttons at the top of the list. You can also type the first letters of a key word to show only choices containing those letters. • If more than one reason, add additional log lines.

HEMATOLOGY





Purpose:
This form is used to document the participant's hematology test results.

General Information/Instructions:
Use this form to report the hematology and differential test results obtained from specimens collected for this visit.

Local Lab reference ranges should automatically appear on lab forms; if that is not the case please contact SCHARP to correct this.

Some lab results are graded based on change from baseline. Note that 'baseline' means tests done at the enrollment visit not the screening visit.

Item-specific Instructions:

Field	Data
Test Result	• *Enter the result of the specified test* • To eliminate the need to round a number, each test result field allows up to 5 digits beyond the decimal point • When working with calculated severity grade ranges (e.g., 1.1-1.3 x ULN), the calculated range may have more significant digits than the lab result. Treat all missing digits in the lab value as zeros. • *If test was not performed, leave blank* • *If result is entered, ensure a severity grade for the result is entered*

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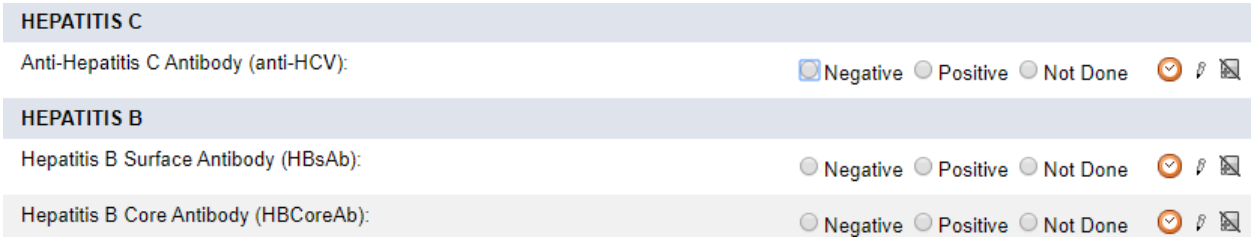
HPTN 083 CRF Completion Guidelines Version 8.1
20MAR2024

Field	Instructions
Was a hematology sample collected?	• Select “Yes” or “No”
Date of collection:	• Enter the date the sample was collected • A complete date is required
Test Severity grade	• *Select a severity grade (1-4) or “not gradable” from the dropdown list* • *If a severity grade is selected, the test result field must not be blank*
Test Adverse event	• *If test is linked to a reported AE, select the AE in the dropdown list provided* • *An AE form must be completed before it can be selected on the Hematology form.*

HEPATITIS TEST RESULTS



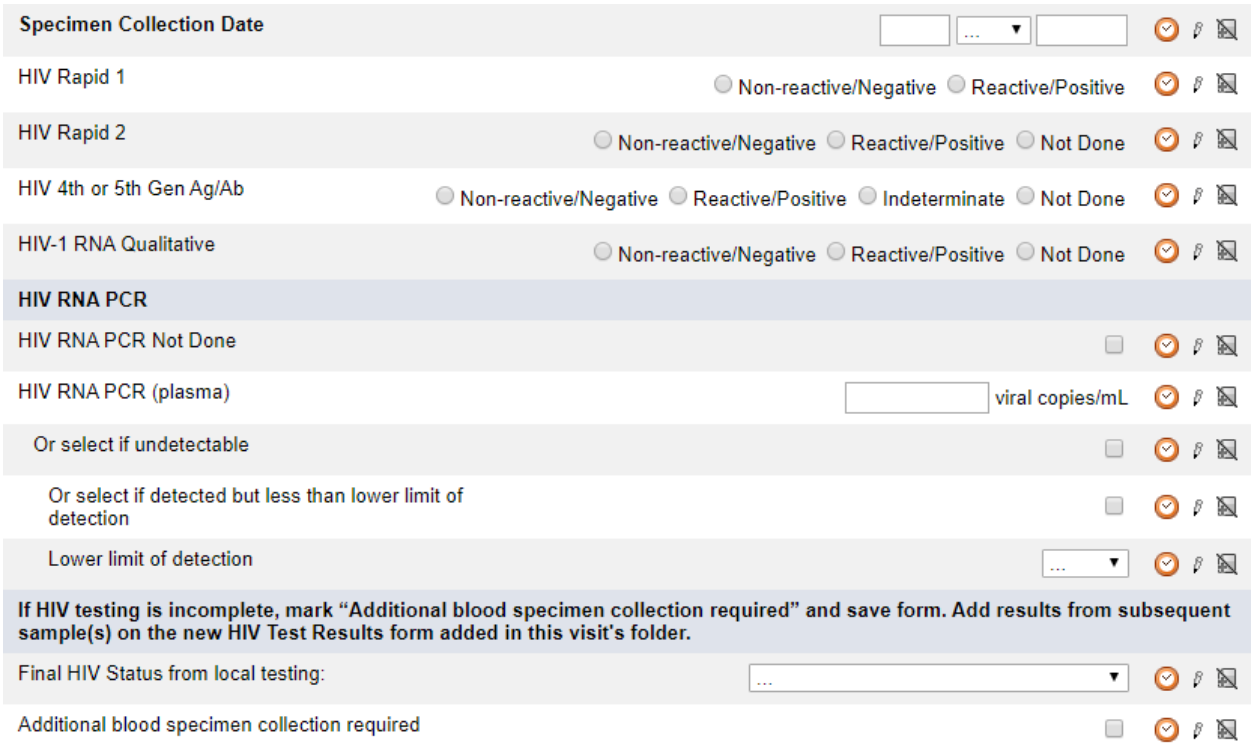
Purpose:
This form is used to document hepatitis test results and confirmatory results from local lab confirmatory testing.

General Instructions:
This form is completed at protocol-specified visits and as clinically indicated at any other visits.

Item-specific Instructions:

Field	Instructions
Anti-Hepatitis C Antibody (anti-HCV):	• Select “Negative”, “Positive”, or “Not Done”
Hepatitis B Surface Antibody (HBsAb):	• Select “Negative”, “Positive”, or “Not Done”
Hepatitis B Core Antibody (HBCoreAb):	• Select “Negative”, “Positive”, or “Not Done”

HIV TEST RESULTS



Purpose:
This form is used to document HIV test results from local lab testing and results provided by the Lab Center used to confirm HIV infection.

General Instructions:
Complete this form at protocol-specified visits and as clinically indicated during follow-up. Record HIV specimen test results on this form as they become available from the local lab.

Item-specific Instructions:

Field	Instructions
Specimen Collection Date	• Enter the date the specimen was collected • A complete date is required
HIV Rapid 1	• An HIV Rapid test is required each time HIV testing is performed. • Select "Non-reactive/Negative" or "Reactive/Positive" as appropriate.

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HPTN 083 CRF Completion Guidelines Version 8.1
20MAR2024

Field	Instructions
HIV Rapid 2	• Select “Non-reactive/Negative”, “Reactive/Positive”, or “Not Done”
HIV 4th or 5th Gen Ag/Ab	• A 4th/5th Gen Combo Antibody and Antigen, EIA/CMIA is required each time HIV testing is performed. • Select “Non-reactive/Negative”, “Reactive/Positive”, “Indeterminate”, or “Not Done”
HIV-1 RNA Qualitative	• Select “Non-reactive/Negative”, “Reactive/Positive”, or “Not Done”
HIV RNA PCR	
HIV RNA PCR Not Done	• Mark checkbox if HIV RNA PCR was not performed • If checked, other fields describing HIV RNA PCR test results should be blank
HIV RNA PCR (plasma)	• Enter the HIV RNA PCR (plasma) result from the source documents in units of viral copies/mL
Or select if undetectable	• Select if RNA PCR test was done but no viral copies were detected; otherwise leave blank.
Or select if detected but less than lower limit of detection	• Select if RNA PCR test was done but result was below the lower limit of detection for the test; otherwise leave blank • If selected, enter lower limit of detection in subsequent field
Lower limit of detection	• Select the lower limit of detection for the test in the drop down list

Field	Instructions
Final HIV Status from local testing:	• Select final HIV Status from local testing • If any Reactive or Positive result is recorded but infection is not yet confirmed, 'Additional HIV Test Results" should be marked as final status. Either an additional HIV Test form should be added to this folder, or confirmatory results should appear in a later visit folder. ○ Exception: If HIV ½ Discriminatory Assay or DNA results were used to confirm HIV infection, mark "Positive" as the final result on this form and complete the Supplemental HIV Results form.
Additional blood specimen collection required	• Check if an additional blood specimen collection is required

If HIV testing is incomplete, mark "Additional blood specimen collection required" and save form. Add results

from subsequent sample(s) on the new HIV Test Results form added in this visit's folder.

INCLUSION / EXCLUSION

Date the participant marked or signed the study Screening and Enrollment consent form.	...
Did participant complete all screening for inclusion and exclusion criteria?	Yes No
The following are inclusion criteria. Any box checked "No" disqualifies the person from enrollment.	
MSM or TGW	Yes No
Male at birth	Yes No
18 years or older at time of screening	Yes No
Willing to provide informed consent for the study	Yes No
At high risk for sexually acquiring HIV infection based on self-report of at least one of the following. **Mark all that apply.**	Yes No
Any condomless receptive anal intercourse in 6 months prior to enrollment (condomless anal intercourse within a monogamous HIV seronegative concordant relationship does not meet this criterion)	
More than five partners in 6 months prior to Enrollment	
Any stimulant drug use in 6 months prior to Enrollment	
Rectal or urethral gonorrhea or chlamydia or incident syphilis in 6 months prior to Enrollment	
SexPro score of ≤ 16 (US sites only)	
Non-reactive / negative HIV test results.	Yes No
Hemoglobin > 11 g/dL	Yes No
Absolute neutrophil count > 750 cells/mm3	Yes No
Platelet count ≥ 100,000/mm3	Yes No

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HPTN 083 CRF Completion Guidelines Version 8.1
20MAR2024

Calculated creatinine clearance ≥ 60 mL/minute using the Cockcroft-Gault equation	Yes	No		
Alanine aminotransferase (ALT) < 2 times the upper limit of normal (ULN)	Yes	No		
Total bilirubin < 2.5 times ULN	Yes	No		
Hepatitis B virus (HBV) surface antigen (HBsAg) negative	Yes	No		
HCV Ab negative	Yes	No		
No Grade 3 or higher laboratory abnormalities obtained at screening, including tests obtained as part of a panel of tests ordered to obtain the protocol-required laboratory test results.	Yes	No		
No medical condition that, in the opinion of the study investigator, would interfere with the conduct of the study	Yes	No		
Willing to undergo all required study procedures	Yes	No		
The following are exclusion criteria. Any box checked "Yes" disqualifies the person from enrollment.				
One or more reactive or positive HIV test result at Screening	Yes	No		
A reactive/positive rapid HIV test at Enrollment	Yes	No		
Active or recent use of any illicit intravenous drugs	Yes	No		
Co-enrollment in any other interventional research study or other concurrent studies that may interfere with this study	Yes	No		
Past or current participation in HIV vaccine trial	Yes	No		
Clinically significant cardiovascular disease	Yes	No		
QTc interval (B or F) > 500 msec	Yes	No		
Inflammatory skin conditions that compromise the safety of IM injections	Yes	No		

Has a tattoo or other dermatological condition overlying the buttock region which may interfere with interpretation of injection site reactions	Yes No
Current or chronic history of liver disease or known hepatic or biliary abnormalities	Yes No
Coagulopathy which would contraindicate IM injection	Yes No
Active or planned use of prohibited medications	Yes No
Known or suspected allergy to study product components (active or placebo), including egg or soy products	Yes No
Surgically-placed or injected buttock implants or fillers, per self-report	Yes No
Alcohol or substance use that would jeopardize the safety of the participant on study	Yes No
History of seizure disorder	Yes No

Purpose:
This form is used to confirm participant eligibility prior to randomization. NOTE: The form was introduced into the study on 15 June 2018 and is only required for participants screened on or after that date.

Once this form is saved the Enrollment folder will appear in the participant's casebook.

General Information/Instructions:
Complete this form at screening prior to randomizing and enrolling the participant.

Item-specific Instructions

Field	Instructions
Date the participant marked or signed the study Screening and Enrollment consent form.	• Enter the date the consent was signed • A complete date is required
Did participant complete all screening for inclusion and exclusion criteria?	• Select either "Yes" or "No" • If "Yes" is selected, then all inclusion and exclusion items must have a response • If "No" is selected, then enter responses only for those criteria assessed
Inclusion Criteria	• Mark appropriate response for each criterion
Exclusion Criteria	• Mark appropriate response for each criterion

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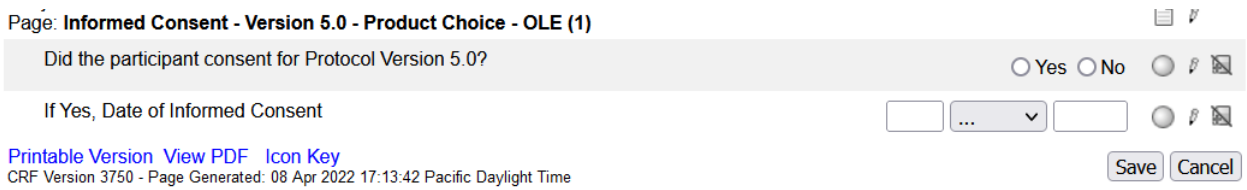
HPTN 083 CRF Completion Guidelines Version 8.1
20MAR2024

Field	Instructions

INFORMED CONSENT – VERSION 5.0



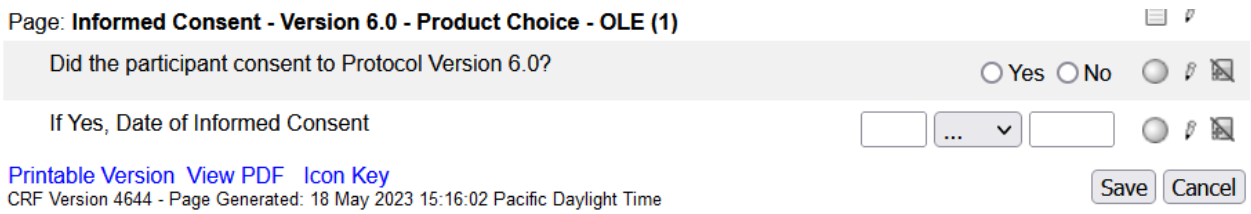
Purpose:
This form is used to document whether participant consented to study protocol v5.0.

General Instructions:
Complete this form at the next visit after your site received v5.0 approval.

Item-specific Instructions:

Field	Instructions
Did the participant consent for Protocol Version 5.0?	• Select either "Yes" or "No" • "Yes" should only be selected if participant consented to Step 6 visits. Otherwise, enter "No". • If "Yes" is selected, then enter Date of Informed Consent in the next response • If "No" is selected, then end of form
If Yes, Date of Informed Consent	• Enter the date version 5.0 consent was signed • A complete date is required

INFORMED CONSENT – VERSION 6.0



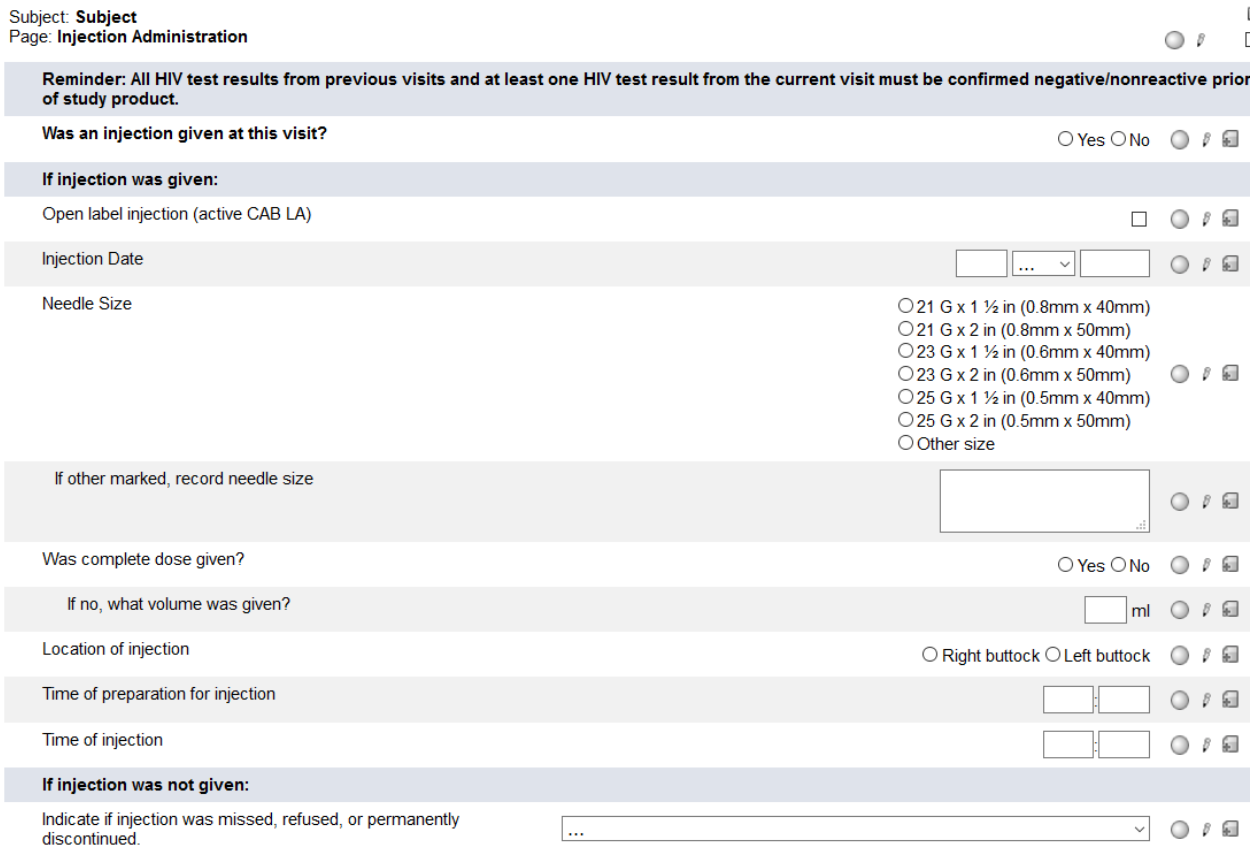
Purpose:
This form is used to document whether participant consented to study protocol v5.0.

General Instructions:
Complete this form at the next visit after your site received v5.0 approval.

Item-specific Instructions:

Field	Instructions
Did the participant consent for Protocol Version 6.0?	• Select either "Yes" or "No" • "Yes" should only be selected if participant consented to Step 7 visits. Otherwise, enter "No". • If "Yes" is selected, then enter Date of Informed Consent in the next response • If "No" is selected, then end of form
If Yes, Date of Informed Consent	• Enter the date version 6.0 consent was signed • A complete date is required

INJECTION ADMINISTRATION


Subject: **Subject**
Page: **Injection Administration**

Reminder: All HIV test results from previous visits and at least one HIV test result from the current visit must be confirmed negative/nonreactive prior of study product.

Was an injection given at this visit? ○ Yes ○ No

If injection was given:

Open label injection (active CAB LA) ☐

Injection Date ... ...

Needle Size
○ 21 G x 1 ½ in (0.8mm x 40mm)
○ 21 G x 2 in (0.8mm x 50mm)
○ 23 G x 1 ½ in (0.6mm x 40mm)
○ 23 G x 2 in (0.6mm x 50mm)
○ 25 G x 1 ½ in (0.5mm x 40mm)
○ 25 G x 2 in (0.5mm x 50mm)
○ Other size

If other marked, record needle size

Was complete dose given? ○ Yes ○ No

If no, what volume was given? ml

Location of injection ○ Right buttock ○ Left buttock

Time of preparation for injection : :

Time of injection : :

If injection was not given:

Indicate if injection was missed, refused, or permanently discontinued. ...

Purpose:
This form is used to summarize information regarding the injection administration at that visit.

General Information/Instructions:
Complete this form at protocol-specified visits after HIV testing has been completed.

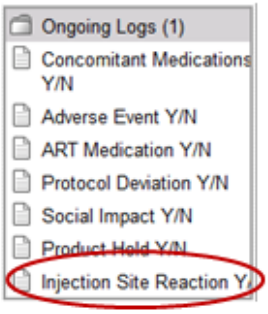
Item-specific Instructions

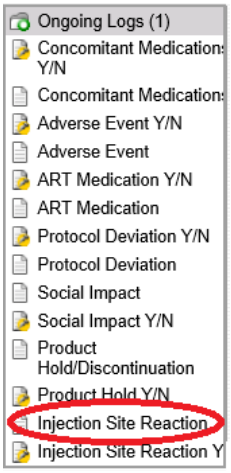
Field	Instructions
Was an injection given at this visit?	• Select either “Yes” or “No”
If injection was given	

Field	Instructions
Open label injection (active CAB LA)	• Mark this box if this injection is for an unblinded CAB participant • Mark this box at all OLE visits
Injection Date	• Enter the date the injection was received • A complete date is required
Needle Size	• Select the appropriate needle size
If other marked, record needle size	• Complete this item if “other size” is marked in the Needle Size item; otherwise leave blank.
Was complete dose given?	• Select either “Yes” or “No” • If “No” is selected, then enter the volume of study drug administered below.
If no, what volume was given?	• If complete dose was given, field should be blank • Enter volume of study drug administered in mL
Location of injection	• Select either “Right buttock” or “Left buttock”
Time of preparation for injection	• Enter a time using a 24-hour clock • Time of preparation must precede the time of injection
Time of injection	• Enter a time using a 24-hour clock

Field	Instructions
If injection was not given:	
Indicate if injection was missed, refused, or permanently discontinued.	• Select either “Injection missed”, “Injection refused”, or “Injection schedule permanently discontinued”

INJECTION SITE REACTION Y/N





Purpose:
This form documents whether any injection site reactions (ISRs) were experienced by the participant during the study due to study drug injections and is used to add the Injection Site Reaction form into the Ongoing Logs folder.

General Instructions:
This form is located within the "Ongoing Logs" folder and is completed only once, at the time the first ISR is reported.

Item-specific Instructions:

Field	Instructions
Has the participant experienced any injection site reactions?	• Select "Yes" or "No" • If "Yes" is selected, the Injection Site Reaction log form appears in the Ongoing Logs folder and can then be completed.

INJECTION SITE REACTION

Date reported to site	...
Event diagnosis	...
Injection site side	Left Right
Onset Date	...
At which visit was this reaction first reported?	...
Interim visit code, if applicable:	
Is the reaction still ongoing?	Yes No
Outcome Date	...
Severity Grade	...
Action Taken with Study Product	...
Other action(s) taken	
None	
Medication	
Therapeutic procedure/surgery	
Diagnostic procedure	
Other	
Other, specify	
Status/Outcome	...
Is this a Serious Adverse Event according to ICH/GCP or protocol guidelines? **If "No", go to following question.**	Yes No
If "Yes", check all that apply.	
Results in death	
Is life-threatening	
Requires inpatient hospitalization or prolongation of existing hospitalization	
Results in persistent or significant disability/incapacity	
Is a congenital anomaly/birth defect	
Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above	
Has or will this reaction be reported as an EAE?	Yes No
If yes, EAE number	

Purpose:
This form is used to document any injection site reactions to study injections either reported by the participant or observed during the clinic visit.

General Information/Instructions:

Injection Site Reactions should only be reported on the ISR form and not on the Adverse Event form - unless the reaction event is not found in the dropdown list of diagnoses. In that case, the reaction should be entered on an AE form.

For every subsequent ISR reported, add a new ISR log line by selecting the “Add a new log line” at the bottom of the form.

Item-specific Instructions

Field	Instructions
Date reported to site	• Enter the date the site first became aware of the reaction. • A complete date is required.
Event diagnosis	• Select from the dropdown list the type of injection site reaction that occurred
Injection site side	• Select “Left” or “Right” for the side on which the injection was given
Onset date	• Record the date participant first experienced the reaction • At minimum, a month and year are required • Date must be on or after the date of study drug injection
At which visit was this reaction first reported?	• Select visit the site first became aware of the ISR from the dropdown list • If interim visit, mark ‘interim visit’ and record the visit code in the next field.

Field	Instructions
Interim visit code, if applicable	• Enter interim visit code in space provided, if applicable.
Is the reaction still ongoing?	• Select “Yes” if the ISR is continuing at the time it is first reported • If “Yes”, leave Outcome Date blank.
Outcome Date	• Enter the date on which the participant no longer experienced the reaction • At minimum, a month and year are required • Date must be on or after the onset date

Severity Grade	• Record the severity grade using the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events* (including relevant appendices/addendums)
	  ○ Grade 1 (Mild)
	  ○ Grade 2 (Moderate)
	  ○ Grade 3 (Severe)
	  ○ Grade 4 (Potentially life-threatening)
	  ○ Grade 5 (Death)

Action Taken with Study Product	• Select “dose not changed” if there is no change to the participant’s planned use (dose, frequency, schedule) of study product as a result of the ISR. • “Dose reduced” and “dose increased” do not apply and should not be selected in HPTN 083. • Select “drug withdrawn” if the ISR results in permanent discontinuation of study product. • Select “drug interrupted” if ISR results in a clinician-initiated product hold. • For multiple ISRs, mark “drug withdrawn” or “drug interrupted” for each ISR contributing to the permanent or temporary discontinuation. Ensure the Product Hold Y/N and Product Hold/Discontinuation forms are completed. • Select “not applicable” if the ISR’s onset date is on or after the date the participant permanently discontinues study product use.

Field	Instructions
Other action(s) taken:	• Select “None” or check all that apply. • Select “Medication” only if participant reports taking medication for the reported reaction. Report medication(s) on the Concomitant Medications log • Select “Therapeutic procedure/surgery” only if participant reports a procedure or surgery. • Select “Diagnostic procedure” only if a diagnostic procedure is reported. • If “Other”, then specify relevant details in the “Other, specify” text field provided.
Status/Outcome	• Select “recovered/resolved” if reaction is no longer present, has returned to baseline severity/frequency, or has increased in severity/frequency. Note that if a participant started taking medication once enrolled to control a reaction, the reaction is not considered resolved while the medication is still indicated. • Select “recovering/resolving” if reaction is continuing and has not yet resolved or returned to baseline severity/frequency. • Select “resolved with sequelae” if participant has recovered from the reaction, but with remaining effects or impairment. These remaining effects can be temporary but are still present at the time of the report. • Select “not recovered/resolved” whenever a reaction is continuing at the time of participant termination from the study. • Select “fatal” only if the severity grade of this reaction is Grade 5. Any other AEs or reactions continuing at the time of death should be recorded as “not recovered/resolved”.
Is this a Serious Adverse Event according to ICH/GCP or protocol guidelines?	• Select “Yes” or “No” • If “Yes” is selected mark at least one item from the list.

Field	Instructions
Has or will this reaction be reported as an EAE?	• Select “Yes” or “No” • For questions about ICH guidelines and EAE reporting, refer to current *Manual for Expedited Reporting of Adverse Events to DAIDS.* • If reported as an EAE (indicated as “yes”), provide the EAE number and complete any subsequent updates to this form on the applicable EAE form.
If yes, EAE number	• Enter EAE number in field provided

INTERIM VISIT SUMMARY

Subject: **Subject**
Page: **Interim Visit Summary**

Visit date

Interim visit code

How many bottles of TDF/FTC (real or placebo) were dispensed at this visit?

How many bottles were lost, stolen, or damaged since the last pill dispensation?

Did the participant exit/terminate the study at this visit? ○ Yes ○ No

Is participant moving to infected visit schedule? ○ Yes ○ No

Is the participant ready to move to Step 3? ○ Yes ○ No

Is the participant moving to yearly visits? ○ Yes ○ No

Complete only if participant is discontinuing Step 1 before Week 5 visit:

Record the date and time of the participant's last dose of Step 1 oral study products.

Is the participant moving to Step 2? ○ Yes ○ No

Mark any forms or procedures completed at this visit.

CD4/viral load ○ Yes

Hematology ○ Yes

Hepatitis Test Results ○ Yes

HIV Test ○ Yes

Electrocardiogram ○ Yes

Local Laboratory Results ○ Yes

Participant Receipt ○ Yes

Participant Transfer ○ Yes

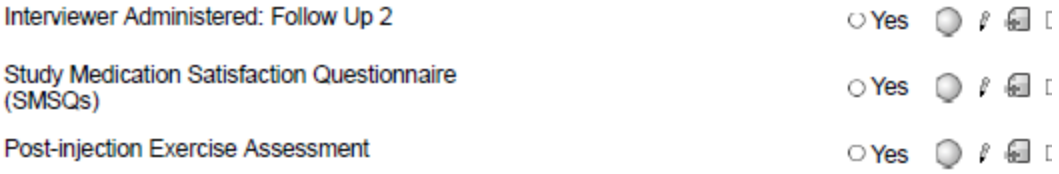
Sexually Transmitted Infections ○ Yes

Specimen Storage ○ Yes

Log Form ○ Yes

Supplemental HIV Results ○ Yes

Interviewer Administered: Follow Up 1 ○ Yes

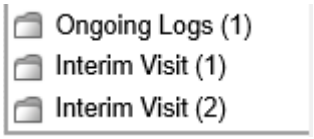


Purpose:
This form is used to summarize information collected at an interim visit and to record all procedures or assessments the participant received at the interim visit (e.g., confirmatory HIV Test Results).

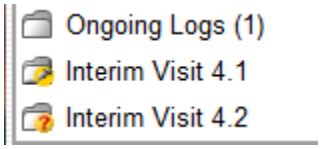
General Information/Instructions:
Complete this form for each interim visit in which new data was collected for a participant. If no data is collected pertaining to HPTN 083 during the interim visit, this form does not need to be entered.

To add an interim visit, select “Interim Visit” from the participant’s homepage using the “Add Event” dropdown.

Interim Visits will generate in numerical order and appear below the Ongoing Logs folder.



Once the Interim Visit Summary form is completed the actual visit code will appear in the list of folders:



Field	Instructions
Visit Date	• A complete date is required.
Interim visit code	• Enter the applicable interim visit code. Note that the code is based on the previous regular visit, not the week. • Refer to the Data Collection SSP for more information on interim visit codes
How many bottles of TDF/FTC (real or placebo) were dispensed at this visit?	• Select the number of bottles from the dropdown list
How many bottles were lost, stolen, or damaged since the last pill dispensation?	• Select the number of bottles from the dropdown list
Did the participant exit/terminate the study at this visit?	• Select “Yes” or “No” • If “Yes”, a Termination form will be added to the visit folder and must be submitted
Is participant moving to the infected visit schedule?	• Select “Yes” or “No” • If “Yes”, the remaining Step 2 visit folders are removed from the participant’s casebook.
Is the participant ready to move to Step 3?	• Select “Yes” or “No” • If “Yes”, any Step 3 Day 0 forms not already present in the folder must be added • If “Yes”, the remaining Step 2 visit folders are removed from the participant’s casebook.

Is the participant moving to yearly visits?	• Select “Yes” or “No” • Only select “Yes” If participant is in Step 1 and has not had a Week 5 injection OR the participant has completed all Step 3 visits. • If “Yes” is selected during Step 1, the Step 2 and Step 3 visit folders are removed from the participant’s casebook.
Record the date and time of the participant’s last dose of Step 1 oral study products.	• Record a response to this question only once, prior to the Week 5 visit • Record the date and time of the participant’s last dose of Step 1 oral study products using a 24-hour clock • If time is not known enter “00:00”
Is the participant moving to Step 2?	• Mark an answer to this question only once, prior to the Week 5 visit • Select “Yes” or “No” • If “No” is selected the remaining Step 2 visit folders are removed from the participant’s casebook.
Mark any forms or procedures completed at this visit	• *Check all additional forms to be completed at this visit* • *Marking one or more forms from the list and saving the Interim Visit form will add those specific forms to the interim visit folder.*

INTERIM VISIT - OLE

Subject: **Subject**
Page: **Interim Visit - OLE**

Visit date	...
Interim visit code	
How many bottles of study drug (TDF/FTC or oral CAB) were dispensed at this visit?	...
Did the participant exit/terminate the study at this visit?	Yes No
Is the participant moving to a new step or visit schedule?	Yes No
If Yes, please indicate which Step or visit schedule?	...
Mark any forms or procedures completed at this visit.	
CD4/Viral Load Results	Yes
Hematology	Yes
Hepatitis Test Results	Yes
HIV Test Results	Yes
Local Laboratory Results	Yes
Participant Receipt	Yes
Participant Transfer	Yes
Sexually Transmitted Infections	Yes
Specimen Storage	Yes
Log Form	Yes
Supplemental HIV Results	Yes

Purpose:
This form is used to summarize information collected at an interim visit done **during the open-label extension (OLE) only**, and to record all procedures or assessments the participant received at the interim visit (e.g., confirmatory HIV Test Results).

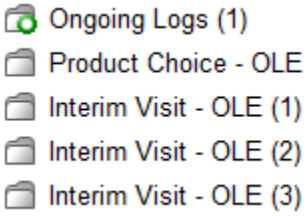
General Information/Instructions:

CONFIDENTIAL DOCUMENT
HPTN 083 CRF Completion Guidelines Version 8.1
20MAR2024

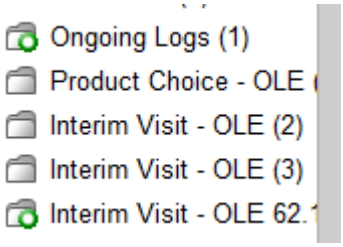
Complete this form for each interim visit in which new data was collected for a participant. If no data is collected pertaining to HPTN 083 during the interim visit, this form does not need to be entered.

To add an interim visit, select “Interim Visit - OLE” from the participant’s homepage using the “Add Event” dropdown.

Interim Visits will generate in numerical order and appear below the Ongoing Logs folder.



Once the Interim Visit Summary form is completed the actual visit code will appear in the list of folders:



Field	Instructions
Visit Date	• A complete date is required.
Interim visit code	• Enter the applicable interim visit code. Note that the code is based on the previous regular visit, not the week. • Refer to the Data Collection SSP for more information on interim visit codes
How many bottles of TDF/FTC (real or placebo) were dispensed at this visit?	• Select the number of bottles from the dropdown list • This question is required at all OLE steps and visits. If no bottles were dispensed, select '0'.
Did the participant exit/terminate the study at this visit?	• Select "Yes" or "No" • If "Yes", a Termination form will be added to the visit folder and must be submitted
Is participant moving to a new step or visit schedule?	• Select "Yes" or "No" • If "Yes", the next question is required • If "No", skip the next question
If Yes, please indicate which Step or visit schedule?	• Select one of the following: Oral CAB (Step 4a), Loading Dose CAB (Step 4b), TDF/FTC (Step 5), Seroconverter Schedule
Mark any forms or procedures completed at this visit	• *Check all additional forms to be completed at this visit* • *Marking one or more forms from the list and saving the Interim Visit form will add those specific forms to the interim visit folder.*

INTERVIEWER ADMINISTERED BASELINE

Purpose:
This form is used to document participant socialization, beliefs, and behaviors at baseline.

General Information/Instructions:
Interview is to be conducted during V2.0 – Day 0/Enrollment

- All interviews are to be conducted according to GCP and protocol guidelines
- Read instructions and each question to the participant, then list possible answer choices
- Record the participant's responses in the fields provided
- If the participant does not wish to answer or does not know, mark "prefer not to answer" when available or leave field blank and respond to system auto-query with "Unknown" or "Does not wish to answer".

INTERVIEWER ADMINISTERED FOLLOW UP 1

Purpose:
This form is used to document participant socialization, beliefs, and behaviors during follow-up visits throughout the course of the study.

General Information/Instructions:

- All interviews are to be conducted according to GCP and protocol guidelines
- Read instructions and each question to the participant, then list possible answer choices
- Record the participant's responses in the fields provided
- If the participant does not wish to answer or does not know, mark "prefer not to answer" when available or leave field blank and respond to system auto-query with "Unknown" or "Does not wish to answer".

INTERVIEWER ADMINISTERED FOLLOW UP 2

Purpose:
This form is used to document participant feelings, social support, and feelings about PrEP use during follow-up visits throughout the course of the study.

General Information/Instructions:

- All interviews are to be conducted according to GCP and protocol guidelines
- Read instructions and each question to the participant, then list possible answer choices
- Record the participant's responses in the fields provided
- If the participant does not wish to answer or does not know, mark "prefer not to answer" when available or leave field blank and respond to system auto-query with "Unknown" or "Does not wish to answer".

INTERVIEWER ADMINISTERED: OLE

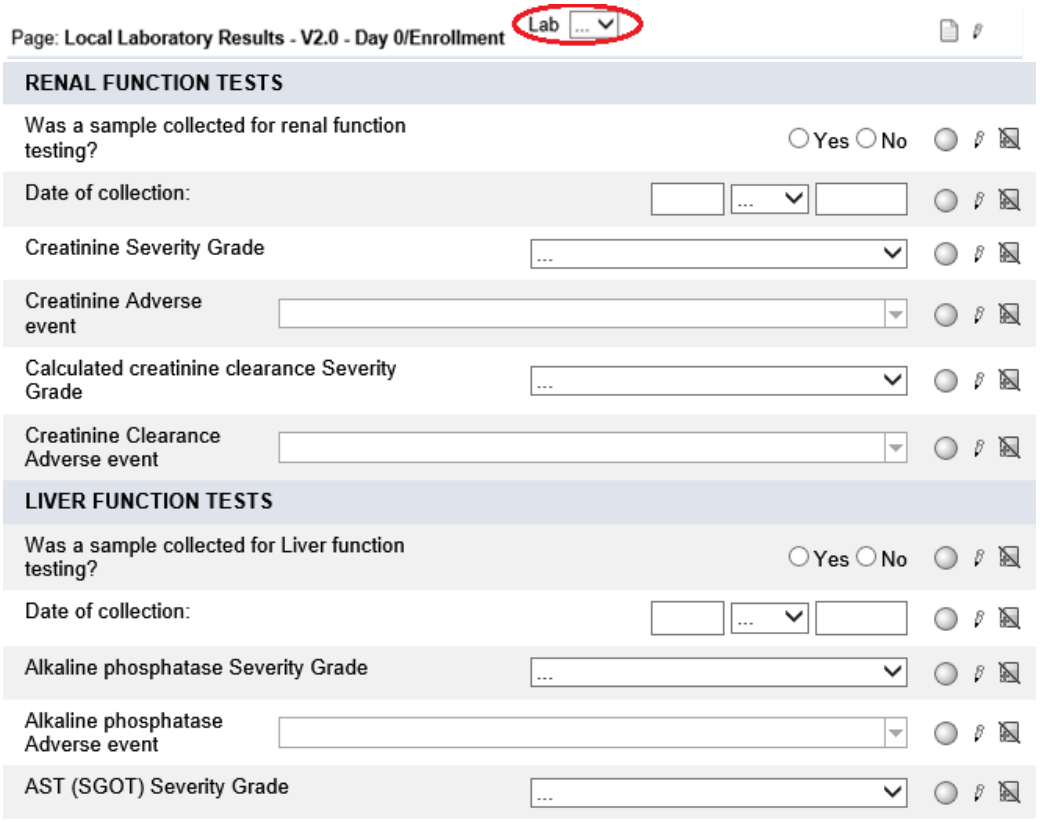
Purpose:

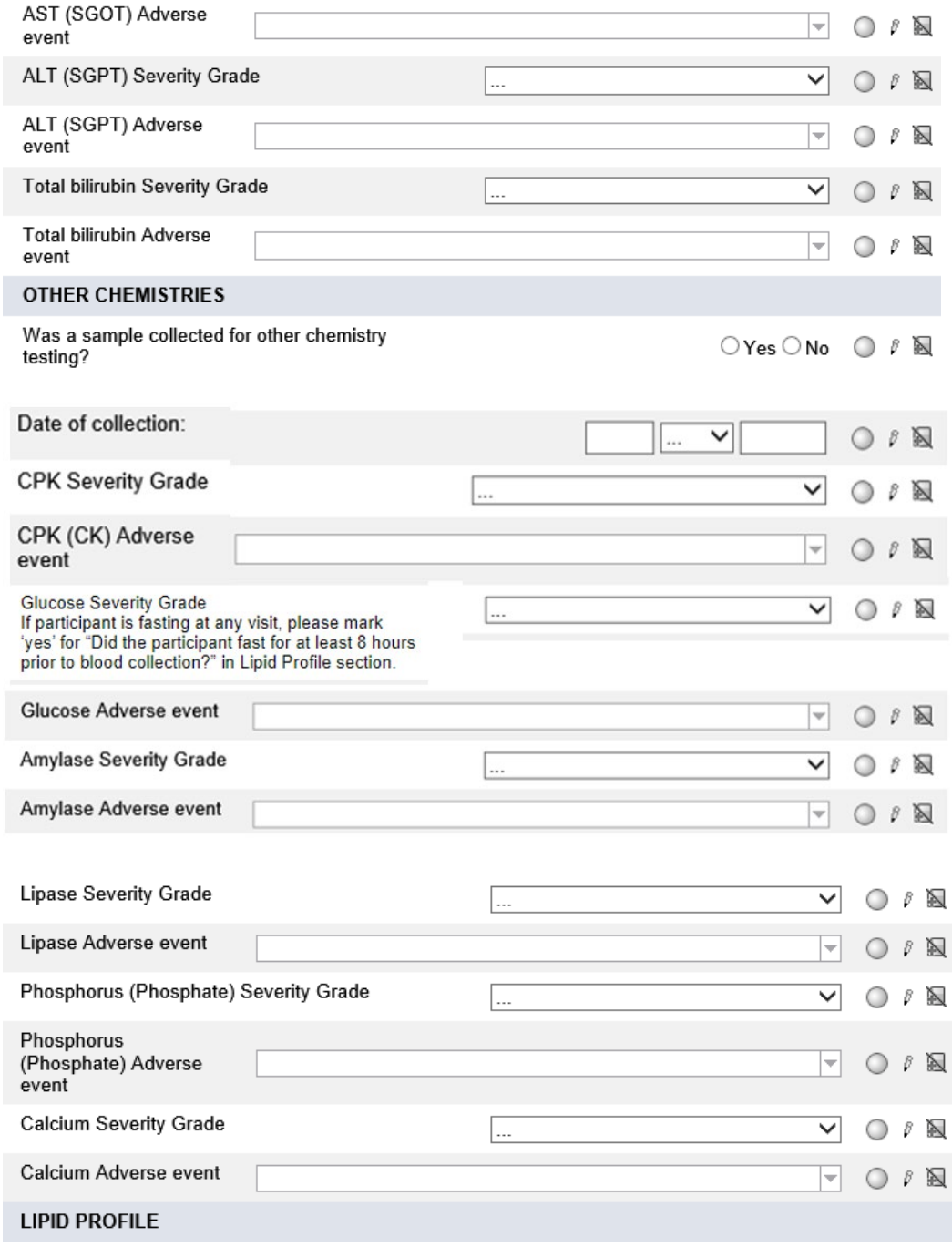
This form is used to document participant's choices and feelings about using PrEP during follow-ups visits throughout the course of the **OLE** part of the study.

General Instructions:

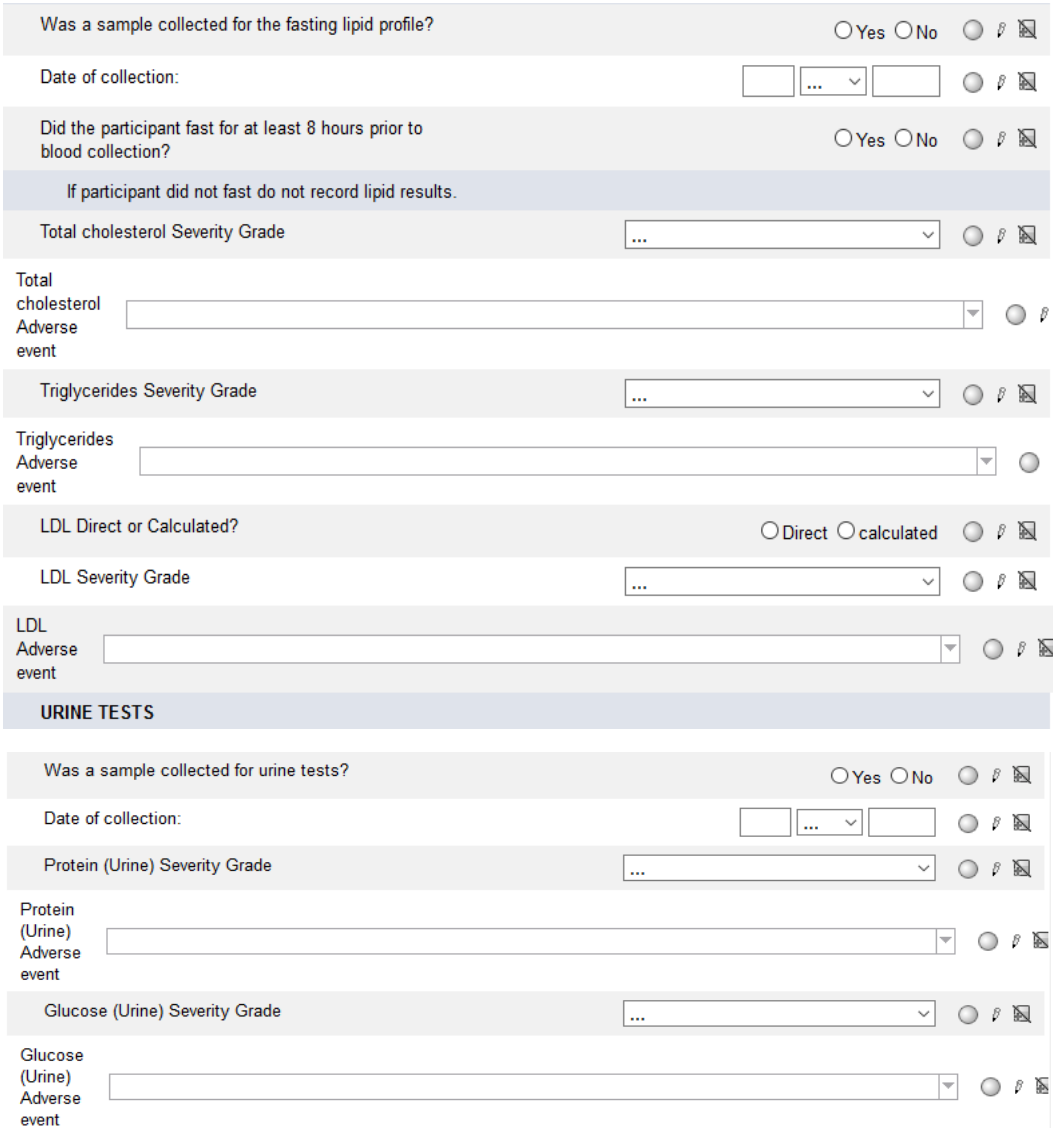
- All interviews are to be conducted according to GCP and protocol guidelines
- Read instructions and each question to the participant, then list possible answer choices
- Record the participant's responses in the fields provided
- When survey is administered ALL questions need to be answered. If the participant does not wish to answer, mark "prefer not to answer". When a question is not applicable, select "NA".
- If the entire survey is not done mark the box "**Survey not done**" on the top of the form.

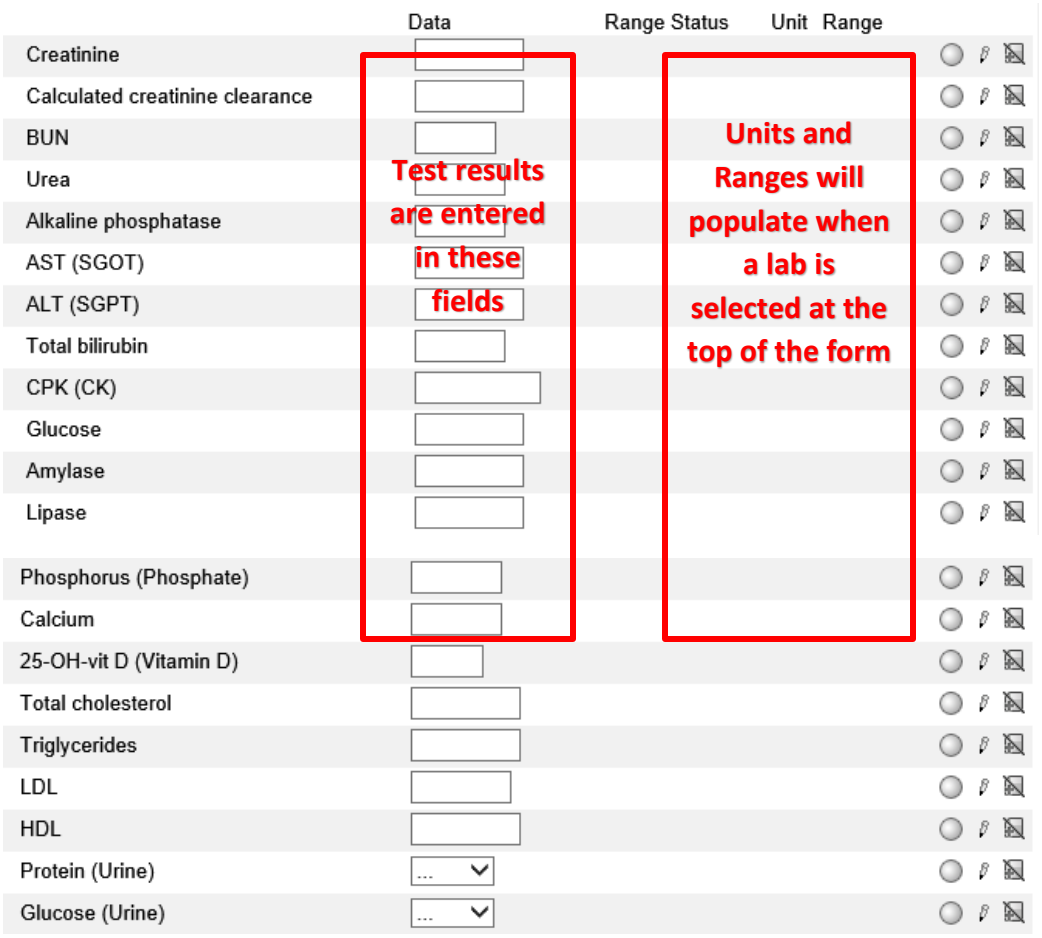
LOCAL LABORATORY RESULTS





CONFIDENTIAL DOCUMENT
HPTN 083 CRF Completion Guidelines Version 8.1
20MAR2024





Purpose:
This form is used to document the participant's local lab test results.

General Information/Instructions:
Use this form to report test results obtained from specimens collected for this visit.

Local Lab reference ranges should automatically appear on lab forms; if that is not the case please contact SCHARP to correct this.

Some lab results are graded based on change from baseline. Note that 'baseline' means tests done at the enrollment visit, not the screening visit.

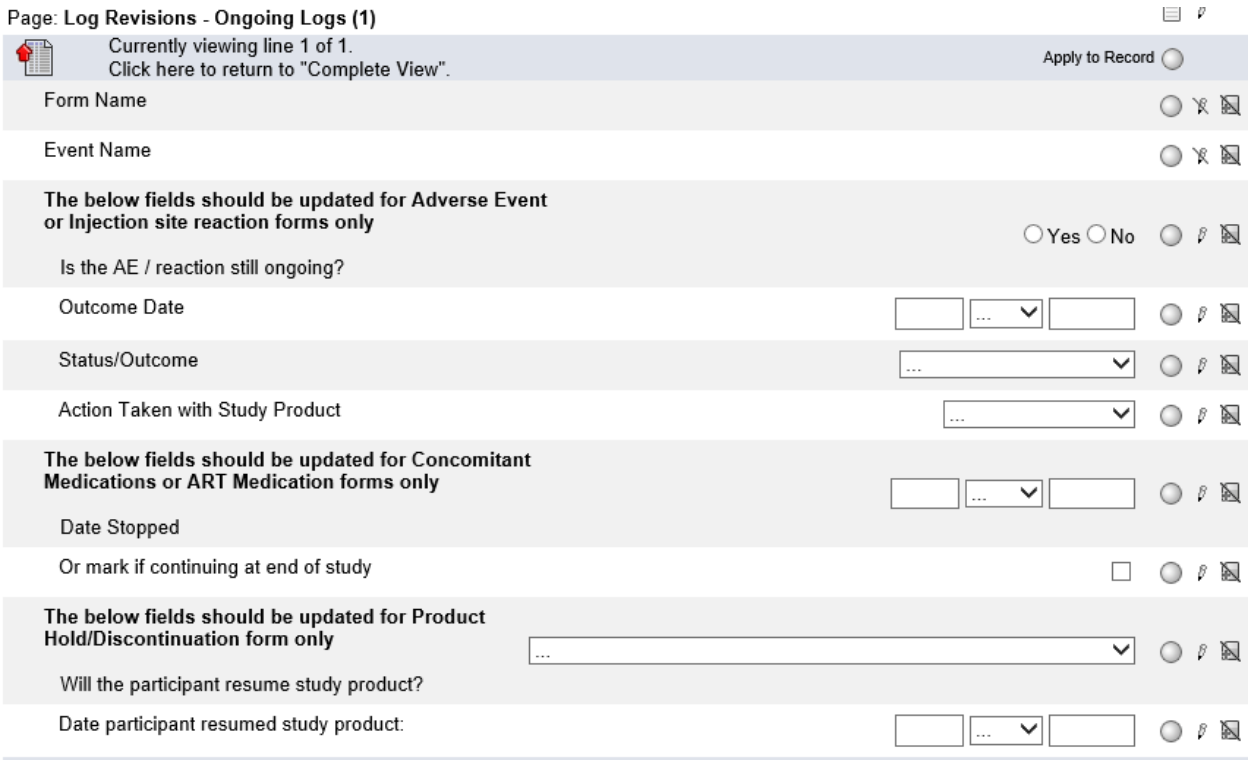
If participant fasted at a non-fasting visit, mark 'yes' to "Did the participant fast for at least 8 hours prior to blood collection" in the Lipid Profile section.

Item-specific Instructions:

Field	Data
Test Result	• Enter the result of the specified test • To eliminate the need to round a number, each test result field allows up to 5 digits beyond the decimal point • When working with calculated severity grade ranges (e.g., 1.1-1.3 x ULN), the calculated range may have more significant digits than the lab result. Treat all missing digits in the lab value as zeros. • If test was not performed, leave blank • If test is entered, ensure a severity grade for the result is entered, if the severity grade field for that result is present on the form

Field	Instructions
Was a sample collected for testing?	• *Select "Yes" or "No"*
Date of collection	• *Enter the date the specimen was collected* • *A complete date is required*
Test severity grade	• *Select a severity grade (1-4) or "not gradable" from the dropdown list* • *If a severity grade is selected, the test result field must not be blank* • *Only select "Not gradable" if the lab result is normal or not gradable. Do not select if a result is not entered for that lab test*
Test Adverse event	• *If test is linked to a reported AE, select the AE in the dropdown list provided* • *An AE form must be completed before it can be selected on the Local Lab Results form.*

LOG REVISIONS

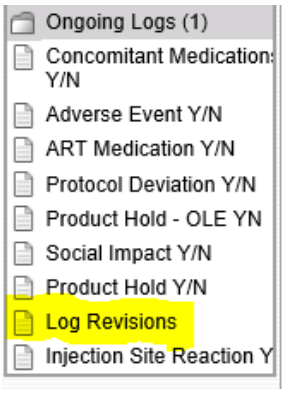


Purpose:

The Log Revision form is used to update Concomitant Medications, Adverse Event, ART Medication, Product Hold/Discontinuation, and Injection Site Reaction logs (Ongoing Logs) that are **ongoing** AND **data entry locked** in Rave.

General Instructions:

The Log Revision form will be pre-populated with Ongoing logs that are both **ongoing** AND **data entry locked** in Rave. To update a qualifying Ongoing log, select the log on the Log Revision form and update.



The below fields should be updated for Adverse Event or Injection site reaction forms only: Use this section of the Log Revision form to update Outcome Date, Status/Outcome and Action Taken with Study Product for AEs and ISRs that are ongoing AND are data entry locked in Rave.

The below fields should be updated for Concomitant Medications or ART Medication forms only: Use this section of the Log Revision form to update "Date Stopped" and "Or mark if continuing at the end of study" for ConMed and ART logs that have "Date Stopped" and "Or mark if continuing at the end of study" blank AND are data entry locked in Rave.

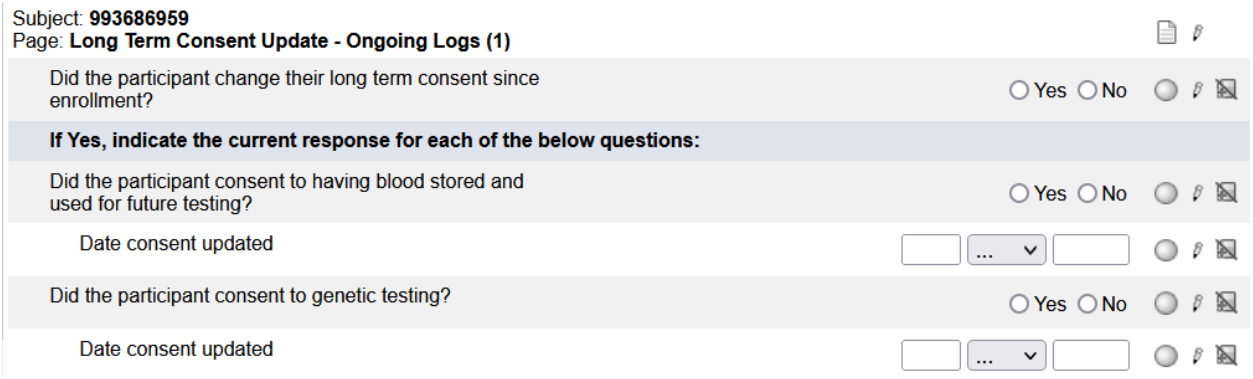
The below fields should be updated for Product Hold/Discontinuation form only:

Use this section of the Log Revision form to update "Will the participant resume study product?" and "Date participant resumed study product:" for Product Hold/Discontinuations that have "Will the participant resume study product?" marked as "Yes" and the "Date resumed" blank AND are data entry locked in Rave.

Field	Instructions
Form Name	• This field is pre-populated. Do not complete.
Event Name	• This field is pre-populated. Do not complete.
Log Line Number	• This field is pre-populated. Do not complete.
Event Term	• This field is pre-populated. Do not complete.

Is the AE / reaction still ongoing?	• Use only to update Adverse Event or Injection Site Reaction log • Select “Yes” or “No”
Outcome Date	• Enter full date in DD-MMM-YYYY format if available • A partial date UN-MM-YYYY is allowed
Status/Outcome	• Refer to Adverse Events or ISR section of CCGs for specific details.
Action Taken with Study Product	• Refer to Adverse Events or ISR section of CCGs for specific details.
Date Stopped	• Use to update Concomitant Medication and ART Medication • Enter full date in DD-MMM-YYYY format if available • A partial date UN-MM-YYYY or UN-UNK-YYYY is allowed
Or mark if continuing at end of study	• Mark box if medication was continuing at the time of study completion
Will the participant resume study product?	• Use to update Product Hold/Discontinuation only • Select “Yes” or “No”
Date participant resumed study product:	• Enter full date in DD-MMM-YYYY format

LONG TERM CONSENT UPDATE



Purpose:

Complete this form if a participant has changed either of their long term consents since enrollment.

General Information/Instructions:
To add this form, select "Long Term Consent Update" from the participant's homepage using the "Add Event" dropdown.

Item-specific Instructions:

Field	Instructions
Did the participant change their long term consent since enrollment?	• Select "Yes" or "No" • If "Yes" is entered, complete both questions below about a change in consent • If "No", end of form
Did the participant consent to having blood stored and used for future testing?	• Select "Yes" or "No" • If "Yes", enter date in next response
Date consent updated	• Enter date that blood storage consent was updated • A complete date is required
Did the participant consent to genetic testing?	• Select "Yes" or "No" • If "Yes", enter date in next response
Date consent updated	• Enter date that genetic testing consent was updated • A complete date is required

CONFIDENTIAL DOCUMENT
HPTN 083 CRF Completion Guidelines Version 8.1
20MAR2024

MISSED VISIT

Purpose:
Complete this form each time an enrolled participant misses a required visit and will not be completing procedures for that visit.

General Information/Instructions:

A missed visit form will be added to a visit folder if the response to “Did the participant complete this visit?” on the Date of Visit form is “No”.

Item-specific Instructions:

Field	Instructions
Target Visit Date	• Record the target date of the visit • A complete date is required
Reason visit was missed	• Select the reason that the participant missed this visit from the dropdown list • If the reason is not included in this list, select “other”, and specify the reason in the “If other, specify” text field provided

PARTICIPANT RECEIPT

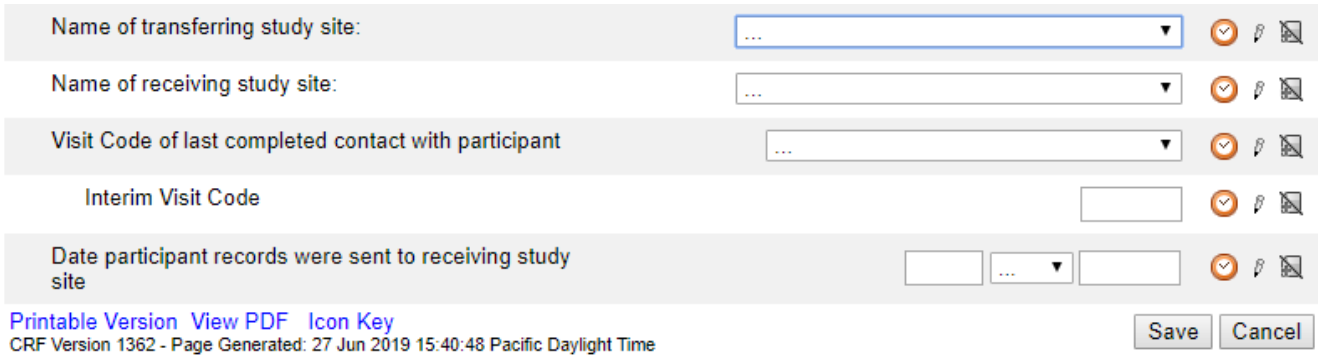
Purpose:
Complete this form when a participant is transferring to another study clinic/site.

General Instructions:
This form is completed by the receiving site. Marking "Participant Receipt" under the Additional Forms section on the Date of Visit or Interim Visit form will add the Receipt form to the visit folder.

Item-specific Instructions:

Field	Instructions
Name of receiving study site:	• Select the applicable site from the dropdown list • Site should match the name of receiving site on the Participant Transfer form
Name of transferring study site:	• Select the applicable site from the dropdown list • Site should match the name of transferring site on the Participant Transfer form
Date informed consent signed at receiving site	• A complete date is required

PARTICIPANT TRANSFER



Purpose:
Complete this form when a participant is transferring to another study clinic/site.

General Instructions:
This form is completed by the transferring site (the site the participant is leaving). Marking "Participant Transfer" under the Additional Forms section on the Date of Visit or Interim Visit form will add the Transfer form to the visit folder.

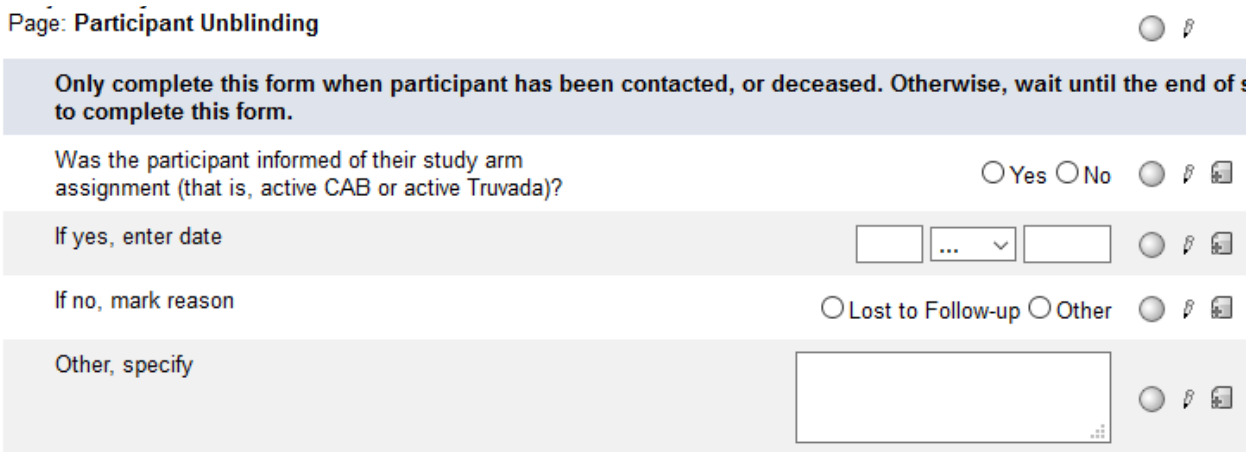
To complete a participant transfer, contact the SCHARP Clinical Data Manager (CDM) to confirm all outstanding queries are resolved.

Item-specific Instructions:

Field	Instructions
Name of transferring study site:	• Select the applicable site from the dropdown list • Site should match the name of transferring site on the Participant Receipt form
Name of receiving study site:	• Select the applicable site from the dropdown list • Site should match the name of receiving site on the Participant Receipt form

Visit Code of last completed contact with participant	• Select the applicable VISIT from the dropdown list • If interim visit, select “Interim Visit Code”
Interim Visit Code	• Enter interim visit code, if applicable
Date participant records were sent to receiving study site	• A complete date is required

PARTICIPANT UNBLINDING



Purpose:
Complete this form when a participant is unblinded after site approval of LOA #3.

General Instructions:
This form is completed at the visit where participant is informed of his study regimen. If this contact happens over the phone or in between regular visits, an interim visit should be completed to document this event.

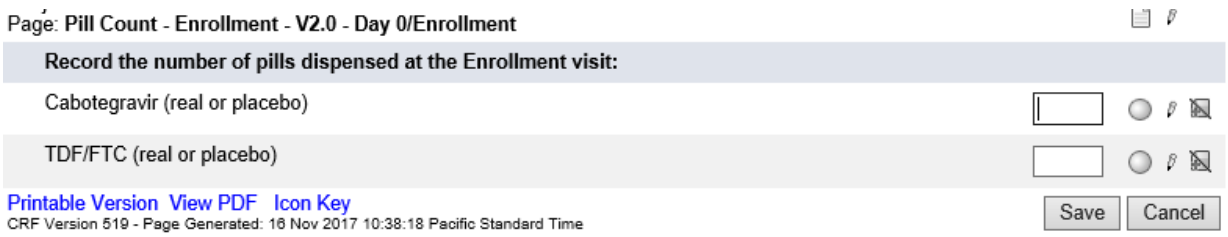
Item-specific Instructions:

Field	Instructions
Was the participant informed of their study arm assignment (that is, active CAB or active Truvada)?	• Enter “Yes” or “No”
If yes, enter date	• If participant has been notified of his study regimen, enter the date of contact. • A complete date is required

CONFIDENTIAL DOCUMENT
HPTN 083 CRF Completion Guidelines Version 8.1
20MAR2024

If no, mark reason	• If participant terminated and has not been informed of his regimen, enter either “Lost to Follow-up” or “Other” • If “Other” is entered, record the reason in “Other, specify” field.

PILL COUNT - ENROLLMENT



Purpose:
This form is used to document the participant's pill dispensation at the enrollment visit.

General Instructions:
Complete this form at Visit 2.0 – Day 0/Enrollment.

Item-specific Instructions:

Field	Instructions
Cabotegravir (real or placebo)	• Enter the number of cabotegravir **(real or placebo)** pills that were dispensed in the field provided
TDF/FTC (real or placebo)	• Enter the number of TDF/FTC **(real or placebo)** pills that were dispensed in the field provided

PILL COUNT – FOLLOW UP

Purpose:
This form is used to document the participant's pill dispensation through week 4.

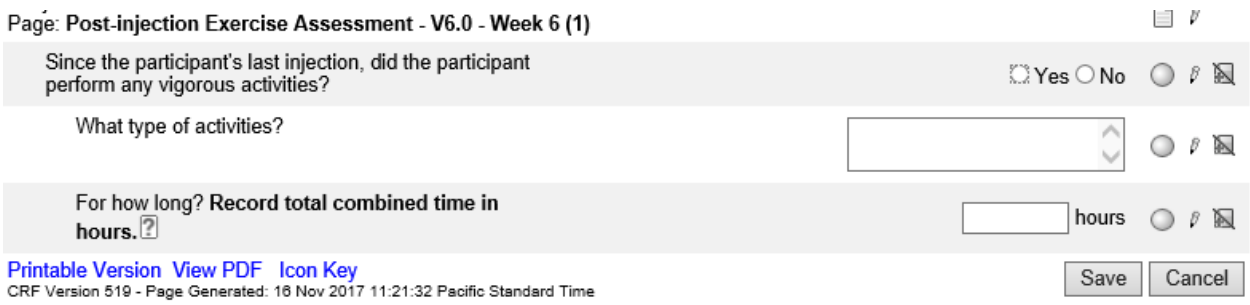
General Instructions:
Complete this form at Visit 3.0 - Week 2 and 4.0 - Week 4.

Item-specific Instructions:

Field	Instructions
Did the participant bring in any pills at this visit? If yes, record the number of pills brought in at this visit.	• Select "Yes" or "No" • If "No" is selected, move to the pill dispensation section below
Date of Pill Count	• A complete date is required

Field	Instructions
Cabotegravir (real or placebo)	• Enter the number of cabotegravir (real or placebo) pills that were returned in the field provided
TDF/FTC (real or placebo)	• Enter the number of TDF/FTC (real or placebo) pills that were returned in the field provided
Was the participant dispensed any additional pills at this visit? If yes, record the number of pills dispensed at this visit.	• Select “Yes” or “No” • Mark “Yes” only if ***new***, complete bottles are dispensed. Do not include pills counted and returned to participant. • If “No” is selected, remaining fields should be blank.
Cabotegravir (real or placebo)	• Enter the number of new cabotegravir (real or placebo) pills dispensed in the field provided • Do not record pills already counted and returned to the participant.
TDF/FTC (real or placebo)	• Enter the number of new TDF/FTC (real or placebo) pills dispensed in the field provided • Do not record pills already counted and returned to the participant.

POST-INJECTION EXERCISE ASSESSMENT



Purpose:
This form is used to document the participant's level of physical activity.

General Information/Instructions:

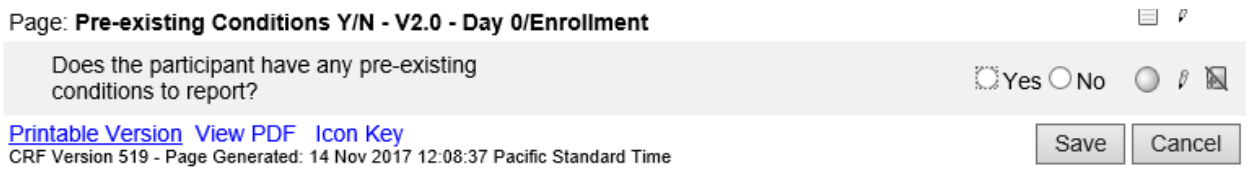
CONFIDENTIAL DOCUMENT
HPTN 083 CRF Completion Guidelines Version 8.1
20MAR2024

This form is required at V6.0 – Week 6 and every other subsequent visit in Step 2 of the study.

Item-specific Instructions:

Field	Instructions
Since the participant's last injection, did the participant perform any vigorous activities?	• Select either “Yes” or “No”
What type of activities?	• Briefly describe activities in text field provided
For how long? Record in total combined time, in hours and minutes.	• Enter the total number of hours and minutes the participant engaged in vigorous activities. • Record partial hours using a decimal.

PRE-EXISTING CONDITIONS Y/N



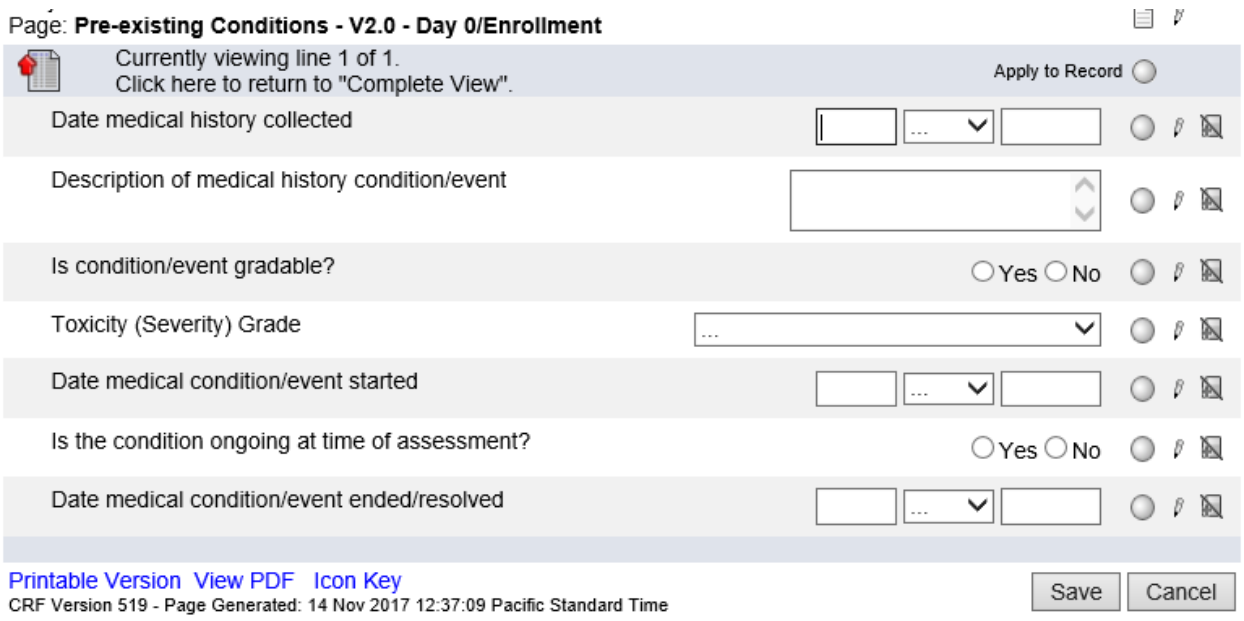
Purpose:
To document whether any pre-existing medical conditions/events were reported at the Screening visit or recalled by the participant during follow-up.

General Instructions:
This form appears in the Visit 2.0/Day 0 visit. Note that this form is not present within the "Ongoing Logs" folder.

Item-specific Instructions:

Field	Instructions
Does the participant have any pre-existing conditions to report?	• Select either "Yes" or "No" • If "Yes" is marked and the form saved, the "Pre-existing Conditions" log form appears in the Enrollment folder and can then be completed.

PRE-EXISTING CONDITIONS



Purpose:
This form is used to document the participant's pre-existing medical conditions, including but not limited to: history of hospitalizations, surgeries, allergies, any condition that required prescription medication, and acute or chronic conditions ongoing at screening and/or that occur between screening and enrollment.

If, during follow-up, a pre-existing condition resolves or increases in severity or frequency from baseline, this must be documented, but not on the Pre-Existing Conditions CRF, which is intended to remain a snapshot of the participant's medical history at enrollment.

This form will appear in the V2.0 – Day 0/Enrollment folder after the "Pre-existing Conditions" prompt has been answered as "Yes". Use the "Add a new Log line" button to add an additional baseline medical history condition/event.

General Instructions:

- Record any relevant medical conditions. This includes conditions and symptoms reported by the participant as well as any conditions identified via physical exam or laboratory testing.
- If needed, record any pre-existing medical conditions identified during follow-up. Write a chart note to explain why the entry was added after the Enrollment Visit.
- Complete a separate entry (e.g. log line) for each pre-existing condition/event when entering into the study database.

Item-specific Instructions:

Field	Instructions
Date medical history collected	• Record the date medical history was collected • A complete date is required
Description of medical history condition/event	• Briefly describe event • Whenever possible, provide a diagnosis instead of listing a cluster of symptoms • If no diagnosis is identified, each symptom must be recorded as a separate log line • If an abnormal lab value is reported at the Enrollment visit, record the lab assay with the direction (i.e., increased or decreased) of the abnormality *ex: "decreased hematocrit" or "increased ALT"* • Additional information on the frequency and duration of chronic condition outbreaks can also be provided within this description
Is condition/event gradable?	• Select "Yes" or "No" • If a condition is not gradable (below Grade 1), select "No"

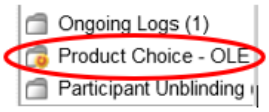
Toxicity (Severity) Grade	• This item is required if "Is condition/event gradable?" is "Yes".
	• If the item improves in severity or resolves during the study, then the Toxicity Grade should remain unchanged on this CRF
	• Record the severity grade using the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events* (including relevant appendices/addendums)
	  ○ Grade 1 (Mild)
	  ○ Grade 2 (Moderate)
	  ○ Grade 3 (Severe)
	  ○ Grade 4 (Potentially life-threatening)

Field	Instructions
Date medical condition/event started	• Record the date the medical condition was first diagnosed or the date the surgery/procedure was performed as applicable. • If the participant is unable to recall the exact date, obtain best estimate. At a minimum, a year is required. • If the exact day is unknown, enter “UN” for the day field. If the exact month is unknown, then select “UNK” for the month field. For example, a partial date may be recorded as: UN-Jan-2010 or UN-UNK-2010.
Is the condition ongoing at time of assessment?	• Select “Yes” for chronic conditions, as well as any other conditions that are currently ongoing at the time of assessment (i.e. at Screening and/or Enrollment). • If the condition resolves during follow-up, this item should remain unchanged on this CRF.
Date medical condition/event ended/resolved	• This item is only required if “Is the condition ongoing?” is “No” at the time of enrollment. • At a minimum, a year is required. • Record the date the medical condition was considered resolved. • For surgeries/procedures, record the date the surgery/procedure was completed.

PRODUCT CHOICE - OLE

Purpose:
This form should be completed at the first visit after approval of protocol v4.0 when the participant decides whether or not to continue in the open-label extension (OLE). It records the participant's decision, as well as the participant's choice of product if participant is moving to the open-label extension (OLE).

General Instructions:
This form is located below the Ongoing Logs folder on the left navigation bar.



Form: Product Choice - OLE
Generated On: 18 Nov 2021 02:38:39

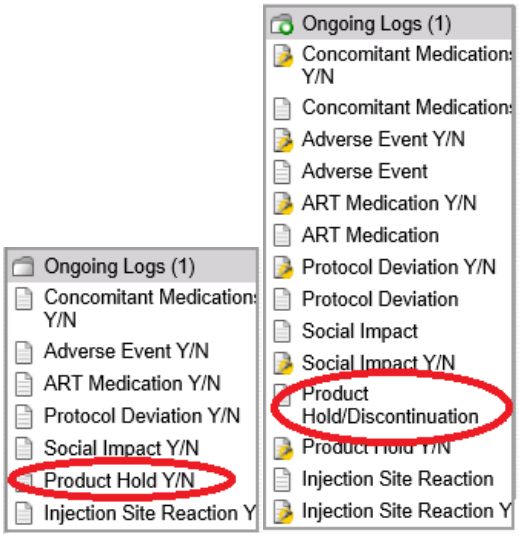
Will participant move to Open Label Extension (OLE)?	Yes ☐ No ☐
Date decision was made on whether to move to Open-label extension?	
If No, Reason (end of form)	Study participation too burdensome ☐ Already accessed TDF/FTC through another mechanism ☐ Prefer to take TAF/FTC ☐ Relocating to area where study is not offered ☐ Prefer not to answer ☐ Prefers TDF/FTC but not eligible for study-provided TDF/FTC ☐ Other ☐
Other, specify	
If Yes, Date of Informed Consent	
Select OLE Regimen	CAB ☐ TDF/FTC ☐ Seroconverter schedule – continuing from Version 3.0 of the protocol ☐ Open Label Truvada Schedule – continuing from Version 3.0 of the protocol ☐
If CAB, specify introductory regimen (mark only one):	Oral CAB (Step 4a) ☐ Loading Dose (4-week interval) CAB-LA (Step 4b) ☐ Standard Dose (8-week interval) CAB-LA (Step 4c) ☐
If CAB regimen selected, Reason	Prefer injections and/or don't like pills ☐ CAB was shown to be superior to Truvada for HIV prevention ☐ Want to avoid potential side effects of Truvada ☐ Other ☐
Other, specify	
If TDF/FTC regimen selected, Reason	Don't like injections and/or prefer pills ☐ The potential side effects of Truvada are better understood than those of Cabotegravir ☐ Concerned about resistance if injectable PrEP fails ☐ Other ☐
Other, specify	

Item-specific Instructions:

Field	Instructions
Will participant move to Open Label Extension (OLE)?	• Select "Yes" or "No".
Date the decision was made on whether to move to Open-label extension?	• Enter the date the decision was made on whether or not to move to open-label extension. • This response is required for all participants who are offered the open-label extension.

If No, Reason (end of form)	• If participant chooses not to move to open-label extension, select the reason. • If "Other" is selected, enter reason in "Other, specify" field. • If site has LOA #3 approval, complete termination procedures in v60 – Exit Visit folder, including Termination form. • If site does not yet have LOA #3 approval, complete termination procedures in a v3.0 interim visit, based on the last visit attended or missed.
If Yes, Date of Informed Consent	• Enter the date participant signed consent for open-label extension. • If participant chooses not to move to open-label extension, leave this date blank.
Select OLE Regimen	• Select "CAB", "TDF/FTC", "Seroconverter schedule", or "Open Label Truvada schedule"
If CAB, specify introductory regimen (mark only one):	• If participant chooses CAB, select either "Oral CAB (Step 4a)", "Loading Dose (4-week interval) CAB-LA (Step 4b)", or "Standard Dose (8-week interval) CAB-LA (Step 4c)".
If CAB regimen selected, Reason	• If participant chooses CAB, select the reason. • If "Other" is selected, enter reason in "Other, specify" field.
If TDF/FTC regimen selected, Reason	• If participant chooses TDF/FTC, select the reason. • If "Other" is selected, enter reason in "Other, specify" field. • If "OLE Regimen" is "Open Label Truvada Schedule – continuing from Version 3.0 of the protocol", this response should be blank.

PRODUCT HOLD Y/N



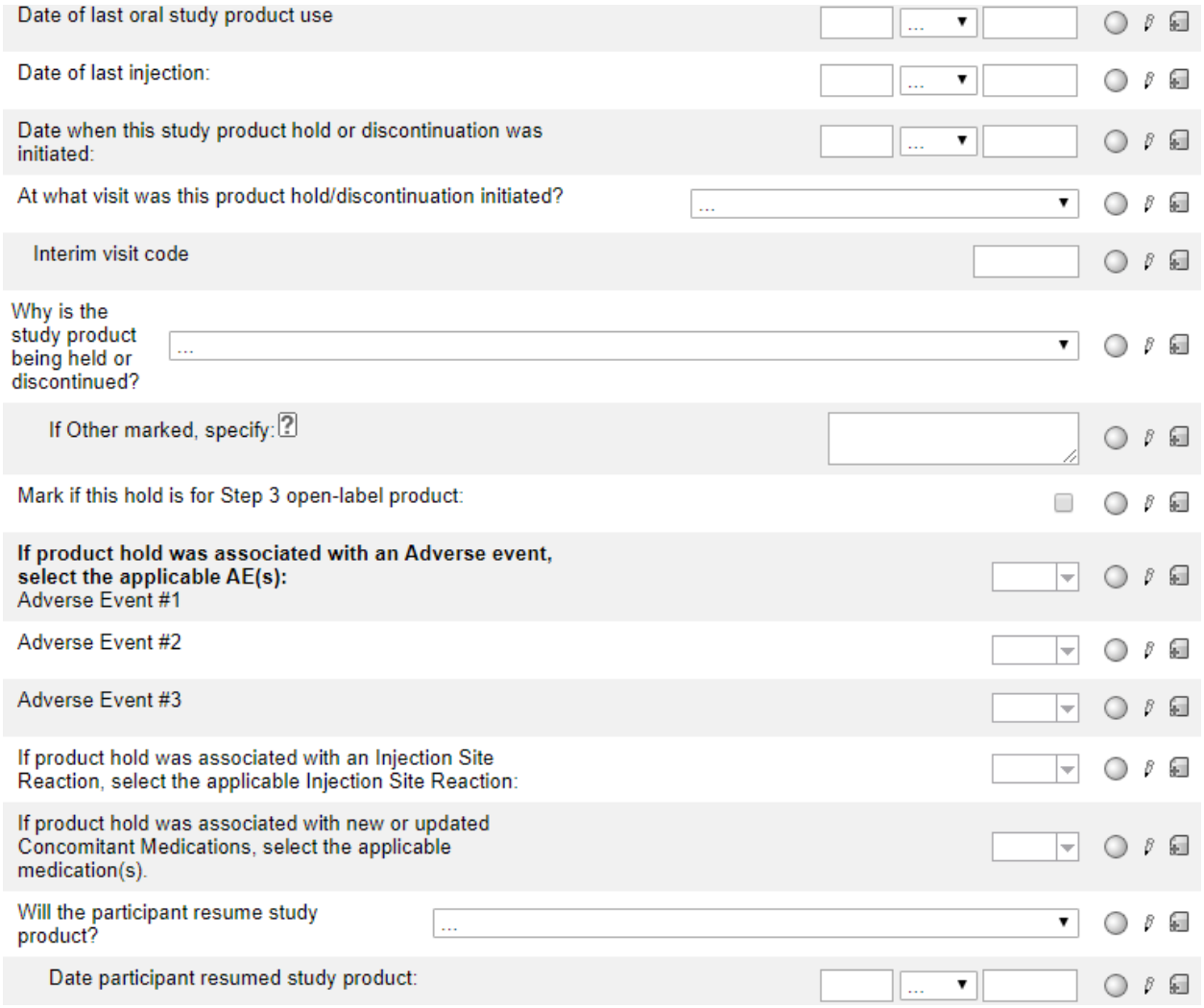
Purpose:
This form documents whether a participant's study product is temporarily or permanently discontinued.

General Instructions:
This form is located in the "Ongoing Logs" folder. Complete this form once when study product use is temporarily or permanently discontinued.

Item-specific Instructions:

Field	Instructions
Is there a product hold or discontinuation to report?	• Select "Yes" or "No". • If "Yes" is selected and the form saved, the Product Hold/Discontinuation log form appears in the folder and can then be completed.

PRODUCT HOLD/DISCONTINUATION



Purpose:
This form documents a participant's temporary or permanent discontinuation of study product use.

General Instructions:
This form is present within the "Ongoing Logs" folder. Complete this form for each enrolled participant when study product use is temporarily or permanently discontinued.

A Product Hold form is expected in the following circumstances:

- A participant in Step 1 moves to Yearly visits prior to first injection
- A participant in Step 2 moves to Step 3
- A participant in Step 3 discontinues use of open-label daily oral TDF/FTC

CONFIDENTIAL DOCUMENT
HPTN 083 CRF Completion Guidelines Version 8.1
20MAR2024

This log is not completed if a participant finishes study product as required per protocol, if a participant terminates the study early, or to document adherence issues.

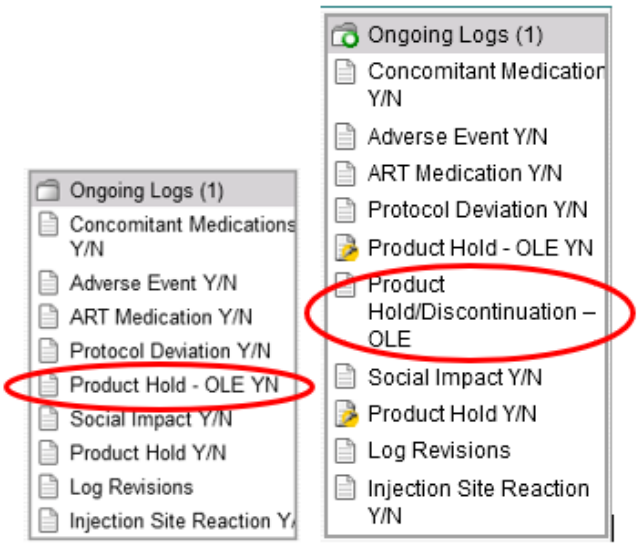
If, at the same visit, a product hold/discontinuation is initiated for more than one reason, complete a separate Product Hold/Discontinuation log line for each reason. The same visit code should be used on each entry.

Item-specific Instructions:

Field	Instructions
Date of last oral study product use	• Enter the date of the last use of oral study product • Month and year are required; if the day is unknown enter UN
Date of last injection:	• Enter the date of the last injection of study product • A complete date is required • If participant did not reach Step 2, leave field blank; in response to query enter 'did not reach Step 2'
Date when this study product hold or discontinuation was initiated:	• Record the date when the participant was temporarily or permanently discontinued from study product • A complete date is required
At what visit was this product hold/discontinuation initiated?	• Select the visit at which study product hold/discontinuation began • If hold occurred at an interim visit, select 'interim visit' from the drop-down menu and record interim visit number in field below
Interim visit code	• If hold occurred at an interim visit, enter interim visit code
Why is the study product being held or discontinued?	• Select the primary reason from the dropdown menu • If "Clinical AE (protocol mandated)" or "Laboratory AE (clinical mandated)" is marked, select the appropriate AE(s) from the dropdown lists below • If the primary reason is 'Other clinical reason' or 'Other participant request', provide additional details in the "If Other marked, specify" text field provided

Mark if this hold is for Step 3 open-label product	• Mark this box if the reported Product Hold/Discontinuation is for Step 3 open-label study product
If product hold was associated with an Adverse event, select the applicable AE(s):	• Select related adverse event(s) from the dropdown list • Up to 3 adverse events can be selected.
If product hold was associated with an Injection Site Reaction, select the applicable Injection Site Reaction:	• Select any related injection site reactions from the drop-down list
If product hold was associated with new or updated Concomitant Medications, select the applicable medication(s):	• Select any medication entered on the CM form that was added as a result of product hold
Will the participant resume study product?	• Select either “Yes”, “No (permanently discontinued)”, “No (hold continuing/ permanently discontinued for another reason)
Date participant resumed study product:	• Enter the date the participant resumed taking study drug • A complete date is required

PRODUCT HOLD OLE - Y/N



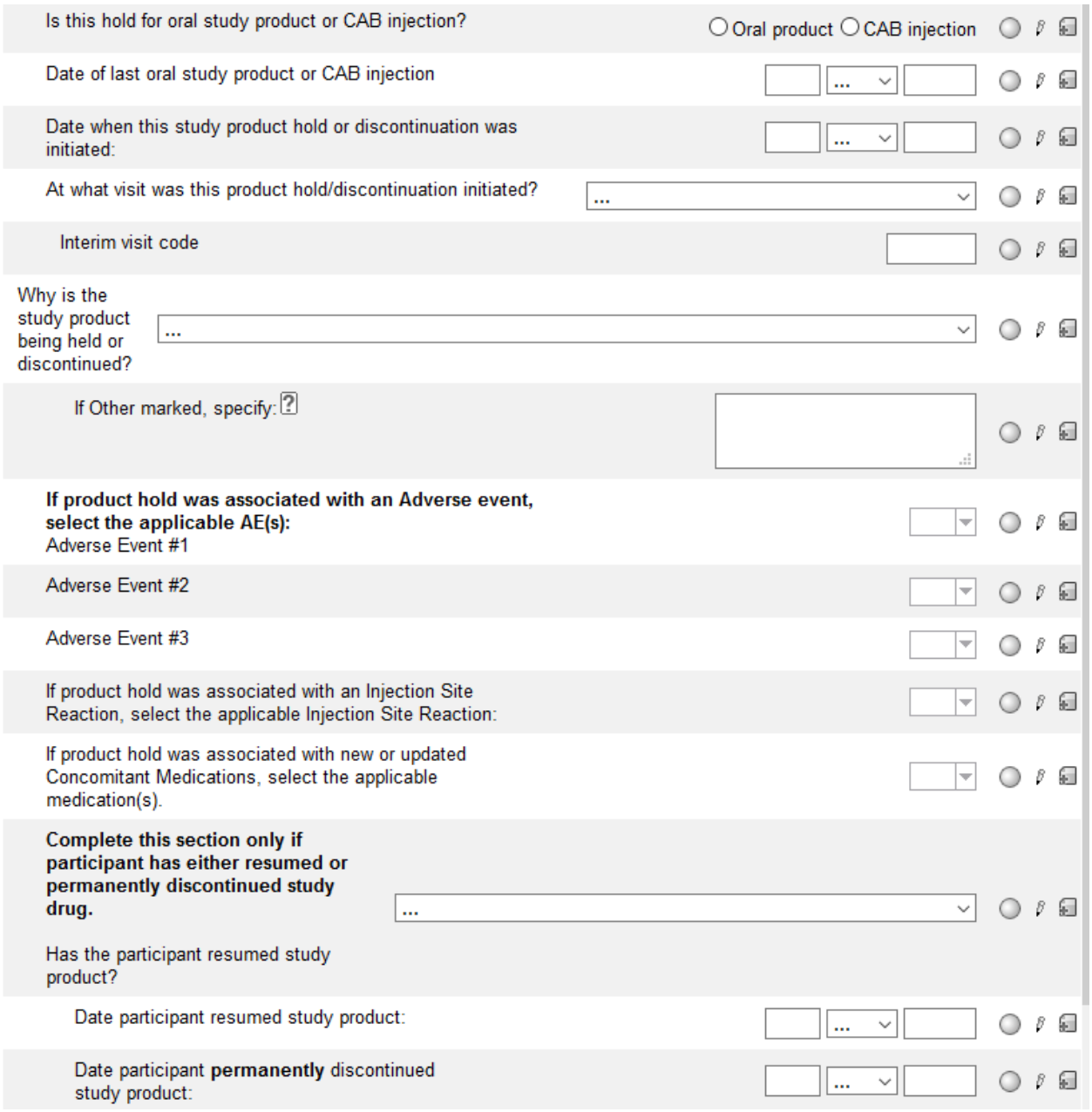
Purpose:
This form documents whether a participant's study product is temporarily or permanently discontinued **during the open-label extension (OLE) only**.

General Instructions:
This form is located in the "Ongoing Logs" folder. Complete this form once when study product use is temporarily or permanently discontinued.

Item-specific Instructions:

Field	Instructions
Is there a product hold or discontinuation to report?	• Select "Yes" or "No". • If "Yes" is selected and the form saved, the Product Hold/Discontinuation - OLE log form appears in the folder and can then be completed.

PRODUCT HOLD/DISCONTINUATION - OLE



Purpose:
This form documents a participant's temporary or permanent discontinuation of study product use **during the open-label extension (OLE) only**.

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20MAR2024

General Instructions:
This form is present within the “Ongoing Logs” folder. Complete this form for each enrolled participant when study product use is temporarily or permanently discontinued. This form should also be completed when a participant switches regimens during the OLE.

This log is not completed if a participant finishes study product as required per protocol, if a participant terminates the study early, or to document adherence issues.

If, at the same visit, a product hold/discontinuation is initiated for more than one reason, complete a separate Product Hold/Discontinuation log line for each reason. The same visit code should be used on each entry.

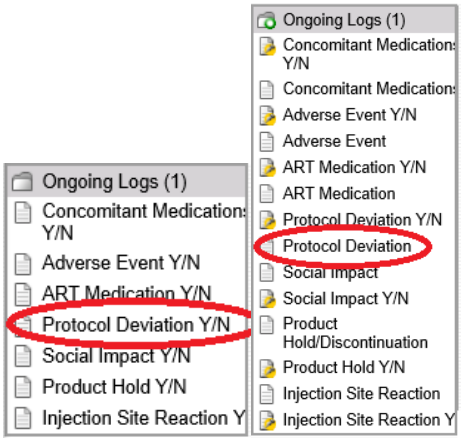
Item-specific Instructions:

Field	Instructions
Which study product is being held?	• Mark “Oral CAB”, “CAB-LA injection”, or “TDF/FTC”
Date of last oral study product or CAB injection	• Enter the date of the last use of oral study product or CAB injection *in the current Step* (i.e. open-label extension). • Month and year are required; if the day is unknown enter UN
Date when this study product hold or discontinuation was initiated:	• Record the date when the participant was temporarily or permanently discontinued from study product • A complete date is required
At what visit was this product hold/discontinuation initiated?	• Select the visit at which study product hold/discontinuation began • If hold occurred at an interim visit, select ‘interim visit’ from the drop-down menu and record interim visit number in field below • Visit code must match the Step of the product being held.
Interim visit code	• If hold occurred at an interim visit, enter interim visit code
Why is the study product being held or discontinued?	• Select the primary reason from the dropdown menu • If the primary reason is 'Other clinical reason' or 'Other participant request', provide additional details in the “If Other marked, specify” text field provided

If product hold was associated with an Adverse event, select the applicable AE(s):	• Select related adverse event(s) from the dropdown list • Up to 3 adverse events can be selected. • If "Clinical AE (protocol mandated)" or "Laboratory AE (clinical mandated)" is marked, select the appropriate AE(s) from the dropdown lists below. • An AE may also be selected if "CMC recommendation based on a clinical event" or "CMC recommendation based on a laboratory value" is marked.
If product hold was associated with an Injection Site Reaction, select the applicable Injection Site Reaction:	• Select any related injection site reactions from the drop-down list
If product hold was associated with new or updated Concomitant Medications, select the applicable medication(s):	• Select any medication entered on the CM form that was added as a result of product hold
Has the participant resumed study product?	• Complete this question only if participant has either resumed or permanently discontinued study product; OR if participant has terminated. • Select either "Yes", "No (permanently discontinued)", "No (hold continuing/ permanently discontinued for another reason). • If participant has not resumed study product at termination, update this form by selecting "No (permanently discontinued)".
Date participant resumed study product:	• Enter the date the participant resumed taking study drug • A complete date is required • If participant has not resumed study product, leave this date blank.

Date participant *permanently* discontinued study product:	• Enter the date the participant permanently discontinued study drug. • A complete date is required. • If participant has not resumed study product at termination, update this form by entering termination date here.

PROTOCOL DEVIATION Y/N



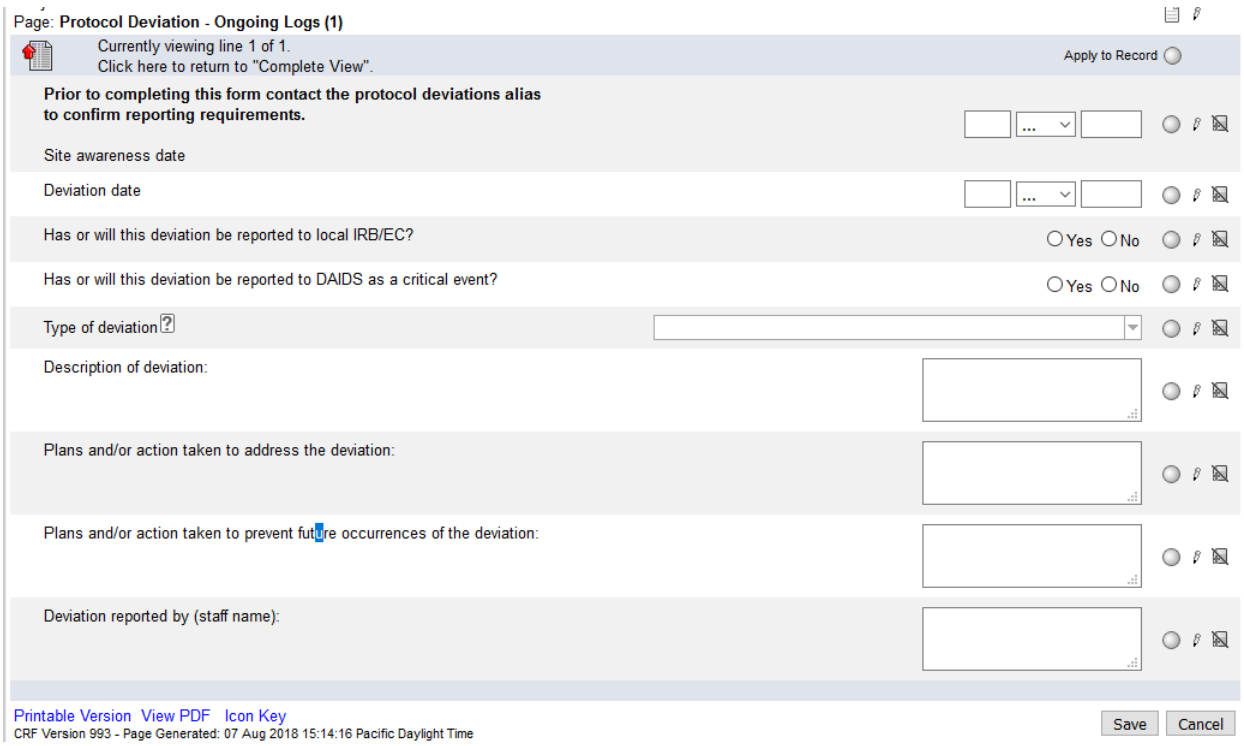
Purpose:
This form documents if a protocol deviation has occurred.

Generation Instructions:
This form is present within the “Ongoing Logs” folder and needs to be marked only once.

Item-specific Instructions:

Field	Instructions
Have any protocol deviations occurred?	• Select “Yes” or “No” • If “Yes” is selected, then the Protocol Deviation log form appears in the Ongoing Logs folder and can then be completed

PROTOCOL DEVIATION



Purpose:
This form documents reportable protocol deviations identified for study participants during the implementation of HPTN 083.

General Information/Instructions:
Prior to completing a deviation form contact the 083pd@hptn.org alias to confirm whether an event is considered a reportable deviation.

Complete this form each time a reportable protocol deviation is identified. Complete one page per protocol deviation when entering in the study database. To add an additional deviation within Medidata Rave, clicking “Add a new Log line” will add an additional page for a new deviation to be completed.

Reportable protocol deviations are defined by the HPTN as individual incidents, trends or omissions that result in:

- Significant added risk to the participant
- Non-adherence to significant protocol requirements
- Significant non-adherence to GCP

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HPTN 083 CRF Completion Guidelines Version 8.1
20MAR2024

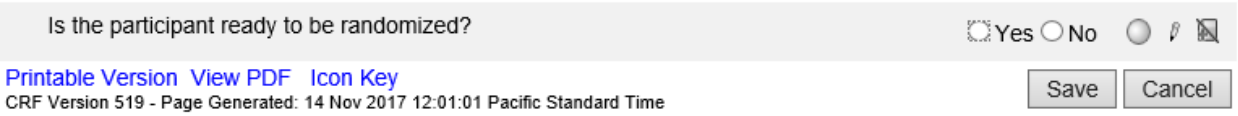
Item-specific Instructions:

Field	Instructions
Site awareness date	• Record the date the site became aware of the deviation • A complete date is required
Deviation date	• Record the date the deviation occurred (start date) • At a minimum, the Year is required.
Has or will this deviation be reported to local IRB/EC?	• Select “Yes” or “No”
Has or will this deviation be reported to DAIDS as a critical event?	• Select “Yes” or “No”
Type of deviation	• Select the applicable deviation from the search list. • The first few letters of the description can be typed in the search list to find the applicable deviation to be entered. You can also use the dropdown arrow to review a listing of the deviation types. To move between pages of deviation types click on the “<<Back” and “Next>>” buttons at the top of the list. • *Please see table below for the types of deviations.*
Description of deviation	• Use text field to briefly describe specific details of deviation
Plans and/or action taken to address the deviation	• Use text field to provide a brief description of plans to address deviation
Plans and/or action taken to prevent future occurrences of the deviation	• Use text field to provide a brief description of plans to prevent similar deviations in the future
Deviation reported by (staff name):	• Enter name of staff member that reported the deviation

PROTOCOL DEVIATION CODE LIST
Description
Inappropriate enrollment: The participant enrolled and not all eligibility requirements were met.
Failure to follow trial randomization or blinding procedures: Include instances where randomization procedures were not followed by site staff, or product blinding procedures were not followed by pharmacy staff.
Study product management deviation: The site staff did not instruct the participant to hold, permanently discontinue, or resume study product use per protocol requirements.
Study product dispensing error: The wrong study product was dispensed to a participant, or study product was dispensed to a participant who permanently discontinued study product use.
Conduct of non-protocol procedure: A clinical or administrative procedure was performed that was not specified in the protocol and was not covered under local standard of care practice.
Breach of confidentiality: Include potential and actual cases where participant confidentiality is breached. For example, a staff member put a participant's name on a case report form or in an email to protocol leadership.
Physical assessment deviation: Examples include a protocol-specified exam or assessment consistently not being performed (a single missed exam during one participant visit would not be considered a reportable protocol deviation).
Lab assessment deviation: Examples include a protocol-specified laboratory assay consistently not being performed (a single missed assay during one participant visit would not be considered a reportable protocol deviation).

Use of non-IRB/EC-approved materials: Include use of ANY study-related material that requires IRB or EC approval for use per site requirements.
Informed assent/consent process deviation: Examples include failure to accurately execute and/or document any part of the informed consent process.
Failure to complete eligibility assessment prior to randomization / incomplete assessment of eligibility prior to enrollment: Examples include failure to complete any required assessment within 45 days of screening specimen collection.
Other

RANDOMIZATION



Purpose:
The Randomization form will randomize the participant within Medidata.

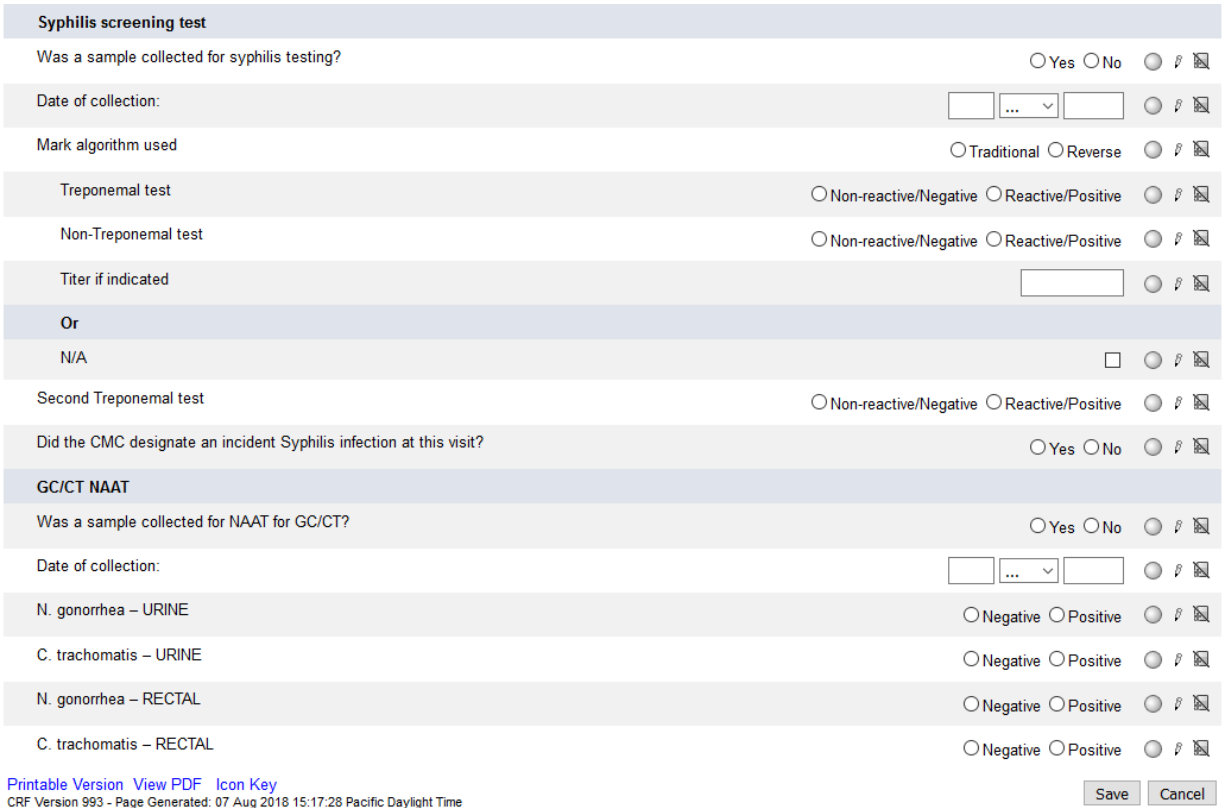
General Instructions:
Prior to entering this form, confirm the correct PTID has been selected for randomization and the participant is eligible for the study.

One randomization is complete, a confirmation will appear on the form stating “Subject successfully randomized.”

Item-specific Instructions:

Field	Instructions
Is the participant ready to be randomized?	• Select “Yes” or “No”

SEXUALLY TRANSMITTED INFECTIONS



Syphilis screening test	
Was a sample collected for syphilis testing?	○ Yes ○ No
Date of collection:	...
Mark algorithm used	○ Traditional ○ Reverse
Treponemal test	○ Non-reactive/Negative ○ Reactive/Positive
Non-Treponemal test	○ Non-reactive/Negative ○ Reactive/Positive
Titer if indicated	
Or	
N/A	☐
Second Treponemal test	○ Non-reactive/Negative ○ Reactive/Positive
Did the CMC designate an incident Syphilis infection at this visit?	○ Yes ○ No
GC/CT NAAT	
Was a sample collected for NAAT for GC/CT?	○ Yes ○ No
Date of collection:	...
N. gonorrhea – URINE	○ Negative ○ Positive
C. trachomatis – URINE	○ Negative ○ Positive
N. gonorrhea – RECTAL	○ Negative ○ Positive
C. trachomatis – RECTAL	○ Negative ○ Positive

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CRF Version 993 - Page Generated: 07 Aug 2018 15:17:28 Pacific Daylight Time

Save Cancel

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HPTN 083 CRF Completion Guidelines Version 8.1
20MAR2024

Printable Version View PDF Icon Key
CRF Version 148 - Page Generated: 15 Nov 2017 14:51:37 Pacific Standard Time

Save Cancel

Purpose:
This form is used to document STI test results performed by the local site laboratory.

General Instructions:
Complete this form at required protocol visits and as indicated during the study.

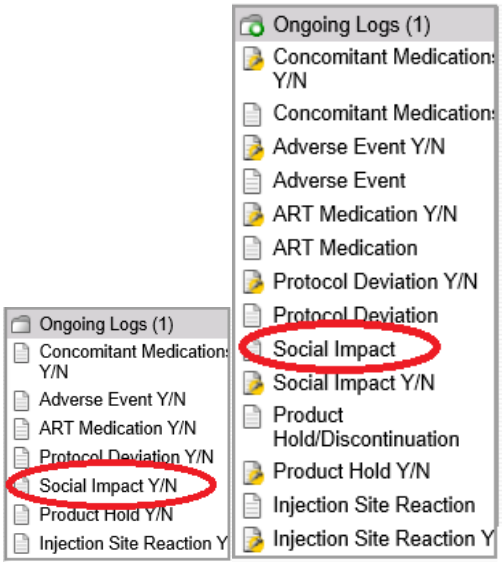
If an STI is diagnosed during screening, record STI diagnoses in Pre-existing Conditions form.

Item-specific Instructions:

Field	Instructions
Was a sample collected for syphilis testing?	• Select “Yes” or “No”
Date of collection:	• A complete date is required
Mark algorithm used	• Select “Traditional” or “Reverse” • If “Traditional”, a result is required for “Non-Treponemal test” • If “Reverse”, a result is required for “Treponemal test”
Treponemal test	• Select “Non-reactive/Negative” or “Reactive/Positive”
Non-Treponemal test	• Select “Non-reactive/Negative” or “Reactive/Positive” • If response is “Reactive/Positive” then “Titer if indicated” is required.
Titer if indicated	• Enter titer if it is indicated
Or	
N/A	• Mark if Titer is not indicated

Field	Instructions
Second Treponemal test	• Select “Non-reactive/Negative” or “Reactive/Positive”
Did the CMC designate an incident Syphilis infection at this visit?	• Select “Yes”, “No”, or “IoR designated incident syphilis infection” in accordance with CMC communication. • A response to this question is required at all visits if any test result is “Reactive/Positive”. • At OLE visits only, enter “IoR designated incident syphilis infection” if IoR deemed a new infection after a positive result. • Select “Yes” or “IoR designated incident syphilis infection” only once for the same event regardless of multiple reactive results.
GC/CT NAAT	
Was a sample collected for NAAT for GC/CT?	• Select “Yes” or “No”
Date of collection:	• A complete date is required
N. gonorrhea – URINE	• Select “Negative” or “Positive”
C. trachomatis – URINE	• Select “Negative” or “Positive”
N. gonorrhea – RECTAL	• Select “Negative” or “Positive”
C. trachomatis – RECTAL	• Select “Negative” or “Positive”

SOCIAL IMPACT Y/N



Purpose:
This form documents if a social impact has occurred.

Generation Instructions:
This form is present within the “Ongoing Logs” folder and needs to be marked only once.

Item-specific Instructions:

Field	Instructions
Has the participant reported a social impact during the study?	• Select “Yes” or “No” • If “Yes” is selected, then the Social Impact log form appears in the Ongoing Logs folder and can then be completed

SOCIAL IMPACT

Purpose:
It is possible that participants' involvement in the study could become known to others, and that a social impact may result (i.e., because participants could be perceived as being HIV-infected or at risk or "high risk" for HIV infection). This form documents social impacts that the participant thinks are related to participation in the study.

General Instructions:
Complete this form on an as-needed basis.

Item-specific Instructions:

Field	Instructions
Date reported	• Enter the date the social impact was reported to the site • A complete date is required
Concisely describe social impact	• Describe the social impact
Onset date	• Enter the date on which the impact began • A complete date is preferred, if day or month is unknown, use UN or UNK respectively.
Social impact type	• Select appropriate social impact type from the dropdown list • If “Other – Had other problems not covered in the codes above” is selected, specify social impact type in “If other, specify” text field

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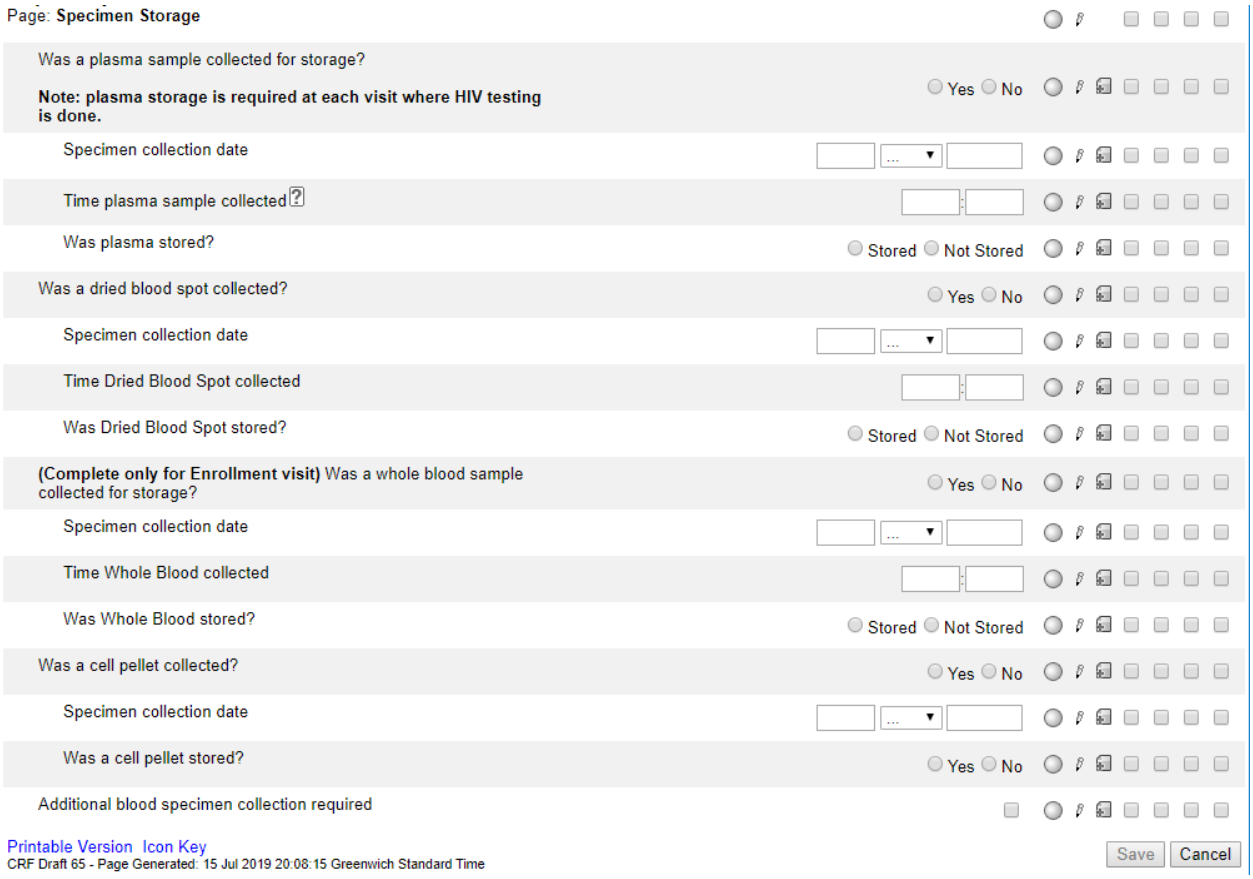
20MAR2024

SPECIMEN STORAGE



Purpose:
This form is used to document collection and storage of protocol-required laboratory specimens.

General Instructions:
Complete this form as required per the protocol, and as indicated at other visits during follow-up.
A plasma sample must be stored each time an HIV Test is performed.

Item-specific Instructions:

Field	Instructions
Was a plasma sample collected for storage?	• Select "Yes" or "No" • If "Yes", enter the date/time of collection and whether or not sample was stored

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HPTN 083 CRF Completion Guidelines Version 8.1
20MAR2024

Field	Instructions
Specimen collection date	• Record the date that the specimen(s) was collected • A complete date is required
Time plasma sample collected	• Record the time the specimen(s) was collected using a 24-hour clock
Was plasma stored?	• Select “Stored” or “Not Stored”
Was a dried blood spot collected?	• Select “Yes” or “No” ○ Select “No” if participant did not consent to genetic testing. • If “Yes”, enter the date/time of collection and whether or not sample was stored
Specimen collection date	• Record the date the specimen(s) was collected • A complete date is required
Time Dried Blood Spot collected	• Enter time of sample(s) collection using a 24-hour clock
Was Dried Blood Spot stored?	• Select “Stored” or “Not Stored” • If sample was not collected, leave this response blank.
(Complete only for Enrollment Visit) Was a whole blood sample collected for storage?	• Select “Yes” or “No” at Enrollment visit only. • At all other visits, leave blank. • If “Yes”, enter the date/time of collection and whether or not sample was stored
Specimen collection date	• Record the date that the specimen(s) was collected • A complete date is required
Time Whole Blood collected	• Enter time of sample(s) collection using a 24-hour clock
Was Whole Blood stored?	• Select “Stored” or “Not Stored”

Field	Instructions
Was a cell pellet collected?	• Select “Yes” or “No” • If “Yes”, enter the date/time of collection and whether or not sample was stored
Specimen collection date	• Record the date that the specimen(s) was collected • A complete date is required
Was a cell pellet stored?	• Select “Stored” or “Not Stored”
Additional blood specimen collection required	• Select “Yes” or “No” • If ”Yes” selected and the form is saved, an additional Specimen Storage form is added in the visit’s folder where additional information can be entered.

STUDY MEDICATION SATISFACTION QUESTIONNAIRE (SMSQs)

Purpose:
This form is used to document participant satisfaction with the study medication.

General Information/Instructions:

- All interviews are to be conducted according to GCP and protocol guidelines
- Read instructions and each question to the participant, then list possible answer choices
- Record the participant's responses in the fields provided
- If the participant does not wish to answer or does not know, leave field blank and answer system auto-query with "Unknown" or "Does not wish to answer" to confirm
- If the entire survey is not done mark the box "Survey not done"

STUDY MEDICATION SATISFACTION QUESTIONNAIRE CHANGE (SMSQc)

Purpose:
This form is used to document changes in participant satisfaction with the study medication during the preceding weeks.

General Information/Instructions:
This form is required at V10.0 – Week 19 of the study.

- All interviews are to be conducted according to GCP and protocol guidelines
- Read instructions and each question to the participant, then list possible answer choices
- Record the participant's responses in the fields provided
- If the participant does not wish to answer or does not know, leave field blank and answer system auto-query with "Unknown" or "Does not wish to answer" to confirm
- If the entire survey is not done mark the box "Survey not done"

STUDY MEDICATION SATISFACTION QUESTIONNAIRE: OLE

Purpose:
This form is used to document changes in participant satisfaction with the study medication during the preceding weeks during the OLE part of the study.

General Information/Instructions:

- All interviews are to be conducted according to GCP and protocol guidelines
- Read instructions and each question to the participant, then list possible answer choices
- Record the participant's responses in the fields provided
- If the participant does not wish to answer, select "Prefer not to answer" where available, otherwise, select "NA". If participant does not know or question is not applicable, select "NA".
- If the entire survey is not done mark the box "Survey not done" on top of the form

SUPPLEMENTAL HIV TEST RESULTS

Form: Supplemental HIV Results
Generated On: 16 Dec 2019 17:53:52

HIV 1/2 Discriminatory Assay

Mark 'Not Done' OR enter Specimen Collection date and mark result:

Not Done ☐

OR

Specimen Collection Date _____

Assay Result

- ☐ Assay result not provided
- ☐ HIV Negative
- ☐ HIV-1 Positive
- ☐ HIV-2 Positive
- ☐ HIV-2 Positive with HIV-1 Cross-Reactivity
- ☐ HIV-1 Positive, Untypable
- ☐ HIV-1 Indeterminate
- ☐ HIV-2 Indeterminate
- ☐ HIV Indeterminate
- ☐ Other

Other assay result: _____

Comments (max. 200 characters) _____

Laboratory Reported HIV Interpretation

Mark 'Not Reported' if not provided by testing laboratory OR mark interpretation:

Not Reported ☐

OR

Interpretation

- ☐ HIV Negative
- ☐ HIV-1 antigen and HIV-1/HIV-2 antibodies were not detected. No laboratory evidence of HIV infection.
- ☐ HIV-1 antibodies were not confirmed and HIV-1 RNA was not detected.
- ☐ HIV-1 Positive
- ☐ HIV-2 Positive
- ☐ HIV-2 Positive - This result is distinct from HIV Positive, Untypable.
- ☐ HIV Positive
- ☐ Acute HIV-1 Positive
- ☐ HIV-1 Negative, HIV-2 inconclusive
- ☐ Inconclusive
- ☐ Other

Other interpretation: _____

Comments (max. 200 characters) _____

HIV DNA

HPTN083_version 1 of 2

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HPTN 083 CRF Completion Guidelines Version 8.1
20MAR2024

Mark 'Not performed/Not reported by Lab' OR enter Specimen Collection date and complete appropriate result field:	
Not performed/Not reported by Lab (add comment)	☐
OR	
Specimen Collection Date	
DNA Result	Detectable DNA result (record below) ☐ Detectable DNA , but below limit of detection (<4.09 copies per million cells) ☐ Detectable DNA, above the reportable range of the assay (>100 copies per million cells) ☐ Undetectable DNA, below limit of detection (<4.09 copies per million cells) ☐
Detectable DNA result:	Fixed Unit: copies per million cells
Comments (max. 200 characters)	

Purpose:
This form is used to document all HIV 1/2 discriminatory results and DNA test results.

General Instructions:

Complete this form any time specimens are drawn for HIV 1/2 or DNA testing.

Marking the response next to this form name on the Date of Visit, Interim, or Yearly Summary form will add the Supplemental HIV form to that visit folder.

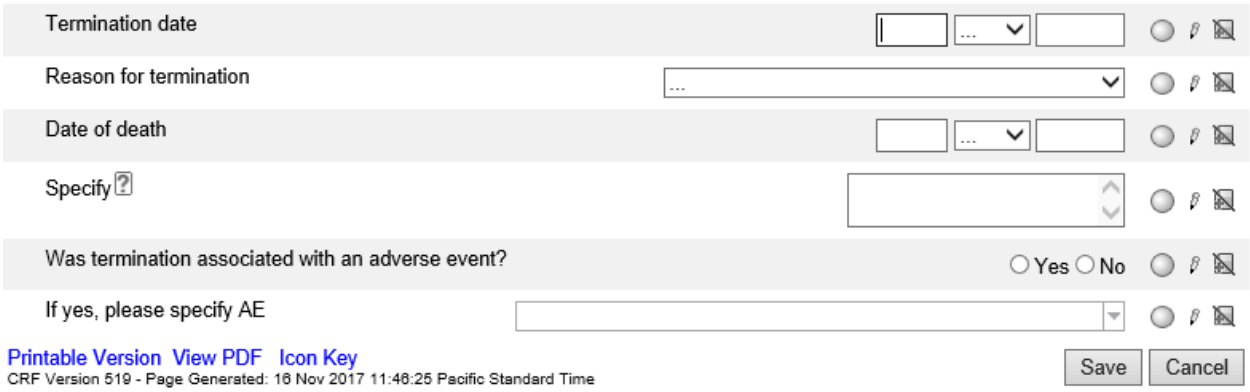
Item-specific Instructions:

Field	Instructions
HIV 1/2 Discriminatory Assay	• Mark 'Not Done' if test was not performed • If 'Not Done' is marked, the Specimen Collection Date and Assay Result should be blank
Specimen Collection Date	• Enter the date the specimen was collected • A complete date is required
Assay Result	• Select the appropriate result • If result not provided, mark 'Assay result not provided' • If the result does not appear on the list of options, mark 'Other' and report assay result in the field below

Other assay result	• If result does not appear on the list of options, mark 'Other' in the item above and record result.
Comments	• Record any additional comments that may help describe the assay result. • Assay results should only be recorded in the Assay Result or Other Assay Result field.
Laboratory Reported HIV Interpretation	• Mark 'Not Reported' if not provided by testing lab Or mark interpretation. • If 'Not Reported' is marked, other fields describing Lab Reported HIV Interpretation should be blank
Interpretation	• Select the appropriate interpretation • If the appropriate interpretation does not appear on the list of options, mark 'Other' and report interpretation in the field below
Other interpretation	• If result does not appear on the list of options, mark 'Other' in the item above and record result.
Comments	• Record any additional comments that may help describe the result interpretation. • Result interpretations should only be recorded in the Interpretation or Other interpretation field.
HIV DNA	• Mark 'Not performed/not reported by Lab' if not provided by testing lab or complete appropriate result field. • If 'Not performed/not reported by Lab' is marked, other fields describing HIV DNA should be blank
Specimen Collection Date	• Enter the date the specimen was collected • A complete date is required

DNA Result	• Select the appropriate result • If result is detectable and in range enter the result in the field below
Detectable DNA Result	• Enter detectable DNA result; otherwise leave item blank
Comments	• Record any additional comments that may help describe the results. • Results should only be recorded in the DNA Result field

TERMINATION



Purpose:
This form is used to document a participant's exit from the study (i.e. study termination).

General Instructions:

Complete this form for each enrolled participant at either the scheduled exit/end of study visit or when the participant is confirmed to no longer be participating in the study.

Participants cannot be terminated for relocating or considered lost to follow up until the end of the study. During the study, those participants who are currently lost to follow up or relocated must have a Missed Visit form completed for all missed visits.

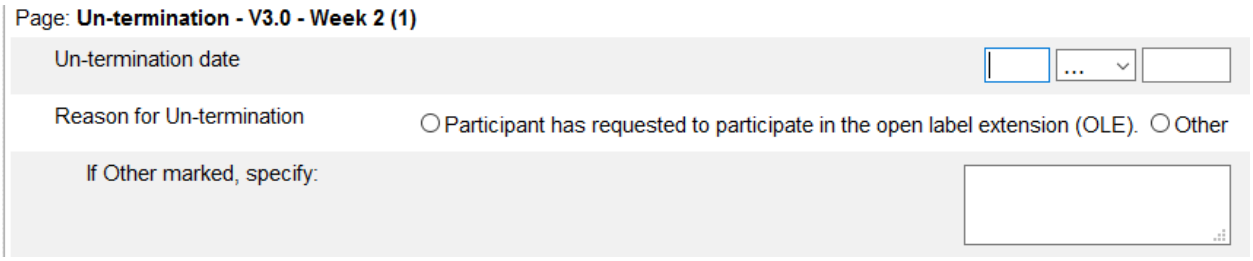
The Termination form is added to the visit folder (protocol or interim visit) for the visit at which the site determines the participant to be terminating. Marking "Yes" to "Did the participant exit/terminate the study at this visit?" on either the Date of Visit or Interim Visit Summary form and saving the form will add the Termination form to that visit folder.

Item-specific Instructions:

Field	Instructions

Termination date	• A complete date is required
Reason for termination	• Select the reason for termination from the study from the dropdown list. • If “linkage to local CAB” is selected, complete a ConMed log to record outside CAB injection.
Date of death	• If “Death” is selected, record date of death
Specify	• If reason for termination is “Death” or “other”, provide additional details in the text field provided, including cause of death if applicable.
Was termination associated with an adverse event?	• Select “Yes” or “No”
If yes, please specify AE	• If the participant terminated from the study due to an AE, choose the applicable AE from the dropdown list • An AE form must be completed for the event before it can be selected in the dropdown list

UN-TERMINATION


Page: **Un-termination - V3.0 - Week 2 (1)**

Un-termination date ...

Reason for Un-termination ○ Participant has requested to participate in the open label extension (OLE). ○ Other

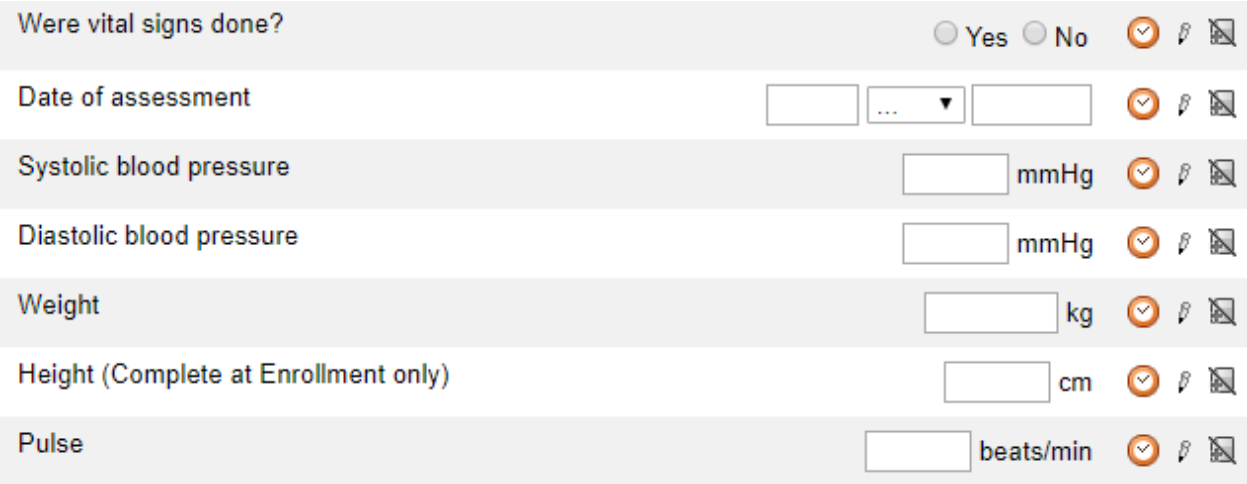
If Other marked, specify:

Purpose:
This form is used to re-activate terminated participants back into the study after site acceptance of protocol v4.0.

Item-specific Instructions:

Field	Instructions
Un-termination date	• Enter date participant was re-activated into the study. • A full date is required.
Reason for Un-termination	• Select either 'Participant has requested to participate in the open label extension (OLE) or 'Other'. • If 'Other' is selected, enter reason in 'If other marked, specify'.

VITAL SIGNS

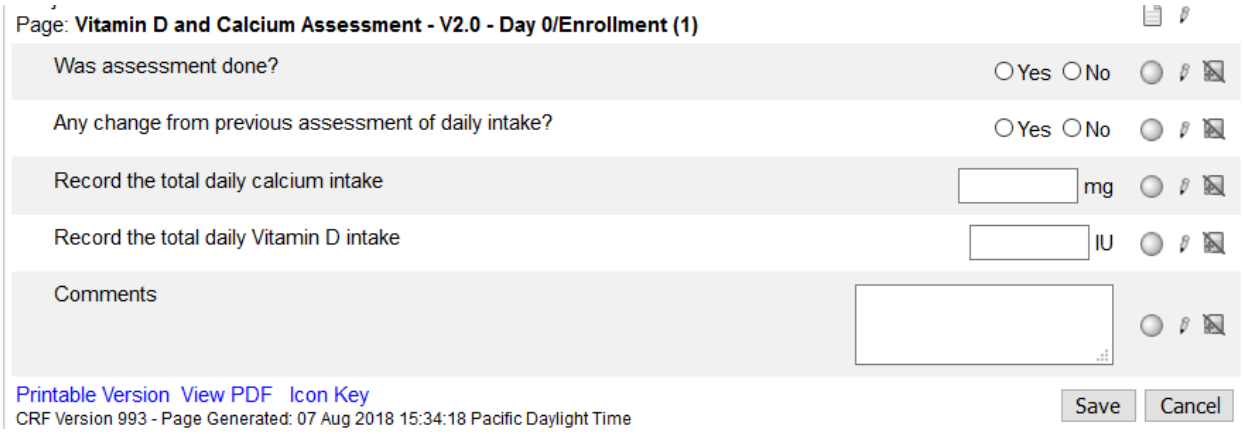


Purpose:
This form is used to document a participant's blood pressure, weight, pulse, and Height (enrollment only).

Item-specific Instructions:

Field	Instructions
Were vital signs done?	• Select "Yes" or "No"
Date of assessment	• A complete date is required
Systolic blood pressure	• Enter the systolic blood pressure in units of "mmHG"
Diastolic blood pressure	• Enter the diastolic blood pressure in units of "mmHG"
Weight	• Enter the weight in units of "kg" • Up to one decimal place can be entered
Height	• Enter the height in units of "cm" • This item is required only at the enrollment visit • Up to one decimal place can be entered
Pulse	• Enter the pulse in units of beats/minute

VITAMIN D AND CALCIUM ASSESSMENT



Purpose:
This form is used to document a participant's calcium and Vitamin D intake as well as any changes from previous assessments.

Item-specific Instructions:

Field	Instructions
Was assessment done?	• Select "Yes" or "No"
Any change from previous assessment of daily intake?	• Select "Yes" or "No"
Record the total daily calcium intake	• Enter the daily calcium intake in units of "mg"
Record the total daily Vitamin D intake	• Enter the daily Vitamin D intake in units of "IU".
Comments	• Enter any additional comments as needed

YEARLY VISIT SUMMARY

Page: **Yearly Visit Summary**

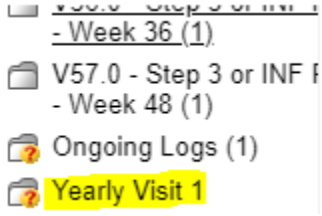
Did the participant complete this visit?	Yes No
Visit Date:	...
Yearly visit code	...
Did the participant exit/terminate the study at this visit?	Yes No
Is the participant confirmed HIV infected?	Yes No
Mark any forms or procedures completed at this visit.	
Hematology	Yes No
Hepatitis Test Results	Yes No
Electrocardiogram	Yes No
Local Laboratory Results	Yes No
Participant Receipt	Yes No
Participant Transfer	Yes No
Sexually Transmitted Infections	Yes No
Supplemental HIV Results	Yes No

Purpose:
This form is used to summarize information collected at a yearly visit and to record all procedures or assessments the participant received at the interim visit (e.g., HIV Test Results).

General Information/Instructions:
Complete this form for each expected yearly visit.

To add a “yearly visit” folder, select “Yearly Visit” from the participant’s homepage using the “Add Event” dropdown.

Yearly Visits will generate in numerical order and appear below the Ongoing Logs folder.



Item-specific Instructions:

Field	Instructions
Did the participant complete this visit?	• Select "Yes" or "No" • Selecting "No" will generate a Missed Visit form
Visit Date	• A complete date is required.
Yearly visit code	• Select the appropriate visit code from the drop-down list
Did the participant exit/terminate the study at this visit?	• Select "Yes" or "No" • If "Yes", a Termination form will be added to the visit folder and must be submitted
Is the participant confirmed HIV infected?	• Select "Yes" or "No" •
Mark any forms or procedures completed at this visit	• *Check all additional forms to be completed at this visit* • *Marking one or more forms from the list and saving the Interim Visit form will add those specific forms to the interim visit folder.*

Change History

Summary of Changes to Study CCGs

Version		Affected Section(s) or Form(s)	Summary of Revisions
Number	**Date**		

CONFIDENTIAL DOCUMENT
HPTN 083 CRF Completion Guidelines Version 8.1
20MAR2024

01.0	24 Jan 2018	N/A	Original version
02.0	15 July 2019	Form-Specific Instructions	• New form – Inclusion/Exclusion New form – Inclusion/Exclusion • New form – Vital Signs • New form – Yearly Visit Summary • Updated screen shots of forms: o Adverse Event o Concomitant Medications form o Date of Visit form o Hepatitis Test Results o HIV Test Results o Injection Administration o Injection Site Reaction o Participant Transfer o Product Hold/Discontinuation o Sexually Transmitted Infections o Specimen Storage o Vitamin D and Calcium Assessment • Moved general instructions and description of database functionality from appendix to the top of document • Added or updated instructions for CRFs modified in migration or those needing further clarification: o Adverse Event o Concomitant Medications o Date of Visit o Local Lab Results (allow up to 5 digits beyond decimal) o Hematology Results o Hepatitis Test Results o HIV Test Results o Injection Administration o Interim Visit Summary o Local Lab Results

			○ Participant Transfer ○ Pre-Existing Conditions ○ Product Hold/Discontinuation ○ Protocol Deviation ○ Sexually Transmitted Infections ○ Specimen Storage ○ Vital Signs ○ Vitamin D and Calcium Assessment
03.0	25 Mar 2021	Form-Specific Instructions	○ New item added to Yearly Visit Summary to allow for missed yearly visit. ○ Instructions added regarding dynamic search lists where selection of an AE becomes nonconformant due to data being revised on original AE log line. ○ Updated screen shots of forms and added or updated instructions: ○ ART Medication ○ Date of Visit ○ Interim Visit ○ HIV Test Results ○ Product Hold/Discontinuation ○ Vital Signs ○ Yearly Visit Summary ○ New form – Supplemental HIV Test Results ○ Added instructions to Local Lab Results to mark fasting item if participant fasted at a non-fasting visit. ○ Updated instructions to Pre-existing Conditions so that conditions are not updated on this form after enrollment ○ New form – Participant Unblinding ○ New forms:

			○ Date of Visit – OLE ○ Date of Visit – HIV ○ Interim Visit – OLE ○ Product Hold – OLE Y/N ○ Product Hold/Discontinuation – OLE ○ Product Choice – OLE ○ Log Revisions ○ Interviewer Administered – OLE ○ SMSQ – OLE Un-termination
04.0	14Jan2022	Form-Specific Instructions	○ New form – Long Term Consent Update ○ New screenshot and options added to Product Choice-OLE ○ New instructions added to Interviewer Administered – OLE to indicate that a response is required at all visits ○ New instructions added to Interviewer Administered – OLE to indicate that a response is required at all visits New instruction added to Sexually Transmitted Infections form to indicate that a response is always required after a positive result for “Did the CMC designate a syphilis infection?” even in v4.0.
05.0	20May2022	Form-Specific Instructions	○ New form: Informed Consent – Version 5.0 ○ New instruction added to Sexually Transmitted Infections form to indicate which test is used for Traditional and Reverse algorithms. ○ New instructions added to Product Choice to clarify which visit to use for terminating participants who do not move to the OLE.

			New instruction added to Product Choice to clarify that participants moving from Step 3 to Step 5 should not have a reason entered in “If TDF/FTC regimen selected, Reason”.
06.0	29Jul2022	Form-Specific Instructions	○ New response option on Termination form, “Reason for termination”: “linkage to local CAB”. ○ New response option on Sexually Transmitted Infections form, “Did CMC designate an incident syphilis infection”: “IoR designated incident syphilis infection (OLE visits only)”. ○ New instruction added to Sexually Transmitted Infections form to only enter “IoR designated incident syphilis infection” at OLE visits. New instruction added to Injection Administration form to mark “Open label injection (active CAB LA)” at all OLE visits.
07.0	20Jun2023	Form-Specific Instructions	○ New form: Informed Consent – Version 6.0 ○ New instruction added to AE form for visit code. ○ New instruction added to AE form for alternate etiology. ○ New instruction added to Product Hold-OLE form for visit code. ○ New instruction added to Informed Consent – Version 5.0 for date entry. New instruction added to Long Term Consent Update for date entry.
08.0	13Feb2024	Form-Specific Instructions	○ New instruction added to Hematology for “Test Result” field. New instruction added for Local Laboratory Results for “Test Result” field.

08.1	18MAR2024	All sections	Updated template version