CRF Completion Guidelines (CCGs)

Protocol #: HPTN 084

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CRF Completion Guidelines

Protocol Title:	A Phase 3 Double Blind Safety and Efficacy Study of Long-Acting Injectable Cabotegravir Compared to Daily Oral TDF/FTC for Pre-Exposure Prophylaxis in HIV-Uninfected Women
Protocol Number:	HPTN 084
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GENERAL CRF COMPLETION GUIDELINES

The following instructions are general data completion instructions intended to assist site staff when completing Medidata Rave electronic Case Report Forms (eCRFs) for HPTN 084. Detailed guidance on general navigation and use of Medidata Rave is provided in the Medidata Rave Electronic Data Capture (EDC) Training Manual, which is posted on the HPTN 084 Atlas web page, located here:

https://atlas.scharp.org/cpas/project/HPTN/084/begin.view

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General eCRF Completion Guidelines

- **Do not share your username or password to the HPTN084 database with any other site staff member** (i.e. do not let someone else enter data for you).
- All data entered in the electronic form should correspond accurately with source documents.
- Complete all required fields on the screen. A skip pattern, as noted in the CCGs, is the only valid reason to leave a response blank.
- Ensure all entries are in English and are accurate, consistent, complete, and medically logical.
- Ensure there are no missing data in the form.
- Where requested to "specify" for an item, ensure an entry has been made.
- Study visit dates should be complete and chronological according to the protocol.
- All date fields are entered as Day/Month/Year (dd/mmm/yyyy) (e.g. 16 ARP 2018).
- Do not enter and save text as a response in items with dropdown menus. Such text responses will be flagged as non-conformant data.
- Avoid using abbreviations and symbols wherever possible.
- Do not use special characters unless explicitly stated
- Do not hit the Return key in text fields.
- If corrections are needed, click the "pencil" icon to the right of the field. The field will become editable. Correct the value and give the reason for the change, if needed.

Log Forms

Log (or repeating) forms are used when multiple entries of the same type of information could occur. Log forms can be shown in "portrait view" (shows you once instance of the form) and "grid view" or "complete view" (shows you all entries made on the log form). The following HPTN084 eCRFs are log forms or use the log field format: Adverse Event, Contraception, HIV Test Results, Concomitant

Medications, Social Impact, Injection Site Reaction, Protocol Deviation, Medical History, Pregnancy Outcome, Product Hold/Discontinuation, and Open Label Truvada.

Log Form General Instructions

- Each log form has a "trigger" form that is required to be completed. Answering "Yes" to the trigger form populates the actual log form in the folder.
- The log's first entry will appear as a blank form page. Once filled and saved, this entry appears as a row on the form in the grid view.
- Click "Add a new Log line" to add a new entry to the log form (i.e. add a new row of data). You will be redirected to another blank form to enter complete details.
- Clicking a field on any row of the log form while it is in "complete" or "grid" view opens the form for that row's entry.
- Existing entries may only be edited from the form page (i.e. when you are in "portrait view").
- Log lines can be inactivated (e.g. if a logline was entered in error). Click "Inactivate" and select the appropriate log line to be inactivated. **NOTE: Before inactivating a log line, make sure all queries on that form have been resolved.**
- Log lines that have been inactivated can also be reactivated if needed (e.g. if a line has been inactivated in error). Click "Reactivate" and specify the log line number that should be reactivated.

Recording Dates

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, and "yyyy" represents the four digits of the year. In the study database, these three-letter abbreviation for the month will be selected from a dropdown list in the month field.

Some items allow for partial dates (*this will be noted below in the form-specific guidelines*). When recording partial dates, the following guidance applies:

- Enter UN for the day
- Select "UNK" for the month from the dropdown menu

Recording Time

Time is entered using the 24-hour clock (00:00-23:59), in which hours are designated from 0–23. For example, in the 24-hour clock 2:25 p.m. translates to 14:25 (2 p.m. = 14), which would be recorded as follows:

Midnight is recorded as 00:00, not 24:00.

Recording Numbers (Non-Dates/Times)

When recording numbers, enter the whole number without leading zeros. Instead of "00", this should be recorded as "0". The number 3 should be recorded as 3, not "03" and so on.

Data Corrections and Additions

Sometimes, data on a CRF may need to be changed, clarified, or amended. There are many reasons why data may need to be changed, such as in response to a query or as a result of site review.

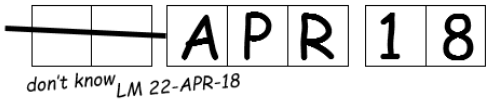
If the eCRF is source, it is sufficient to make data updates in the study database itself. If a paper CRF is completed, it is important to make changes to the original paper CRF first, then enter the updated data onto the eCRF.

Handling Missing and Unknown Data

If the answer to an item is not known, is not available, or if the participant refuses to answer for a required item:

On paper CRFs and source documents: draw a single horizontal line through the applicable item and initial and date the item for which the data is unknown. 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 item that is refused, missing, unknown, or not applicable, regardless of whether it is marked as such during the initial paper form completion, or as an update to the form.



On eCRFs: enter "UN" or select the "UNK" option from the dropdown list of the applicable field for which the data is missing/unknown.

If an entire form cannot be completed because those procedures were not done, mark the form in such a way that indicates that the procedures were not done or not collected. If there is no option to do this, please contact the SCHARP Clinical Data Manager.

Entering Local Laboratory Results

- When recording local lab results onto eCRFs, first select the site name from the drop-down menu on the top of the eCRF. When doing so, the units of measurement and local reference ranges will auto-populate onto the form.
- **Note: If you have used a back-up lab and need to update reference ranges, email sc.labnormals@scharp.org.**
- Record local lab results using the SCHARP standard units of measurement (which map to the units of measurement found in the DAIDS Toxicity Table).
- If local lab results are reported in units other than the SCHARP standard units of measurement, the local lab results will need to be converted to the correct units of measurement. The following validated conversion tool should be used: https://atlas.scharp.org/cpas/project/Collaborators/Lab%20Unit%20Conversion%20Tool/begin.view
- Once labs are in correct units, rounding may be needed depending on the format of the variable.
    - A format determines how data is entered and stored within Rave. For numbers, this refers to the number of values that can be entered in a number field and where a decimal can be placed. For example:
    - A format of "4" accepts any whole number with 4 digits total or fewer than 4 digits (e.g. 1, 11, 111).

- A format of 3.1 accepts a total of no more than 3 digits, with up to 1 digit allowed to the right of the decimal point (e.g. 1.8, 12.3, 123).
- Refer to form-specific instructions below to find the format of each variable.

Grading Local Laboratory Results

- All lab results recorded onto eCRFs must be graded using the DAIDS Toxicity Table as reference. If a lab result does not appear in the DAIDS Toxicity Table, then it does not need to be graded.
- Always compare the severity grade range in the DAIDS Toxicity Table to the value that was recorded on the eCRF (not the lab-reported value).
    - If the lab value recorded on the eCRF has more significant digits than the severity grade range in the DAIDS Toxicity Table, DO NOT ROUND THE LAB VALUE ON THE CRF (any more than it may have already been rounded in order to record it on the eCRF). Grade the lab value as recorded exactly on the eCRF. For example, if the lab value recorded on the eCRF is 10.58 but a grade 1 for that analyte, according to the DAIDS Toxicity Table, is 10.6 to <11.5, do not round 10.58 to 10.6. Grade the lab value of 10.58 (you can mentally add zeros to the severity grade range such that 10.6 – <11.5 becomes 10.60 – <11.50).
- The DAIDS Toxicity Table may require you to calculate a grade range based on the local lab's upper or lower limit of normal for that analyte (e.g. Grade 1 Creatinine = 1.1 – 1.3 x ULN)
    - If calculated grade range has more digits than the recorded lab value, treat the "missing" lab value digits as zero. For example, if Calculated Grade 1 range for analyte = 1.43 – 1.95 but value recorded on eCRF = 1.4, treat the value recorded on the eCRF as 1.40. Then grade 1.40. DO NOT ROUND THE CALCULATED SEVERITY GRADE RANGE.
    - If a lab value falls between two calculated severity grades, assign the higher grade according to the DAIDS Toxicity Table.
- Some labs can be graded in multiple ways, such as creatinine and calculated creatinine clearance. For example, a grade 2 creatinine is >1.3 to 1.8 x ULN OR an increase of 1.3 to 1.5 x participant's baseline value. Remember to compare follow-up values of these analytes to baseline values and grade these analytes using both criteria listed in the DAIDS Toxicity Table.
- Once a lab value has been graded, record the severity grade at the top of the lab results form by selecting the applicable grade from the dropdown menu for each corresponding lab analyte. If the analyte does not meet criteria for severity grade 1 or greater per the DAIDS Toxicity Table, select the "Not gradable" option.
- If an abnormal lab finding meets AE reporting criteria, select the corresponding AE within the dropdown menu for that analyte on the same form. Note that the AE must be entered within the Ongoing Logs folder prior to completing this item in order to link the associated AE to the abnormal lab value.

Missed Visits

If a scheduled visit was missed, answer "Did the participant complete this visit?" on the Date of Visit eCRF as "No". After this form is saved, the Missed Visit eCRF will be added to the visit folder for completion. No other eCRFs will be able to be completed.

Add Event

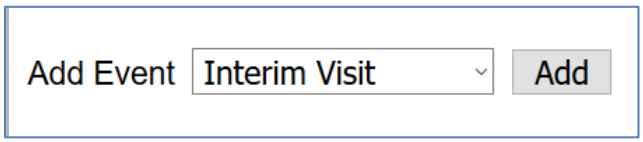
The Add Event dropdown menu can add folders and forms to a participant's casebook. The following folders and forms can be added to a participant's casebook in HPTN084:

- Interim Visits
- Open Label Truvada

- Pregnancy Visits
- Pregnancy History CRF
- Yearly Visits
- Early Unblinding CRF

Interim Visits

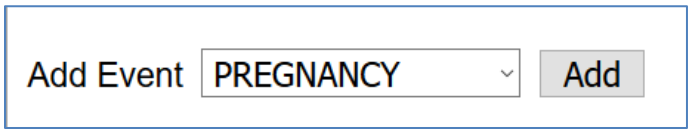
- Should unscheduled assessments be required for a non-routine visit or procedure, add the visit by clicking on the Add Event button. Select "Interim Visit". An Interim Visit folder will appear in the participant's casebook.



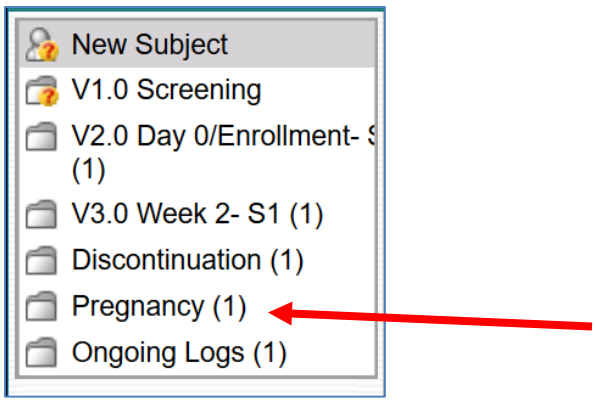
- Open the Interim Visit folder to access the Interim Visit form.
- Tick the box next to any forms that were completed to document the visit. The selected forms will then be populated automatically within the applicable Interim Visit folder (with the exception of any log forms that are selected).

Pregnancy Visits

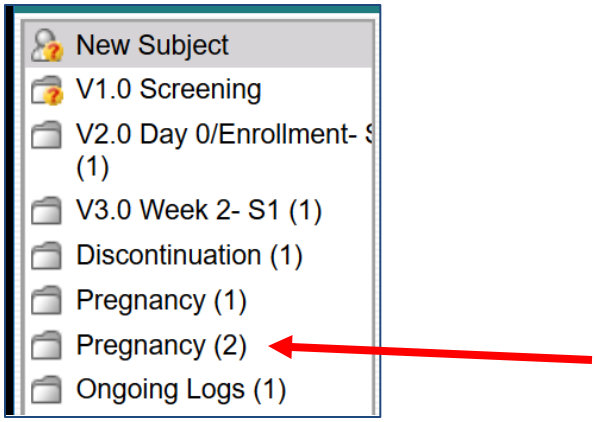
- If a woman is moving to the pregnancy visit schedule, use the Add Event feature to first add a Pregnancy folder to the participant's case book.



- This will be considered the parent Pregnancy folder for all visits that occur during this particular pregnancy.

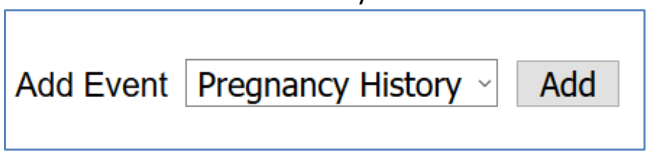


- Should a second pregnancy occur, a new second parent Pregnancy folder will need to be added to the database using the Add Event feature again.

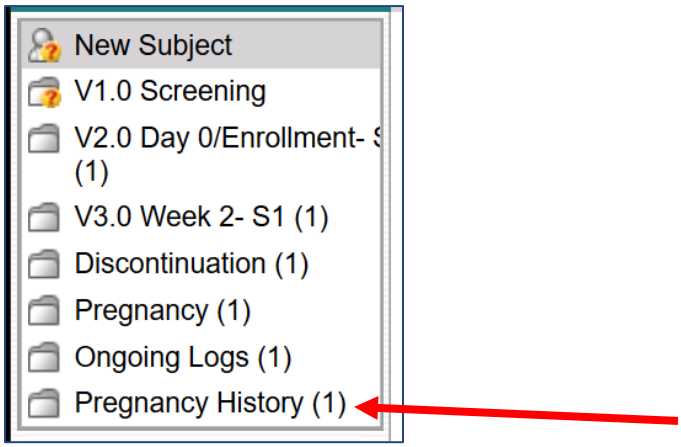


- The Pregnancy folder name will be updated to include the date the pregnancy was reported. For example, "Pregnancy (01August2018)".

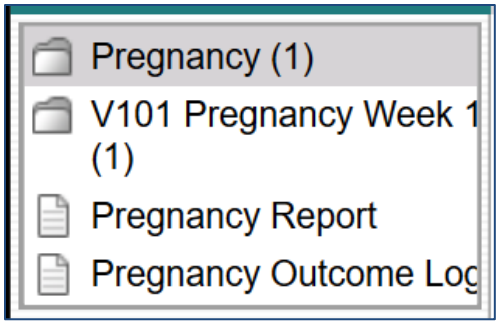
- Use the Add Event feature to also add the Pregnancy History form once during the participant's course of time in the study.



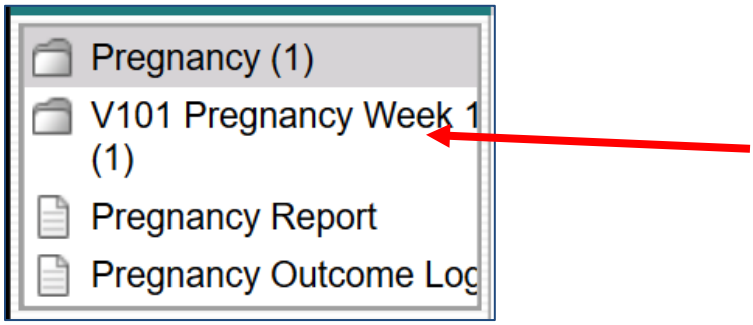
- The form will be located in the participant's casebook. It will not be located in the Pregnancy Visit folders themselves, as it only gets completed once during the study for a given participant.



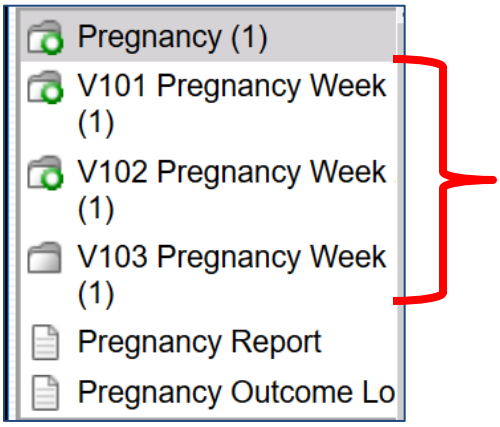
- Navigate to the parent Pregnancy folder to find the Pregnancy Report CRF, the Pregnancy Outcome Log, and a sub-folder for the first Pregnancy Visit.



- To document each visit associated with the pregnancy visit schedule, navigate to the sub-folder located within the parent Pregnancy folder.



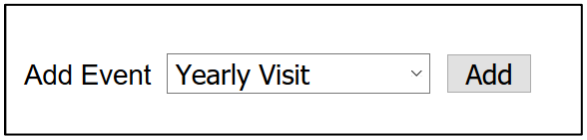
- Inside the sub-folder you will find the Date of Visit – Pregnancy form. Complete all items on this form. When the form is saved, additional CRFs needed to document the visit will be added to this sub-folder. In addition, the next Pregnancy Visit sub-folder will be added to the larger Pregnancy parent folder.
- To document the use of oral Truvada during pregnancy, the Open Label Truvada Log form should be used. This form lives in the Ongoing Logs folder.
- If additional forms are needed to document the Pregnancy Visit beyond the ones mentioned above, mark "yes" to "Did the participant have any additional procedures at this visit?". The Additional Procedures CRF will then be added to this sub-folder.
- As new pregnancy visits occur, navigate to each Pregnancy Visit sub-folder to find the forms needed to document that pregnancy visit.



- If the participant moves back to Step 2 after the pregnancy (and/or subsequent breastfeeding period), mark item 4 on the Date of Visit – Pregnancy form, "Is the participant moving to a different step or visit schedule?" as "Yes". Then mark item 4a, "If yes, please indicate which step or visit schedule" as "Back to Step 2".
- Any regular Step 2 study visits that are not completed due to the participant being on the pregnancy visit schedule need to be documented as missed visits using the Missed Visit CRF, with the reason for the missed visit in item 2 being recorded as "participant on pregnancy visit schedule". Participants on the pregnancy schedule will still be counted as "retained" in Step 2.

Yearly Visit Schedule

- If a participant is moving to a yearly visit schedule, use the Add Event feature to add a Yearly Visit folder to the participant's casebook.



- Inside the Yearly Visit folder will be a Date of Visit – Yearly CRF, to document the visit, an HIV Test Results CRF, and a Plasma Storage CRF.
- If additional forms are needed to document the visit, answer the question on the Date of Visit – Yearly CRF "Did the participant have any additional procedures at this visit?" as "Yes" and the Additional Procedures CRF will populate into the Yearly Visit folder. Mark any forms needed on the Additional Procedures CRF and those forms will appear in the Yearly Visit folder.
- Up to five Yearly Visit folders can be added per participant.
- Any regular Step 2 study visits that are not completed due to the participant being on the yearly visit schedule need to be documented as missed visits using the Missed Visit CRF, with the reason for the missed visit in item 2 being recorded as "Other". In the "If other, specify" box indicate that the participant is on a yearly visit schedule.

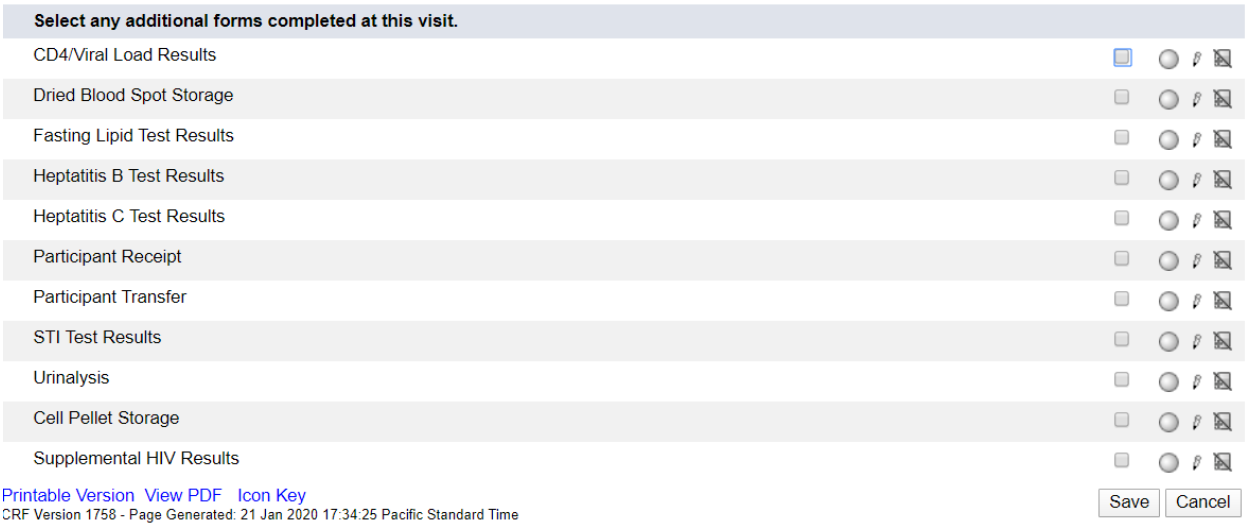
Electronic Signatures

The Investigator of Record (IoR) will sign CRF pages after the participant's data has been reviewed and no further changes or additions to the forms are necessary. The SCHARP Clinical Data Manager(s) will provide directions for the timing of when the Investigator should perform the final review and sign the form pages. **Please note that if an eCRF is signed off and a query is applied to the form or a change to the form occurs during the study, the electronic signature will be broken and the IoR will need to re-sign the form.**

Screen Failures

If a participant does not enroll in the study, the only required forms at Screening that need to be completed to document the visit are: Screening Outcome, HIV Test Results, Plasma Storage, and VOICE Risk Score. While no other forms are required to document the visit, it is okay if all the Screening forms are completed even if a participant does not enroll in the study; forms should not be deleted or inactivated.

ADDITIONAL PROCEDURES



Purpose

This form allows sites to add additional CRFs (beyond the ones required for that visit) to the current visit folder.

General Instructions

This form will populate within every regularly scheduled follow-up visit folder if, on the Date of Visit CRFs (e.g. Step 1, 2, 3, Pregnancy), the question “Did the participant have any additional procedures at this visit?” Is answered “Yes”.

Item-specific Instructions

Select the check boxes next to the CRFs included on the Additional Procedures form for those forms that need to be added to the visit folder and save the form. Once this form is saved the forms that were checked will appear in the current visit folder.

ADDITIONAL PROCEDURES - OLE

Select any additional forms completed at this visit.	
CD4/Viral Load Results	☐
Chemistry Testing	☐
Counseling	☐
Dried Blood Spot Storage	☐
Fasting Lipid Test Results	☐
Hematology	☐
HIV Supplemental Results	☐
Infant Assessment	☐
Infant Breastmilk Feeding Assessment	☐
Infant Specimen Collection - Plasma	☐
Liver Function Test Results	☐
Participant Receipt	☐
Participant Transfer	☐
Plasma Storage	☐
Pregnancy Test Results - OLE	☐

Purpose

This form allows sites to add additional CRFs (beyond the ones required for that visit) to the current visit folder for the OLE Visits.

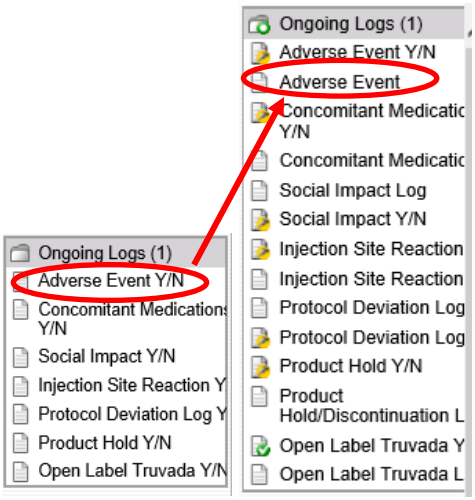
General Instructions

This form will populate within every regularly scheduled follow-up visit folder if, on the Date of Visit - OLE CRF, the question “Did the participant have any additional procedures at this visit?” is answered “Yes”.

Item-specific Instructions

Select the check boxes next to the CRFs included on the Additional Procedures form for those forms that need to be added to the visit folder and save the form. Once this form is saved the forms that were checked will appear in the current visit folder.

ADVERSE EVENT Y/N



Purpose

This form documents if an adverse event was experienced by the participant during the study.

General Instructions

This form is located within the "Ongoing Logs" folder. It is used to trigger the Adverse Event Log. Once it has been saved it does not need to be completed again throughout the duration of the study.

Item-specific Instructions

Field	Instructions
Has the participant experienced an Adverse Event during the study?	• If "Yes" is selected and the form saved, then the "Adverse Event" Log appears in the folder and can be completed.

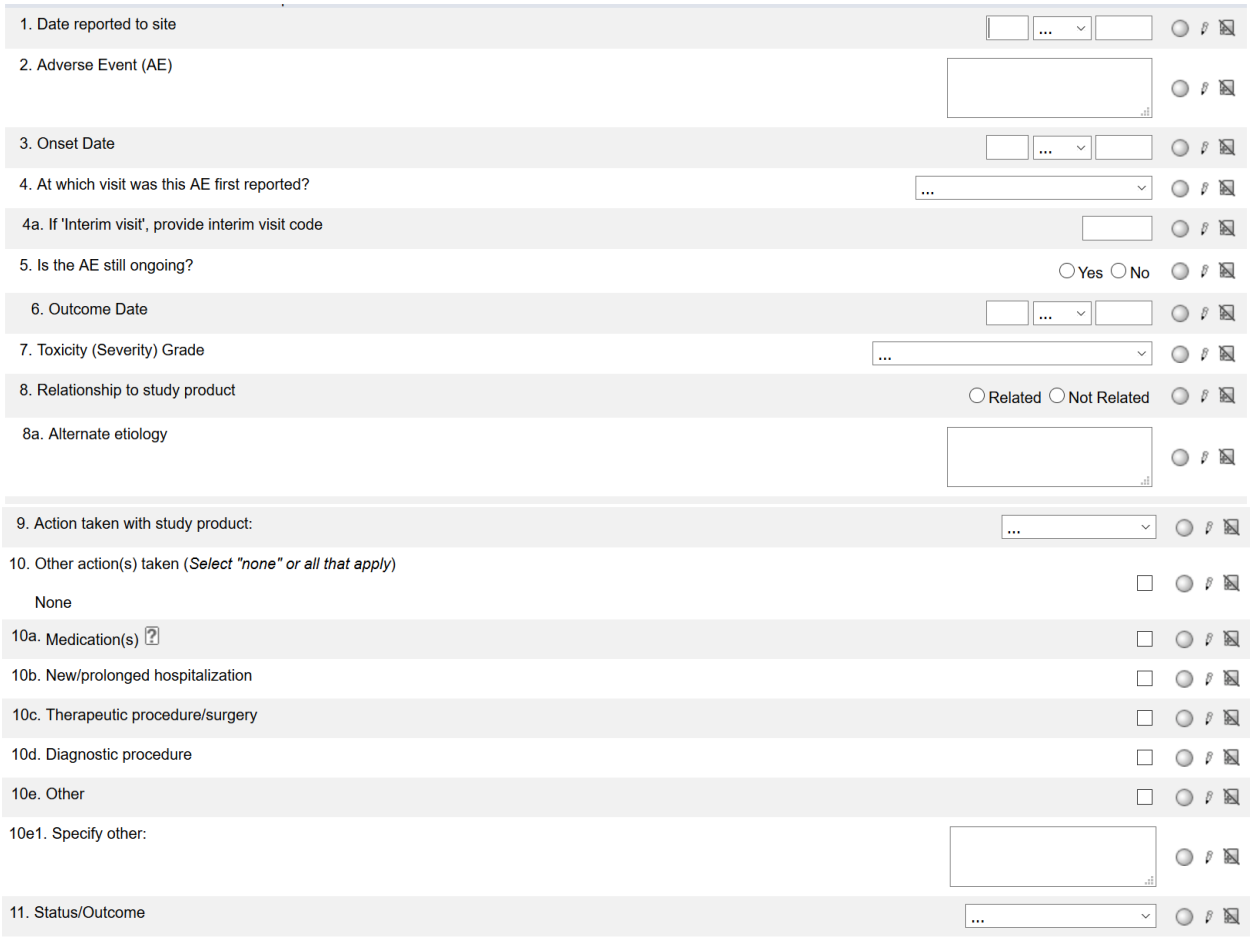
ADVERSE EVENT

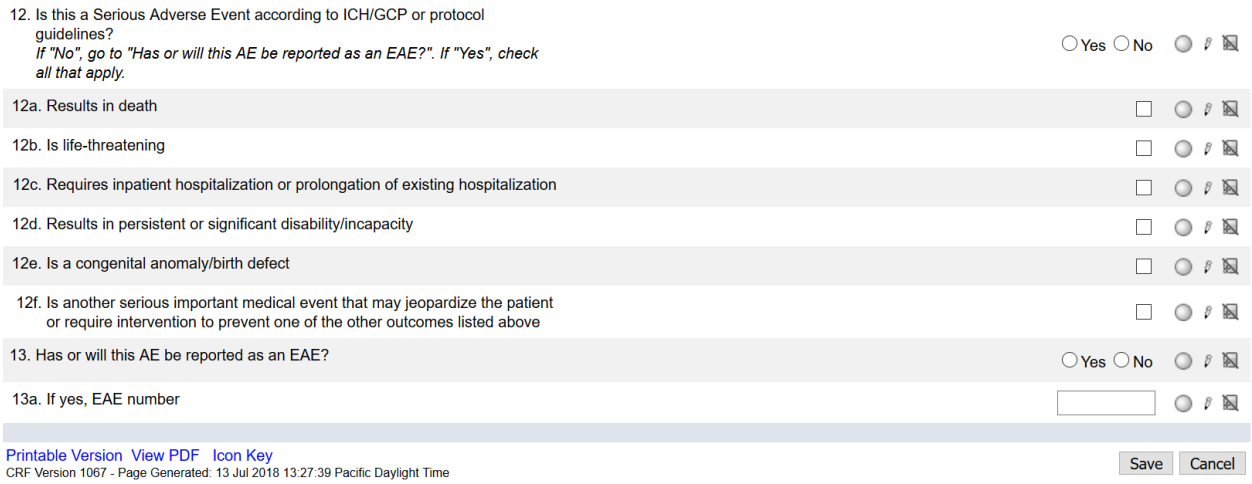
Purpose

This form is used 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). Add additional log lines by clicking “Add a new Log line”, located at the bottom of the form. Record a diagnosis/anatomical location if available. HIV infection should not be reported on this form. Only list conditions that start on or after the enrollment date; otherwise record conditions as pre-existing on the Medical History CRF. Record increases in severity/frequency as new events with corresponding start/stop dates. Injection Site Reactions are not reported on this form, they are reported on their own form, the Injection Site Reaction Log.





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. • A complete date is required.
Adverse Event (AE)	• Describe the AE using medical terminology. • 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. • If a cluster of symptoms reported on separate Adverse Experience Log lines are 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 by selecting the 'Inactivate' option [Note: Before inactivating the log line, make sure all queries for that AE page have been resolved]. • If an abnormal lab value is reported, record the lab assay with the direction (i.e. "increased" or "decreased") of the abnormality. For example, "decreased hematocrit" or "increased ALT".
Onset Date	• Record the date participant first experienced symptoms, the date the AE was discovered during a clinical/physical exam, or the specimen collection date of an abnormal lab result as appropriate. • At minimum, a month and year are required. If day is unknown, enter "UN" for the day.
At which visit was this AE first reported?	• Select the visit when the site first became aware of the AE. • If an interim visit, select "Interim Visit".

Field	Instructions
Interim visit code	• If "Interim Visit" is selected for "At which visit was this AE first reported", enter interim visit code in space provided. Otherwise leave this item blank.
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 only if "Is the AE still ongoing? is "No". • At a minimum, a month and year are required. If day is unknown, enter "UN" for the day. • The outcome date may be a date in which the participant reports no longer experiencing the AE, the date of visit, or a 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). o Grade 1 (Mild) o Grade 2 (Moderate) o Grade 3 (Severe) o Grade 4 (Potentially life-threatening) o Grade 5 (Death)
Relationship to study product	• Record the 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.
Alternate etiology	• If the AE is not related to study agent, record rationale or alternate etiology.

Field	Instructions
Action Taken with Study Product	• Select "dose not changed" if there is no change to the participant's planned use (dose, frequency, or schedule) of study product as a result of the AE. • "Dose reduced" and "dose increased" do not apply and should not be selected in HPTN084. • Select "drug withdrawn" if the AE results in permanent discontinuation of study product. • Select "drug interrupted" if AE results in a product hold. • For multiple AEs, mark "drug withdrawn" or "drug interrupted" for each AE contributing to the permanent discontinuation or temporary hold. Ensure the Product Hold Y/N and Product Hold/Discontinuation forms are completed. • Select "not applicable" if 1) the AE's onset date is on or after the date the participant permanently discontinues study product use; 2) study product is held or permanently discontinued for a different reason; or 3) the AE is Grade 5 - death.
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. • If "Other", specify relevant details in the "Other, specify" text field provided.
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 at the time it is reported 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".

Field	Instructions
Is this a Serious Adverse Event according to ICH/GCP or protocol guidelines?	• If "Yes" is selected, mark all applicable items in 12a-12f that best indicate why this AE is being reported as a serious adverse event. • For more information about ICH guidelines and SAEs refer to the current *Manual for Expedited Reporting of Adverse Events to DAIDS.*
Has or will this AE be reported as an EAE?	• For more information 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.

ADVERSE EVENT Infant Y/N

Purpose
This form documents if an adverse event was experienced by the infant during the sub-study.

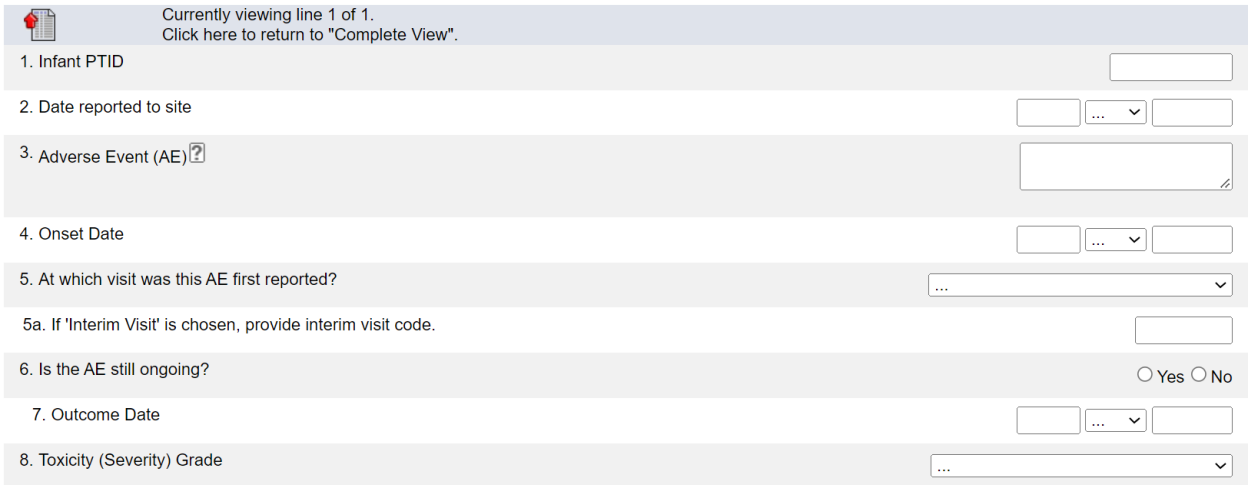
General Instructions
This form is located within the "Ongoing Logs" folder. It is used to trigger the Adverse Event - Infant Log. Once it has been saved it does not need to be completed again throughout the duration of the study.

Item-specific Instructions

Field	Instructions
Has the infant experienced an Adverse Event during the study?	• If "Yes" is selected and the form saved, then the "Adverse Event - Infant" Log appears in the folder and can be completed.

ADVERSE EVENT - INFANT

Page: **Adverse Event - Infant**



9. Relationship to Study Product	○ Related ○ Not Related
9a. Alternate etiology	
10. Action Taken with Study Product:	...
11a. Other action(s) taken (*Select "none" or all that apply*) None	☐
11b. Medication(s)	☐
11c. Therapeutic procedure/surgery	☐
11d. Diagnostic procedure	☐
11e. Other	☐
11e1. Specify other:	
12. Status/Outcome	...
13. Is this a Serious Adverse Event according to ICH/GCP or protocol guidelines? *If "No", go to "Has or will this AE be reported as an EAE?". If "Yes", check all that apply.*	○ Yes ○ No
13a. Results in death	☐
13b. Is life-threatening	☐
13c. Requires inpatient hospitalization or prolongation of existing hospitalization	☐
13d. Results in persistent or significant disability/incapacity	☐
13e. Is a congenital anomaly/birth defect	☐
13f. Is another serious important medical event that may jeopardize the patient or require intervention to prevent one of the other outcomes listed above	☐
14. Has or will this AE be reported as an EAE?	○ Yes ○ No
14a. If yes, EAE number	

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Purpose

This form is used to document *Infant Adverse Events (AE)* in the Pregnancy and Infant Sub-study. Infant AEs are NOT to be reported on the Adverse Events page as that is for the mother only.

General Instructions

This form is found in the ongoing logs folder for all live births as indicated on the Pregnancy Outcome OLE CRF.

Complete one log line for each Adverse Event (AE) for the infant. Add additional log lines by clicking "Add a new Log line", located at the bottom of the form. Record a diagnosis/anatomical location if available. HIV infection should not be reported on this form. Record increases in severity/frequency as new events with corresponding start/stop dates.

Adverse Event reporting period for Infants is up to and including 24 weeks post-partum.

See SSP section 10.3.1 "Considerations for Infants in Step 4d" for more details.

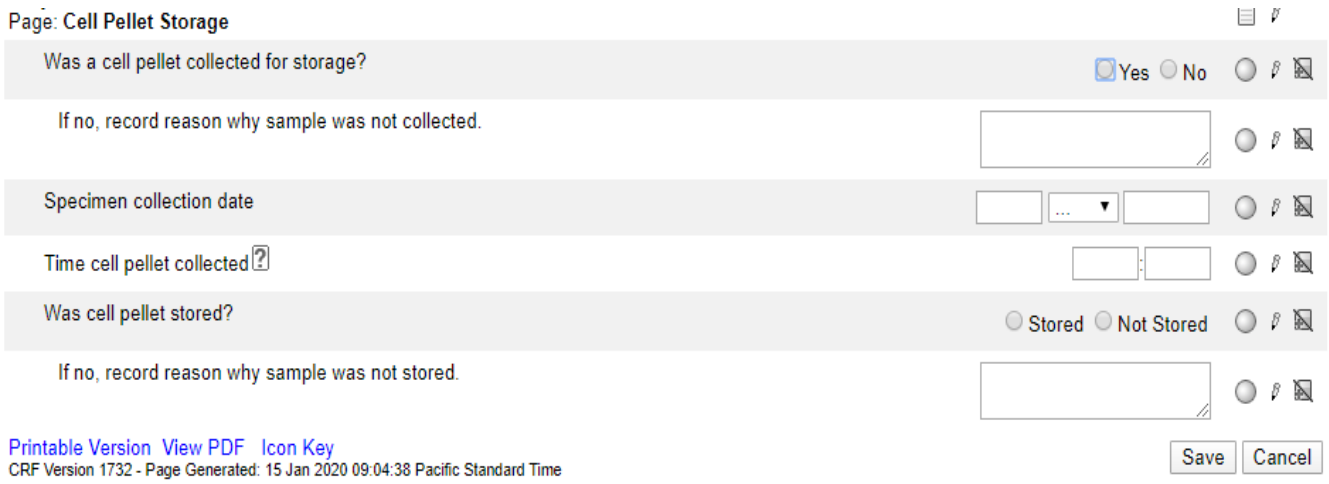
Item-specific Instructions

Field	Instructions
Infant PTID	• Enter Infant's PTID that was generated by Rave and is recorded on the respective Sub-Study Pregnancy Outcome -OLE CRF.
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. • A complete date is required.
Adverse Event (AE)	• Describe the AE using medical terminology. • 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. • If a cluster of symptoms reported on separate Adverse Experience Log lines are 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 by selecting the 'Inactivate' option [Note: Before inactivating the log line, make sure all queries for that AE page have been resolved]. • If an abnormal lab value is reported, record the lab assay with the direction (i.e. "increased" or "decreased") of the abnormality. For example, "decreased hematocrit" or "increased ALT".
Onset Date	• Record the date participant first experienced symptoms, the date the AE was discovered during a clinical/physical exam, or the specimen collection date of an abnormal lab result as appropriate. • At minimum, a month and year are required. If day is unknown, enter "UN" for the day.
At which visit was this AE first reported?	• Select the visit when the site first became aware of the AE. • If an interim visit, select "Interim Visit".
Interim visit code	• If "Interim Visit" is selected for "At which visit was this AE first reported", enter interim visit code in space provided. Otherwise leave this item blank.

Field	Instructions
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 only if "Is the AE still ongoing? is "No". • At a minimum, a month and year are required. If day is unknown, enter "UN" for the day. • The outcome date may be a date in which the participant reports no longer experiencing the AE, the date of visit, or a 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). • Only Grade 2 (moderate) and more severe AEs are to be reported for infants. Grade 1 (mild) infant AEs need only be recorded in source documentation. o Grade 2 (Moderate) o Grade 3 (Severe) o Grade 4 (Potentially life-threatening) o Grade 5 (Death)
Relationship to study product	• *Refer to SSP section Considerations for Infants in Step 4d regarding infants and relationship to study drugs***.** • Record the 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.
Alternate etiology	• If the AE is not related to study agent, record rationale or alternate etiology.
Action Taken with Study Product	• Select "not applicable"

Field	Instructions
Other action(s) taken	• Select "None" or check all that apply. • Select "Medication" only if infant is given medication, and record in source documentation. Medications for infants should NOT be reported on a Concomitant Medications Log. • If "Other", specify relevant details in the "Other, specify" text field provided.
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 at the time it is reported 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?	• If "Yes" is selected, mark all applicable items in 12a-12f that best indicate why this AE is being reported as a serious adverse event. • For more information about ICH guidelines and SAEs refer to the current *Manual for Expedited Reporting of Adverse Events to DAIDS.*
Has or will this AE be reported as an EAE?	• For more information 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.

CELL PELLET STORAGE



Purpose

This form is used to document the collection and storage of cell pellets for the purpose of proviral HIV DNA testing requested by HPTN LC.

General Instructions

Form can be added to a given visit folder by indicating on the Date of Visit form that additional procedures were performed.

Item-specific Instructions

Field	Instructions
Was a cell pellet collected for storage?	• Select "Yes" if cell pellet was collected for storage. • Select "No" if plasma sample was not collected for storage and provide reason below.
If no, record reason why sample was not collected.	• If cell pellet was not collected, a reason why not is required.
Specimen collection date	• Enter the date the sample was collected. • A complete date is required.
Time cell pellet collected	• Time should be reported using the 24-hour clock.
Was cell pellet stored?	• Select "Stored" or "Not Stored". • If "Not Stored", provide reason below.

Field	Instructions
If no, record reason why sample was not stored.	• If cell pellet was not stored, provide reason here.

CD4/VIRAL LOAD RESULTS

Purpose

To document CD4 and HIV viral load results for HIV infected participants.

General Instructions

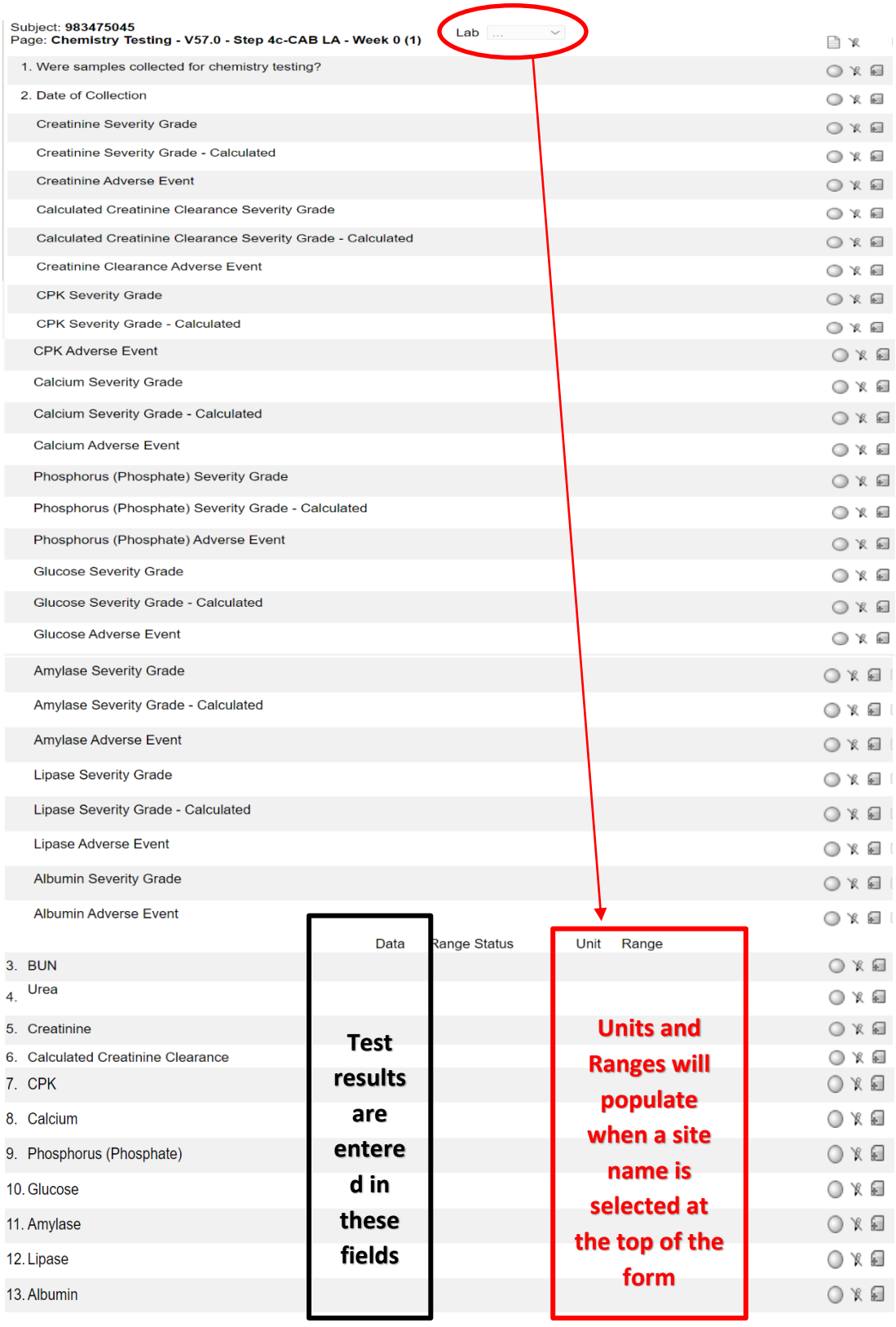
Complete this form when a participant is HIV positive per Protocol Appendix II. To add this form to a participant's visit folder, select "CD4/Viral Load Results" on the Additional Procedures CRF Once the Additional Procedures form is saved, the CD4/Viral Load Results form appears in the visit folder. *Note: To populate the Additional Procedures CRF, the Date of Visit CRF must be answered as "Yes" to "Did the participant have any additional procedures at this visit?"*

Item-specific Instructions

Field	Instructions
Was a CD4 done?	• If "No" is selected, leave the rest of the CD4 items blank and move on to the first question in the Viral Load section.
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/mm^3". • If sample was unable to be analyzed, mark "Or Select if unable to analyze".
Or Select if unable to analyze	• Mark this box if the sample was unable to be analyzed.

Field	Instructions
Was a viral load done?	• If "No" is selected, do not complete the remaining items on the form.
Date of collection:	• If viral load was done, enter the date sample was collected. • A complete date is required.
Operator	• If a number for the viral load is provided on the lab report, ">", "<", or "=" must be selected.
HIV RNA PCR (plasma)	• Enter the HIV RNA PCR value in "viral copies/mL". • A maximum of nine digits is allowed.
Detected, less than LLQ or LLD	• If a lab result says "Detected, under lower limit of quantification", mark this box. Otherwise, leave blank.
Detected, greater than the upper limit of quantification	• If a lab result says "Detected, greater than the upper limit of quantification", mark this box. Otherwise, leave blank.
Target not detected	• If a lab result says "HIV-1 RNA target not detected", mark this box. Otherwise, leave blank.

CHEMISTRY TESTING



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

General Information/Instructions
This form is completed at protocol-specified visits and if clinically indicated at any other visit. If a sample was not collected, do not record any additional information on the form.
Item-specific Instructions
Enter lab data in the following sequence:

Field	Instructions
Lab	• **Select the site name from the drop-down menu to populate local lab reference ranges (and units) in the lab results section**. • **Date of birth on the Demographics CRF must be entered in order to populate the local reference ranges.** • If site name is not listed under "Lab" contact the SCHARP CDM.
Test Results	• Enter the result of the specified test (bottom of form) in the standard units of measurement used for this study (see below). • If results from the local lab are not reported in the standard units of measurement, the units will need to be converted using the Lab Conversion Tool on Atlas. • If test was not performed or the results were not reported, leave blank and record a comment in the query message box (if query fires). *For example, if CPK was not performed, leave the item blank and save the form. When a query fires record "not done" in the query message box.* • Either BUN or Urea need to be reported (not both). • If result is entered, ensure a severity grade for the result is entered (only for analytes that can be graded per the DAIDS Tox Table).

Data Formats and Units of Measurement

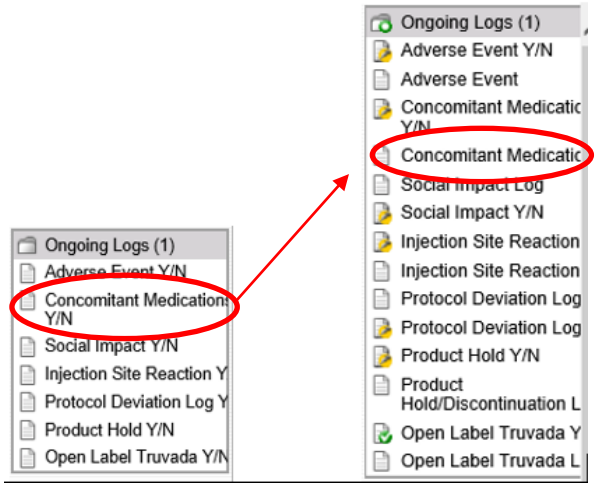
Test*	Data Format Requirements	Unit Requirements
BUN	5.2	mg/dL
Urea	5.2	mmol/L
Creatinine	5.2	mg/dL
Calculated Creatinine Clearance	5.2	mL/min
CPK	7.2	U/L
Calcium	5.2	mg/dL
Phosphorus (Phosphate)	5.2	mg/dL
Glucose	5.2	mg/dL
Amylase	5.2	U/L

Test*	Data Format Requirements	Unit Requirements
Lipase	5.2	U/L
Albumin	3.1	g/dL

*The tests are listed as required post-screening. Only Creatinine and Creatinine Clearance are collected at Screening on the Screening Chemistries CRF.

Field	Instructions
Were samples collected for chemistry testing?	• If "No" is selected, leave the rest of the items on the form blank.
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.
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 Chemistry Testing form.

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.

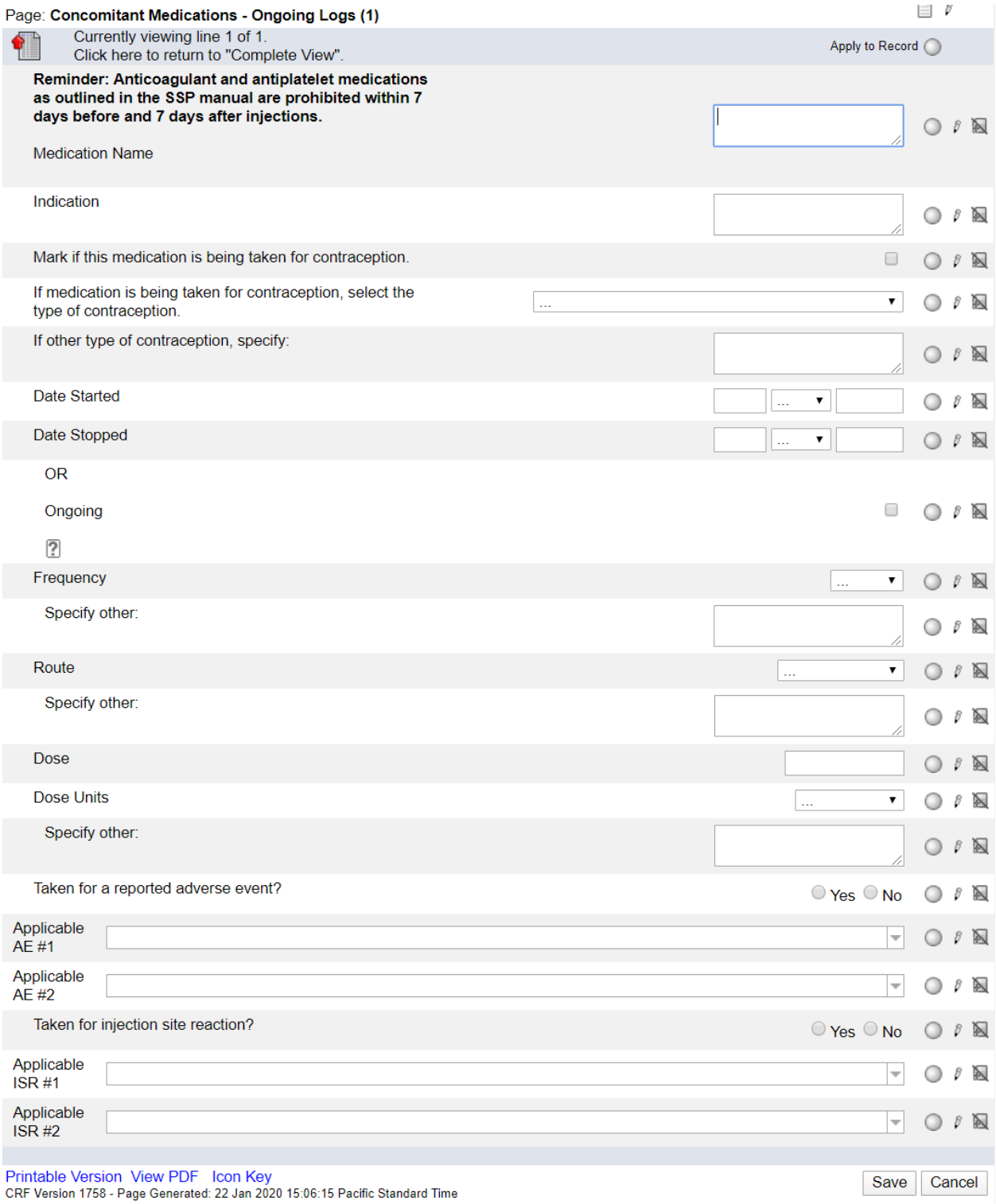
General Instructions

This summary form is located within the Ongoing Logs folder.

Item-specific Instructions

Field	Instructions
Were any concomitant medications taken?	• If "Yes" is selected and the form saved, the Concomitant Medications Log will appear within the Ongoing Logs folder.

CONCOMITANT MEDICATIONS LOG



Purpose

This log form is used to document all medications taken by the participant. This includes, but is not limited to: prescription medications, non-prescription (i.e., over-the-counter) medications, contraceptive hormonal medications (this includes hormonal and non-hormonal IUDs), 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" link to add an additional concomitant medication.
- Record medications taken by the participant starting at Screening. **For long-acting injectable contraceptives, record the last injection received, even if was received prior to Screening.**
- For oral contraceptives, it is not necessary to record each unique pill pack on the CRF.
- Do not record the use of alcohol, tobacco, or caffeine (unless taken in pill form) on the Concomitant Medications Log.
- If medication recorded taken as a contraceptive, Contraception form should also be completed.

Item-specific Instructions

Field	Instructions
Medication Name	• Record the trade or generic name of the medication, whichever the participant reports. • A combination medication can be recorded as one entry. • If a medication's trade or generic name is unknown, record "unknown" and a description or drug class (e.g. "unknown white tablet", "unknown antibiotic").
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 this medication is being taken for contraception	• Tick the box for any item that the participant is using for contraception. Otherwise leave the box blank.
If medication is being taken for contraception, select the type of contraception	• If the box that says "Mark if this medication is being taken for contraception" is marked, select the type of contraception from the drop-down menu. Otherwise leave this item blank.

Date Started	• Enter the date the medication was initiated. • If participant is unable to recall exact date of medication initiation, obtain their best estimate. • A year is required at minimum. • For contraceptive implants or devices, such as IUDs, record the date the implant or device was inserted.
Date Stopped	• Enter the stop date of this medication if known. • A month and year are required at minimum. • If the medication is a vaccination, the "Date Started" and "Date Stopped" should be the same. • For injectable contraception, record each injection the participant receives throughout the course of the study. The start and stop dates of the injection will be the same. • For contraceptive implants or devices, such as IUDs, record the date the implant or device was removed. • At the participant's Study Exit/Termination Visit, the "Date Stopped" must be recorded for each medication OR the "Ongoing" box must be checked.
Ongoing	• Select if medication is given on an ongoing basis. • Select if participant is currently using a contraceptive implant or device.

Frequency	• Select the frequency from options provided in the dropdown list.
	• *Common frequency abbreviations:*
	  ○ PRN: as needed
	  ○ QD: every day
	  ○ QH: every hour
	  ○ QAM: every morning
	  ○ QPM: every afternoon or evening
	  ○ QHS: every night at bedtime
	  ○ BID: twice daily
	  ○ TID: three times daily
	  ○ QID: four times daily
	  ○ ONCE: one time
	  ○ Other
	• If "Other" is selected, record frequency in the corresponding "Specify other" text field provided.
	• If participant is currently using a contraceptive implant or IUD, select "Other" and indicate "Continuous" in "Specify other" text field.

Route	• Select the route from options provided in the dropdown list. • If "Other" is selected, specify route in the corresponding "Specify other" text field provided. • If participant is using an intrauterine device, select "Other" as route and indicate "intrauterine" in the "Specify other" text field. • If participant is using an implant, select "Other" as route and indicate "sub-dermal" in the "Specify other" text field.
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 participant is using a medical device with no active medication, such as a copper IUD, indicate dose as "1". • 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 participant is using a medical device with no active medication, such as a copper IUD, indicate dose unit as "Other" and indicate "device" in the "Specific other" text field. • If "Other" is selected, record a response to the "If Other, specify" text field provided.
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 to the con med being reported using the "Applicable AE" fields.
Applicable AE #1 and Applicable AE #2	• If the medication was taken for a reported AE, select appropriate AE from the dropdown list. • If the same medication is taken for 2 reported AEs, both AE fields should be used to report each individual AE. • The AE form must be completed before it can be linked on the Concomitant Medications Log.
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 to the con med being reported using the "Applicable ISR" fields.

Applicable ISR #1 and Applicable ISR #2	• If the medication was taken for a reported ISR, select ISR from the dropdown list. • If the same medication is taken for 2 reported ISRs, both ISR fields can be used to report each individual ISR. • The ISR form must be completed before it can be linked on the Concomitant Medications Log.

CONSENT – PREGNANCY AND INFANT SUB-STUDY

Page: **Consent - Pregnancy Infant Sub-study**

For which OLE regimen did the participant consent during pregnancy?	○ CAB LA ○ TDF/FTC ○ None
Did the participant consent to having her sample collected during pregnancy?	○ Yes ○ No
If yes, did the participant consent to having her sample stored for future testing during pregnancy?	○ Yes ○ No
Did the participant consent to having her infant's sample collected after pregnancy?	○ Yes ○ No
If yes, did the participant consent to having her infant's sample stored for future testing during pregnancy?	○ Yes ○ No

Purpose

This form is used to document consent details for the Pregnancy and Infant Sub-study.

General Information/Instructions

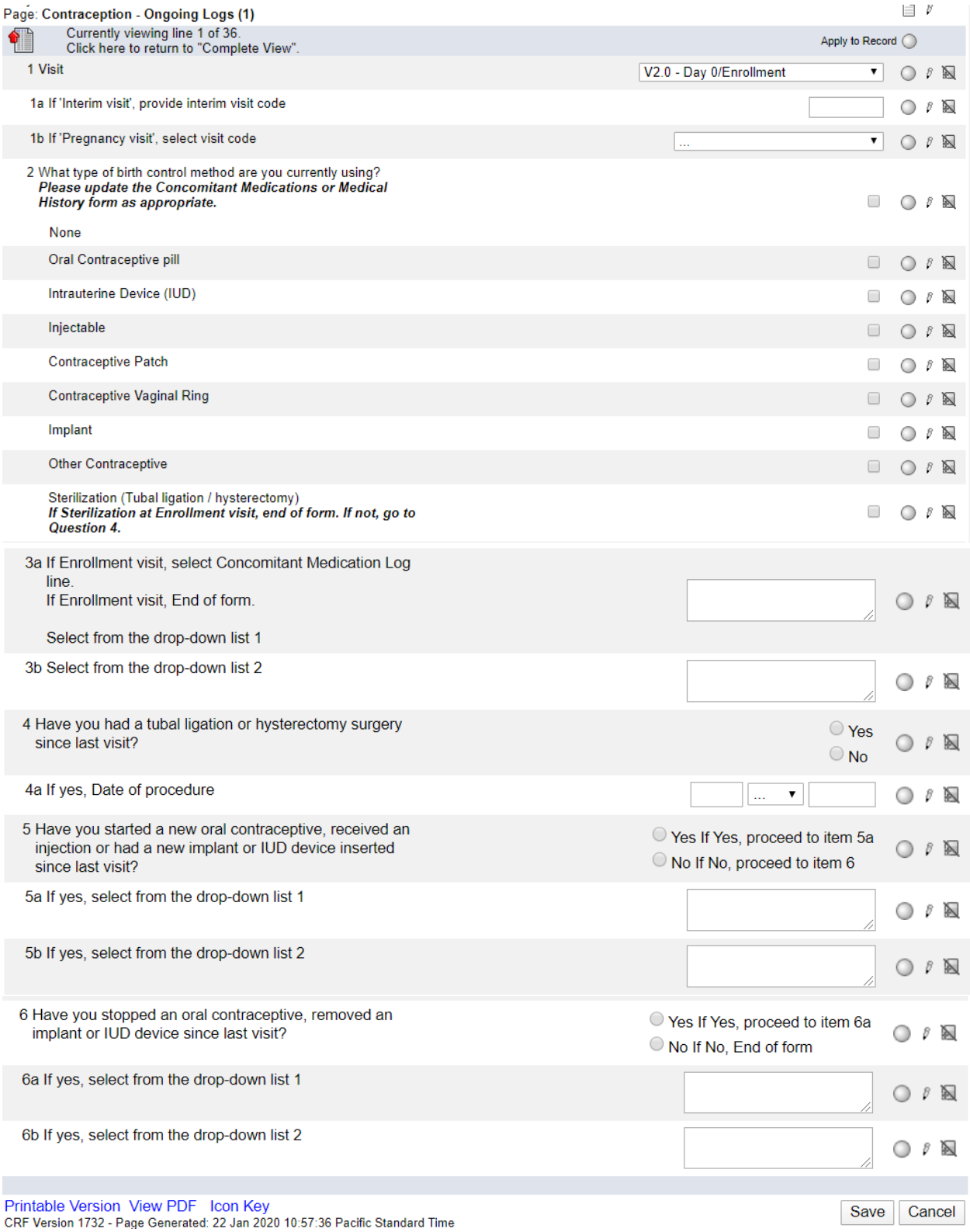
This form is populated when on the "Pregnancy Test Results- OLE" form, item 7., "Did the participant consent to participate in Pregnancy and Infant Sub-Study?" is "Yes". It is also generated if Step 4d is selected on the Product Choice CRF.

Item-specific Instructions

Field	Instructions
For which OLE regimen did the participant consent during pregnancy?	• Select "CAB-LA", "TDF/FTC", or "None".
Did the participant consent to having her sample collected during pregnancy?	• Indicate "Yes" or "No". • This includes all specimen samples for the mother.
If yes, did the participant consent to having her sample stored for future testing during pregnancy?	• Indicate "Yes" or "No". • This includes specimen samples that may be stored for the mother.
Did the participant consent to having her infant's sample collected after pregnancy?	• Indicate "Yes" or "No". • This includes all specimen samples collected for the infant.

Field	Instructions
If yes, did the participant consent to having her infant's sample stored for future testing during pregnancy?	• Indicate "Yes" or "No". • This includes all specimen samples that may be stored for the infant.

CONTRACEPTION



Page: **Contraception - Ongoing Logs (1)**

Currently viewing line 1 of 36.
Click here to return to "Complete View".

Apply to Record

1 Visit	V2.0 - Day 0/Enrollment
1a If 'Interim visit', provide interim visit code	
1b If 'Pregnancy visit', select visit code	...
2 What type of birth control method are you currently using? ***Please update the Concomitant Medications or Medical History form as appropriate.***	
None	
Oral Contraceptive pill	
Intrauterine Device (IUD)	
Injectable	
Contraceptive Patch	
Contraceptive Vaginal Ring	
Implant	
Other Contraceptive	
Sterilization (Tubal ligation / hysterectomy) ***If Sterilization at Enrollment visit, end of form. If not, go to Question 4.***	
3a If Enrollment visit, select Concomitant Medication Log line. If Enrollment visit, End of form. Select from the drop-down list 1	
3b Select from the drop-down list 2	
4 Have you had a tubal ligation or hysterectomy surgery since last visit?	Yes / No
4a If yes, Date of procedure	...
5 Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit?	Yes If Yes, proceed to item 5a / No If No, proceed to item 6
5a If yes, select from the drop-down list 1	
5b If yes, select from the drop-down list 2	
6 Have you stopped an oral contraceptive, removed an implant or IUD device since last visit?	Yes If Yes, proceed to item 6a / No If No, End of form
6a If yes, select from the drop-down list 1	
6b If yes, select from the drop-down list 2	

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Save Cancel

10	V11.0 - Step 2 Week 25	–	–	☐	☐
11	V12.0 - Step 2 Week 33	–	–	☐	☐
12	V13.0 - Step 2 Week 41	–	–	☐	☐
13	V14.0 - Step 2 Week 42	–	–	☐	☐
14	V15.0 - Step 2 Week 49	–	–	☐	☐
15	V16.0 - Step 2 Week 57	–	–	☐	☐
16	V17.0 - Step 2 Week 65	–	–	☐	☐
17	V18.0 - Step 2 Week 73	–	–	☐	☐
18	V19.0 - Step 2 Week 81	–	–	☐	☐
19	V20.0 - Step 2 Week 89	–	–	☐	☐
20	V21.0 - Step 2 Week 97	–	–	☐	☐
	Add a new Log line Inactivate				

Purpose

This form is used to capture information regarding contraceptive use and any associated changes.

General Instructions

Complete this form at all study visits starting at Enrollment. Please note: All contraceptives should still continue to be recorded in the Concomitant Medications Log and Medical History Log. Initially only visit 2.0/Enrollment will be available on the form and once the form is submitted all the visits until Visit 37 would appear as Log Lines. This form will need to be completed retrospectively for all participants for their completed visits. Please enter the medications on the Concomitant medications form first and then they can be selected from the drop-down list on this form.

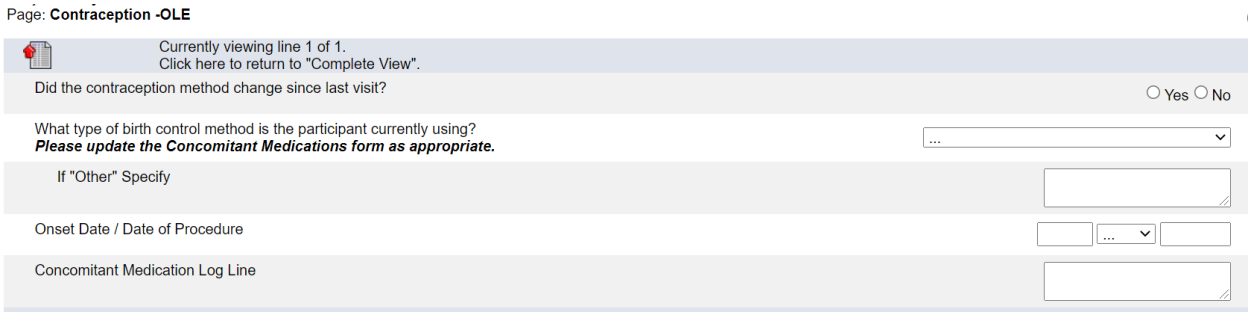
Item-specific Instructions

Field	Instructions
Visit	• This field is pre-populated with general visits. Please DO NOT change the visit code for pre-populated log lines. • If a visit is need from the alternate schedules (i.e. Interim Visit, Open Label Truvada visit, etc.), add a new log line from the bottom of the form and select the visit from the drop-down list.
If 'Interim visit', provide interim visit code	• If "Interim Visit" is selected for "Visit", enter interim visit code in space provided. Otherwise leave this item blank.
	• Tick off all the methods the participant is currently using as form of birth control.

Field	Instructions
What type of birth control method are you currently using?	• More than one method may be selected.
None	• Mark this if participant is currently not using any form of birth control. • If this is selected other methods should not be marked.
Oral Contraceptive pill	• Mark this if participant is using any type of contraceptive medication taken orally.
Intrauterine Device (IUD)	• Mark this if participant is using a hormonal or non-hormone releasing intrauterine device.
Injectable	• Mark if participant is using an injectable contraceptive, this may include DMPA, NET-EN, SAYANA or others.
Contraceptive Patch	• Mark if participant is using a contraceptive patch.
Contraceptive Vaginal Ring	• Mark if participant is using a contraceptive vaginal ring.
Implant	• Mark if participant is using a subdermal contraceptive implant.
Other Contraceptive	• Mark this if the participant is using a contraceptive method that is not listed.
Sterilization (Tubal ligation / hysterectomy)	• Mark if participant has undergone any sterilization procedures. • If sterilization occurred prior to study enrollment, also record in Medical History Log form.
Have you had a tubal ligation or hysterectomy surgery since last visit?	• Select “Yes” if participant has undergone a sterilization procedure since the last visit. • If the participant has had a sterilization procedure *prior* to the last visit, leave this blank.

Field	Instructions
If yes, Date of procedure	• Enter Date of procedure if participant has had a sterilization procedure since the last visit. • A complete date is required.
Have you started a new oral contraceptive, received an injection or had a new implant or IUD device inserted since last visit?	• Select "Yes" if participant has switched to a different type of contraceptive medication(s) since the last visit or had a new injection. • Select "No" if participant continues to use the same contraceptive medications from the previous visit. • If there is a change in the contraception, select the corresponding concomitant medication from the drop-down list in Questions 5a and 5b as applicable.
Have you stopped an oral contraceptive, removed an implant or IUD device since last visit?	• Select "Yes" if participant has discontinued the use of a contraceptive medication(s) since the last visit. • Select "No", if participant is continuing to use the same type of contraceptive medication since the last visit. • If the participant discontinued a contraception, select the corresponding concomitant medication from the drop-down list in Questions 6a and 6b as applicable.

CONTRACEPTION – OLE


Page: **Contraception -OLE**

Currently viewing line 1 of 1.
Click here to return to "Complete View".

Did the contraception method change since last visit? ○ Yes ○ No

What type of birth control method is the participant currently using?
Please update the Concomitant Medications form as appropriate.

If "Other" Specify

Onset Date / Date of Procedure

Concomitant Medication Log Line

Purpose

This form is used to capture information regarding contraception during the OLE.

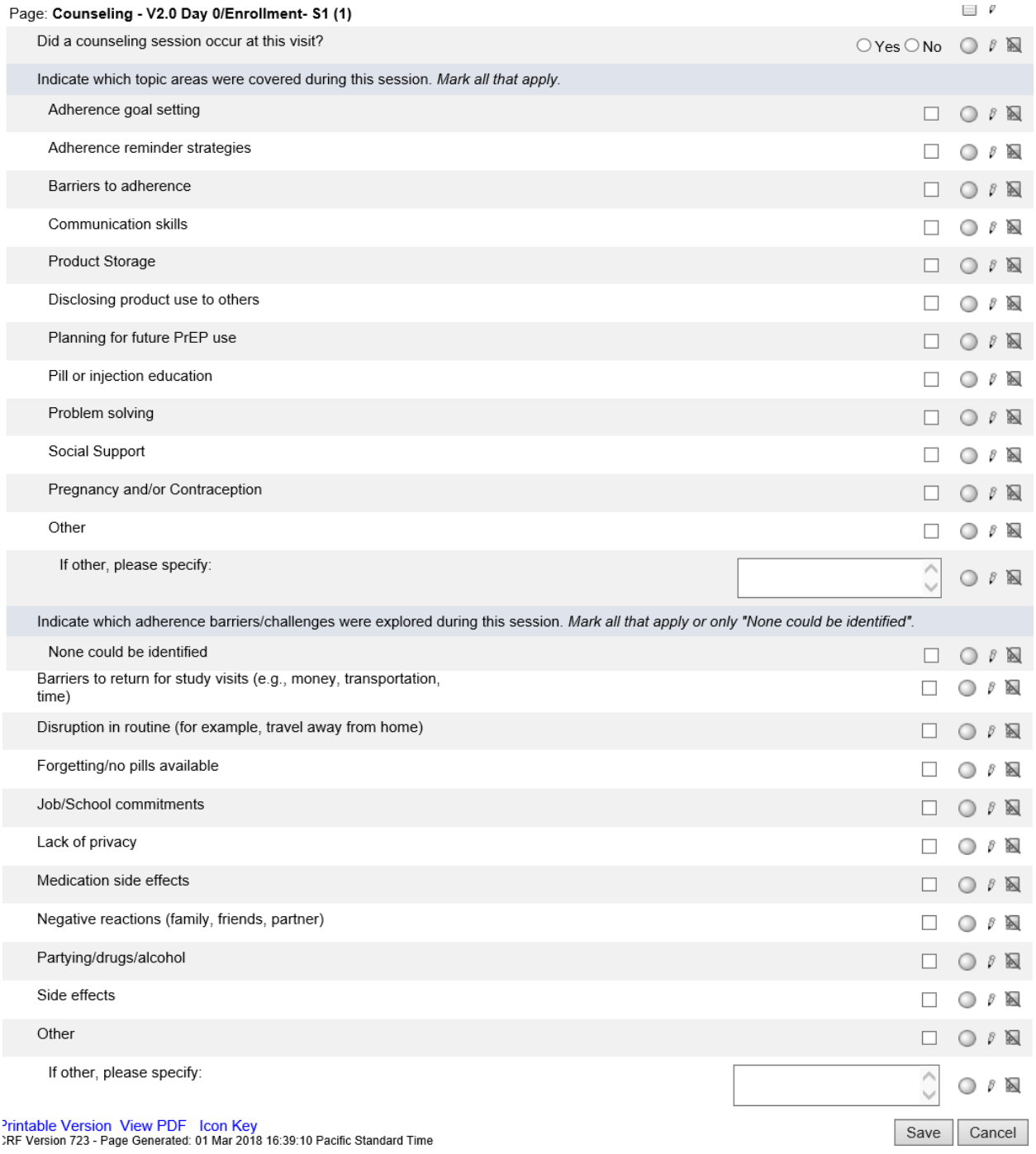
General Instructions

Complete this form at all OLE visits as required. *This CRF replaces the Contraception CRF in the first part of the study that is located in the ongoing logs folder and is no longer required.*

Item-specific Instructions

Field	Instructions
Did the contraception method change since last visit?	• Select “Yes” or “No”.
What type of birth control method is the participant currently using? ***Please update the Concomitant Medications form as appropriate.***	• Mark all topic areas that apply. • If “Other” is selected record a brief description of the additional topic in the “If other, please specify” text field provided.
Onset Date / Date of Procedure	• A partial date is allowed. Month and year are required.
Concomitant Medication Log Line	• Conmed must be entered first. Select Conmed.

COUNSELING


Page: **Counseling - V2.0 Day 0/Enrollment- S1 (1)**

Did a counseling session occur at this visit? ○ Yes ○ No

Indicate which topic areas were covered during this session. *Mark all that apply.*

- Adherence goal setting
- Adherence reminder strategies
- Barriers to adherence
- Communication skills
- Product Storage
- Disclosing product use to others
- Planning for future PrEP use
- Pill or injection education
- Problem solving
- Social Support
- Pregnancy and/or Contraception
- Other
- If other, please specify:

Indicate which adherence barriers/challenges were explored during this session. *Mark all that apply or only "None could be identified".*

- None could be identified
- Barriers to return for study visits (e.g., money, transportation, time)
- Disruption in routine (for example, travel away from home)
- Forgetting/no pills available
- Job/School commitments
- Lack of privacy
- Medication side effects
- Negative reactions (family, friends, partner)
- Partying/drugs/alcohol
- Side effects
- Other
- If other, please specify:

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Save Cancel

Purpose

This form is used to capture information regarding adherence counseling.

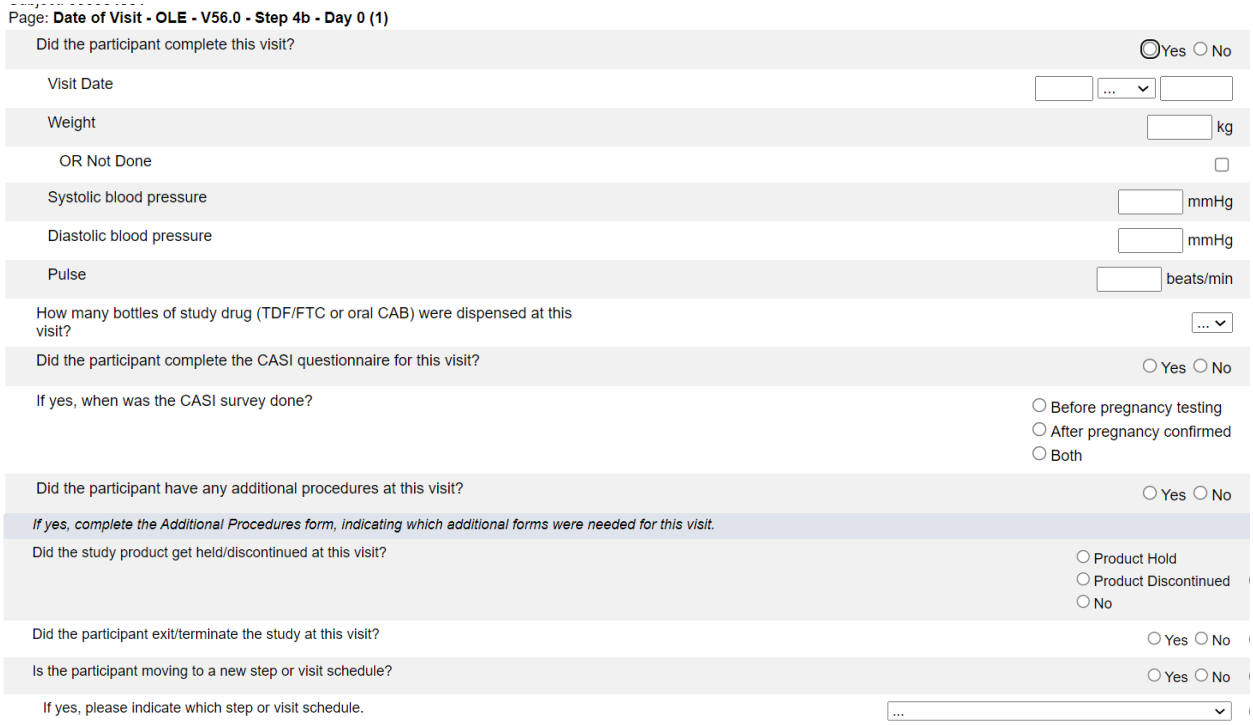
General Instructions

Complete this form at all study visits starting at Enrollment.

Item-specific Instructions

Field	Instructions
Did a counseling session occur at this visit?	• Select "Yes" or "No". • If "No" is selected, do not complete any additional items on the form.
Indicate which topic areas were covered during this session.	• Mark all topic areas that apply. • If "Other" is selected record a brief description of the additional topic in the "If other, please specify" text field provided.
Indicate which adherence barriers/challenges were explored during this session.	• Select all challenges that were mentioned during the session. • If none were identified, mark "None could be identified" • If "Other" is selected record a brief description of the additional challenge in the "If other, please specify" text field provided.

DATE OF VISIT – OLE


Page: **Date of Visit - OLE - V56.0 - Step 4b - Day 0 (1)**

Did the participant complete this visit?	Yes No
Visit Date	...
Weight	kg
OR Not Done	
Systolic blood pressure	mmHg
Diastolic blood pressure	mmHg
Pulse	beats/min
How many bottles of study drug (TDF/FTC or oral CAB) were dispensed at this visit?	...
Did the participant complete the CASI questionnaire for this visit?	Yes No
If yes, when was the CASI survey done?	Before pregnancy testing After pregnancy confirmed Both
Did the participant have any additional procedures at this visit?	Yes No
If yes, complete the Additional Procedures form, indicating which additional forms were needed for this visit.	
Did the study product get held/discontinued at this visit?	Product Hold Product Discontinued No
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.	...

Purpose

This CRF is to document the OLE visits and is the first form completed for OLE visits in Steps 4a.,4b.,4c., and 5.

General Instructions

Complete this form in order to generate the forms required at the current visit as well as to create the next visit folder with its respective Date of Visit – OLE visit as applicable. See item level instructions for the data requirements to populate additional visits and forms.

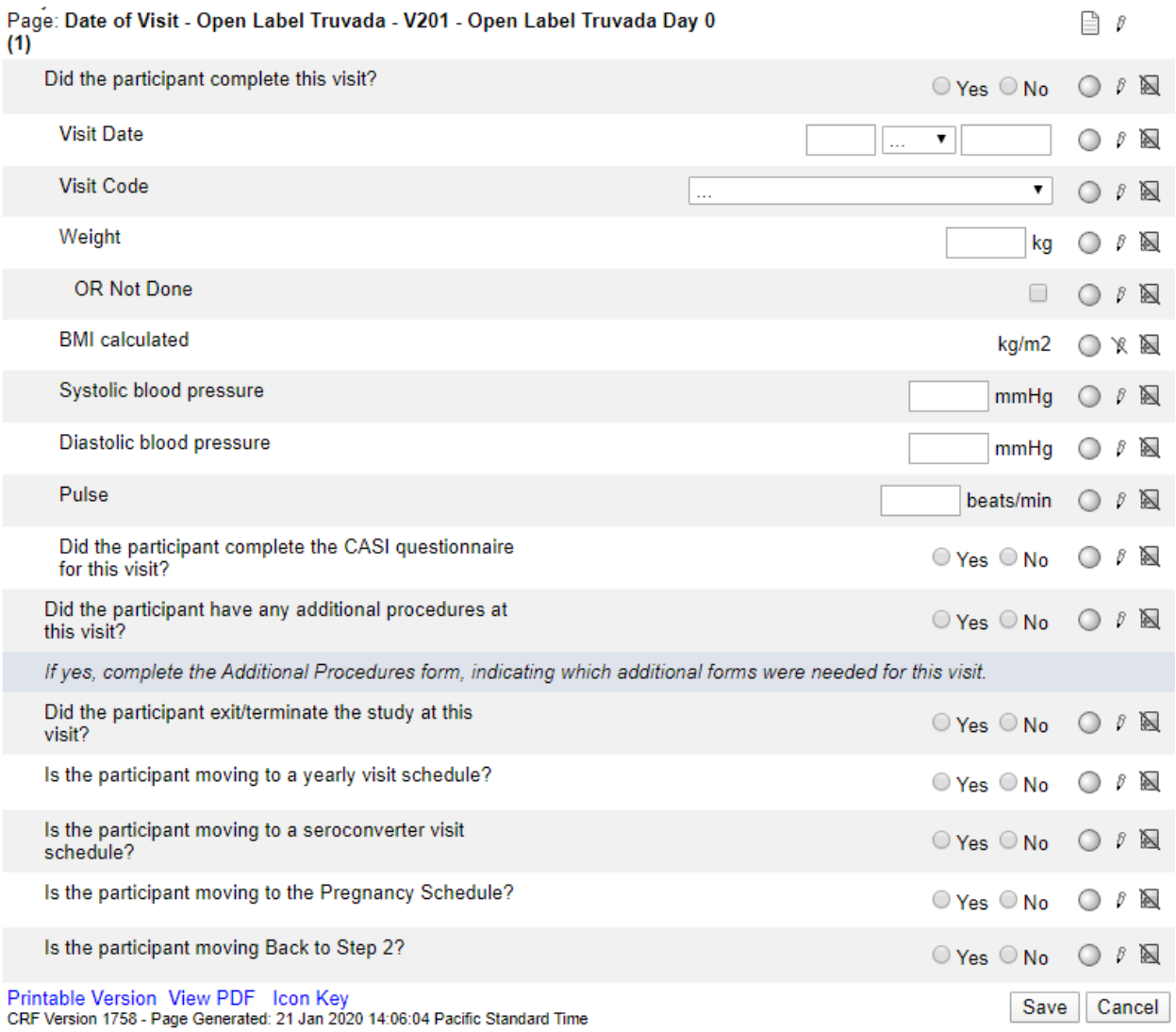
Item-specific Instructions

Field	Instructions
Did the participant complete this visit?	• "Yes" must be answered if at least one assessment within the visit has been completed. This will also populate additional forms required within each visit. • "No" populates the Missed Visit CRF in the current folder.
Visit Date	• A complete date is required.
Weight	• Record weight in kg or mark "OR not done".

Field	Instructions
Systolic blood pressure	• Enter the systolic blood pressure in units of “mmHG”
Diastolic blood pressure	• Enter the diastolic blood pressure in units of “mmHG”
Pulse	• Enter the pulse in units of "beats/minute”.
How many bottles of study drug (TDF/FTC or oral CAB) were dispensed at this visit?	• Enter number of bottles dispensed. If none, enter “0”.
Did the participant complete the CASI questionnaire for this visit?	• Select “Yes” or “No”.
If yes, when was the CASI survey done?	• Indicate when CASI was performed, before or after pregnancy was confirmed.
Did the participant have any additional procedures at this visit?	• If “Yes” is selected, the “Additional Procedures – OLE” CRF will be populated in the current folder.
Did the product get held/discontinued at this visit?	• If “Product hold” or “Product discontinued" is selected, the Product Hold/Discontinuation-OLE CRF must be completed.
Did the participant exit/terminate the study at this visit?	• If “Yes” is selected, complete the “Termination” CRF in the Discontinuations folder.
Is the participant moving to a different step or visit schedule?	• If “No” is marked AND the participant did not exit/terminate at this visit, then the next Step 4 visit will populate if applicable. • If “Yes” is marked, record a response for “If yes, please indicate which schedule”. • The response should be marked Yes if the participant is changing schedules and not moving to the next visit in the same schedule.

Field	Instructions
If yes, please indicate which step or schedule.	• Indicate if schedule change occurs. • Edit checks will fire for steps that are not allowed.

DATE OF VISIT - OPEN LABEL TRUVADA


Page: **Date of Visit - Open Label Truvada - V201 - Open Label Truvada Day 0 (1)**

Did the participant complete this visit?	Yes No
Visit Date	...
Visit Code	...
Weight	kg
OR Not Done	
BMI calculated	kg/m2
Systolic blood pressure	mmHg
Diastolic blood pressure	mmHg
Pulse	beats/min
Did the participant complete the CASI questionnaire for this visit?	Yes No
Did the participant have any additional procedures at this visit?	Yes No
If yes, complete the Additional Procedures form, indicating which additional forms were needed for this visit.	
Did the participant exit/terminate the study at this visit?	Yes No
Is the participant moving to a yearly visit schedule?	Yes No
Is the participant moving to a seroconverter visit schedule?	Yes No
Is the participant moving to the Pregnancy Schedule?	Yes No
Is the participant moving Back to Step 2?	Yes No

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Purpose
If a participant is on the Open Label Truvada schedule, then this form is used to document information about each visit in this schedule.

General Instructions
In order to add these Visits in the Open Label Truvada schedule, use the “add event” feature in Rave (similar to interim visits).

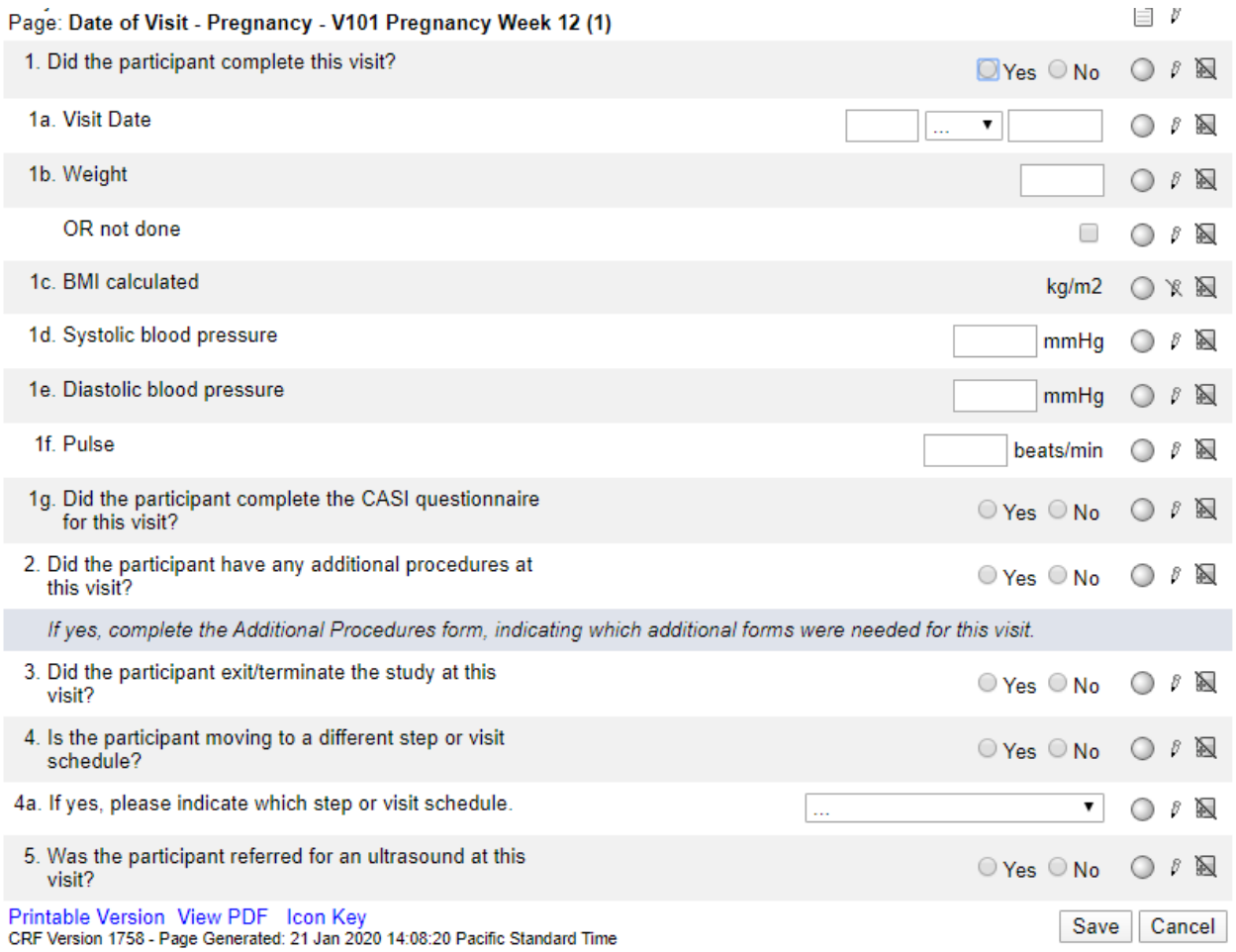
Complete this form in order to generate the forms required at the current Open Label Truvada visit as well as to populate the next visit folder and its respective Date of Visit – Open Label Truvada CRF. See item-specific instructions for the data requirements to populate additional visits and forms.

Item-specific Instructions

Field	Instructions
Did the participant complete this visit?	• "Yes" must be answered if at least one assessment within the visit has been completed. This will also populate additional forms required within each visit. • "No" populates the Missed Visit CRF in the current folder.
Visit Date	• A complete date is required.
Visit Code	• For the first Open Label Truvada visit, select visit code V201, for the second Open Label Truvada visit, select visit code V202, etc. •
Weight	• Record weight in kg or mark "OR not done".
Systolic blood pressure	• Enter the systolic blood pressure in units of "mmHG"
Diastolic blood pressure	• Enter the diastolic blood pressure in units of "mmHG"
Pulse	• Enter the pulse in units of "beats/minute".
Did the participant complete the CASI questionnaire for this visit?	• Select "Yes" or "No".
Did the participant have any additional procedures at this visit?	• If "Yes" is selected, the Additional Procedures CRF will be populated in the current folder.
Did the participant exit/terminate the study at this visit?	• If "Yes" is selected, complete the Termination CRF located in the Discontinuations folder.
Is the participant moving to a yearly visit schedule?	• Select "Yes" if the participant is moving to yearly visit schedule.

Field	Instructions
Is the participant moving to a seroconverter visit schedule?	• Select "Yes" only when the participant is confirmed to be HIV-positive.
Is the participant moving to the Pregnancy Schedule?	• Select "Yes" in the event of a confirmed pregnancy.
Is the participant moving Back to Step 2?	• Select "Yes" if participant is returning to Step 2.

DATE OF VISIT- PREGNANCY

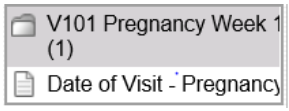


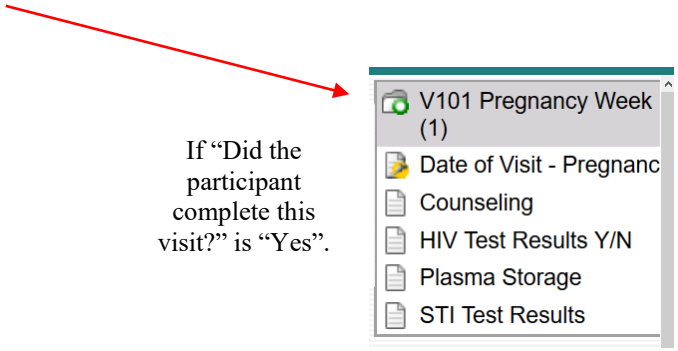
Purpose

If a participant is on the Pregnancy Visit Schedule (which also includes the time period in which she may be breastfeeding post-pregnancy), then this form is used to document information about each Pregnancy Visit.

General Instructions

Complete this form in order to generate the forms required at the current Pregnancy Visit as well as to populate the next visit folder and its respective Date of Visit – Pregnancy CRF. See item level instructions for the data requirements to populate additional visits and forms.



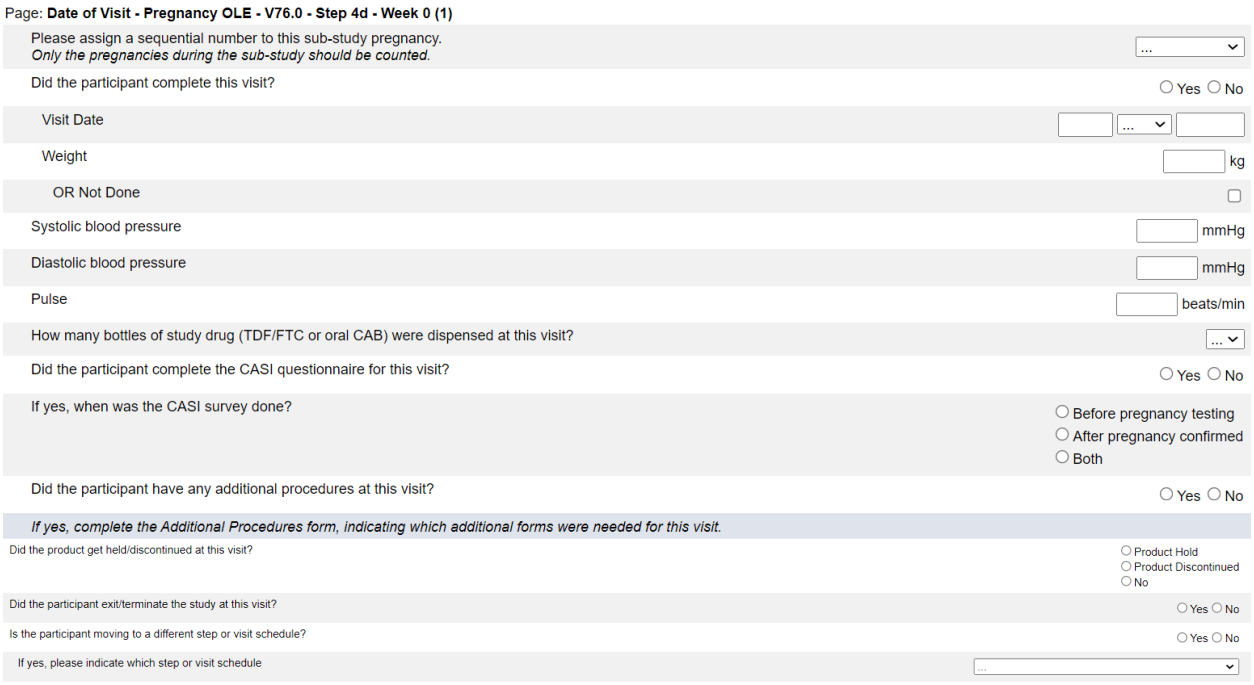


Item-specific Instructions

Field	Instructions
Did the participant complete this visit?	• "Yes" must be answered if at least one assessment within the visit has been completed. This will also populate additional forms required within each visit. • "No" populates the Missed Visit CRF in the current folder.
Visit Date	• A complete date is required.
Weight	• Record weight in kg or mark "OR not done".
Systolic blood pressure	• Enter the systolic blood pressure in units of "mmHG"
Diastolic blood pressure	• Enter the diastolic blood pressure in units of "mmHG"
Pulse	• Enter the pulse in units of "beats/minute".
Did the participant complete the CASI questionnaire for this visit?	• Select "Yes" or "No".
Did the participant have any additional procedures at this visit?	• If "Yes" is selected, the Additional Procedures CRF will be populated in the current folder.
Did the participant exit/terminate the study at this visit?	• If "Yes" is selected, complete the Termination CRF in the Discontinuations folder.

Field	Instructions
Is the participant moving to a different step or visit schedule?	• If "No" is marked AND the participant did not exit/terminate at this visit, then the next Pregnancy Visit folder with respective Date of Visit – Pregnancy CRF will populate. • If "Yes" is marked, record a response for "If yes, please indicate which schedule"
If yes, please indicate which step or schedule.	• "Seroconverter visit schedule" should be selected only when the participant is confirmed to be HIV-positive. • "Back to Step 2" should be selected when no further Pregnancy Visits are expected (pregnancy visits include the time period in which the participant may be breastfeeding post-delivery) and the participant has been approved to move back to Step 2.
Was the participant referred for an ultrasound at this visit?	• Select "Yes" or "No. • If "Yes" is selected, Ultrasound Results form will populate in pregnancy folder.

DATE OF VISIT- PREGNANCY OLE


Page: **Date of Visit - Pregnancy OLE - V76.0 - Step 4d - Week 0 (1)**

Please assign a sequential number to this sub-study pregnancy.
Only the pregnancies during the sub-study should be counted.

Did the participant complete this visit? ○ Yes ○ No

Visit Date

Weight kg

OR Not Done

Systolic blood pressure mmHg

Diastolic blood pressure mmHg

Pulse beats/min

How many bottles of study drug (TDF/FTC or oral CAB) were dispensed at this visit?

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

If yes, when was the CASI survey done?
○ Before pregnancy testing
○ After pregnancy confirmed
○ Both

Did the participant have any additional procedures at this visit? ○ Yes ○ No

If yes, complete the Additional Procedures form, indicating which additional forms were needed for this visit.

Did the product get held/discontinued at this visit?
○ Product Hold
○ Product Discontinued
○ No

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

Is the participant moving to a different step or visit schedule? ○ Yes ○ No

If yes, please indicate which step or visit schedule

Purpose

If a participant is in the Pregnancy and Infant Sub-study, then this form is used to document information about each visit.

General Instructions

Complete this form in order to generate the forms required at the current visit in Step 4d. as well as to populate the next visit folder and its respective forms. See item level instructions for the data requirements to populate additional visits and forms.

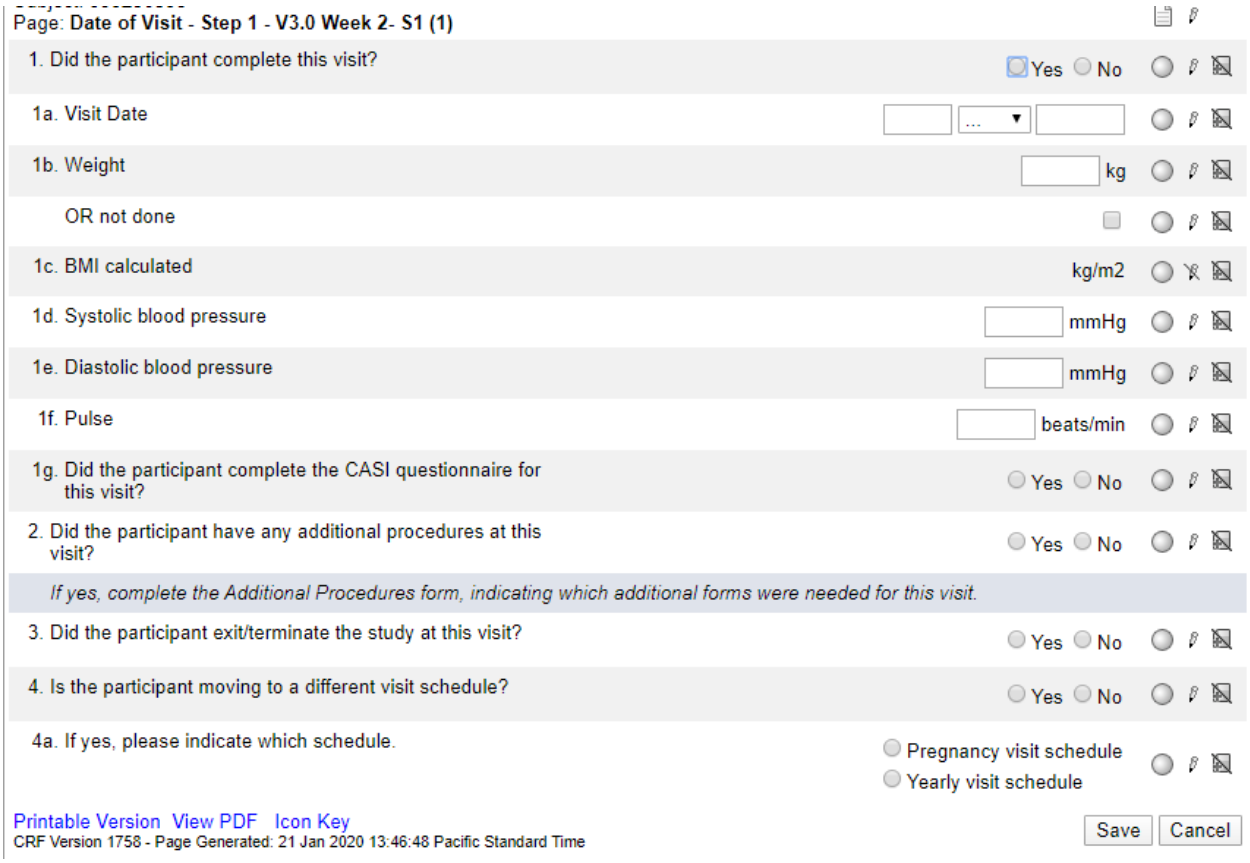
Item-specific Instructions

Field	Instructions
Please assign a sequential number to this sub-study pregnancy.	• Only the pregnancies during the sub-study should be counted.
Did the participant complete this visit?	• "Yes" must be answered if at least one assessment within the visit has been completed. This will also populate additional forms required within each visit. • "No" populates the Missed Visit CRF in the current folder.
Visit Date	• A complete date is required.

Field	Instructions
Weight	• Record weight in kg or mark “OR not done”.
Systolic blood pressure	• Enter the systolic blood pressure in units of “mmHG”
Diastolic blood pressure	• Enter the diastolic blood pressure in units of “mmHG”
Pulse	• Enter the pulse in units of "beats/minute”.
How many bottles of study drug (TDF/FTC or oral CAB) were dispensed at this visit?	• Enter number of bottles dispensed. If none, enter “0”.
Did the participant complete the CASI questionnaire for this visit?	• Select “Yes” or “No”.
If yes, when was the CASI survey done?	• Indicate when CASI was performed, before or after pregnancy was confirmed.
Did the participant have any additional procedures at this visit?	• If “Yes” is selected, the “Additional Procedures – OLE” CRF will be populated in the current folder.
Did the product get held/discontinued at this visit?	• If “Product hold” or “Product discontinued" is selected, the Product Hold/Discontinuation-OLE CRF must be completed.
Did the participant exit/terminate the study at this visit?	• If “Yes” is selected, complete the “Termination” CRF in the Discontinuations folder.
Is the participant moving to a different step or visit schedule?	• If “No” is marked AND the participant did not exit/terminate at this visit, then the next Step 4d. folder with respective Date of Visit – Pregnancy OLE form will populate. • If “Yes” is marked, record a response for “If yes, please indicate which schedule”

Field	Instructions
If yes, please indicate which step or schedule.	• Indicate if schedule change occurs. • Edit checks will fire for steps that are not allowed. • If pregnancy outcome occurs select “Delivery- OLE” from the Add Event feature.

DATE OF VISIT- STEP 1



Purpose

This form is used to document information about each visit during Step 1.

General Instructions

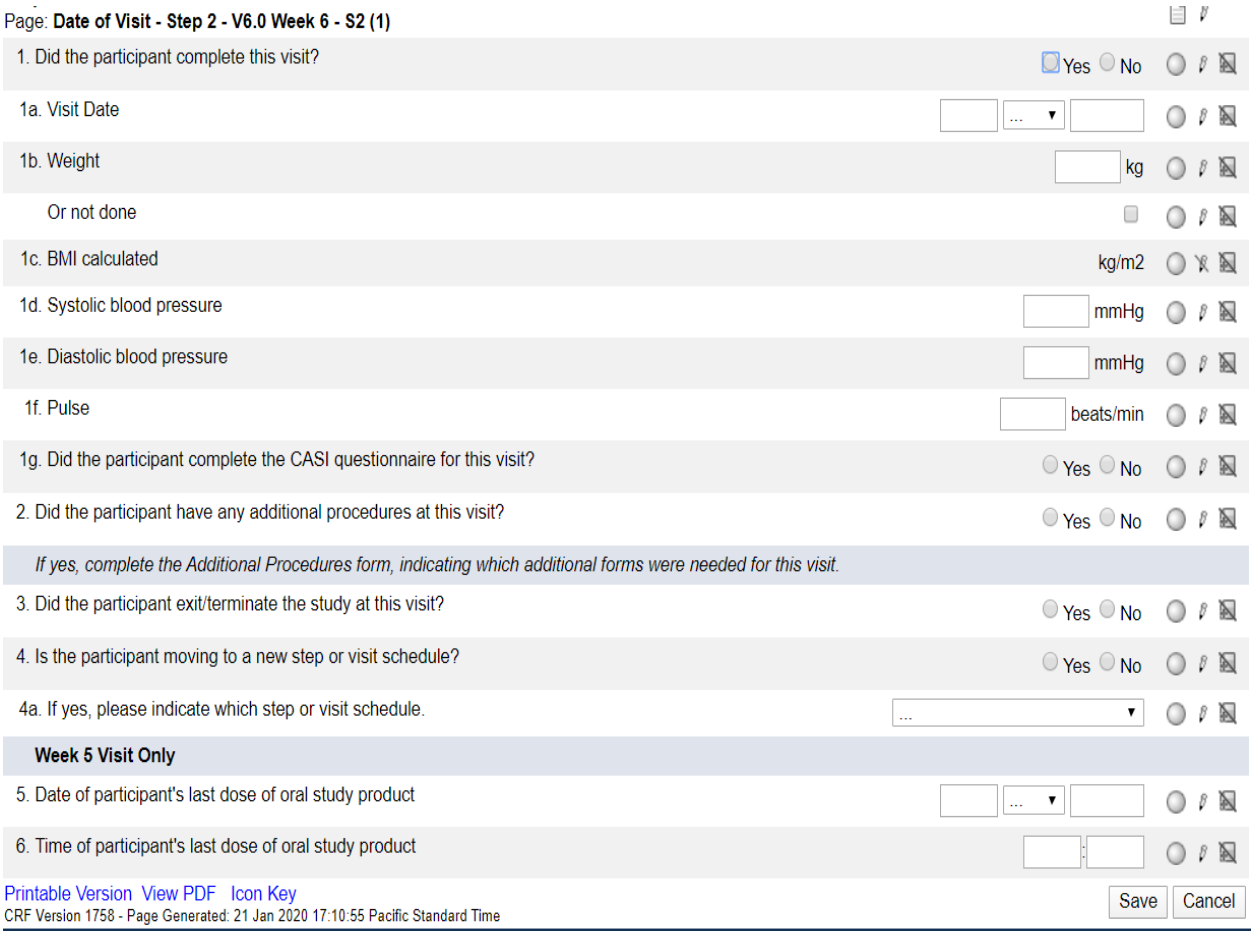
Complete this form in order to generate the forms required at the current visit as well as to create the next visit folder with its respective Date of Visit – Step 1 CRF. See item level instructions for the data requirements to populate additional visits and forms.

Item-specific Instructions

Field	Instructions
Did the participant complete this visit?	• "Yes" must be answered if at least one assessment within the visit has been completed. This will also populate additional forms required within each visit. • "No" populates the Missed Visit CRF in the current folder.
Visit Date	• A complete date is required.

Field	Instructions
Weight	• Record weight in kg or mark "OR not done".
Systolic blood pressure	• Enter the systolic blood pressure in units of "mmHG"
Diastolic blood pressure	• Enter the diastolic blood pressure in units of "mmHG"
Pulse	• Enter the pulse in units of "beats/minute".
Did the participant complete the CASI questionnaire for this visit?	• Select "Yes" or "No".
Did the participant have any additional procedures at this visit?	• If "Yes" is selected, the Additional Procedures CRF will be populated in the current folder.
Did the participant exit/terminate the study at this visit?	• If "Yes" is selected, complete the Termination CRF located in the Discontinuations folder.
Is the participant moving to a different visit schedule?	• If "No" is indicated AND the participant did not exit at this visit, then the next visit folder with respective Date of Visit CRF will populate. • If "Yes" is marked, record a response for "If yes, please indicate which schedule".
If yes, please indicate which schedule.	• Select "Pregnancy Visit Schedule" in the event of a confirmed pregnancy. • Select "Yearly Visit schedule" if the participant is unable to continue to Step 2 due to a safety event or if they are not able to complete the oral dosing in Step 1.

DATE OF VISIT- STEP 2


Page: **Date of Visit - Step 2 - V6.0 Week 6 - S2 (1)**

1. Did the participant complete this visit?	Yes No
1a. Visit Date	...
1b. Weight	kg
Or not done	
1c. BMI calculated	kg/m2
1d. Systolic blood pressure	mmHg
1e. Diastolic blood pressure	mmHg
1f. Pulse	beats/min
1g. Did the participant complete the CASI questionnaire for this visit?	Yes No
2. Did the participant have any additional procedures at this visit?	Yes No
If yes, complete the Additional Procedures form, indicating which additional forms were needed for this visit.	
3. Did the participant exit/terminate the study at this visit?	Yes No
4. Is the participant moving to a new step or visit schedule?	Yes No
4a. If yes, please indicate which step or visit schedule.	...
Week 5 Visit Only	
5. Date of participant's last dose of oral study product	...
6. Time of participant's last dose of oral study product	:

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Purpose

This form is used to document information about each visit during Step 2.

General Instructions

Complete this form in order to generate the forms required at the current visit as well as to create the next visit folder with its respective Date of Visit – Step 2 CRF. See item level instructions for the data requirements to populate additional visits and forms.

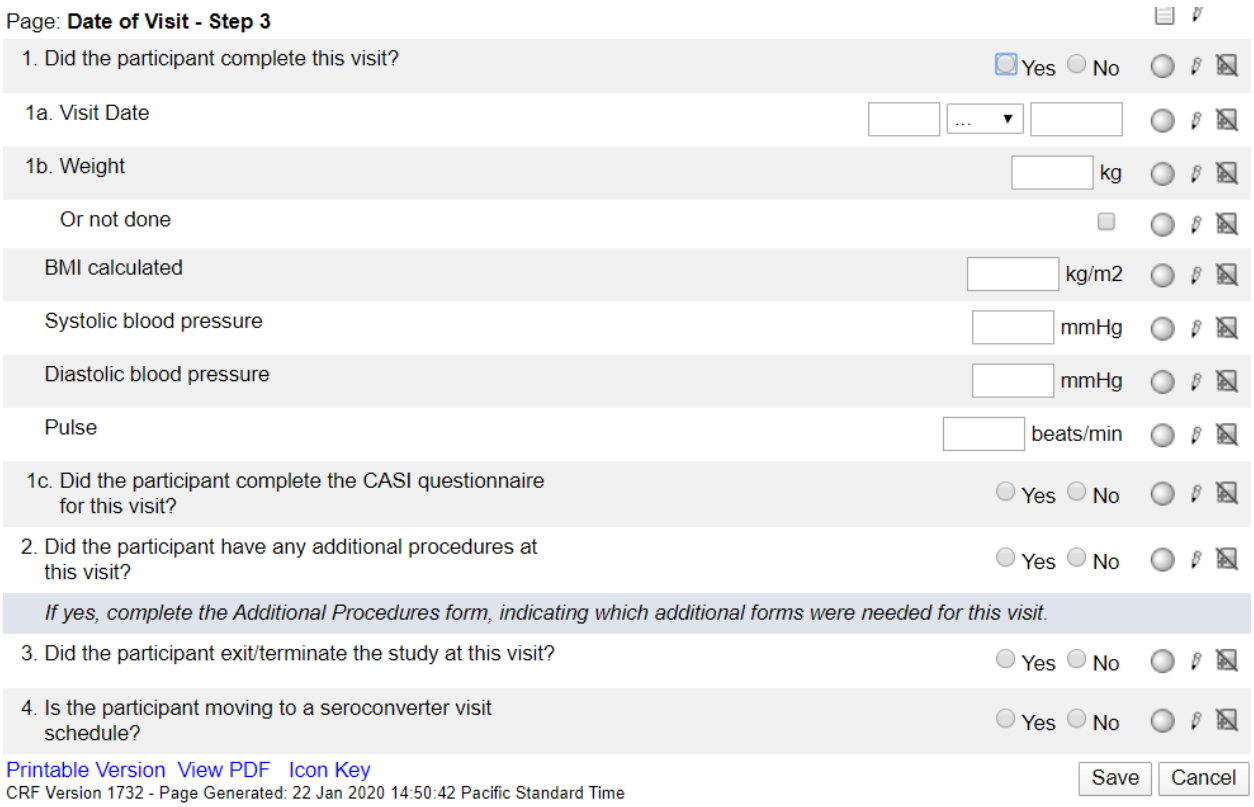
Item-specific Instructions

Field	Instructions
Did the participant complete this visit?	• "Yes" must be answered if at least one assessment within the visit has been completed. This will also populate additional forms required within each visit. • "No" populates the Missed Visit CRF.
Visit Date	• A complete date is required.

Field	Instructions
Weight	• Record weight in kg or select “OR not done”.
Systolic blood pressure	• Enter the systolic blood pressure in units of “mmHG”
Diastolic blood pressure	• Enter the diastolic blood pressure in units of “mmHG”
Pulse	• Enter the pulse in units of “beats/minute”.
Did the participant complete the CASI questionnaire for this visit?	• Select “Yes” or “No”.
Did the participant have any additional procedures at this visit?	• If “Yes” is selected, the Additional Procedures CRF will be populated in the current folder.
Did the participant exit/terminate the study at this visit?	• If “Yes” is selected, complete the Termination CRF in the Discontinuations folder.
Is the participant moving to a new step or visit schedule?	• If “No” is marked and participant did not exit at this study, then the next visit folder with respective Date of Visit CRF will populate. If “Yes” is marked, record a response for “If yes, please indicate which step or visit schedule.”
If yes, please indicate which step or visit schedule.	• Select the step or visit schedule participant is moving to at this visit (if applicable).
Date of participant's last dose of oral study product	• Record a response ONLY at the Week 5 Visit. • Record the date of the participant’s last dose of Step 1 oral study products. • A complete date is required.

Field	Instructions
Time of participant's last dose of oral study product	• Record a response ONLY at the Week 5 Visit. • Time should be reported using the 24-hour clock. • If time is not known enter "00:00".

DATE OF VISIT- STEP 3


Page: **Date of Visit - Step 3**

1. Did the participant complete this visit? Yes No
1a. Visit Date ... ▾
1b. Weight kg
Or not done
BMI calculated kg/m2
Systolic blood pressure mmHg
Diastolic blood pressure mmHg
Pulse beats/min
1c. Did the participant complete the CASI questionnaire for this visit? Yes No
2. Did the participant have any additional procedures at this visit? Yes No
If yes, complete the Additional Procedures form, indicating which additional forms were needed for this visit.
3. Did the participant exit/terminate the study at this visit? Yes No
4. Is the participant moving to a seroconverter visit schedule? Yes No

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Purpose

This form is used to document information about each visit during Step 3.

General Instructions

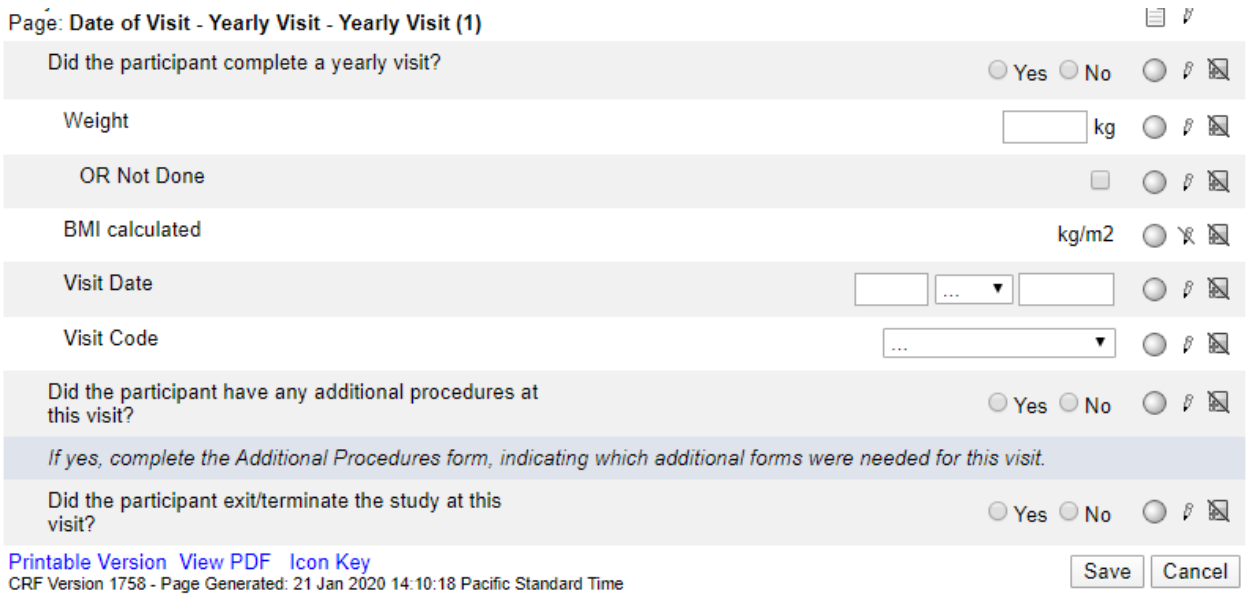
Complete this form in order to generate the forms required at the current visit as well as to create the next visit folder with its respective Date of Visit – Step 3 CRF. See item level instructions for the data requirements to populate additional visits and forms.

Item-specific Instructions

Field	Instructions
Did the participant complete this visit?	• "Yes" must be answered if at least one assessment within the visit has been completed. This will also populate additional forms required within each visit. • "No" populates the Missed Visit CRF.
Visit Date	• A complete date is required.

Field	Instructions
Weight	• Record weight in kg or mark “OR not done”.
Systolic blood pressure	• Enter the systolic blood pressure in units of “mmHG”
Diastolic blood pressure	• Enter the diastolic blood pressure in units of “mmHG”
Pulse	• Enter the pulse in units of “beats/minute”.
Did the participant complete the CASI questionnaire for this visit?	• Select “Yes” or “No”.
Did the participant have any additional procedures at this visit?	• If “Yes” is selected, the Additional Procedures CRF will be populated in the current folder.
Did the participant exit/terminate the study at this visit?	• If “Yes” is selected, complete the Termination CRF in the Discontinuations folder.
Is the participant moving to a seroconverter schedule?	• “Yes”, should only be selected when the participant is confirmed to be HIV-positive.

DATE OF VISIT- YEARLY VISIT



Purpose

This form is used to document information about each yearly visit that is completed.

General Instructions

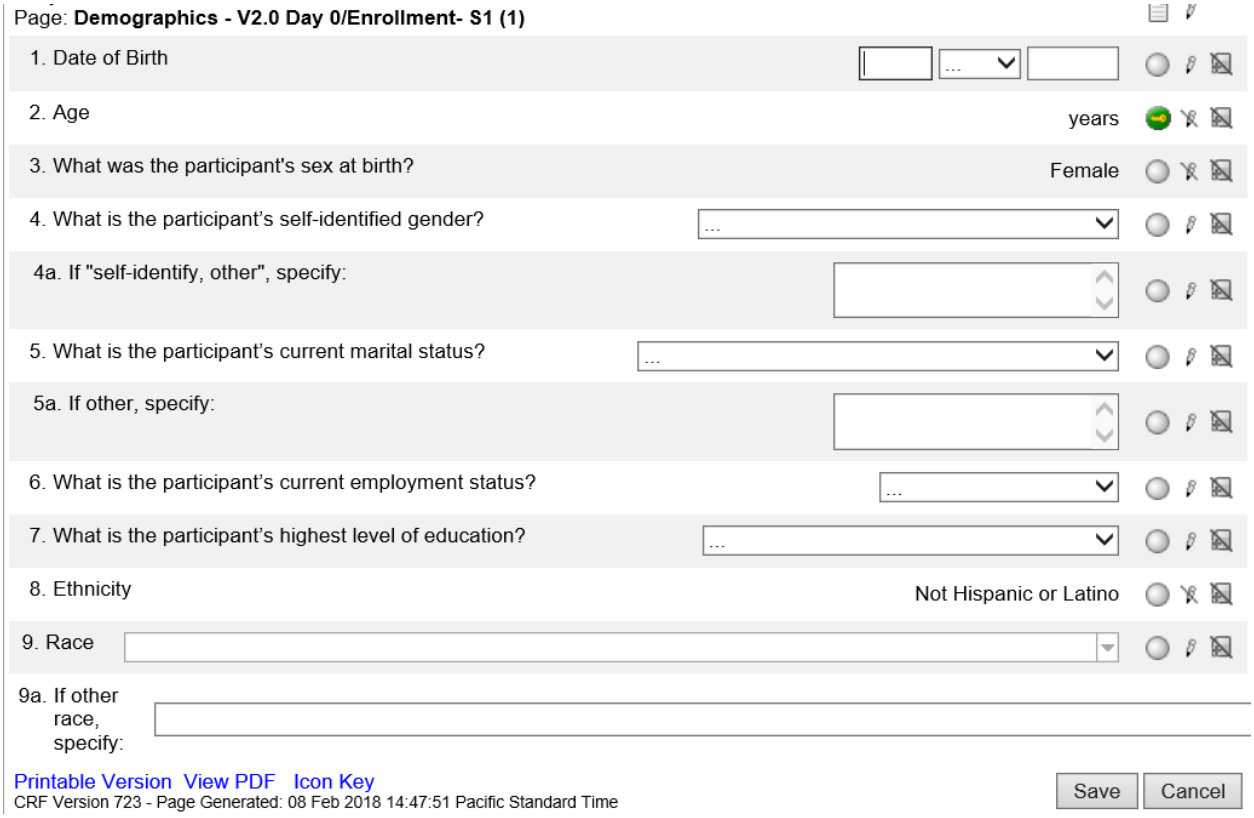
Complete this form in order to generate the forms required at the current visit as well as to create the next visit folder with its respective Date of Visit - Yearly CRF. See item level instructions for the data requirements to populate additional visits and forms.

Item-specific Instructions

Field	Instructions
Did the participant complete a yearly visit?	• "Yes" must be answered if at least one assessment within the visit has been completed. This will also populate additional forms required within each visit. • "No" populates the Missed Visit CRF.
Weight	• Record weight in kg or mark "OR not done" • A maximum of 3 digits is allowed. • Round to the nearest whole number, as decimal points are not allowed.
Visit Date	• A complete date is required.
Visit Code	• For the first yearly visit, select visit code 50.0; for the second yearly visit, select visit code 51.0, etc.

Field	Instructions
Did the participant have any additional procedures at this visit?	• If "Yes" is selected, the Additional Procedures CRF will be populated in the current folder.
Did the participant exit/terminate the study at this visit?	• If "Yes" is selected, complete the Termination CRF in the Discontinuations folder.

DEMOGRAPHICS



Purpose

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

General Instructions

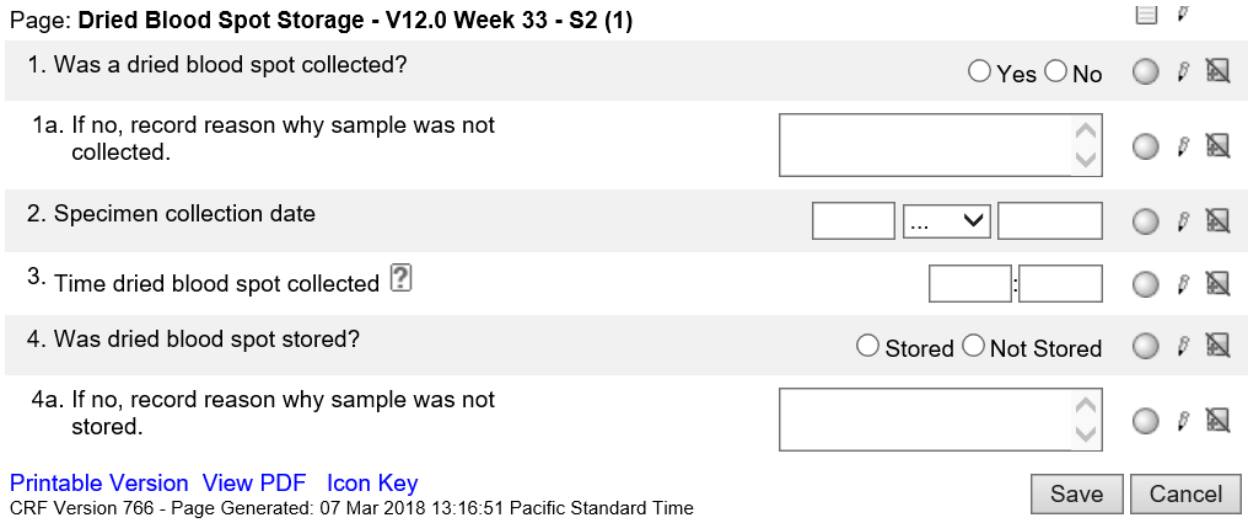
This form is completed at the V2.0 – Day 0/Enrollment Visit. Responses should reflect the participant's status at Screening and should not be changed after Enrollment unless a correction is needed.

Item-specific Instructions

Field	Instructions
What is the participant's date of birth?	• Record the date of birth. • A year is required at minimum. • If day and or month is unknown, partial dates may be entered. Enter "UN" for day and "UNK" for unknown month.
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.*

Field	Instructions
What was the participant's sex at birth?	• *This field is automatically filled as "Female" 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. • This item must be self-reported by the participant. • If "Self-identify, other" is selected, record a response in "Self-identify, other", 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" is selected, record a response in the "If other, specify" text field provided.
What is the participant's current employment status?	• Select the applicable response from the dropdown list based on the participant's response.
What is the participant's highest level of education?	• Complete this item based on participant self-report.
Ethnicity	• *Not Hispanic or Latino is pre-populated. No data entry is required.*
Race	• Select race from the site-provided list of options in the dropdown list. • Record the participant's response based on self-definition. • If "Other, specify" is selected, record a response in the "If other race, specify" text field provided.

DRIED BLOOD SPOT STORAGE



Purpose

This form is used to document collection and storage of dried blood spot specimens.

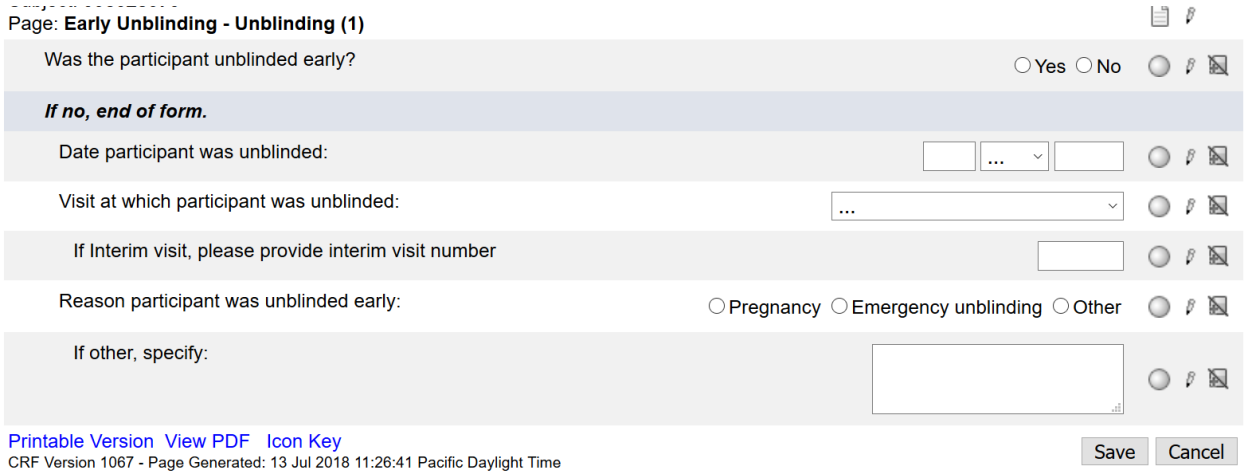
General Information/Instructions

Complete this form at all protocol-specified visits.

Item-specific Instructions

Field	Instructions
Was a dried blood spot collected?	• If "No" is marked, provide the reason why in the text box provided. Leave the remaining items blank.
Specimen collection date	• Enter the date the sample was collected. • A complete date is required.
Time dried blood spot collected	• Record the time using the 24-hour clock.
Was dried blood spot stored?	• If "Not Stored" is selected, record the reason why in the text box provided (item 4a).

EARLY UNBLINDING

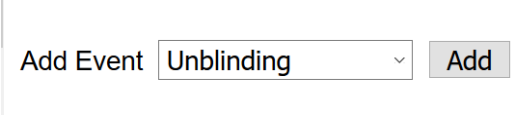


Purpose

This form is used to document when a participant has been unblinded to their treatment arm assignment during the course of the study. This form is not used to document the unblinding that occurs at the end of a trial.

General Instructions

- To add an Early Unblinding CRF, navigate to the "Add Event" dropdown menu located on the participant's homepage and select "Unblinding" from the menu. Then click "Add" and a folder called "Unblinding" will appear in its own folder in the participant's casebook.



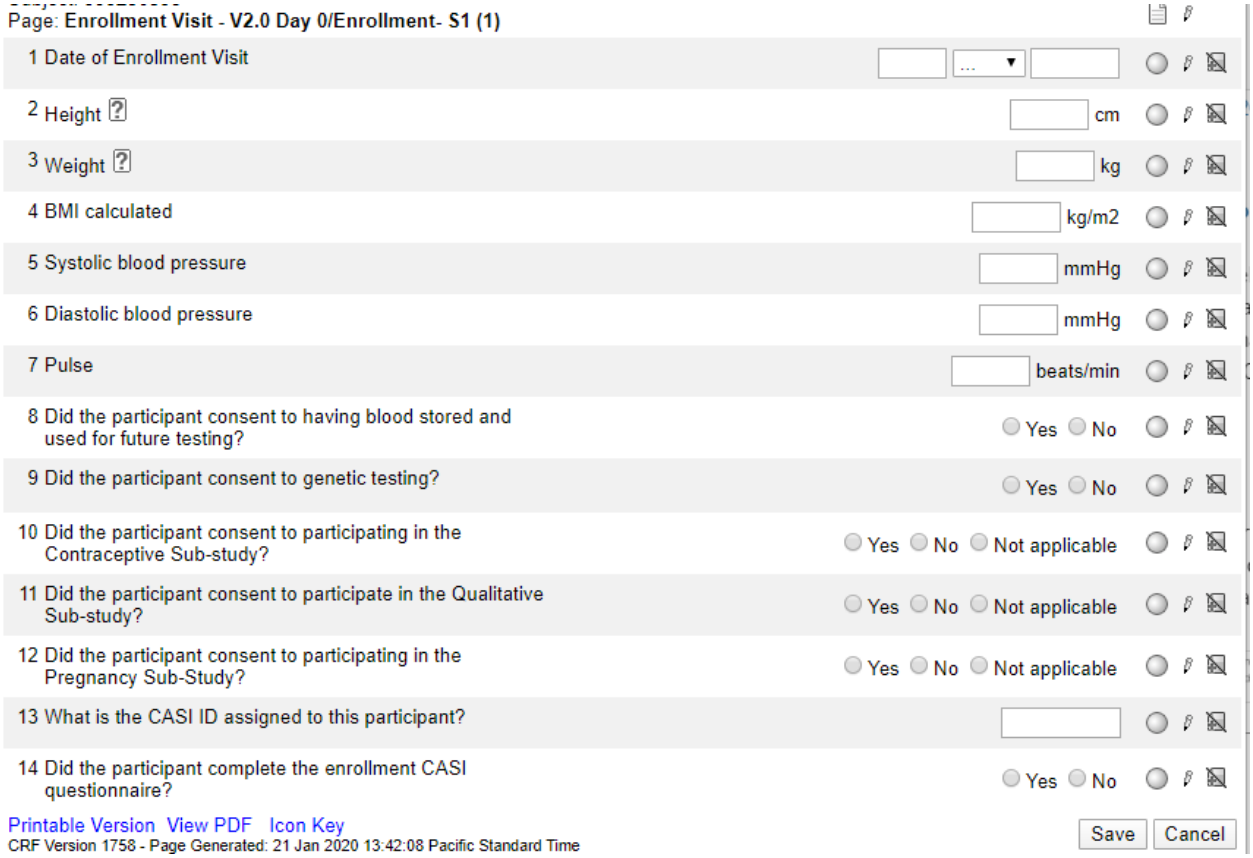
- Navigate to the Unblinding folder in the participant's casebook to find the Early Unblinding CRF.

Item-specific Instructions

Field	Instructions
Was the participant unblinded early?	• Select "Yes" or "No".
Date participant was unblinded:	• Record the date the participant was told what her treatment arm assignment was. • A complete date is required.
Visit at which participant was unblinded:	• Select the visit from the drop-down menu. • If an interim visit, select "Interim Visit".

Field	Instructions
Interim visit code	• If "Interim Visit" is selected for "Visit at which participant was unblinded", enter interim visit code in space provided. Otherwise leave this item blank.
Reason participant was unblinded early:	• Select the appropriate reason from the list. Emergency unblindings are expected to be rare, if they occur at all.
If other, specify:	• If "Reason participant was unblinded early" is "Other" record the reason here in the box provided.

ENROLLMENT VISIT


Page: **Enrollment Visit - V2.0 Day 0/Enrollment- S1 (1)**

1 Date of Enrollment Visit	...
2 Height	cm
3 Weight	kg
4 BMI calculated	kg/m2
5 Systolic blood pressure	mmHg
6 Diastolic blood pressure	mmHg
7 Pulse	beats/min
8 Did the participant consent to having blood stored and used for future testing?	Yes No
9 Did the participant consent to genetic testing?	Yes No
10 Did the participant consent to participating in the Contraceptive Sub-study?	Yes No Not applicable
11 Did the participant consent to participate in the Qualitative Sub-study?	Yes No Not applicable
12 Did the participant consent to participating in the Pregnancy Sub-Study?	Yes No Not applicable
13 What is the CASI ID assigned to this participant?	
14 Did the participant complete the enrollment CASI questionnaire?	Yes No

Printable Version View PDF Icon Key
CRF Version 1758 - Page Generated: 21 Jan 2020 13:42:08 Pacific Standard Time
Save Cancel

Purpose

This form is used to document the administrative details of the participant's enrollment.

General Instructions

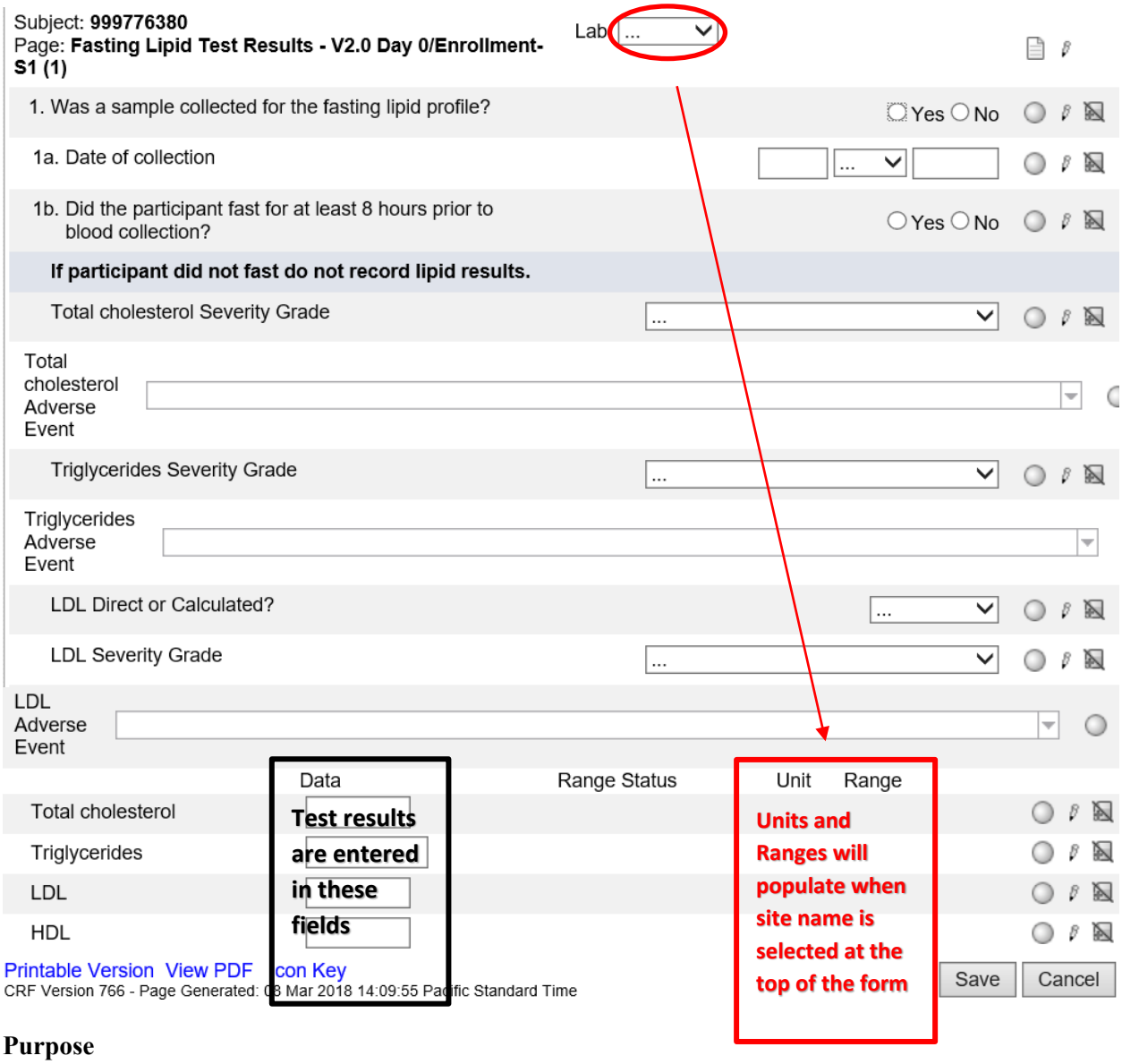
Complete this form only for enrolled participants. Do not complete an Enrollment Visit form for those who have screened out. The participant's responses on their informed consent forms will guide CRF completion expectations.

Item-specific Instructions

Field	Instructions
Date of Enrollment Visit	• A complete date is required.
Height	• Record height in centimeters. • A maximum of 3 digits is allowed. • Round to the nearest whole number, as decimal points are not allowed.

Field	Instructions
Weight	• Record weight in kilograms. • A maximum of 3 digits is allowed. • Round to the nearest whole number, as decimal points are not allowed.
Systolic blood pressure	• Enter the systolic blood pressure in units of "mmHG".
Diastolic blood pressure	• Enter the diastolic blood pressure in units of "mmHG".
Pulse	• Enter the pulse in units of "beats/minute".
Did the participant consent to having blood stored and used for future testing?	• This item does not refer to protocol-required plasma storage; it refers to using remaining stored plasma (after protocol-required testing is complete) for future testing.
Did the participant consent to genetic testing?	• This response should match what was recorded in the participant's informed consent form.
Did the participant consent to participating in the Contraceptive Sub-study?	• Select "Not applicable" if site is not participating in the Contraceptive Sub-study. • If your site is participating in Contraceptive Sub-study, select "Yes" or "No" to match participant's consent form.
Did the participant consent to participate in the Qualitative Sub-study?	• Select "Not applicable" until further notice (as the Qualitative Sub-Study has not yet started).
Did the participant consent to participate in the Pregnancy Sub-study?	• Select "Not applicable" until further notice (as the Pregnancy Sub-Study has not yet started).
What is the CASI ID assigned to this participant?	• Enter the CASI ID that was assigned to the participant and entered into Illume.
Did the participant complete the enrollment CASI questionnaire?	• Select "Yes" or "No".

FASTING LIPID TEST RESULTS



Purpose

This form is used to document the participant's fasting lipids test results.

General Information/Instructions

This form is completed at protocol-specified visits and if clinically indicated at any other visit.

Do not record results if the participant has not been fasting for at least 8 hours (preferably 12 hours). If a sample was not collected, do not record any additional information on the form.

Item-specific Instructions

Enter lab data in the following sequence:

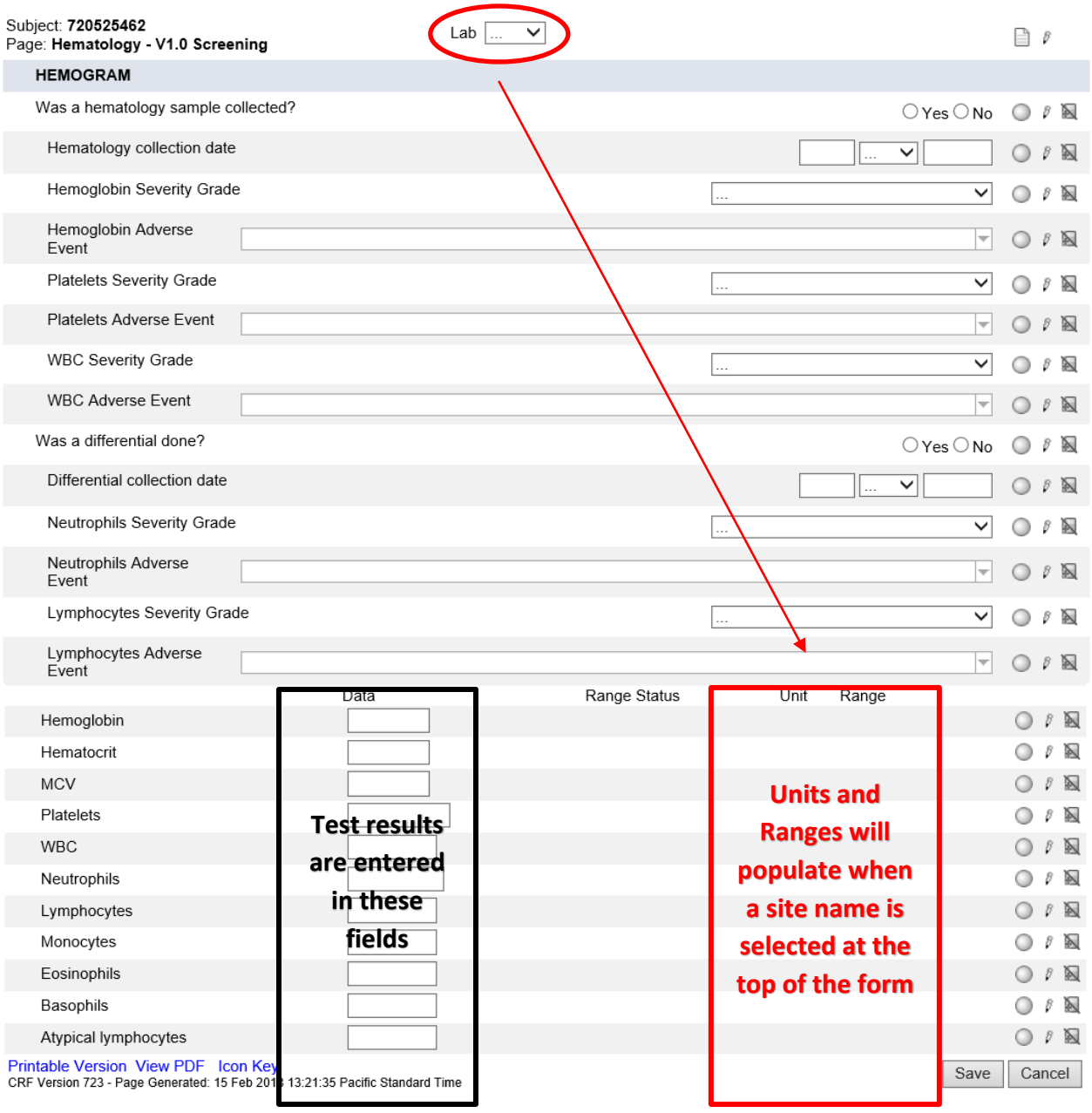
Field	Instructions
Lab	• **Select the site name from the drop-down menu to populate local lab reference ranges (and units) in the lab results section**. • **Date of birth on the Demographics CRF must be entered to populate the local reference ranges.** • If site name is not listed under "Lab" contact the CDM.
Test Results	• Enter the result of the specified test (bottom of form) in the standard units of measurement used for this study (see below). • If test was not performed or the results were not reported, leave blank and record a comment in the query message box (if query fires). *For example, if the triglyceride results were not reported, leave the triglyceride field blank and save the form. When a query fires record "not reported" in the query message box.* • If result is entered, ensure a severity grade for the result is entered (only for analytes that can be graded per the DAIDS Tox Table). • Do not record any test results if the participant was not fasting for at least 8 hours.

Data Formats and Units of Measurement

Field	Data Format Requirements	Unit Requirements
Total cholesterol	5.2	mg/dL
Triglycerides	7.2	mg/dL
LDL	5.2	mg/dL
HDL	5.2	mg/dL

Field	Instructions
Was a sample collected for fasting lipid profile?	• If "No" is selected, leave the rest of the form blank.
Date of collection	• Enter the date the specimen was collected. • A complete date is required.
Did the participant fast for at least 8 hours prior to blood collection?	• Select "Yes" or "No". • If participant did not fast for at least 8 hours do not record lipid results.
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 Fasting Lipid Test Results CRF.

HEMATOLOGY



Purpose

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

General Information/Instructions

This form is completed at protocol-specified visits and as clinically indicated at any other visit. If a sample was not collected, do not record any additional information on the form.

If a query fires at Screening prior to Demographics information being entered lab severity grading discrepancy may fire – ignore this. Lab results recorded at Screening cannot be graded properly until Enrollment.

If participant enrolls and Demographics form is completed, return to lab forms completed at Screening and remove the lab selection and save form. Then re-select "Lab" from drop-down menu and re-save. This should resolve the lab severity grading discrepancies.

Item-specific Instructions

Enter lab data in the following sequence:

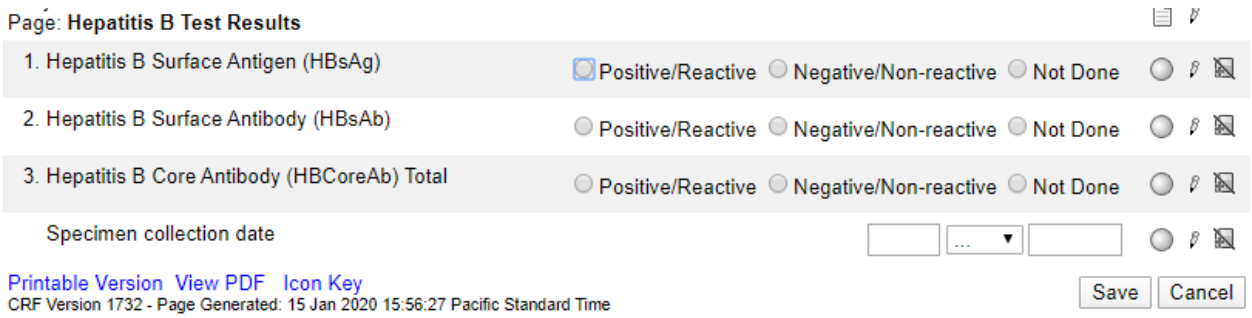
Field	Instructions
Lab	• **Select the site name from the drop-down menu to populate local lab reference ranges (and units) in the lab results section**. • **Date of birth on the Demographics CRF must be entered to populate the local reference ranges.** • If site name is not listed under "Lab" contact the SCHARP CDM.
Test Results	• Enter the result of the specified test (bottom of form) in the standard units of measurement used for this study (see below). • If test was not performed or the results were not reported, leave blank and record a comment in the query message box (if query fires). • With the exception of ***atypical lymphocytes***, if atypical lymphocyte results were not reported, report "0" in the data field and save the form. Do not enter anything in the query response box. • If result is entered, ensure a severity grade for the result is entered (only for analytes that can be graded per the DAIDS Tox Table).

Data Formats and Units of Measurement

Field	Data Format Requirements	Unit Instructions
Hemoglobin	5.2	g/dL
Hematocrit	5.2	%
MCV	5.2	fL
Platelets	10.2	cells/mm^3
WBC	8.2	cells/mm^3
Neutrophils	8.2	cells/mm^3
Lymphocytes	8.2	cells/mm^3
Monocytes	6.2	cells/mm^3
Eosinophils	6.2	cells/mm^3
Basophils	6.2	cells/mm^3
Atypical lymphocytes	6.2	cells/mm^3

Field	Instructions
Was a hematology sample collected?	• If "No" is selected, leave the rest of the form blank.
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.
Was a differential done?	• Select "Yes" or "No".
Differential collection date:	• Enter the date the sample was collected. • A complete date is required.

HEPATITIS B TEST RESULTS



Purpose

This form is used to document hepatitis B test results from the local laboratory.

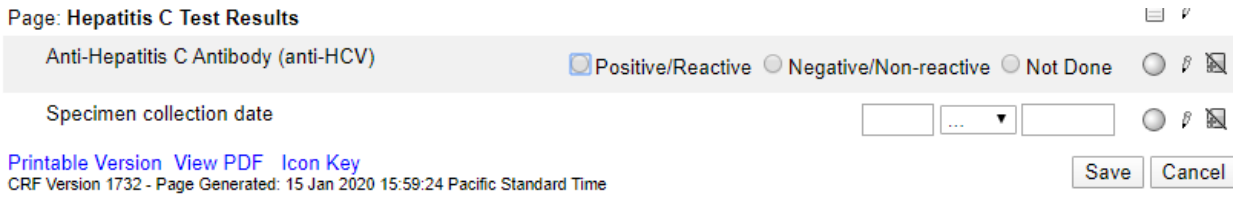
General Instructions

This form is completed at protocol-specified visits and as clinically indicated at any other visit. All fields are required.

Item-specific Instructions

Field	Instructions
Hepatitis B Surface Antigen (HBsAg)	• Select "Positive/Reactive" or "Negative/Non-reactive" or "Not Done".
Hepatitis B Surface Antibody (HBsAb)	• Select "Positive/Reactive" or "Negative/Non-reactive" or "Not Done".
Hepatitis B Core Antibody (HBCoreAb)	• Select "Positive/Reactive" or "Negative/Non-reactive" or "Not Done".
Specimen collection date	• A complete date is required. • Leave blank if test was not done.

HEPATITIS C TEST RESULTS



Purpose

This form is used to document hepatitis C test results from the local laboratory.

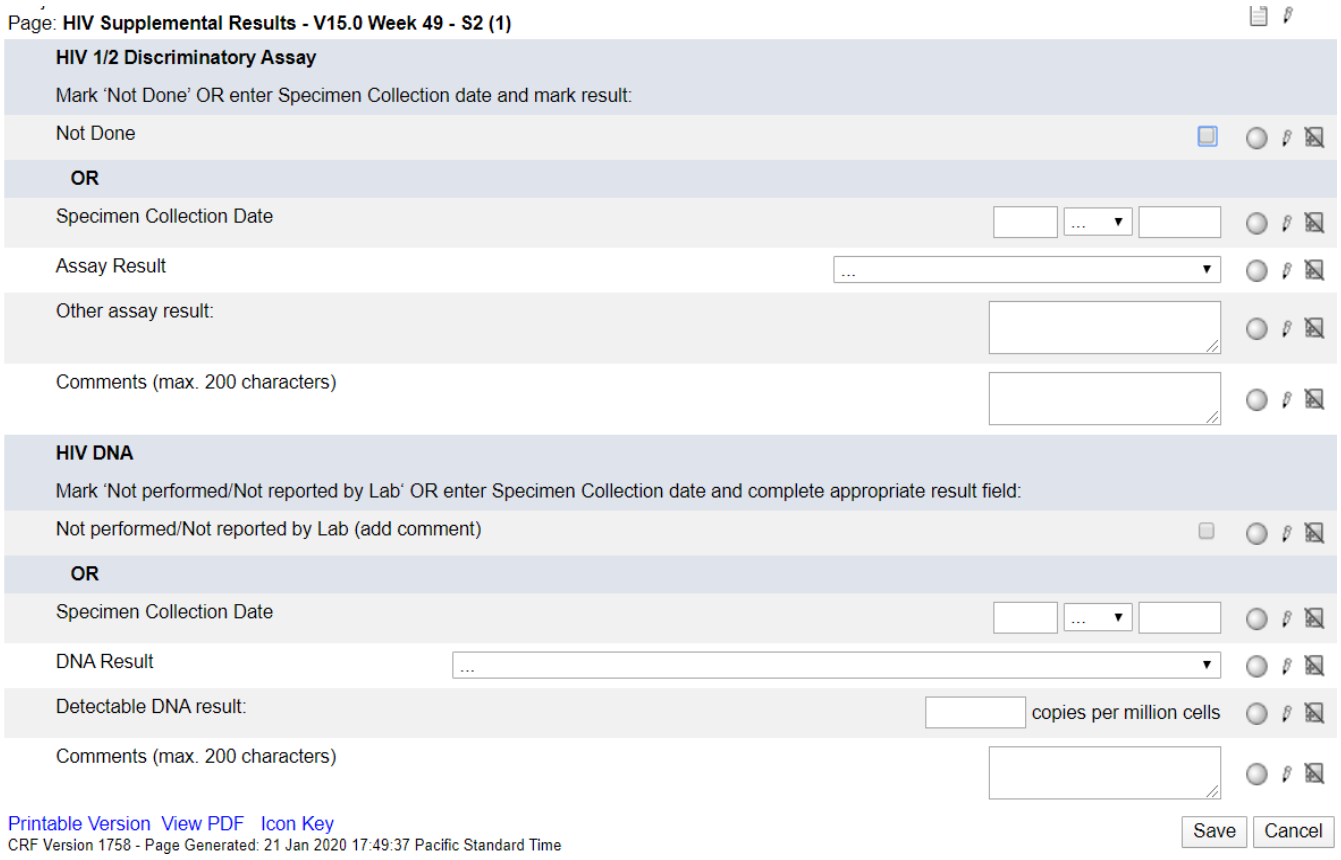
General Instructions

Complete this form at protocol-specified visits and if clinically indicated at any other visit.

Item-specific Instructions

Field	Instructions
Anti-Hepatitis C Antibody (anti-HCV):	• Select "Positive/Reactive" or "Negative/Non-reactive" or "Not Done".
Specimen collection date	• A complete date is required. • Leave blank if test was not done.

HIV SUPPLEMENTAL RESULTS



Purpose

This form is used to document additional HIV testing used to evaluate seroconversion.

General Instructions

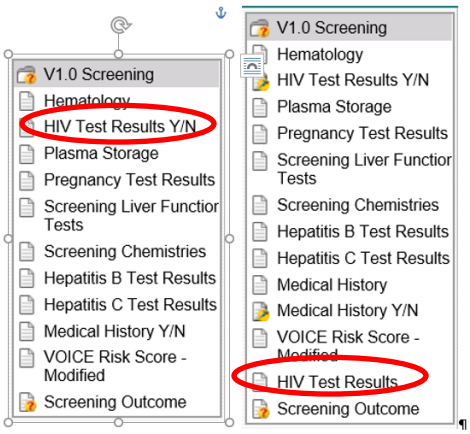
Use this form as needed following HIV algorithm per the SSP.

Item-specific Instructions

Field	Instructions
HIV 1/2 Discriminatory Assay	
Not Done	• Mark if HIV ½ Discriminatory Assay was not done. • Skip to "HIV DNA" Section.
Specimen Collection Date	• If HIV ½ Discriminatory Assay was done, enter the date the specimen was collected. • A complete date is required.

Field	Instructions
Assay Result	• Select assay result from dropdown list.
Other assay result:	• If "Other" is selected from the drop-down list, provide other assay results here.
Comments	• Maximum allowed characters: 200.
HIV DNA	
Not performed/Not reported by Lab	• Mark if HIV DNA test was not performed or not reported by lab. • Provide comments at the end of the form.
Specimen Collection Date	• If HIV DNA test was done, enter the date the specimen was collected. • A complete date is required.
DNA Result	• Select HIV DNA result from dropdown list.
Detectable DNA result:	• If DNA Result is "Detectable DNA result" record the value in copies per million cells. • Value format expected XXX.XX
Comments	• Maximum allowed characters: 200.

HIV TEST RESULTS Y/N



Purpose

This form captures if HIV testing was done at a given visit.

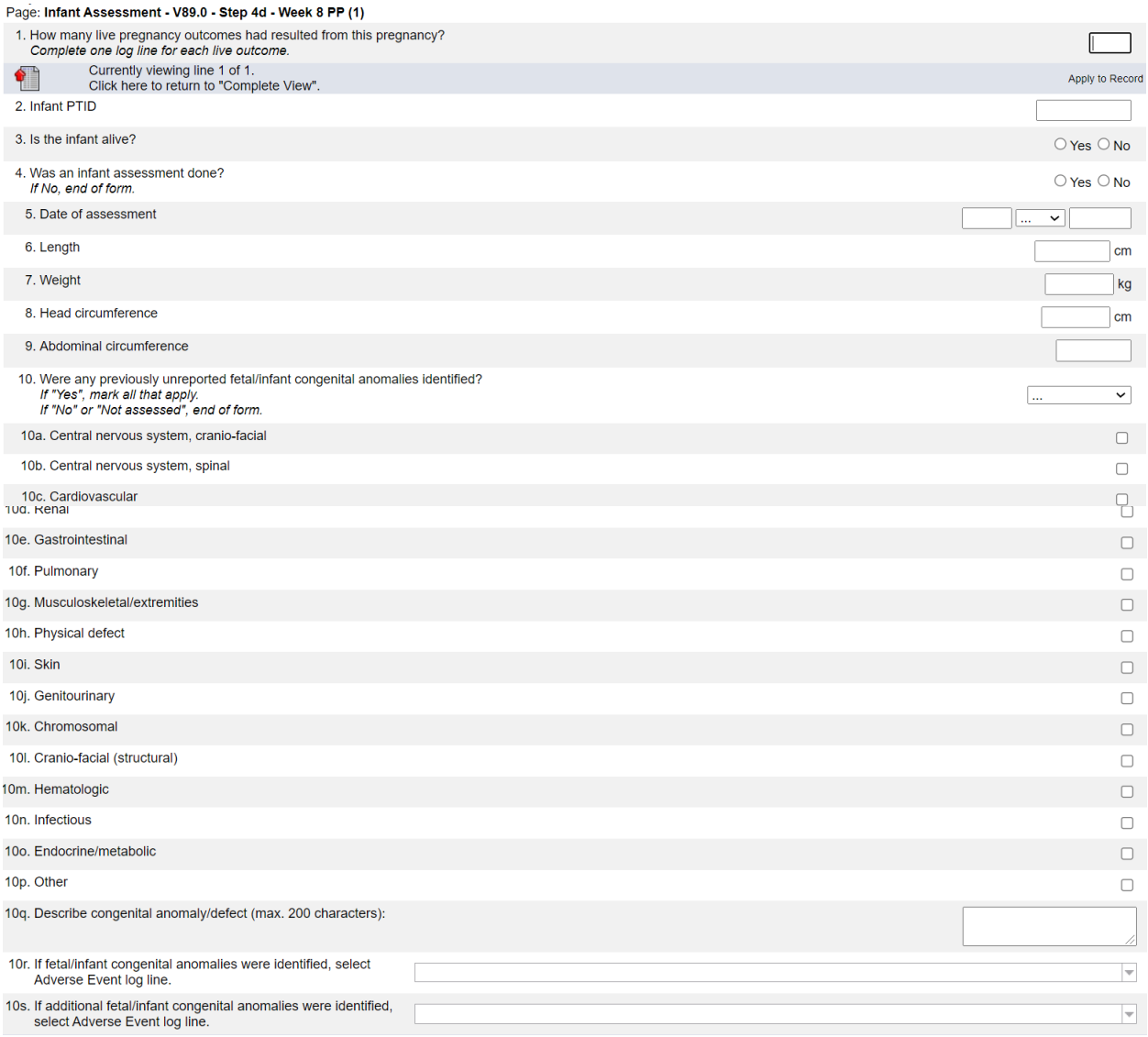
General Instructions

This form will populate the HIV Test Results Log within the current visit folder.

Item-specific Instructions

Field	Instructions
Was an HIV test performed?	• If "Yes" is selected, the HIV Test Results Log will appear in the current visit folder.

INFANT ASSESSMENT- OLE



Page: **Infant Assessment - V89.0 - Step 4d - Week 8 PP (1)**

1. How many live pregnancy outcomes had resulted from this pregnancy?
Complete one log line for each live outcome.

Currently viewing line 1 of 1.
Click here to return to "Complete View".
Apply to Record

2. Infant PTID

3. Is the infant alive? Yes No

4. Was an infant assessment done? Yes No
If No, end of form.

5. Date of assessment

6. Length cm

7. Weight kg

8. Head circumference cm

9. Abdominal circumference

10. Were any previously unreported fetal/infant congenital anomalies identified?
If "Yes", mark all that apply.
If "No" or "Not assessed", end of form.

10a. Central nervous system, cranio-facial
10b. Central nervous system, spinal
10c. Cardiovascular
10d. Renal
10e. Gastrointestinal
10f. Pulmonary
10g. Musculoskeletal/extremities
10h. Physical defect
10i. Skin
10j. Genitourinary
10k. Chromosomal
10l. Cranio-facial (structural)
10m. Hematologic
10n. Infectious
10o. Endocrine/metabolic
10p. Other

10q. Describe congenital anomaly/defect (max. 200 characters):

10r. If fetal/infant congenital anomalies were identified, select Adverse Event log line.

10s. If additional fetal/infant congenital anomalies were identified, select Adverse Event log line.

Purpose

Complete this form when assessing an infant in the Pregnancy and Infant Sub-study per the protocol requirements.

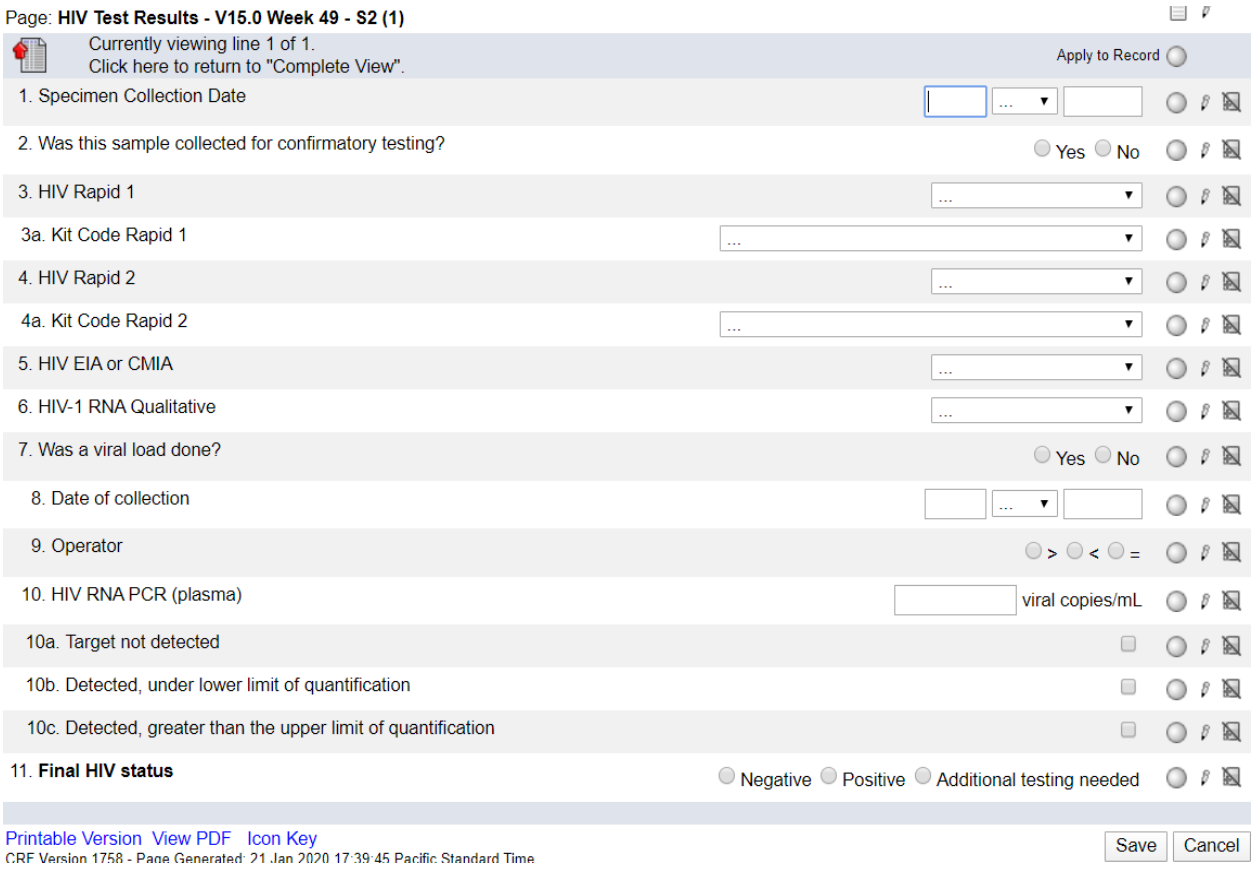
General Instructions

This form is located in the respective Pregnancy and Infant Sub-study postpartum visits.

Item-specific Instructions

Field	Instructions
Infant PTID	• Enter the Infant PTID that was generated in Rave and recorded on the respective Pregnancy Outcome- OLE form.
Is the infant alive?	• If no, end of form. • Ensure to collect respective AEs for the infant where applicable.
Was an infant assessment done?	• If no, end of form.
Date of assessment	• A full date is required.
Length	• Record the infant's length in cm. • Up to two decimal places are allowed.
Weight	• Record the infant's weight in kg. • Up to two decimal places are allowed.
Head circumference	• Record the infant's head circumference in cm. • Up to two decimal places are allowed.
Abdominal circumference	• Record the infant's abdominal circumference in cm or mark the 'not available' box. • Up to two decimal places are allowed.
Were any previously unreported fetal/infant congenital anomalies identified?	• Report as indicated on Pregnancy Outcome- OLE or prior Infant Assessment- OLE as applicable. • If "Yes", mark all that apply.

HIV TEST RESULTS



Purpose

This form is used to document HIV test results from local lab testing.

General Instructions

- Complete this form at protocol-specified visits and if clinically indicated at any other visit.
- Only one specimen collection date can be recorded on the HIV test results CRF, any re-testing with a new sample requires an additional new log line. Please do not remove previous test results.
- Every HIV Test result should have a corresponding plasma storage form with matching dates.
- Record HIV specimen test results on this form as they become available from the local lab.
- If test results are discordant or discrepant at a time point, refer to the HIV algorithm for next steps regarding additional HIV testing.
- **If a sample is positive, all confirmatory testing for that sample will be put on the same HIV Test Results Log form in the same visit folder (new log lines will be added for each specimen collected).**

Item-specific Instructions

Field	Instructions
Specimen Collection Date	• Enter the date the specimen was collected. • A complete date is required.
Was this sample collected for confirmatory testing?	• Select "Yes", if this is a re-draw for confirmation of a previous reactive or positive result. • Select "No" if this blood draw is not to confirm prior test results.
HIV Rapid 1	• Select "Non-reactive/Negative", "Reactive/Positive" or "Not Done", as appropriate. [Note: Per the HIV Testing Algorithm, rapid test 1 is always required.]
Kit Code Rapid 1	• Select a kit code from the approved list. • The Rapid 1 kit code must always be for an FDA-cleared kit.
HIV Rapid 2	• If a second HIV rapid test is performed per local guidelines, record the results here. • If a second HIV rapid test is not performed, select "Not Done".
Kit Code Rapid 2	• Select a kit code from approved list.
HIV EIA or CMIA	• Record the results of the laboratory-based HIV immunoassay here. • Select "Non-reactive/Negative", "Reactive/Positive", or "Not Done".
HIV-1 RNA Qualitative	• Select "Not Done".
Was a viral load done?	• If "No" is selected, items 8 through 10c should be left blank.
Date of Collection	• Enter the date the viral load sample was collected. • A complete date is required.

Field	Instructions
9. Operator	• This is a required field. • If result is "**<XX copies/ml, Not Detected**" (where the <XX refers to the lower limit of quantification but the VL was not detected), then select "<" • If result is "**<XX copies/ml, Detected**" (where the result is interpreted as detected but below the limit of quantification, then select "<" • If result is "**XX viral copies/ml**" (this is interpreted as a detected viral load with known value for the copies/ml), then select "=" • If result is "**>XXXXXX copies/ml, Detected**" (this is interpreted as a detected viral load but above the limit of quantification), then select ">"
10. HIV RNA PCR (plasma)	• This is a required field. • Enter the HIV RNA PCR value in viral copies/mL. • Maximum allowed digits is nine.
10a. Target not detected	• Check this field if result is "<XX copies/ml, Not Detected", otherwise leave blank.
10b. Detected, under lower limit of quantification	• Check this field if result is "<XX copies/ml, detected", otherwise leave blank.
10c. Detected, greater than the upper limit of quantification	• Check this field if result is ">XXXXXX copies/ml, detected", otherwise leave blank.
Final HIV Status	• This is a required field. • Select final HIV Status based on local testing. • If final HIV status is "Negative", proceed with the visit. • If final HIV status is "Positive", refer to the protocol and SSP for next steps. • If final status is "Additional testing needed", add a new log line to the current HIV Test Results form and record additional test results.

INFANT BREASTMILK FEEDING ASSESSMENT

Purpose

This form is used to document infant breastmilk feeding

General Instructions

This form is part of the Pregnancy and Infant Sub-study. Complete at the required study visits.

Item-specific Instructions

Field	Instructions
Infant PTID	• Enter Infant's PTID that was generated by Rave and is recorded on the respective Pregnancy Outcome -OLE CRF.
Was a feeding assessment completed?	• If "No", then no further entry is required.
Date of assessment	• A full date is required.
Has the infant ever been fed breastmilk?	• Indicate if the infant has received breastmilk since birth.
Is the infant currently fed breastmilk?	• Indicate "Yes" or "No".
Date infant last received breast milk	• Month and year are required.

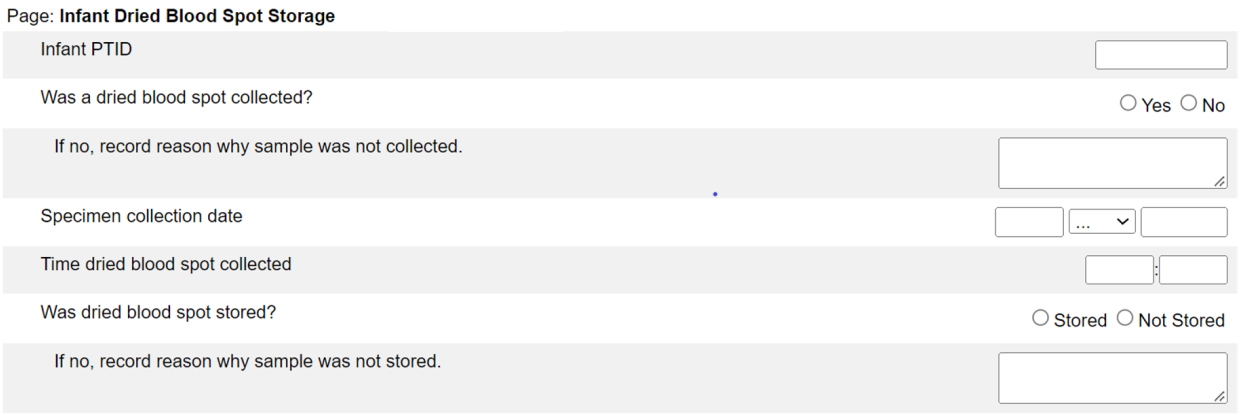
INFANT DRIED BLOOD SPOT STORAGE

Purpose

This form is used to document collection and storage of the infant's blood spot storage for the Pregnancy and Infant Sub-study.

General Instructions

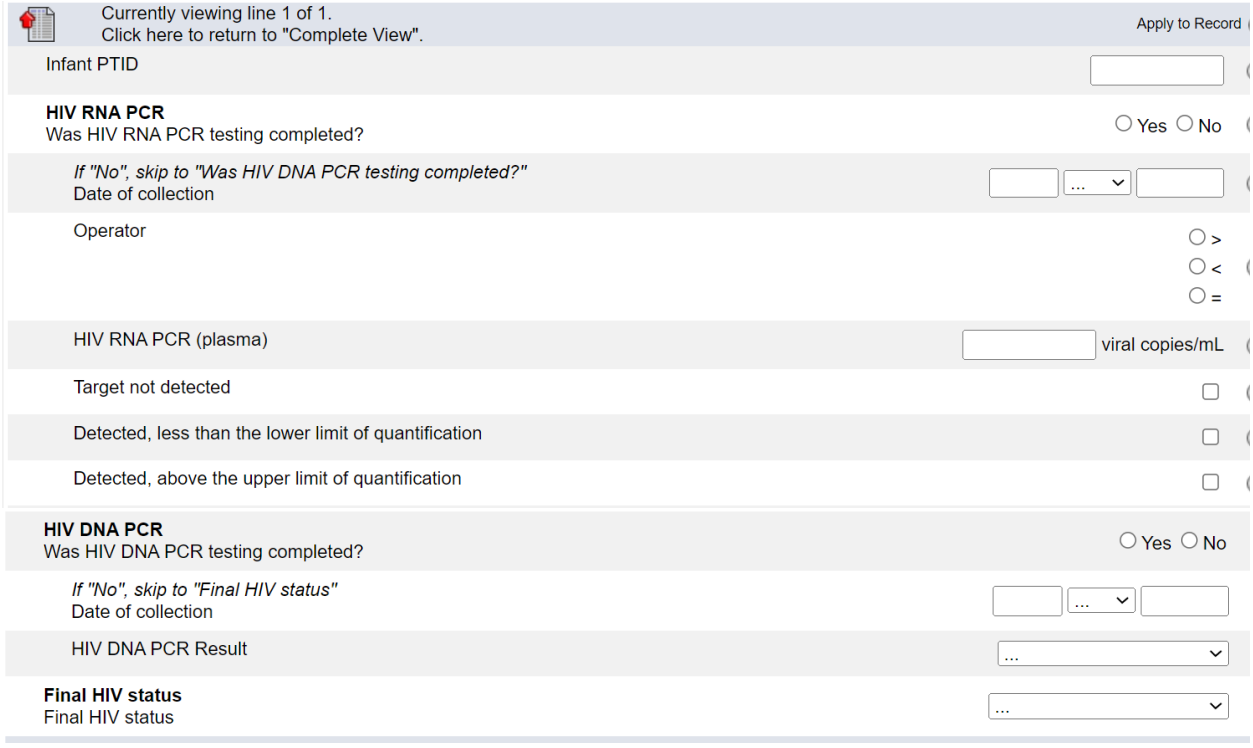
This form is found in the postpartum Pregnancy and Infant Sub-study visit folders, where required.



Item-specific Instructions

Field	Instructions
Infant PTID	• Enter Infant's PTID that was generated by Rave and is recorded on the respective Pregnancy Outcome -OLE CRF.
Was dried blood spot collected?	If "No" record reason why sample was not collected in text box provided.
Specimen collection date:	• Record the date that the specimen was collected. • A complete date is required.
Time dried blood spot collected:	• Record the time the specimen was collected using a 24-hour clock.
Was dried blood spot stored	• If "No", record reason why in text box provided.

INFANT HIV TEST RESULT



Purpose

This form is used to document Infant HIV test results from local lab testing. This form is to be used in the Pregnancy and Infant Sub-study only.

General Instructions

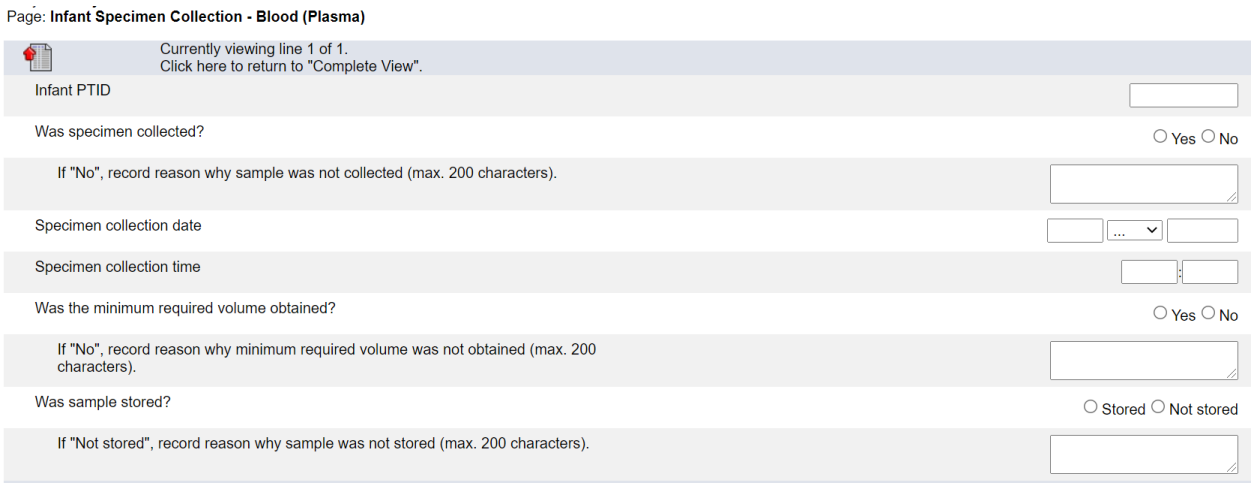
- Complete this form only if mother has a positive HIV test.
- Only one specimen collection date can be recorded on the HIV test results CRF, any re-testing with a new sample requires an additional new log line. Please do not remove previous test results.
- Every HIV Test result should have a corresponding Infant Specimen Collection – Blood (Plasma)with matching dates.
- Record HIV specimen test results on this form as they become available from the local lab.
- If test results are discordant or discrepant at a time point, refer to the HIV algorithm for next steps regarding additional HIV testing.
  If a sample is positive at first or index visit, a confirmatory visit is required.

Item-specific Instructions

Field	Instructions
Infant PTID	• Enter Infant's PTID that was generated by Rave and is recorded on the respective Pregnancy Outcome -OLE CRF.
Was HIV RNA PCR testing completed?	• If "No" skip to "Was HIV DNA PCR testing completed?"
Date of Collection	• Enter the date the viral loadsample was collected. • A complete date is required.
Operator	• This is a required field. • If result is "**<XX copies/ml, Not Detected**" (where the <XX refers to the lower limit of quantification but the VL was not detected), then select "<" • If result is "**<XX copies/ml, Detected**" (where the result is interpreted as detected but below the limit of quantification, then select "<" • If result is "**XX viral copies/ml**" (this is interpreted as a detected viral load with known value for the copies/ml), then select "=" • If result is "**>XXXXXX copies/ml, Detected**" (this is interpreted as a detected viral load but above the limit of quantification), then select ">"
HIV RNA PCR (plasma)	• This is a required field. • If HIV RNA PCR was collected, enter the HIV RNA PCR value in viral copies/mL. • Maximum allowed digits is nine.
Target not detected	• Check this field if result is "<XX copies/ml, **Not Detected**", otherwise leave blank.
Detected, under lower limit of quantification	• Check this field if result is "<XX copies/ml, **Detected**", otherwise leave blank.
Detected, greater than the upper limit of quantification	• Check this field if result is ">XXXXXX copies/ml, detected", otherwise leave blank.

Field	Instructions
HIV DNA PCR	• This is a required field. • If "No" skip to Final HIV status • If HIV DNA PCR was collected, select the HIV DNA PCR result from the drop-down menu.
Final HIV Status	• This is a required field. • Select final HIV Status based on local testing. • If a sample is positive at first visit or Index visit, then "Additional testing needed" should be selected

INFANT SPECIMEN COLLECTION – BLOOD (PLASMA)


Page: **Infant Specimen Collection - Blood (Plasma)**

Currently viewing line 1 of 1.
Click here to return to "Complete View".

Infant PTID	
Was specimen collected?	Yes No
If "No", record reason why sample was not collected (max. 200 characters).	
Specimen collection date	...
Specimen collection time	:
Was the minimum required volume obtained?	Yes No
If "No", record reason why minimum required volume was not obtained (max. 200 characters).	
Was sample stored?	Stored Not stored
If "Not stored", record reason why sample was not stored (max. 200 characters).	

Purpose

This form is used to document collection and storage of the infant's blood plasma for the Pregnancy and Infant Sub-study.

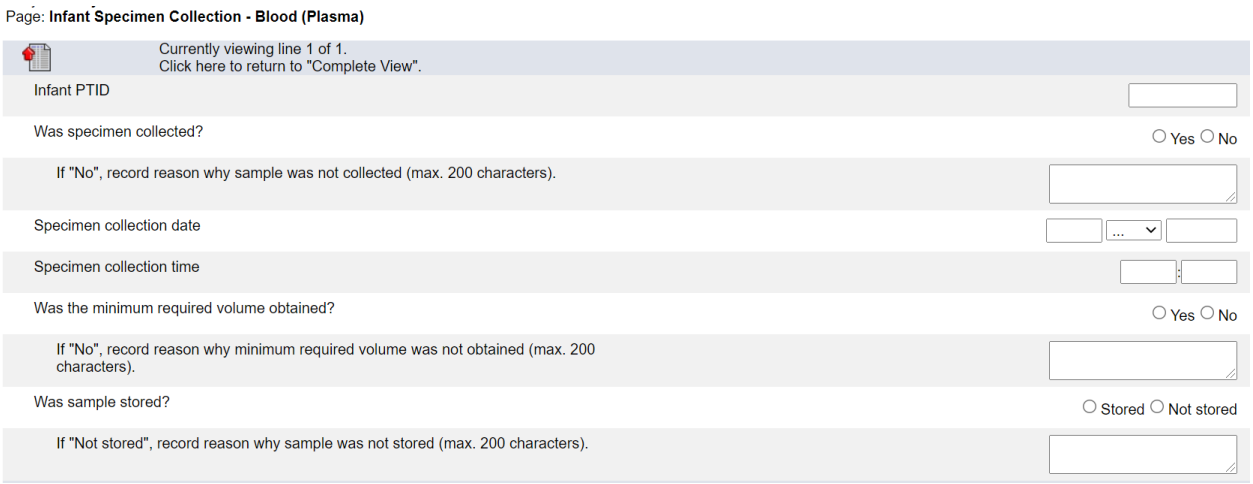
General Instructions

This form is found in the postpartum Pregnancy and Infant Sub-study visit folders, where required.

Item-specific Instructions

Field	Instructions
Infant PTID	• Enter Infant's PTID that was generated by Rave and is recorded on the respective Pregnancy Outcome -OLE CRF.
Was specimen collected?	• If "No" record reason why sample was not collected in text box provided.
Specimen collection date:	• Record the date that the specimen was collected. • A complete date is required.
Specimen collection time:	• Record the time the specimen was collected using a 24-hour clock.
Was the minimum required volume obtained?	• If "No", record reason why in text box provided.
Was sample stored?	• If "Not Stored" is selected, record the reason in the text box provided.

INFANT SPECIMEN COLLECTION – CORD BLOOD


Page: **Infant Specimen Collection - Blood (Plasma)**

Currently viewing line 1 of 1.
Click here to return to "Complete View".

Infant PTID	
Was specimen collected?	Yes No
If "No", record reason why sample was not collected (max. 200 characters).	
Specimen collection date	...
Specimen collection time	:
Was the minimum required volume obtained?	Yes No
If "No", record reason why minimum required volume was not obtained (max. 200 characters).	
Was sample stored?	Stored Not stored
If "Not stored", record reason why sample was not stored (max. 200 characters).	

Purpose

This form is used to document collection and storage of the infant's chord blood for the Pregnancy and Infant Sub-study.

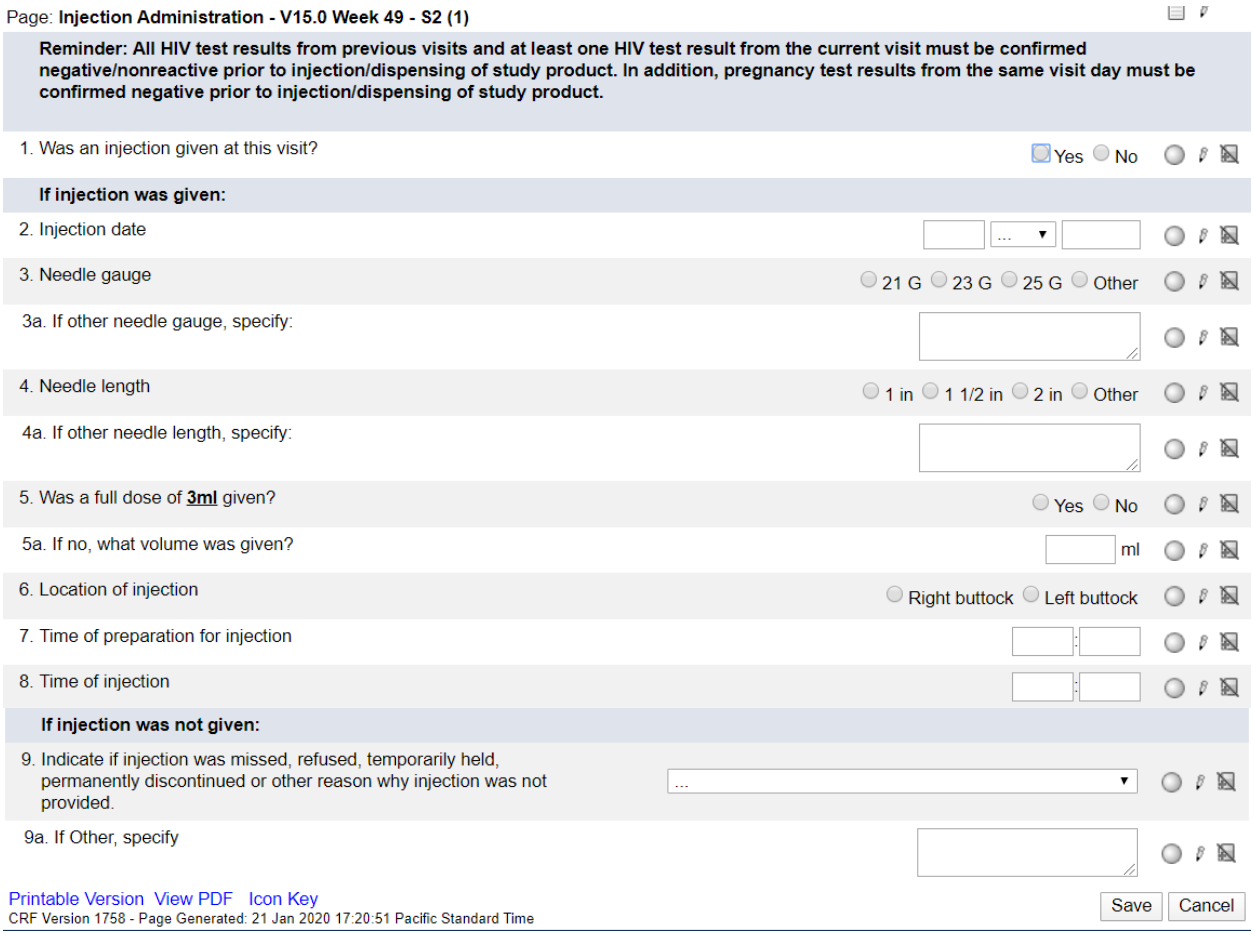
General Instructions

This form is found in the postpartum Pregnancy and Infant Sub-study visit folders, where required.

Item-specific Instructions

Field	Instructions
Infant PTID	• Enter Infant's PTID that was generated by Rave and is recorded on the respective Pregnancy Outcome -OLE CRF.
Was specimen collected?	• If "No" record reason why sample was not collected in text box provided.
Specimen collection date:	• Record the date that the specimen was collected. • A complete date is required.
Specimen collection time:	• Record the time the specimen was collected using a 24-hour clock.
Was the minimum required volume obtained?	• If "No", record reason why in text box provided.
Was sample stored?	• If "Not Stored" is selected, record the reason in the text box provided.

INJECTION ADMINISTRATION


Page: **Injection Administration - V15.0 Week 49 - S2 (1)**

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 to injection/dispensing of study product. In addition, pregnancy test results from the same visit day must be confirmed negative prior to injection/dispensing of study product.

1. Was an injection given at this visit? Yes No

If injection was given:

2. Injection date
3. Needle gauge 21 G 23 G 25 G Other
3a. If other needle gauge, specify:
4. Needle length 1 in 1 1/2 in 2 in Other
4a. If other needle length, specify:
5. Was a full dose of **3ml** given? Yes No
5a. If no, what volume was given? ml
6. Location of injection Right buttock Left buttock
7. Time of preparation for injection
8. Time of injection

If injection was not given:

9. Indicate if injection was missed, refused, temporarily held, permanently discontinued or other reason why injection was not provided.
9a. If Other, specify

Printable Version View PDF Icon Key
CRF Version 1758 - Page Generated: 21 Jan 2020 17:20:51 Pacific Standard Time
Save Cancel

Purpose

This form is used to summarize information regarding the injection administration at a given visit.

General Information/Instructions

Complete this form at protocol-specified visits after HIV and pregnancy testing has been completed.

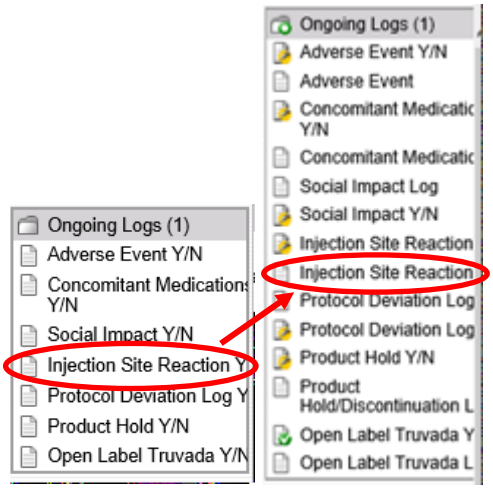
Item-specific Instructions

Field	Instructions
Was an injection given at this visit?	• If "Yes" is selected, complete items 2-8 (underneath the heading "If injection was given"). • If "No" is selected, only complete item 9 (underneath the heading "If injection was not given").
If injection was given:	
Injection date	• Enter the date the injection was received. • A complete date is required.

Field	Instructions
Needle gauge	• Select the appropriate needle gauge from the list provided.
If other needle gauge, specify:	• If "Needle gauge" is "Other", record the other needle gauge used here.
Needle length	• Select the appropriate needle length in inches. • If the needle length provided with the needle is not in inches, convert the unit of measurement to inches and select the needle length that best fits.
If other needle length, specify:	• If "Needle length" is "Other", record the other needle length used here.
Was a full dose of <u>3ml</u> given?	• Select "Yes" when the full dose of 3ml is given per protocol. • If "No" is selected, enter the volume of study drug administered below.
If no, what volume was given?	• If full dose was given, this field should be blank. • Enter volume of study drug administered in mL. • Format allows up to one decimal value.
Location of injection	• Select either "Right buttock" or "Left buttock". • If another location was used, contact the CDM.
Time of preparation for injection	• Enter a time using a 24-hour clock. • Time of preparation must precede the time of injection. • The time of preparation for injection is the time when the pharmacist first enters the needle into the CAB injectable vial or when the pharmacist enters the needle into the port of the intralipid IV bag to withdraw the applicable study product into the syringe to prepare participant's injectable study product.
Time of injection	• Enter a time using a 24-hour clock.
If injection was not given:	

Field	Instructions
Indicate if injection was missed, refused, temporarily held, permanently discontinued or other reason why injection was not provided.	• If the injection was not given at a visit, record the reason here. • Select "Injection missed", "Injection refused", "Injection schedule on hold or permanently discontinued", or "Other, specify" from dropdown list
If Other, specify	• If "Indicate if injection was missed, refused, temporarily held, permanently discontinued or other reason why injection was not provided." is "Other, specify", record the reason here.

INJECTION SITE REACTION Y/N



Purpose

This form documents whether any injection site reactions (ISRs) were experienced by the participant during the study.

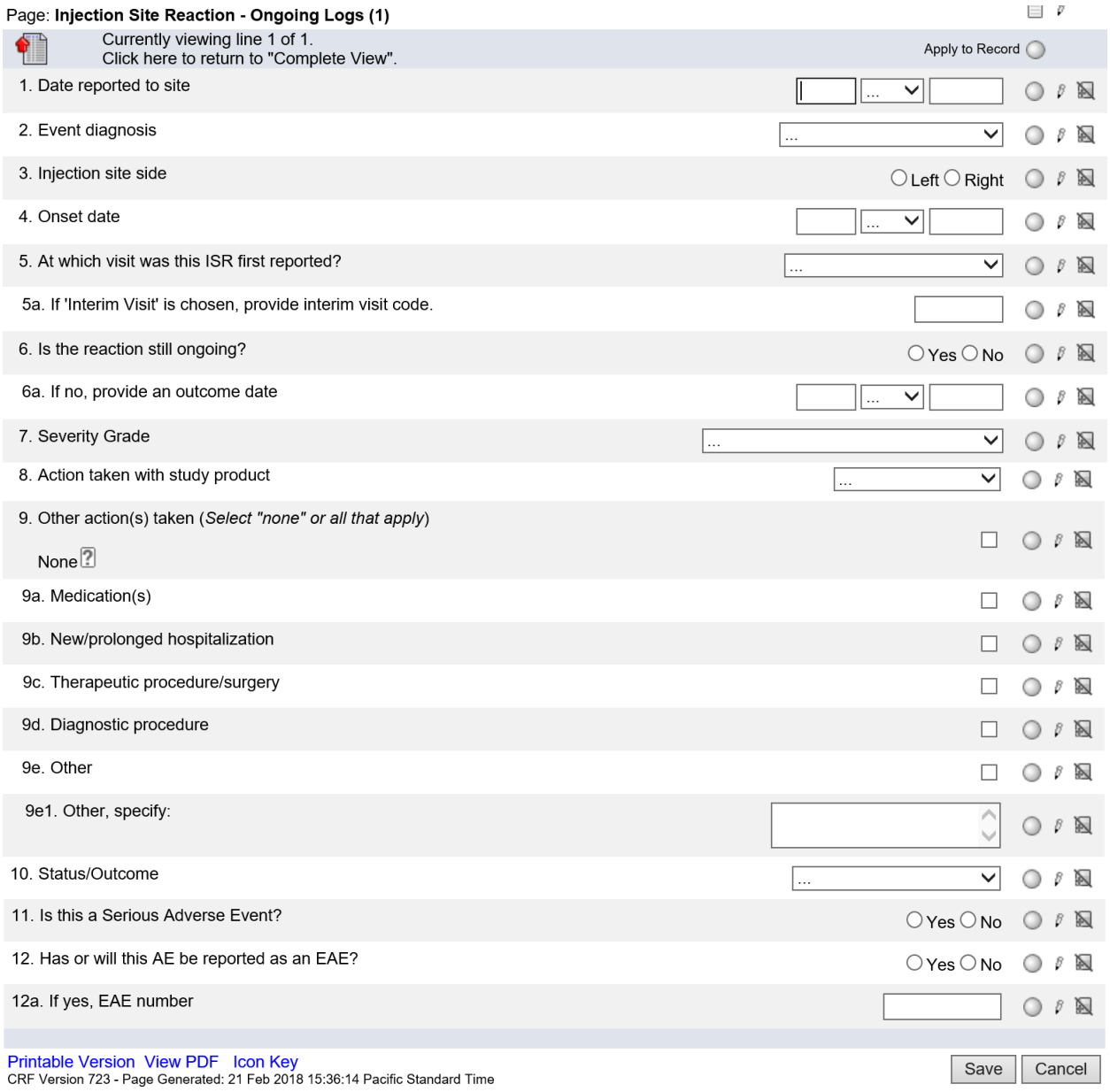
General Instructions

This form is located within the "Ongoing Logs" folder. It is used to trigger the Injection Site Reaction Log. Once it has been saved, it does not need to be completed again throughout the duration of the study.

Item-specific Instructions

Field	Instructions
Has the participant experienced any injection site reactions?	• If "Yes" is selected, the Injection Site Reaction log form appears in the Ongoing Logs folder and can then be completed.

INJECTION SITE REACTION LOG



Purpose

This form is used to document any injection site reaction reported by the participant or observed during the clinic visit.

General Information/Instructions

Injection Site Reactions (ISRs) should only be reported on the ISR Log and not on the AE Log. Complete one log line for each ISR. Add additional log lines by clicking “Add a new log line”, located at the bottom of the form. The ISR Log is only used for ISR’s related to study product; do not record ISRs for routine vaccinations on this form.

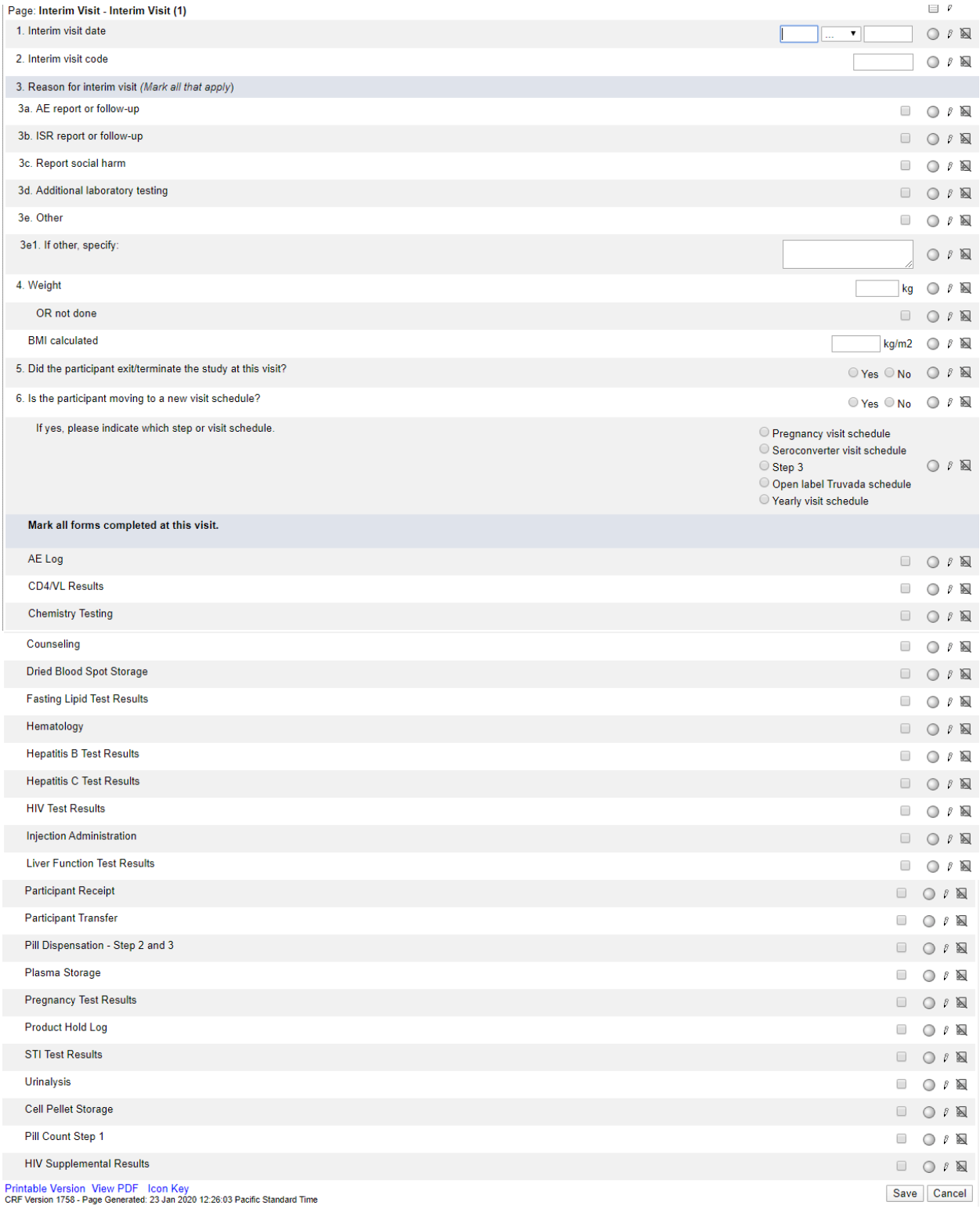
Item-specific Instructions

Field	Instructions
Date reported to site	• Enter the date the site first became aware of the ISR. • A complete date is required.
Event diagnosis	• Select the type of injection site reaction that occurred from the dropdown menu.
Injection site side	• Select "Left" or "Right" for the side of the buttocks on which the injection was given.
Onset date	• Record the date the participant first experienced the reaction. • At minimum, a month and year are required. If day is unknown, enter "UN" for the day. • The onset 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. • If an interim visit, select "Interim Visit".
Interim visit code	• If "Interim Visit" is selected for "At which visit was this reaction first reported", enter interim visit code in space provided. Otherwise leave this item blank.
Is the reaction still ongoing?	• Select "Yes" if the ISR is continuing at the time it is first reported. • Select "No" if the ISR is no longer present. • If a participant is taking a medication to control the ISR that arose during study participation, it is not considered resolved. • If "Yes", leave Outcome Date blank.
If no, provide an outcome date	• Record the outcome date for the ISR only if "Is the reaction still ongoing?" is "No". • At a minimum, a month and year are required. If day is unknown, enter "UN" for the day. • Enter the date in which the participant no longer experienced the reaction.

Field	Instructions
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). o Grade 1 (Mild) o Grade 2 (Moderate) o Grade 3 (Severe) o Grade 4 (Potentially life-threatening) o 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, or schedule) of study product as a result of the ISR. • "Dose reduced" and "dose increased" do not apply and should not be selected in HPTN084. • Select "drug withdrawn" if the ISR results in permanent discontinuation of study product. • Select "drug interrupted" if ISR results in a 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 1) the ISR's onset date is on or after the date the participant permanently discontinues study product use; 2) study product is held or permanently discontinued for a different reason; or 3) the ISR is Grade 5 – death.
Other action(s) taken:	• Select "None" or check all that apply. • Select "Medication" only if participant reports taking medication for the reported ISR. Report medication(s) on the Concomitant Medications Log. • If "Other", specify relevant details in the "Other, specify" text field provided.

Field	Instructions
Status/Outcome	• Select "recovered/resolved" if ISR 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 ISR, the ISR is not considered resolved while the medication is still indicated. • Select "recovering/resolving" if ISR is continuing at the time it is reported and has not yet resolved or returned to baseline severity/frequency. • Select "resolved with sequelae" if participant has recovered from the ISR, 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 an ISR is continuing at the time of participant termination from the study. • Select "fatal" only if the severity grade of this ISR is Grade 5. Any other ISRs continuing at the time of death should be recorded as "not recovered/resolved".
Is this a Serious Adverse Event?	• Select "Yes" or "No".
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



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.

General Information/Instructions

- Complete this form for each interim visit in which new data was collected for a participant. If no study data is collected pertaining to HPTN084 during an interim visit, this form does not need to be completed and an interim visit code does not need to be assigned to the visit (although please document any and all contact with a participant in a chart note). For example, if a participant comes into the office to discuss her study product, but no procedures are performed, then an interim visit form is not required, and the visit would not be assigned an interim visit code. This contact would be documented in a chart note.
- To add an interim visit, select "Interim Visit" from the participant's homepage using the "Add Event" dropdown menu.
- Interim Visits will generate in numerical order and appear below the Ongoing Logs folder.
- Once the Interim Visit form located inside the Interim Visit folder is completed, the actual visit code will appear in the list of folders:

Item Specific Instructions

Field	Instructions
Interim visit date	• A complete date is required.
Interim visit code	• Enter the applicable interim visit code. • Refer to the Data Collection SSP for more information on visit codes.
Reason for interim visit	• Mark all reasons that apply. • If "Other" is marked, provide the reason in the "If other, specify" text box provided.
Weight	• Enter weight in kg or mark "not done".
Did the participant exit/terminate the study at this visit?	• If "Yes" is selected, complete the Termination CRF in the Discontinuations folder.
Mark all forms completed at this visit.	• Mark all forms completed at this visit. • Selecting forms from the list and saving the Interim Visit form will add those specific forms to the Interim Visit folder.

INTERIM VISIT -OLE

Page: **Interim Visit - OLE - Interim Visit - OLE (1)**

1. Interim Visit date	...
2. Interim visit code	
3 Reason for interim visit *(Mark all that apply)*	
3a. AE report or follow-up	☐
3b. ISR report or follow-up	☐
3c. Report social harm	☐
3d. Additional laboratory testing	☐
3e. Other	☐
3e1. If other, specify:	
4. Weight	kg
OR Not Done	☐
5. Systolic blood pressure	mmHg
6. Diastolic blood pressure	mmHg
7. Pulse	beats/min
8. How many bottles of study drug (TDF/FTC or oral CAB) were dispensed at this visit?	...
9. Did the product get held/discontinued at this visit?	○ Product Hold ○ Product Discontinued ○ No
10. Did the participant exit/terminate the study at this visit?	○ Yes ○ No
11. Is the participant moving to a new step or visit schedule?	○ Yes ○ No
11a. If yes, please indicate which step or visit schedule.	...
Mark all forms completed at this visit.	
AE Log	☐
CD4/VL Results	☐
Chemistry Testing	☐
Counseling	☐
Dried Blood Spot Storage	☐
Fasting Lipid Test Results	☐
Hematology	☐
HIV Test Results	☐
HIV Supplemental Results	☐
Infant Assessment	☐
Infant Breastmilk Feeding Assessment	☐
Infant Specimen Collection - Plasma	☐
Liver Function Test Results	☐
Participant Receipt	☐
Participant Transfer	☐
Plasma Storage	☐

Purpose

This form is used to summarize information collected at an interim visit during the OLE portion of the study and to record all procedures or assessments the participant received.

General Information/Instructions

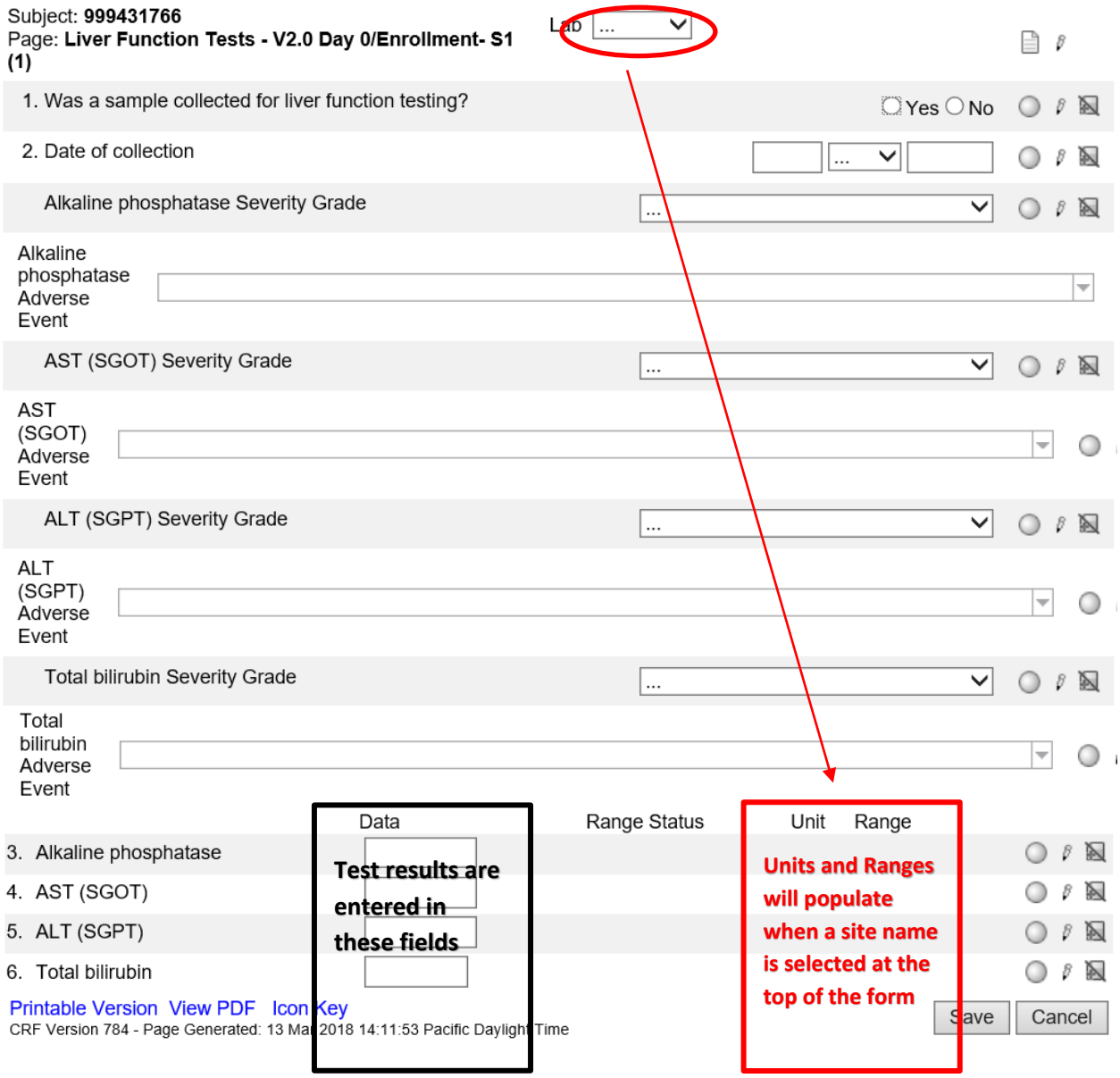
- *This form replaces the Interim Visit form during the OLE portion of the study.*
- To add an interim visit- OLE, select “Interim Visit- OLE” from the participant’s homepage using the “Add Event” dropdown menu.

- Interim Visits- OLE will generate in numerical order and appear below the Ongoing Logs folder.
- Once the Interim Visit form located inside the Interim Visit folder is completed, the actual visit code will appear in the list of folders:

Item Specific Instructions

Field	Instructions
Interim visit date	• A complete date is required.
Interim visit code	• Enter the applicable interim visit code. • Refer to the Data Collection SSP for more information on visit codes.
Reason for interim visit	• Mark all reasons that apply. • If "Other" is marked, provide the reason in the "If other, specify" text box provided.
Weight	• Enter weight in kg or mark "not done".
Systolic blood pressure	• Enter the systolic blood pressure in units of "mmHG"
Diastolic blood pressure	• Enter the diastolic blood pressure in units of "mmHG"
Pulse	• Enter the pulse in units of "beats/minute".
How many bottles of study drug (TDF/FTC or oral CAB) were dispensed at this visit?	• Enter number of bottles dispensed. If none, enter "0".
Did the product get held/discontinued at this visit?	• If "Product hold" or "Product discontinued" is selected, the Product Hold/Discontinuation-OLE CRF must be completed.
Did the participant exit/terminate the study at this visit?	• If "Yes" is selected, complete the Termination CRF in the Discontinuations folder.
Mark all forms completed at this visit.	• Mark all forms completed at this visit. • Selecting forms from the list and saving the Interim Visit form will add those specific forms to the Interim Visit folder.

LIVER FUNCTION TESTS



Purpose

This form is used to document the participant's liver function test results.

General Information/Instructions

This form is completed at protocol-specified visits and if clinically indicated at any other visit. If a sample was not collected, do not record any additional information on the form.

Item-specific Instructions

Enter lab data in the following sequence:

Field	Instructions
Lab	• **Select the site name from the drop-down menu to populate local lab reference ranges (and units) in the lab results section**. • **Date of birth on the Demographics CRF must be entered to populate the local reference ranges.** • If local lab is not listed under "Lab" contact the SCHARP CDM.
Test Results	• Enter the result of the specified test (bottom of form) in the standard units of measurement used for this study (see below). • If results from the local lab are not reported in the standard units of measurement, the units will need to be converted using the Lab Conversion Tool on Atlas. • If test was not performed or the results were not reported, leave blank and record a comment in the query message box (if query fires). *For example, if ALT was not reported, leave the item blank and save the form. When a query fires record "not reported" in the query message box.* • If result is entered, ensure a severity grade for the result is entered (only for analytes that can be graded per the DAIDS Tox Table).

Data Formats and Units of Measurement

Field*	Data Format Requirements	Unit Requirements
Alkaline phosphatase	6.2	U/L
AST (SGOT)	6.2	U/L
ALT (SGPT)	6.2	U/L
Total bilirubin	5.2	mg/dL

*The tests are listed as required post-screening. Only ALT (SGPT) and Total bilirubin are collected at Screening on the Screening Liver Function Test Results CRF.

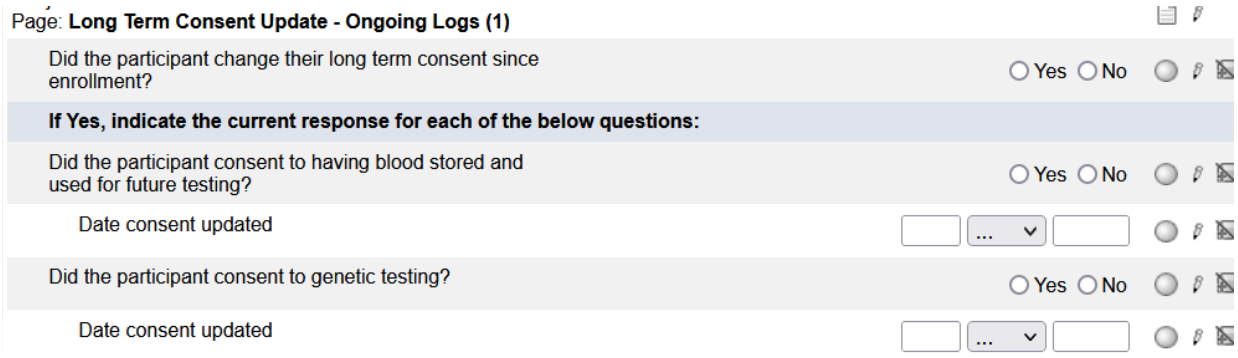
Field	Instructions
Was a sample collected for liver function testing?	• If "No" is selected, leave the rest of the form blank.
Date of collection	• Enter the date the specimen was collected. • A complete date is required.
Test severity grade	• Select a severity grade (1-4) or "not gradable" from the dropdown list. • If a severity grade is selected, the test result field must not be blank.

Field	Instructions
Was a sample collected for liver function testing?	• If "No" is selected, leave the rest of the form blank.
Date of collection	• Enter the date the specimen was collected. • A complete date is required.
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 Liver Function Tests form.

LOG REVISION

Need to add a screenshot, not sure how to get a blank one in UAT

LONG TERM CONSENT UPDATE



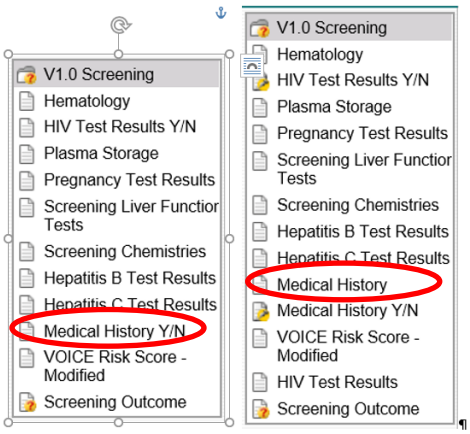
Purpose:
Complete this form if a participant has changed either of their long-term consents since enrollment.

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"
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"
Date consent updated	• Enter date that genetic testing consent was updated • A complete date is required

MEDICAL HISTORY Y/N



Purpose

This form is used to document whether any pre-existing medical conditions/events were reported at the Screening Visit.

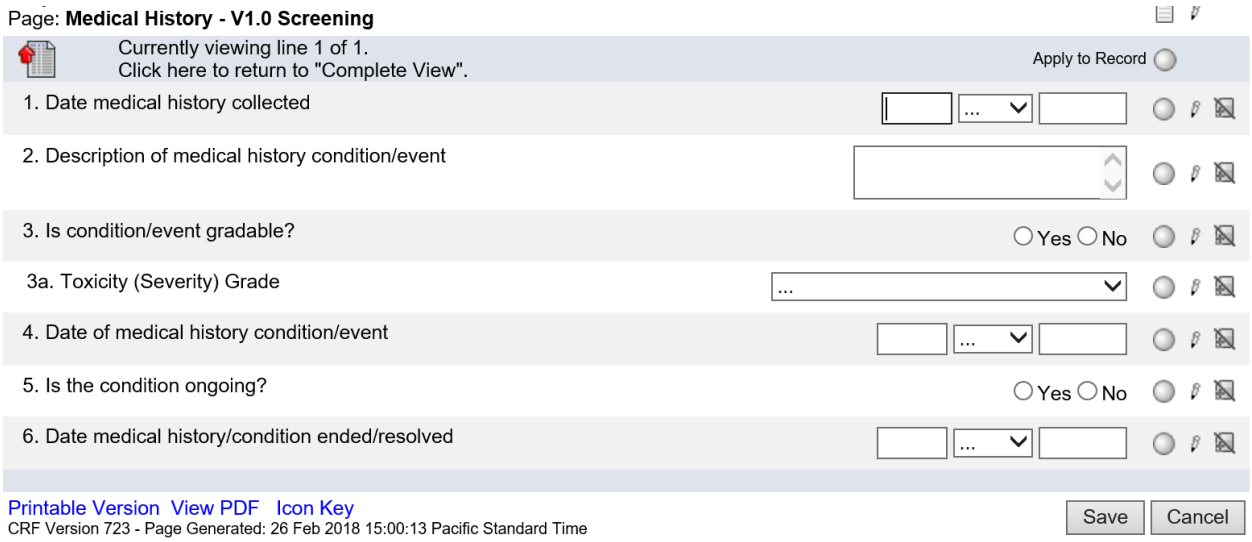
General Instructions

This form appears in the Screening Visit folder, but it should be re-reviewed and updated, as appropriate, at the Enrollment Visit. Note that this form is not present within the "Ongoing Logs" folder.

Item-specific Instructions

Field	Instructions
Does the participant have any medical history to report?	• If "Yes" is marked and the form is saved, the Medical History Log appears in the Screening Visit folder and can then be completed.

MEDICAL HISTORY



Purpose

This form is used to document a participant's medical history or 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.

General Instructions

- This form will appear in the Screening Visit folder after the "Medical History Y/N" prompt has been answered as "Yes".
- Use the "Add a new Log line" button to add an additional baseline medical history condition/event.
- 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 the Enrollment Visit.
- If a medical condition presents during enrollment visit, including lab abnormalities, update the Medical History Log.
- If a participant reports at Screening or Enrollment that he/she has seasonal allergies but is currently not experiencing any signs or symptoms, seasonal allergies should still be recorded on the MH Log. The highest severity grade the participant has experienced for the allergies (when they were at their worst) would be recorded. If the participant later on in the course of the study has a flare up of the allergies, the flare up should only be recorded on an AE Log form if the severity or frequency has increased by at least a grade from Enrollment. If the flare up is the same severity/frequency that was noted on the PRE at Enrollment, no AE needs to be reported. This guidance applies for other chronic conditions with periodic flare ups.
- Complete a separate entry (e.g. log line) for each pre-existing condition/event.

Item-specific Instructions

Field	Instructions
Date medical history collected	• Record the date medical history was collected by the site. • A complete date is required.
Description of medical history condition/event	• Briefly describe the 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 Screening or 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?	• If a condition is not gradable (below Grade 1), select "No".

Toxicity (Severity) Grade	• This item is only required if "Is condition/event gradable?" is "Yes".
	• 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)
	  o Grade 1 (Mild)
	  o Grade 2 (Moderate)
	  o Grade 3 (Severe)
	  o Grade 4 (Potentially life-threatening)
	• If the condition improves in severity or resolves during the study, the Toxicity Grade should remain unchanged on this CRF.
	• If the condition worsens in severity (e.g. goes from a grade 1 to a grade 2), the Toxicity Grade should also remain unchanged on this CRF. However, this worsened condition must be reported as an adverse event on the AE Log.

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. • At a minimum the 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 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.

MISSED VISIT

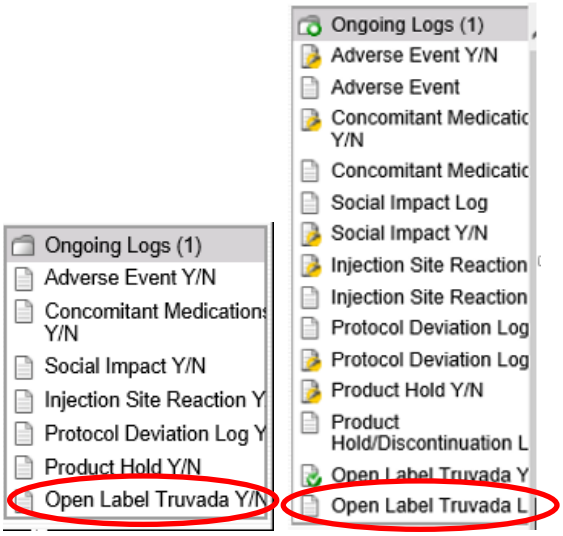
Purpose
This form is used to document a missed study visit.

General Information/Instructions
Complete this form each time an enrolled participant misses a required visit according to the visit window outlined in the protocol or Study Specific Procedures (SSP) section. A Missed Visit form will be added to a visit folder if the response to "Did the participant complete this visit?" on any of the Date of Visit forms is "No".

Item-specific Instructions

Field	Instructions
Target visit date	• Record the target date of the visit that was missed. • A complete date is required.
Reason visit was missed	• Select the reason for the missed 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. • If a participant has missed a regularly Step 1, 2 or 3 study visit because they are on an alternate schedule (i.e. pregnancy schedule or yearly visit schedule), select the appropriate 'alternate schedule' from the list of reasons.

OPEN LABEL TRUVADA Y/N



Purpose

This form is used to document when open label Truvada is given to a participant during the study (e.g. when a pregnant participant receives open label Truvada for a period of time).

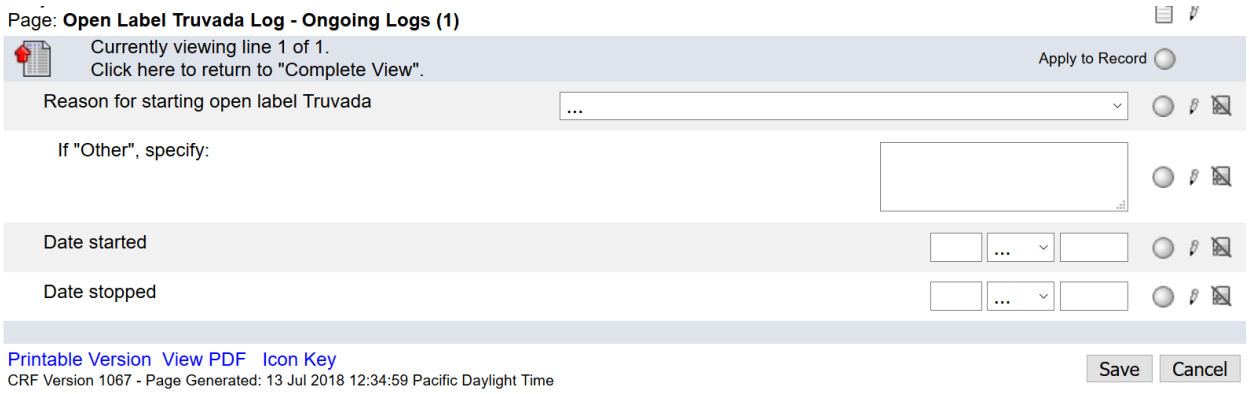
General Instructions

This form is located within the "Ongoing Logs" folder and is completed once. This form should not be used to capture Truvada given to participants during Step 3 dosing.

Item-specific Instructions

Field	Instructions
Is the participant taking open label Truvada?	• If "Yes" is selected and the form saved, the Open Label Truvada Log appears in the folder and should be completed. • "Yes" should only be selected if, during Step 2, it is determined per protocol that Truvada should be given on an open label basis (for example in the event of pregnancy). • Do not fill out this form to capture Truvada dosing in Step 3.

OPEN LABEL TRUVADA LOG



Purpose

This form is used to document information about participants receiving open label Truvada (i.e. a pregnant participant or a participant who stops receiving injections but decides to stay in the study and receive open label Truvada).

General Instructions

This form is located within the "Ongoing Logs" folder. This form should not be completed to capture Step 3 dosing.

Item-specific Instructions

Field	Instructions
Reason for starting open label Truvada	• Select the appropriate reason for starting open label Truvada from the dropdown menu. Note: Moving to Step 3 is not one of the reasons provided. Step 3 dosing will be recorded separately.
If "Other", specify	• If "Other" is selected for "Reason for starting open label Truvada", record the reason here. Otherwise, leave the item blank.
Date started	• A complete date is required.
Date stopped	• A complete date is required.

PARTICIPANT RECEIPT

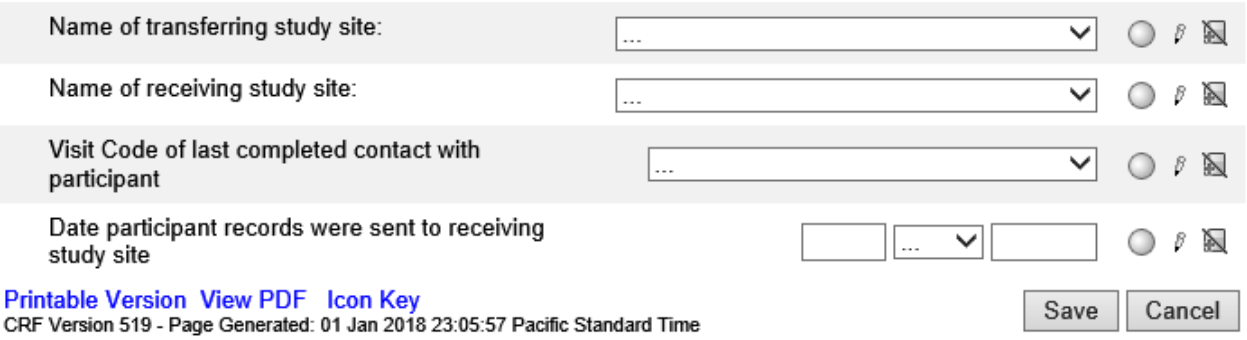
Purpose
Complete this form when a participant is transferring to another clinic/site within this study.

General Instructions
This form is completed by the receiving site only when the participant being transferred has provided informed consent at the receiving study clinic/site. Marking "Participant Receipt" under the Additional Forms section on any Date of Visit or Interim Visit form will add the Participant Receipt form to the current 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 before the participant is transferred to a new site.

Item-specific Instructions

Field	Instructions
Name of transferring study site	• Select the applicable site from the dropdown list.
Name of receiving study site	• Select the applicable site from the dropdown list.
Visit code of last completed contact with participant	• Select the applicable visit code from the dropdown list. • If "Interim Visit" is selected, record interim visit code in the text box provided.
Date participant records were sent to receiving study site	• A complete date is required.

PILL COUNT - ENROLLMENT

Purpose

This form is used to document the participant's pill dispensation at the Enrollment Visit.

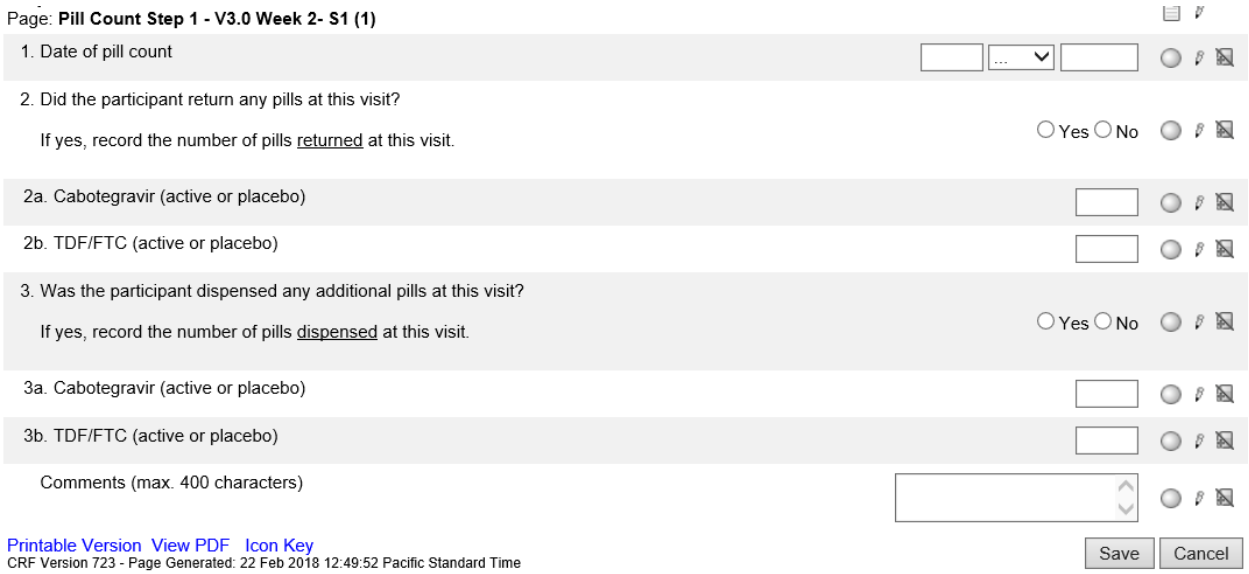
General Instructions

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

Item-specific Instructions

Field	Instructions
Cabotegravir (active or placebo)	• Enter the number of cabotegravir pills (active or placebo) that were dispensed at the Enrollment Visit in the field provided.
TDF/FTC (active or placebo)	• Enter the number of TDF/FTC pills (active or placebo) that were dispensed at the Enrollment Visit in the field provided.
Comments	• This field is not required. • Provide comments to explain an unexpected amount of pills dispensed or any other unusual circumstances with pill dispensation at Enrollment. • Maximum allowed characters: 400.

PILL COUNT – STEP 1


Page: **Pill Count Step 1 - V3.0 Week 2- S1 (1)**

1. Date of pill count

2. Did the participant return any pills at this visit?

If yes, record the number of pills returned at this visit. Yes No

2a. Cabotegravir (active or placebo)

2b. TDF/FTC (active or placebo)

3. Was the participant dispensed any additional pills at this visit?

If yes, record the number of pills dispensed at this visit. Yes No

3a. Cabotegravir (active or placebo)

3b. TDF/FTC (active or placebo)

Comments (max. 400 characters)

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Save Cancel

Purpose

This form is used to document the participant's pill counts (i.e. returns and dispensations) during Step 1.

General Instructions

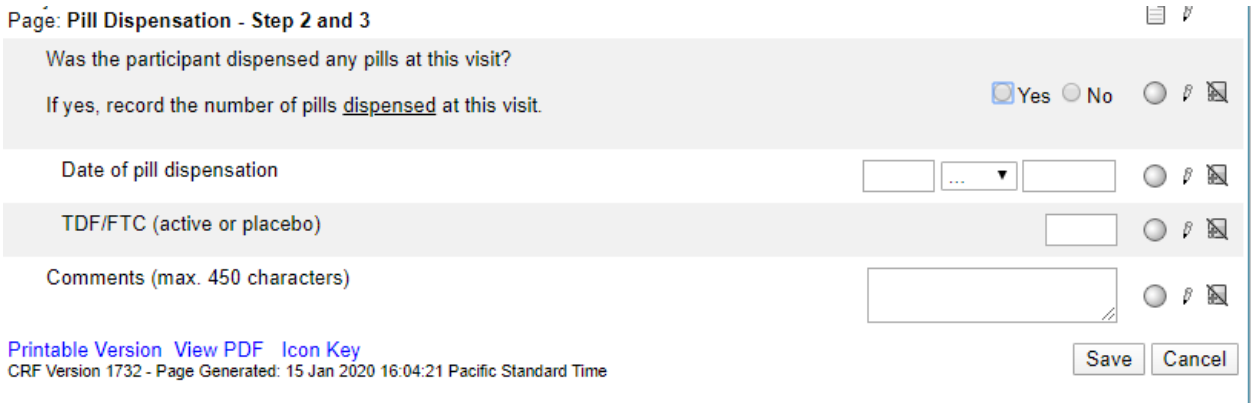
Complete this form at Visit 3.0 - Week 2 and Visit 4.0 - Week 3.

Item-specific Instructions

Field	Instructions
Date of pill count	• Record the date the pill count was performed. • A complete date is required.
Did the participant return any pills at this visit?	• If "No" is selected, move to item 3 (the pill dispensation section).
Cabotegravir (active or placebo)	• Enter the number of cabotegravir (active or placebo) pills that were *returned*.
TDF/FTC (active or placebo)	• Enter the number of TDF/FTC (active or placebo) pills that were *returned*.

Field	Instructions
Was the participant dispensed any additional pills at this visit?	• Mark "Yes" only if ***additional*** pills are dispensed. Do not include pills counted and returned to the participant. • If "No" is selected, remaining fields should be left blank.
Cabotegravir (active or placebo)	• Enter the number of new cabotegravir pills (active or placebo) dispensed. • Do not record pills already counted and returned to the participant.
TDF/FTC (active or placebo)	• Enter the number of new TDF/FTC pills (active or placebo) dispensed. • Do not record pills already counted and returned to the participant.
Comments	• This field is not required. • Provide comments to explain an unexpected amount of pills dispensed or returned or any other unusual circumstances regarding the pill count. • Maximum allowed characters: 400.

PILL DISPENSATION – STEP 2 AND 3



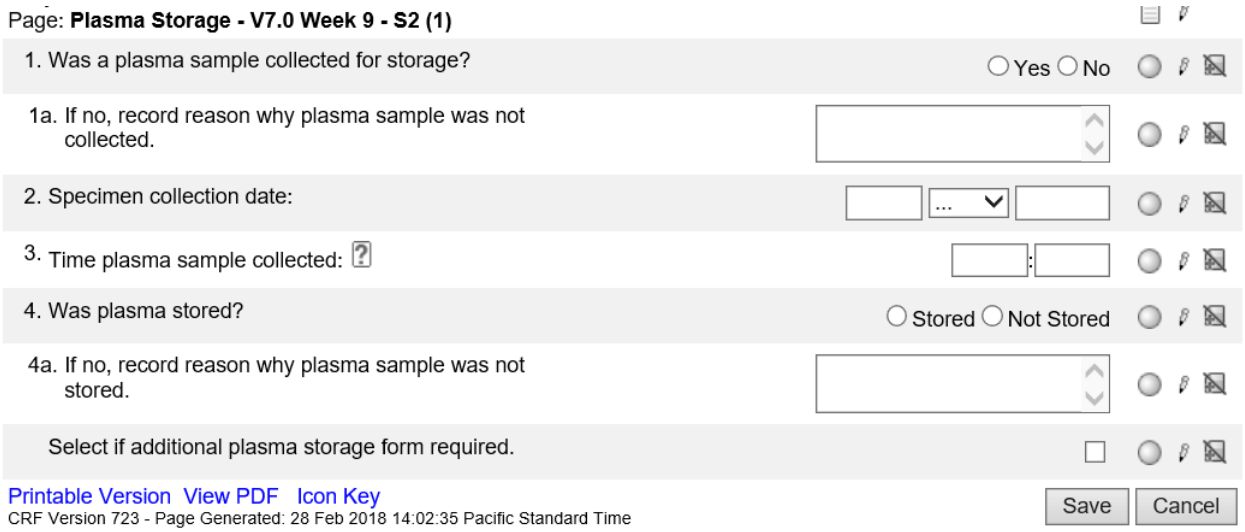
Purpose
This form is used to document pills dispensed to participants during Steps 2 and 3.

General Instructions
Complete this form at all Step 2 and Step 3 visits.

Item-specific Instructions

Field	Instructions
Was the participant dispensed any pills at this visit?	• Mark "Yes" only if pills are dispensed. • If "No" is selected, the remaining fields should be left blank.
Date of pill dispensation	• A complete date is required.
TDF/FTC (active or placebo)	• Enter the number of new TDF/FTC pills (active or placebo) dispensed. • **Do not record pills already counted and returned to the participant.**
Comments	• This field is not required. • Provide comments to explain an unexpected amount of pills dispensed or any other unusual circumstances. • Maximum allowable characters: 450

PLASMA STORAGE



Purpose

This form is used to document collection and storage of plasma specimens.

General Instructions

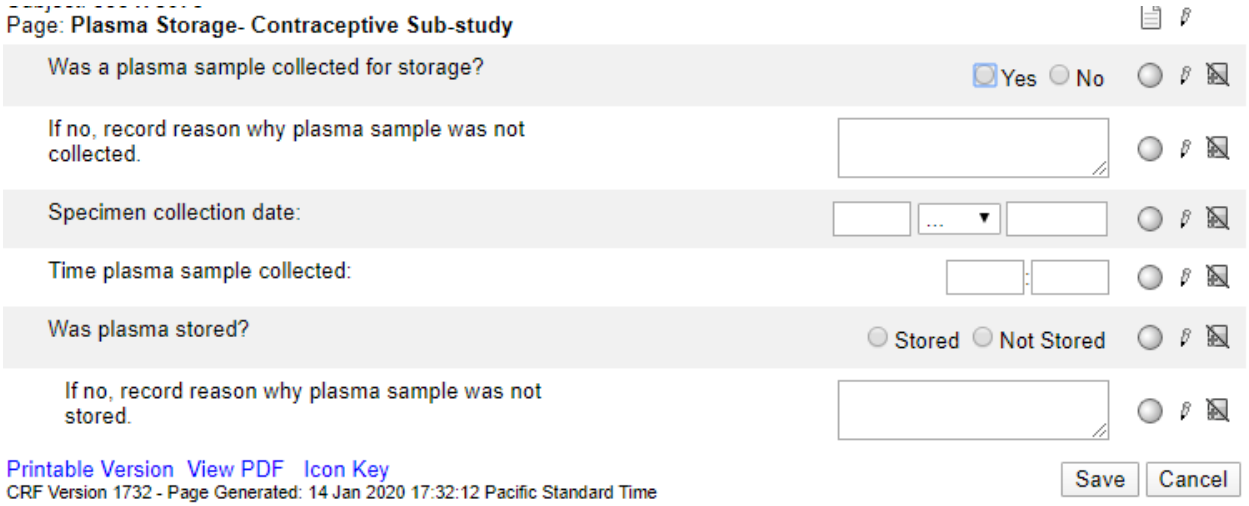
Complete this form at all protocol-specified visits. **Remember:** **For every HIV Test Result that is provided a corresponding plasma storage form should be entered with a matching date and vice versa.**

Item-specific Instructions

Field	Instructions
Was a plasma sample collected for storage?	• Select "Yes" if plasma sample was collected for storage and complete Questions 2 – 4. • Select "No" if plasma sample was not collected for storage and provide reason below.
If no, record reason why plasma sample was not collected.	• If plasma sample was not collected for storage, record reason here. • Leave remaining Questions 2 – 4 blank.
Specimen collection date	• Record the date that the specimen was collected. • A complete date is required.

Field	Instructions
Time plasma sample collected	• Record the time the specimen was collected using a 24-hour clock.
Was plasma stored?	• If "Not Stored" is selected, record the reason why in the text box provided (item 4a).
Select if additional plasma storage form required.	• Mark this box if an additional Plasma Storage form is needed for a given visit. • Once the form is saved, an additional Plasma Storage form will populate in the current folder. • For example, if an HIV test re-draw is required (i.e. for confirmatory testing) and more plasma needs to be stored as a result, mark this box. Once the form is saved an additional Plasma Storage CRF will populate in the current folder.

PLASMA STORAGE – CONTRACEPTIVE SUB-STUDY



Purpose

This form is used to document collection and storage of plasma specimens for the Contraceptive Sub-study.

General Instructions

This form is required only if participant consented to participate in Contraceptive Sub-study.

Item-specific Instructions

Field	Instructions
Was a plasma sample collected for storage?	• Select "Yes" if plasma sample was collected for storage. Select "No" if plasma sample was not collected for storage and provide reason below.
If no, record reason why plasma sample was not collected.	• If plasma sample was not collected for storage, record reason here. • Leave remaining questions blank.
Specimen collection date	• Record the date that the specimen was collected. • A complete date is required.
Time plasma sample collected	• Record the time the specimen was collected using a 24-hour clock.
Was plasma stored?	• If "Not Stored" is selected, record the reason why in the text box provided.
If no, record reason why plasma sample was not stored.	• If plasma was not stored, record reason here.

PREGNANCY HISTORY


Page: **Pregnancy History - Pregnancy History (1)**

1. Has the participant ever been pregnant before? ☐ Yes ○ No

If no, end of form.

2. Number of full term live births (≥37 weeks)
3. Number of premature live births (less than 37 weeks)
4. Number of spontaneous fetal deaths and/or still births (≥20 weeks)
5. Number of spontaneous abortions (less than 20 weeks)
6. Number of therapeutic/elective abortions
7. Number of ectopic pregnancies
8. Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies? ○ Yes ○ No

8a. If yes, specify:

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Save Cancel

Purpose

This form is used to document a participant's pregnancy history.

Generation Instructions

- Complete this form only once per participant, even if she has multiple pregnancies during follow-up.
- To add a Pregnancy History form, navigate to the "Add Event" dropdown menu located on the participant's homepage and select "Pregnancy History" from the menu. Then click "Add" and the Pregnancy History form will appear in its own folder in the participant's casebook.

Item-specific Instructions

Field	Instructions
Has the participant ever been pregnant before?	• If "Yes" is selected, complete the remainder of the form. • If "No" is selected, leave the rest of the form blank.
Number of full-term live births (≥37 weeks)	• A whole number is required if a participant has been pregnant.
Number of premature live births (less than 37 weeks)	• A whole number is required if a participant has been pregnant.

Number of spontaneous fetal deaths and/or still births (≥20 weeks)	• A whole number is required if a participant has been pregnant.
Number of spontaneous abortions (less than 20 weeks)	• A whole number is required if a participant has been pregnant.
Number of therapeutic/elective abortions	• A whole number is required if a participant has been pregnant.
Number of ectopic pregnancies	• A whole number is required if a participant has been pregnant.
Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies?	• If "Yes" is selected, provide concise details in the "If yes, specify" box provided.

PREGNANCY OUTCOME LOG

Page: **Pregnancy Outcome Log - Pregnancy (1)**

1. Did this pregnancy have an obtainable outcome? ○ Yes ○ No

2. If an outcome was not obtainable, please specify why:

END OF FORM.

3. How many pregnancy outcomes resulted from this reported pregnancy?

Currently viewing line 1 of 1.
Click here to return to "Complete View".

Apply to Record

4. Pregnancy outcome date

5. Place of delivery/outcome

5a. If other, specify:

6. Pregnancy outcome

6a. If other, specify:

6b. If outcome was full-term or premature live birth, select delivery method.

Delivery method

7. Provide a brief narrative of the circumstances.

8. Were there any delivery-related complications? ○ Yes ○ No ○ Unknown

If yes, select all delivery related complications that apply:

8a. Intrapartum hemorrhage ☐

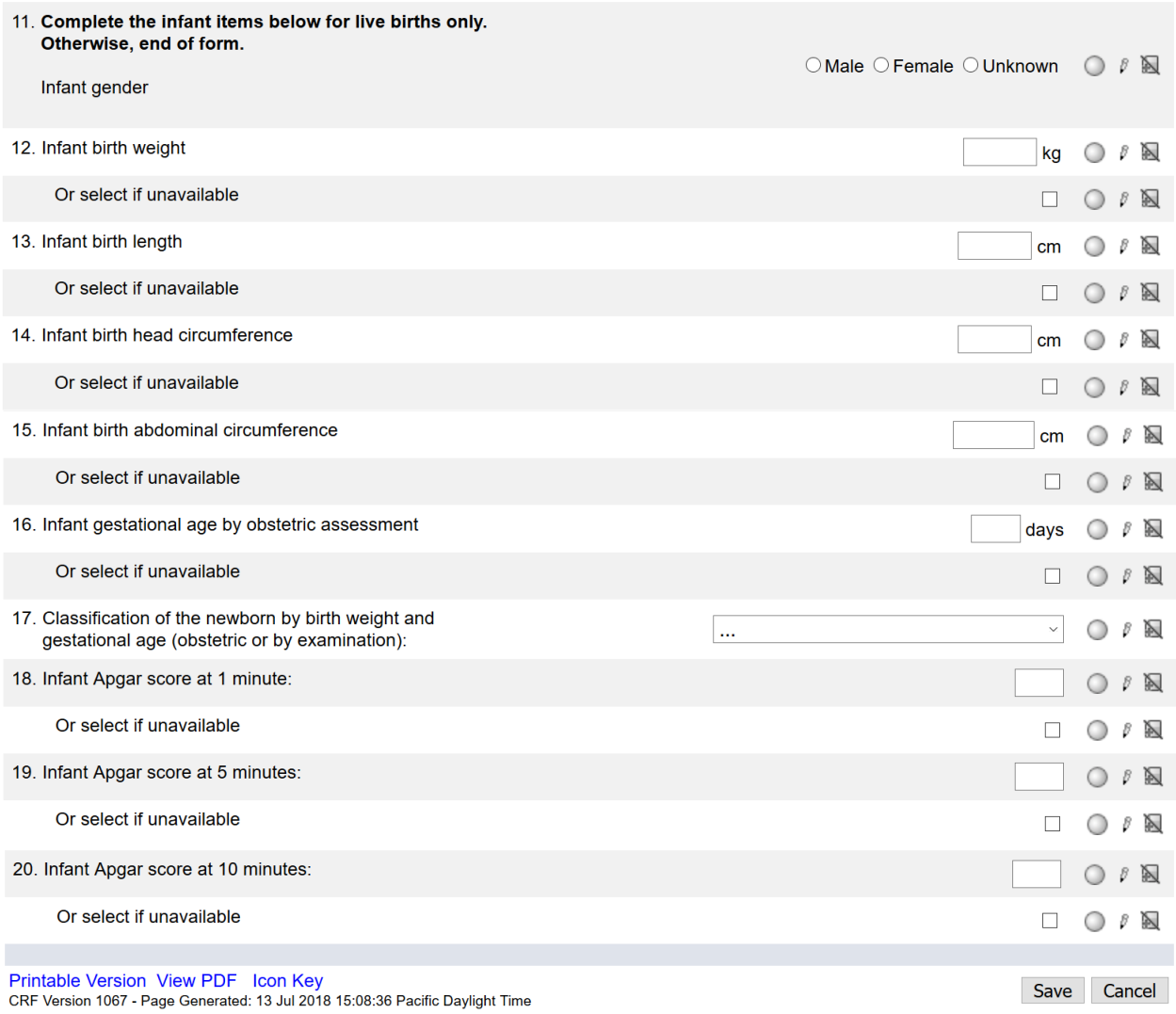
8b. Postpartum hemorrhage ☐

8c. Non-reassuring fetal status ☐

8d. Chorioamnionitis ☐

8e. Other ☐

8e1. If other, specify:	
9. Were there any non-delivery-related complications?	○ Yes ○ No ○ Unknown
If yes, select all non-delivery related complications that apply:	
9a. Hypertensive disorders of pregnancy	☐
9b. Gestational diabetes	☐
9c. Other	☐
9c1. If other, specify:	
10. Were any fetal/infant congenital anomalies identified?	...
If yes, please select all anomalies that apply:	
10a. Central nervous system, cranio-facial	☐
10b. Central nervous system, spinal	☐
10c. Cardiovascular	☐
10d. Renal	☐
10e. Gastrointestinal	☐
10f. Pulmonary	☐
10g. Musculoskeletal/extemities	☐
10h. Physical defect	☐
10i. Skin	☐
10j. Genitourinary	☐
10k. Chromosomal	☐
10l. Craniofacial (structural)	☐
10m. Hemotologic	☐
10n. Infectious	☐
10o. Endocrine/metabolic	☐
10p. Other	☐
10p1. If Other, describe the congenital anomaly/defect:	



Purpose

Complete this form when reporting a pregnancy outcome.

General Instructions

A Pregnancy Outcome form is required for each pregnancy that the participant experiences during the study. To complete a Pregnancy Outcome form, use the Add Event dropdown menu on the participant's home page to add a **Pregnancy folder**. The Pregnancy folder will contain the Pregnancy Outcome Log, along with other relevant pregnancy forms.

Item-specific Instructions

Field	Instructions
Did this pregnancy have an obtainable outcome	• If "No" is marked, then provide the reason an outcome is not obtainable in the text box provided. The remainder of the form (after providing the reason) should be left blank.

Field	Instructions
If an outcome was not obtainable, please specify why:	• Provide a response here only if the answer to "Did this pregnancy have an obtainable outcome" is "No". Otherwise leave blank. • Provide a concise reason.
If the pregnancy did not have an obtainable outcome, leave the rest of the form blank.	
How many pregnancy outcomes resulted from this reported pregnancy?	• An outcome can be an infant or a fetus. • A logline should be provided for each outcome obtained. For example, the conception of twins will result in two outcomes, thus two loglines.
Pregnancy outcome date	• Provide the date the outcome occurred. A month and year are required at minimum. If the day is unknown enter 'UN' for the day portion of the date field.
Place of delivery/outcome	• If "Other" is selected, record the other place of delivery/outcome in the "If other, specify" text box provided (item 5a).
Pregnancy outcome	• If "Other" is selected, record the other pregnancy outcome in the "If other, specify" text box provided (item 6a).
Delivery method	• Provide the delivery method only if full-term or premature live birth is selected. • Otherwise leave this item blank.
Provide a brief narrative of the circumstances	• This item is required if "Did this pregnancy have an obtainable outcome" is "Yes". Meaning, this field is required for all pregnancy outcome types.
Were there any delivery-related complications?	• If "Yes" is selected, mark all delivery-related complications that apply. • If "Other" is marked, record the other delivery-related complication in the "If other, specify" text box provided (item 8e1).

Field	Instructions
Were there any non-delivery-related complications?	• If "Yes" is selected, mark all non-delivery-related complications that apply. • If "Other" is marked, record the other non-delivery-related complications in the "If other, specify" text box provided (item 9c1).
Were any fetal/infant congenital anomalies identified?	• If "Yes" is selected, mark all anomalies that apply. • If "Other" is marked, record the other congenital anomaly in the "If other, specify" text box provided (item 10p1). • **Per LoA #2, please update this item as new information becomes available (i.e. if any new congenital anomalies are identified up until the child is 1 year old).**
The remainder of the form should be completed for live births only.	
Infant gender	• Select "Male", "Female", or "Unknown"
Infant birth weight	• Record the birth weight in kg or mark the 'not available' box. • Up to two decimal places are allowed.
Infant birth length	• Record the birth length in cm or mark the 'not available' box. • Up to two decimal places are allowed.
Infant birth head circumference	• Record the birth head circumference in cm or mark the 'not available' box. • Up to two decimal places are allowed.
Infant birth abdominal circumference	• Record the birth abdominal circumference in cm or mark the 'not available' box. • Up to two decimal places are allowed.
Infant gestational age by obstetric assessment	• Record gestational age in days or mark the 'not available' box. • Up to three decimal places are allowed.
Classification of the newborn by birth weight and gestational age (obstetric or by examination):	• If classification is unavailable, select "classification not available" from the dropdown menu.

Field	Instructions
Infant Apgar score at 1 minute:	• Provide a score or mark the 'not available' box.
Infant Apgar score at 5 minutes:	• Provide a score or mark the 'not available' box.
Infant Apgar score at 10 minutes:	• Provide a score or mark the 'not available' box.

PREGNANCY OUTCOME LOG- OLE

Page: **Pregnancy Outcome Log - OLE - Delivery - OLE (1)**

1. Did this pregnancy have an obtainable outcome?	Yes / No
1a. If an outcome was not obtainable, please specify why:	
END OF FORM.	
2. How many pregnancy outcomes resulted from this reported pregnancy?	
Currently viewing line 1 of 1. Click here to return to "Complete View".	Apply to Reco
3. Infant PTID	
4. Pregnancy outcome date	
5. Place of delivery/outcome	
5a. If other, specify:	
6. Pregnancy outcome	
6a. If Stillbirth, Intrauterine fetal demise (≥ 20 weeks) or Other, specify:	
6b. If outcome was full-term or premature live birth, select delivery methods. Delivery method	
7. Provide a brief narrative of the circumstances.	
8. Were there any delivery-related complications?	Yes / No / Unknown
If yes, select all delivery related complications that apply:	
8a. Intrapartum hemorrhage	☐
8b. Postpartum hemorrhage	☐
8c. Non-reassuring fetal status	☐
8d. Chorioamnionitis	☐
8e. Other	☐
8e1. If other, specify:	
9. Were there any non-delivery-related complications?	Yes / No / Unknown
If yes, select all non-delivery related complications that apply:	
9a. Hypertensive disorders of pregnancy	☐
9b. Gestational diabetes	☐
9c. Other	☐
9c1. Other, specify	
10. Were any fetal/infant congenital anomalies identified?	
If yes, please select all anomalies that apply:	
10a. Central nervous system, cranio-facial	☐
10b. Central nervous system, spinal	☐
10c. Cardiovascular	☐
10d. Renal	☐
10e. Gastrointestinal	☐
10f. Pulmonary	☐
10g. Musculoskeletal/extremities	☐
10h. Physical defect	☐
10i. Skin	☐
10j. Genitourinary	☐
10k. Chromosomal	☐
10l. Craniofacial (structural)	☐
10m. Hematologic	☐
10n. Infectious	☐
10o. Endocrine/metabolic	☐

Purpose

Complete this form when reporting a pregnancy outcome.

General Instructions

This form is located in the **'Delivery - OLE'** folder using the Add Event dropdown. A Pregnancy Outcome-OLE form is required for each pregnancy that the participant experiences during the study.

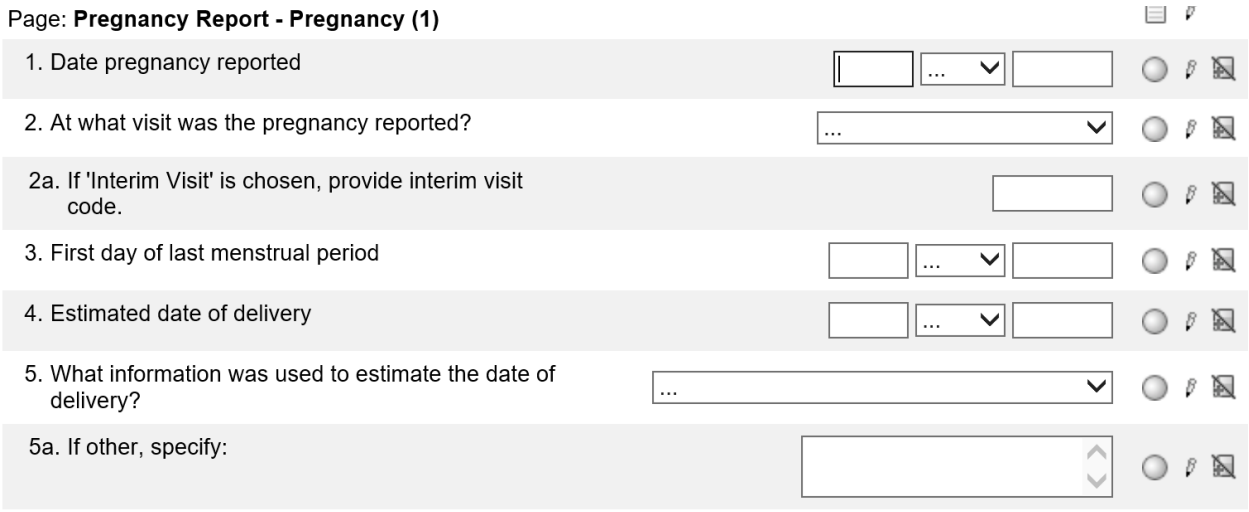
Item-specific Instructions

Field	Instructions
Did this pregnancy have an obtainable outcome	• If "No" is marked, then provide the reason an outcome is not obtainable in the text box provided. The remainder of the form (after providing the reason) should be left blank.
If an outcome was not obtainable, please specify why:	• Provide a response here only if the answer to "Did this pregnancy have an obtainable outcome" is "No". Otherwise leave blank. • Provide a concise reason.
If the pregnancy did not have an obtainable outcome, leave the rest of the form blank.	
How many pregnancy outcomes resulted from this reported pregnancy?	• An outcome can be an infant or a fetus. • A logline should be provided for each outcome obtained. For example, the conception of twins will result in two outcomes, thus two loglines.
Infant PTID	• **An Infant PTID needs to be generated in Rave at the home page level like generating PTIDs at the beginning of the study.** • Once the PTID is generated, it should be recorded on this form and all the other forms where the Infant PTID is required.
Pregnancy outcome date	• Provide the date the outcome occurred. A month and year are required at minimum. If the day is unknown enter 'UN' for the day portion of the date field.
Place of delivery/outcome	• If "Other" is selected, record the other place of delivery/outcome in the "If other, specify" text box provided (item 5a).
Pregnancy outcome	• If "Other" or if "Stillbirth", "Intrauterine fetal demise (≥ 20 weeks)" is selected, record the other pregnancy outcome in the following "If other, specify" text box provided (item 6b).

Field	Instructions
Delivery method	• Provide the delivery method only if full-term or premature live birth is selected. • Otherwise leave this item blank.
Provide a brief narrative of the circumstances	• This item is required if "Did this pregnancy have an obtainable outcome" is "Yes". Meaning, this field is required for all pregnancy outcome types.
Were there any delivery-related complications?	• If "Yes" is selected, mark all delivery-related complications that apply. • If "Other" is marked, record the other delivery-related complication in the "If other, specify" text box provided (item 8e1).
Were there any non-delivery-related complications?	• If "Yes" is selected, mark all non-delivery-related complications that apply. • If "Other" is marked, record the other non-delivery-related complications in the "If other, specify" text box provided (item 9c1).
Were any fetal/infant congenital anomalies identified?	• If "Yes" is selected, mark all anomalies that apply. • If "Other" is marked, record the other congenital anomaly in the "If other, specify" text box provided (item 10p1).
The remainder of the form should be completed for live births only.	
Infant gender	• Select "Male", "Female", or "Unknown"
Infant birth weight	• Record the birth weight in kg or mark the 'not available' box. • Up to two decimal places are allowed.
Infant birth length	• Record the birth length in cm or mark the 'not available' box. • Up to two decimal places are allowed.
Infant birth head circumference	• Record the birth head circumference in cm or mark the 'not available' box. • Up to two decimal places are allowed.

Field	Instructions
Infant birth abdominal circumference	• Record the birth abdominal circumference in cm or mark the 'not available' box. • Up to two decimal places are allowed.
Infant gestational age by obstetric assessment	• Record gestational age in days or mark the 'not available' box. • Up to three decimal places are allowed.
Classification of the newborn by birth weight and gestational age (obstetric or by examination):	• If classification is unavailable, select "classification not available" from the dropdown menu.
Infant Apgar score at 1 minute:	• Provide a score or mark the 'not available' box.
Infant Apgar score at 5 minutes:	• Provide a score or mark the 'not available' box.
Infant Apgar score at 10 minutes:	• Provide a score or mark the 'not available' box.

PREGNANCY REPORT



Purpose

Complete this form when reporting a pregnancy of a study participant post enrollment through study discontinuation if pregnancy was first detected during Version 2.0 of the protocol.

General Instructions

A Pregnancy Report form is required for each pregnancy that the participant experiences during the study, regardless of the pregnancy outcome. To complete a Pregnancy Report form, use the Add Event dropdown menu on the participant's home page to add a **Pregnancy folder**. The Pregnancy folder will contain the Pregnancy Report, along with other relevant pregnancy forms.

Item-specific Instructions

Field	Instructions
Date pregnancy reported	• A complete date is required. • The date should be the same as the first positive pregnancy test result date.
At what visit was the pregnancy reported?	• Select the appropriate visit code. • If "Interim visit" is selected an "Interim visit code" is required.
First day of last menstrual period	• A partial date may be reported. UN may be entered for day and UNK may be entered for month. A year is always required.
Estimated date of delivery	• A partial date may be reported. UN may be entered for day and UNK may be entered for month. A year is always required.

Field	Instructions
What primary information was used to estimate the date of delivery?	• If a different method was used other than what is listed, select "Other" and briefly describe in the "If other, specify" text field.

PREGNANCY REPORT - OLE

Purpose

Complete this form when reporting a pregnancy in the OLE portion of the study.

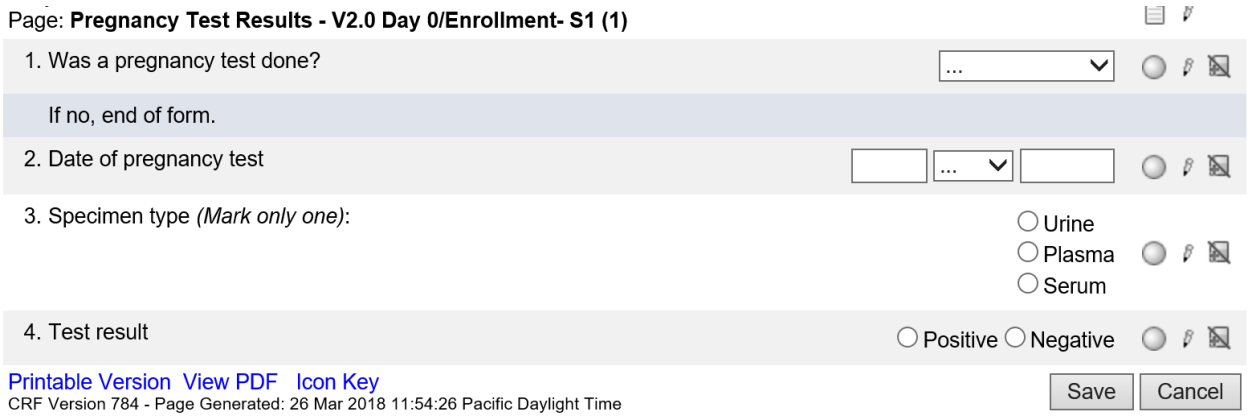
General Instructions

Two positive pregnancy test results on the "Pregnancy Test Results- OLE" form will populate this form in the current OLE visit folder.

Item-specific Instructions

Field	Instructions
Date pregnancy reported	• A complete date is required. • The date should be the same as the first positive pregnancy test result date.
At what visit was the pregnancy reported?	• Select the appropriate visit code. • If "Interim visit" is selected an "Interim visit code" is required.
First day of last menstrual period	• A partial date may be reported. UN may be entered for day and UNK may be entered for month. A year is always required.
Estimated date of delivery	• A partial date may be reported. UN may be entered for day and UNK may be entered for month. A year is always required.
What primary information was used to estimate the date of delivery?	• If a different method was used other than what is listed, select "Other" and briefly describe in the "If other, specify" text field.

PREGNANCY TEST RESULTS



Purpose

This form is used to document all pregnancy tests during the study.

General Instructions

Complete this form as required per the protocol and as clinically indicated. A pregnancy test must always be done before an injection of the study product is given to a participant.

Item-specific Instructions

Field	Instructions
Was a pregnancy test done?	• If "No" is selected, leave remaining items on the form blank.
Date of pregnancy test	• Record the date that the specimen (urine, plasma or serum) was collected. • A complete date is required.
Specimen type *(Mark only one)*:	• Select the appropriate specimen type.
Test result	• All "Positive" test results must be communicated to the CMC within 7 days of site awareness. • Confirmatory pregnancy testing is required per protocol within 4 weeks of the first positive pregnancy test result.

PREGNANCY TEST RESULTS- OLE


Page: **Pregnancy Test Results - OLE**

1. Was a pregnancy test done?	...
If no, end of form.	
2. Date of pregnancy test	...
3. Specimen type *(Mark only one)*:	○ Urine ○ Plasma ○ Serum
4. Test result *If Negative, end of form.*	○ Positive ○ Negative
5. If Test result is positive, was the pregnancy confirmed on a second independent sample on same day? *If No, go to Question 6.*	○ Yes ○ No
5a. If Yes, Specimen type *(Mark only one)*:	○ Urine ○ Plasma ○ Serum
5b. If Yes, Test result	○ Positive ○ Negative
6. Is the participant eligible for Pregnancy and Infant Sub-Study?	○ Yes ○ No
7. Did the participant consent to participate in Pregnancy and Infant Sub-Study?	○ Yes ○ No
8. Select if additional pregnancy test results form is required.	☐

Purpose

This form is used to document all pregnancy tests during the OLE portion of the study.

General Instructions

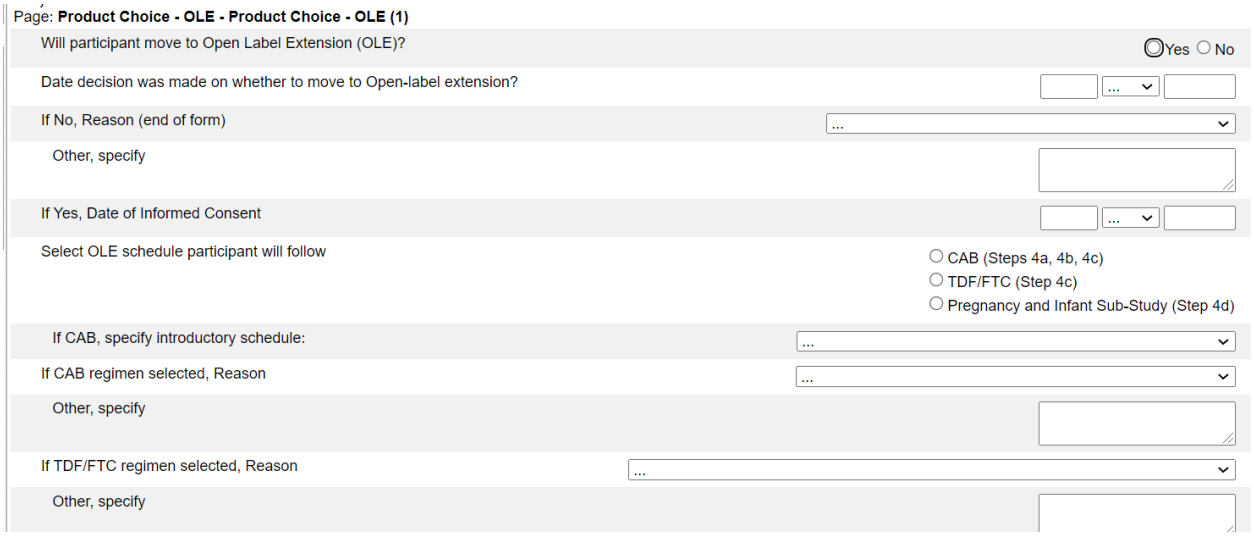
Complete this form as required per the protocol and as clinically indicated. A pregnancy test must always be done before an injection of the study product is given to a participant. To confirm a positive pregnancy, two pregnancy tests on the are required on independent samples in the OLE. All pregnancies that occur during the course of the study must be reported to the CMC within seven days of site awareness.

Item-specific Instructions

Field	Instructions
Was a pregnancy test done?	• If "No" is selected, leave remaining items on the form blank.
Date of pregnancy test	• Record the date that the specimen (urine, plasma or serum) was collected. • A complete date is required.
Specimen type *(Mark only one)*:	• Select the appropriate specimen type.
Test result	• Select results.

Field	Instructions
If Test result is positive, was the pregnancy confirmed on a second independent sample on same day?	• If No, use question 8 to generate an additional form.
If Yes, Specimen type (Mark only one):	• Select the appropriate specimen type for the second sample.
If Yes, Test result	• Two positive tests require the "Pregnancy Report- OLE" form to be completed. • This form will be populated in current folder when 2 positive tests are entered.
Is the participant eligible for Pregnancy and Infant Sub-Study?	• Two positive pregnancy tests and at least one injection of CAB-LA are required to enroll in the Pregnancy and Infant Sub-study.
Did the participant consent to participate in Pregnancy and Infant Sub-Study?	• "Yes" will load the "Consent – Pregnancy and Infant Sub-Study" CRF.
Select if additional pregnancy test results form is required.	• Select this if additional pregnancy test was done on a different day. This will populate an additional pregnancy test.

PRODUCT CHOICE


Page: **Product Choice - OLE - Product Choice - OLE (1)**

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) ...

Other, specify

If Yes, Date of Informed Consent ... ...

Select OLE schedule participant will follow
○ CAB (Steps 4a, 4b, 4c)
○ TDF/FTC (Step 4c)
○ Pregnancy and Infant Sub-Study (Step 4d)

If CAB, specify introductory schedule: ...

If CAB regimen selected, Reason ...

Other, specify

If TDF/FTC regimen selected, Reason ...

Other, specify

Purpose

This form should be completed at the first visit after approval of protocol v3.0 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

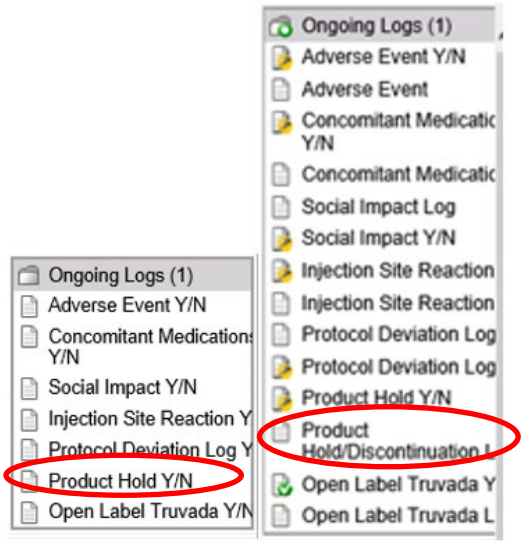
This form is located on the left navigation bar.

Item-specific Instructions

Field	Instructions
Will participant move to Open Label Extension (OLE)?	• If "No" is selected, only answer next two questions, unless other specify is required.
Date decision was made on whether to move to Open-label extension?	• A full date is required.
If No, Reason (end of form)	• Select reason participant will not enroll, then end of form. • Complete Termination CRF in the discontinuation folder and add anInterim Visit indicating termination.
Other, specify	• Provide response only if other is selected above.
If Yes, Date of Informed Consent	• A full date is required.

Field	Instructions
Select OLE schedule participant will follow	• Select schedule from options. This will load the appropriate visits and CRFs
If CAB, specify introductory schedule:	• Indicate CAB schedule. • If oral dosing will occur select 4a. • If loading dose is required select 4 b • If participant will go directly into the 8 week schedule select 4c.
If CAB regimen selected, Reason	• Required if CAB is selected.
Other, specify	• Provide response only if other is selected above.
If TDF/FTC regimen selected, Reason	• Required if TDF/FTC is selected.
Other, specify	• Provide response only if other is selected above.

PRODUCT HOLD Y/N



Purpose

This form is used to document whether a participant's study product is temporarily or permanently discontinued.

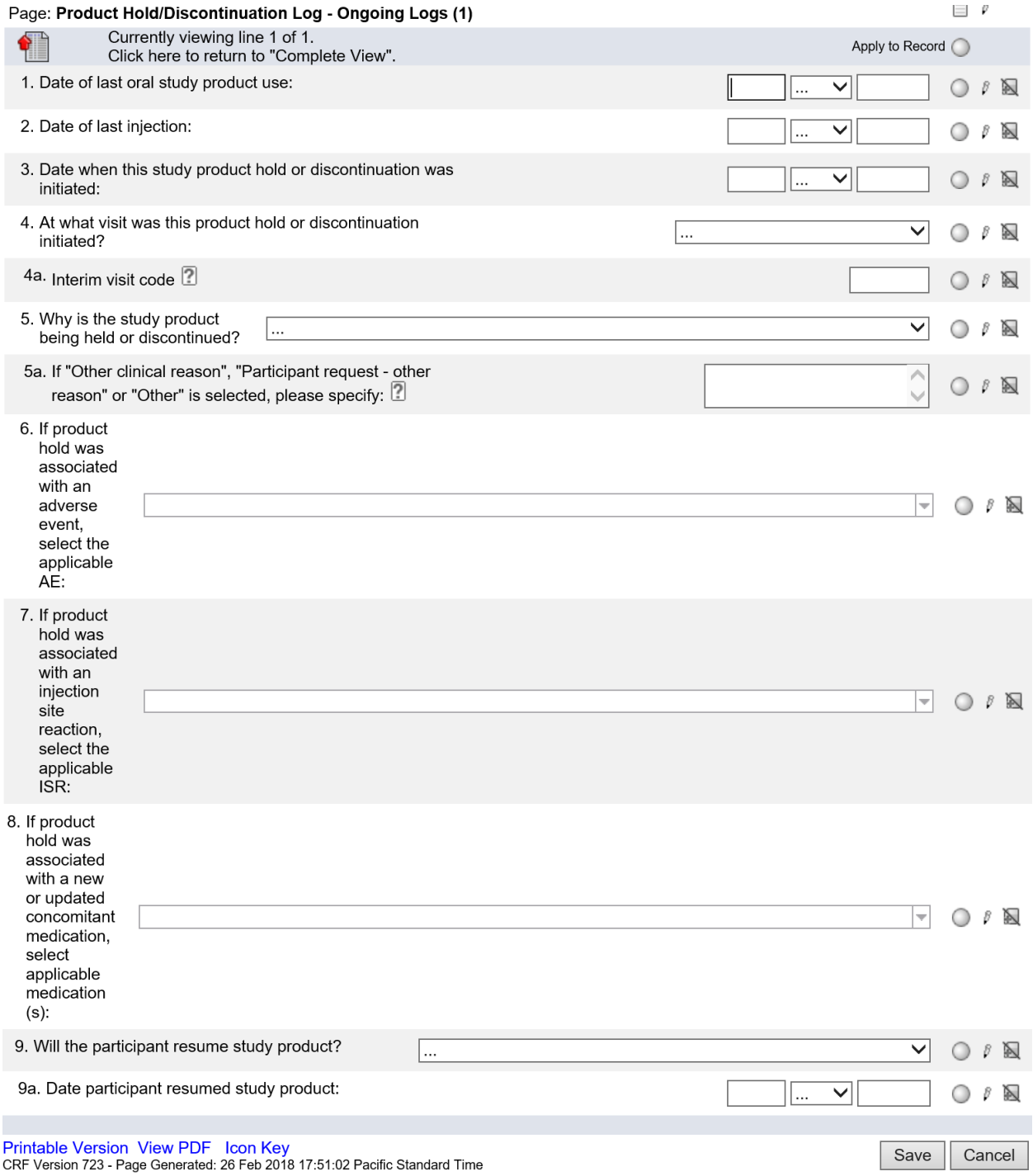
General Instructions

This form is located in the "Ongoing Logs" folder. Complete this form once when a temporary study product or permanent product discontinuation is initiated by either by a study clinician or the participant herself.

Item-specific Instructions

Field	Instructions
Is there a product hold or discontinuation to report?	• If "Yes" is selected and the form saved, the Product Hold/Discontinuation Log appears in the folder and can then be completed.

PRODUCT HOLD/DISCONTINUATION LOG


Page: **Product Hold/Discontinuation Log - Ongoing Logs (1)**

Currently viewing line 1 of 1.
Click here to return to "Complete View".

Apply to Record

1. Date of last oral study product use:
2. Date of last injection:
3. Date when this study product hold or discontinuation was initiated:
4. At what visit was this product hold or discontinuation initiated?
4a. Interim visit code
5. Why is the study product being held or discontinued?
5a. If "Other clinical reason", "Participant request - other reason" or "Other" is selected, please specify:
6. If product hold was associated with an adverse event, select the applicable AE:
7. If product hold was associated with an injection site reaction, select the applicable ISR:
8. If product hold was associated with a new or updated concomitant medication, select applicable medication (s):
9. Will the participant resume study product?
9a. Date participant resumed study product:

Printable Version View PDF Icon Key
CRF Version 723 - Page Generated: 26 Feb 2018 17:51:02 Pacific Standard Time

Save Cancel

Purpose

This form is used to document temporary holds or early permanent discontinuations of 'blinded' study product use only. For participants receiving Open Label Truvada, please record holds on the Open Label Truvada form.

CONFIDENTIAL DOCUMENT

General Instructions

This form is present within the "Ongoing Logs" folder. Complete this form each time a participant is instructed by a site clinician to temporarily hold or permanently discontinue study product use prior to her expected termination of study product. The log is also completed if the participant decides on her own to discontinue study product use (i.e. she no longer wishes to take study product and, therefore, no longer wants to be dispensed study product). 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, as each reason for a hold needs to be tracked separately. The same visit code should be used on each entry (i.e. log line).

Item-specific Instructions

Field	Instructions
Date of last oral study product use	• A complete date is required. • Use a best estimate if the actual date cannot be determined.
Date of last injection:	• A complete date is required. • If participant did not reach Step 2, leave field blank.
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 the study product hold or discontinuation began. • If "Interim Visit" is selected, record an interim visit code in the "Interim visit code" field (item 4a).
Interim visit code	• Enter an interim visit code only if "Interim Visit" is selected above.
Why is the study product being held or discontinued?	• Select the primary reason from the dropdown menu. • If "Clinical AE" or "Laboratory AE" are recorded, select the appropriate AE from the dropdown list in item 6. • If "Injection site reaction" is recorded, select the appropriate ISR from the dropdown list in item 7. • If "Reported use of prohibited concomitant medication" is recorded, select the appropriate concomitant medication from the dropdown list in item 8.

	• If the primary reason is "Other clinical reason", "Participant request – other reason" or "Other" is recorded, provide additional details in the 'other specify' text field provided (item 5a).
If product hold was associated with an Adverse event, select the applicable AE:	• Select related adverse event from the dropdown list, if applicable.
If product hold was associated with an Injection Site Reaction, select the applicable Injection Site Reaction:	• Select related injection site reaction from the dropdown list, if applicable.
If product hold was associated with new or updated Concomitant Medications, select the applicable medication(s):	• Select associated concomitant medication from the dropdown menu, if applicable.
Will the participant resume study product?	• A response is not required. • Complete this item once study staff have determined that the participant can resume study product use or have determined that the participant is permanently discontinued from study product. • Select "Yes" if study staff instructed the participant that she can resume use of study product. • Select "No (permanently discontinued)" if the participant was permanently discontinued from study product use. • If the reason for the product hold has resolved but there is another concurrent reason for continuing this product hold, select "No (hold continuing/permanently discontinued for another reason)".
Date participant resumed study product:	• Enter the date the participant was instructed by a study staff member that she could resume use of study product. • A complete date is required.

PRODUCT HOLD Y/N-OLE

Purpose

This form is used in the OLE portion of the study to document temporary holds or early permanent discontinuations. The "Product Hold Permanent Discontinuation" CRF was designed for blinded study drug use and should not be used in the OLE.

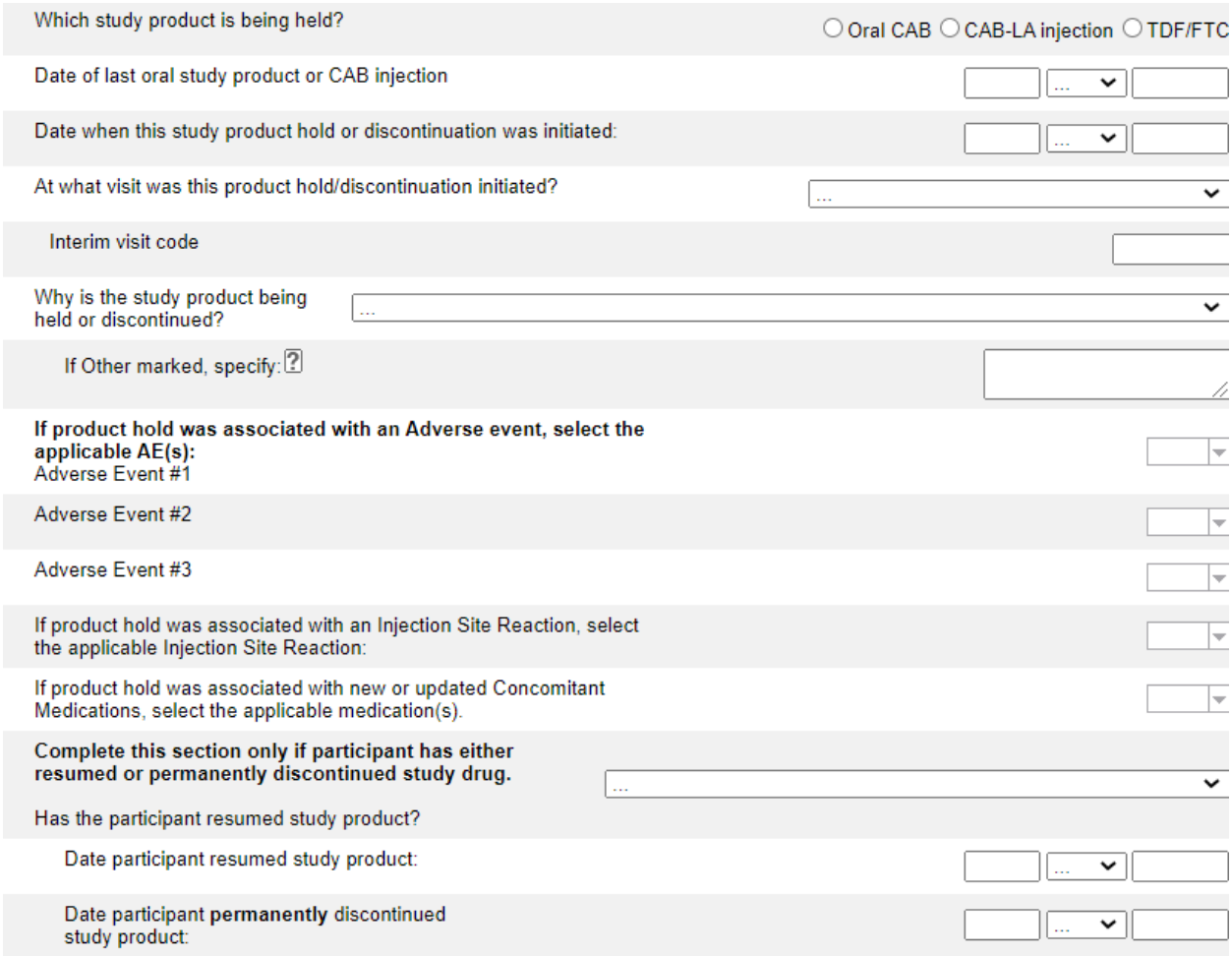
General Instructions

This form is located in the "Ongoing Logs" folder. Complete this form once when a temporary study product or permanent product discontinuation is initiated by either by a study clinician or the participant herself.

Item-specific Instructions

Field	Instructions
Is there a product hold or discontinuation to report?	• If "Yes" is selected and the form saved, the Product Hold/Discontinuation Log appears in the folder and can then be completed.

PRODUCT HOLD/DISCONTINUATION LOG- OLE



Purpose

This form is used in the OLE portion of the study to document temporary holds or early permanent discontinuations. The "Product Hold Permanent Discontinuation" CRF was designed for blinded study drug use and should not be used in the OLE.

General Instructions

This form is present within the "Ongoing Logs" folder when the Product choice form is submitted confirming participant will move to OLE portion of the study. Complete this form each time a participant is instructed by a site clinician to temporarily hold or permanently discontinue study product use prior to her expected termination of study product. The log is also completed if the participant decides on her own to discontinue study product use (i.e. she no longer wishes to take study product and, therefore, no longer wants to be dispensed study product). 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, as each reason for a hold needs to be tracked separately. The same visit code should be used on each entry (i.e. log line).

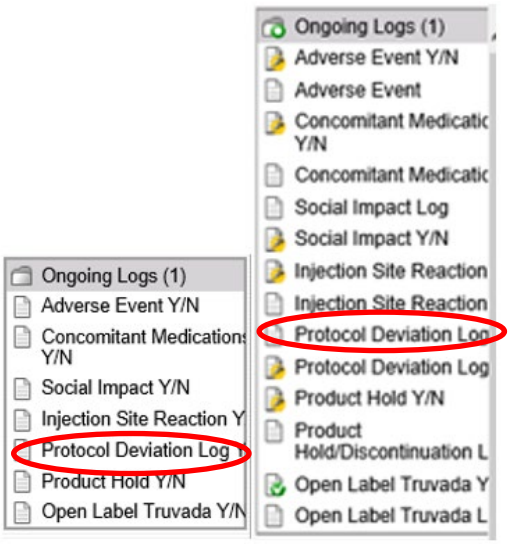
Item-specific Instructions

Field	Instructions
Which study product is being held?	• Only one drug can be selected.
Date of last oral study product or CAB injection:	• A complete date is required.
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 the study product hold or discontinuation began. • If "Interim Visit" is selected, record an interim visit code in the "Interim visit code" field (item 4a).
Interim visit code	• Enter an interim visit code only if "Interim Visit" is selected above.
Why is the study product being held or discontinued?	• Select the primary reason from the dropdown menu. • If "Clinical AE" or "Laboratory AE" are recorded, select the appropriate AE from the dropdown list in item 6.

	• If "Injection site reaction" is recorded, select the appropriate ISR from the dropdown list in item 7. • If "Reported use of prohibited concomitant medication" is recorded, select the appropriate concomitant medication from the dropdown list in item 8. • If the primary reason is "Other clinical reason", "Participant request – other reason" or "Other" is recorded, provide additional details in the 'other specify' text field provided (item 5a).
If product hold was associated with an Adverse event, select the applicable AE:	• Select related adverse event from the dropdown list, if applicable.
If product hold was associated with an Injection Site Reaction, select the applicable Injection Site Reaction:	• Select related injection site reaction from the dropdown list, if applicable.
If product hold was associated with new or updated Concomitant Medications, select the applicable medication(s):	• Select associated concomitant medication from the dropdown menu, if applicable.
Will the participant resume study product?	• A response is not required. • Complete this item once study staff have determined that the participant can resume study product use or have determined that the participant is permanently discontinued from study product. • Select "Yes" if study staff instructed the participant that she can resume use of study product. • Select "No (permanently discontinued)" if the participant was permanently discontinued from study product use. • If the reason for the product hold has resolved but there is another concurrent reason for continuing this product hold, select "No (hold continuing/permanently discontinued for another reason)".
Date participant resumed study product:	• Enter the date the participant was instructed by a study staff member that she could resume use of study product. • A complete date is required.

Date participant permanently discontinued study product:	• A complete date is required.

PROTOCOL DEVIATION Y/N



Purpose:
This form is used to document if a protocol deviation has occurred.

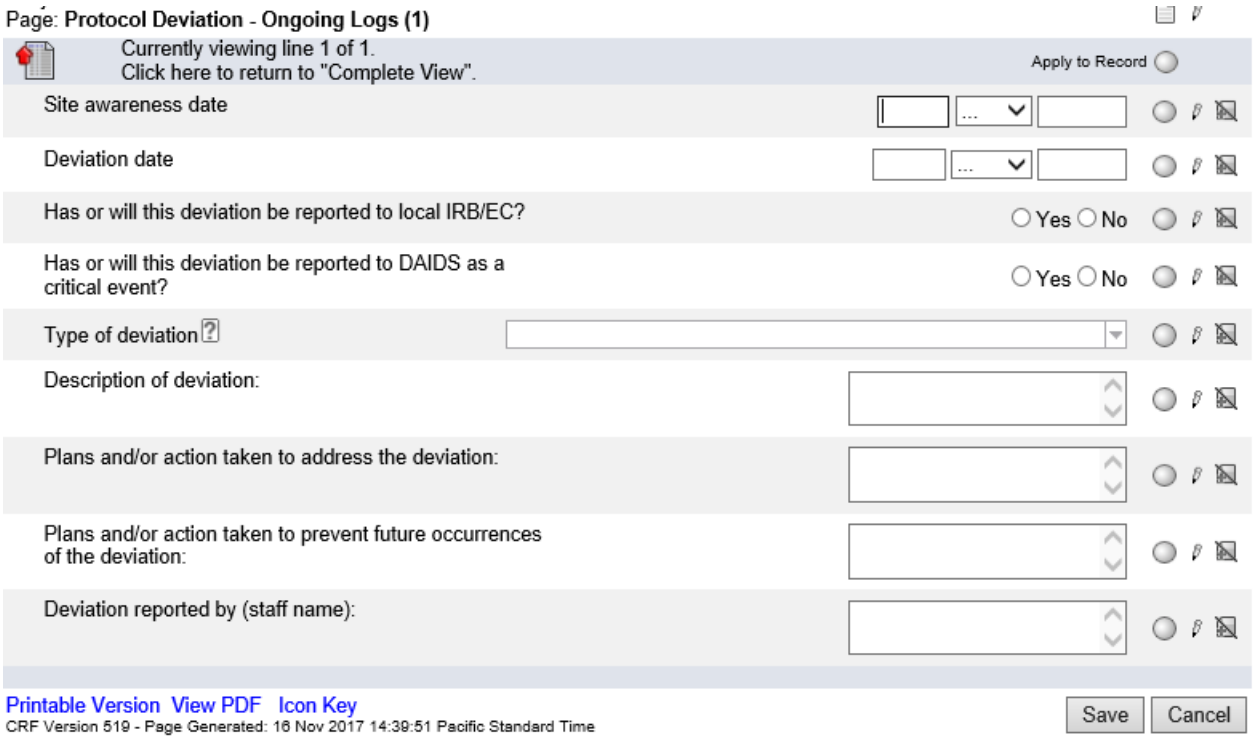
Generation Instructions
This form is present within the "Ongoing Logs" folder and needs to be marked only once.

Item-specific Instructions

Field	Instructions
Have any protocol deviations occurred?	

	• If "Yes" is selected, the Protocol Deviation Log will appear in the Ongoing Logs folder and can then be completed.

PROTOCOL DEVIATION LOG



Purpose

This form documents reportable protocol deviations identified for study participants during the implementation of HPTN084.

General Information/Instructions

Prior to completing a Protocol Deviation form contact the 084protdev@hptn.org alias to report the deviation. The alias can also be used 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. If a deviation applies to more than one PTID complete a Protocol Deviation Log for each PTID that is affected; each PTID needs to have a record of the Protocol Deviation on their own Deviation Log. To add an additional deviation within Medidata Rave, click “Add a new Log line” to add an additional log line.

Reportable protocol deviations are defined by the HPTN (HPTN MOP Section 12) as individual incidents, trends or omissions that result in:

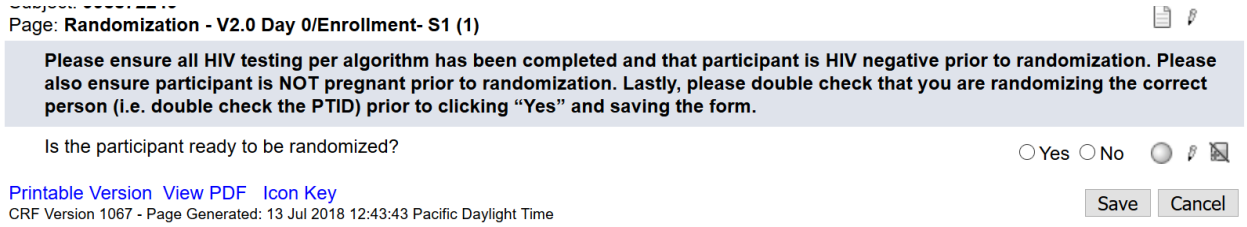
- Significant added risk to the participant
- Non-adherence to significant protocol requirements
- Significant non-adherence to GCP

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). • A complete date 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. *See table below for the types of deviations.* • The first few letters of the description can be typed in the dynamic 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.
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 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.
Other

RANDOMIZATION


Page: **Randomization - V2.0 Day 0/Enrollment- S1 (1)**

Please ensure all HIV testing per algorithm has been completed and that participant is HIV negative prior to randomization. Please also ensure participant is NOT pregnant prior to randomization. Lastly, please double check that you are randomizing the correct person (i.e. double check the PTID) prior to clicking "Yes" and saving the form.

Is the participant ready to be randomized? ○ Yes ○ No

Printable Version View PDF Icon Key

CRF Version 1067 - Page Generated: 13 Jul 2018 12:43:43 Pacific Daylight Time

Save Cancel

Purpose

The Randomization form is used to officially randomize a participant within the Medidata/Balance system for HPTN084. This form is completed at Enrollment for participants who have provided informed consent and who are eligible to participate in the study.

General Instructions

Complete this form for each participant who is eligible to be randomized (i.e. enrolled) into the study. All efforts must be made to ensure the correct PTID is selected for the participant prior to randomization, as **a participant cannot be un-randomized once this form is saved**.

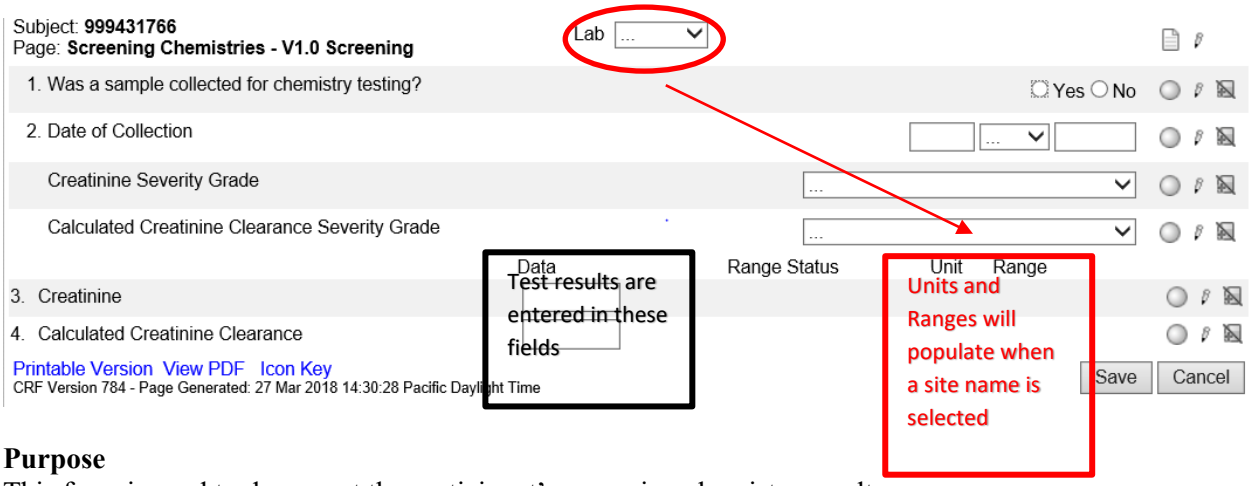
Prior to entering this form, confirm the participant is eligible for the study. Ensure all HIV testing per algorithm has been completed and that participant is HIV negative prior to randomization. Additionally, ensure the participant is NOT pregnant prior to randomization.

One randomization is complete, a confirmation will appear on the form stating, "Subject successfully randomized." In addition, a confirmation email will be sent to the following site user roles: CRC, pharmacist, ready only and Investigator. **Note the receipt of this email does not impact whether a participant is randomized.** In the event an email is not received confirming the randomization, contact SCHARP CDM for a copy of the email. Do not email Medidata.

Item-specific Instructions

Field	Instructions
Is the participant ready to be randomized?	• Select "Yes" or "No" and save the form. • If the participant is successfully randomized, a note will appear under this item that says, "Subject successfully randomized." If this note does not appear, contact the SCHAPR CDM (do not contact Medidata), as the randomization was not completed. • Once a participant is randomized, the treatment is assigned in Medidata Balance. • The randomization cannot be undone once this form is saved.

SCREENING CHEMISTRIES



Purpose

This form is used to document the participant's screening chemistry results.

General Information/Instructions

This form is completed only at Screening. If a sample was not collected, do not record any additional information on the form.

Item-specific Instructions

Enter lab data in the following sequence:

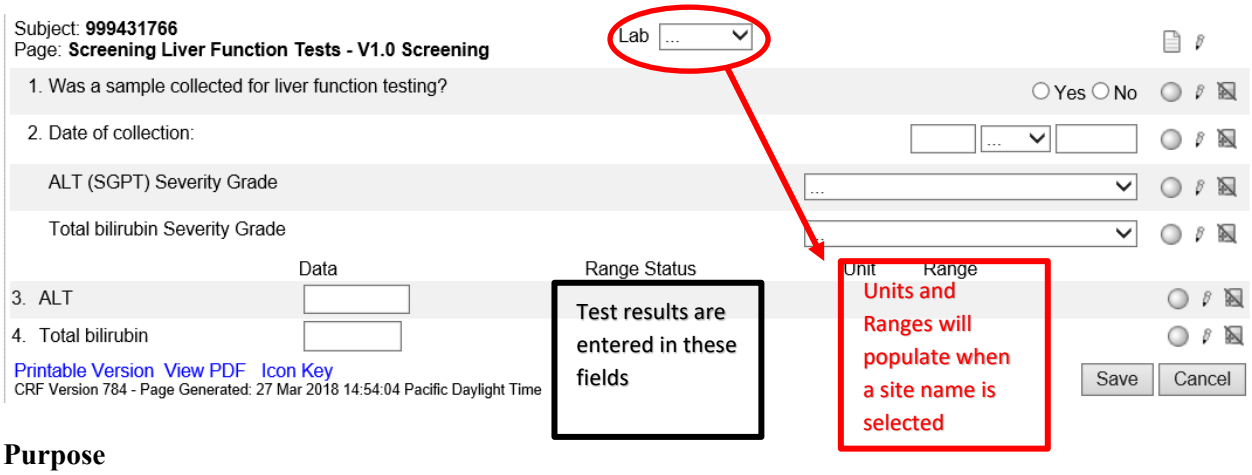
Field	Instructions
Lab	• **Select the site name from the drop-down menu to populate local lab reference ranges (and units) in the lab results section**. • If local lab is not listed under "Lab" contact the SCHARP CDM.
Test Results	• Enter the result of the specified test (bottom of form) in the standard units of measurement used for this study (see below). • If test was not performed or the results were not reported, leave blank and record a comment in the query message box (if query fires). *For example, if the creatinine results were not reported, leave the creatinine field blank and save the form. When a query fires record "not reported" in the query message box.* • If result is entered, ensure a severity grade for the result is entered.

Data Formats and Units of Measurement

Test*	Data Format Requirements	Unit Requirements
Creatinine	5.2	mg/dL
Calculated Creatinine Clearance	5.2	mL/min

Field	Instructions
Was a sample collected for chemistry testing?	• If "No" is selected, leave remaining items on the form blank.
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.

SCREENING LIVER FUNCTION TESTS



Purpose

This form is used to document the participant's screening liver function test results.

General Information/Instructions

This form is completed at Screening only. If a sample was not collected, do not record any additional information on the form.

Item-specific Instructions

Enter lab data in the following sequence:

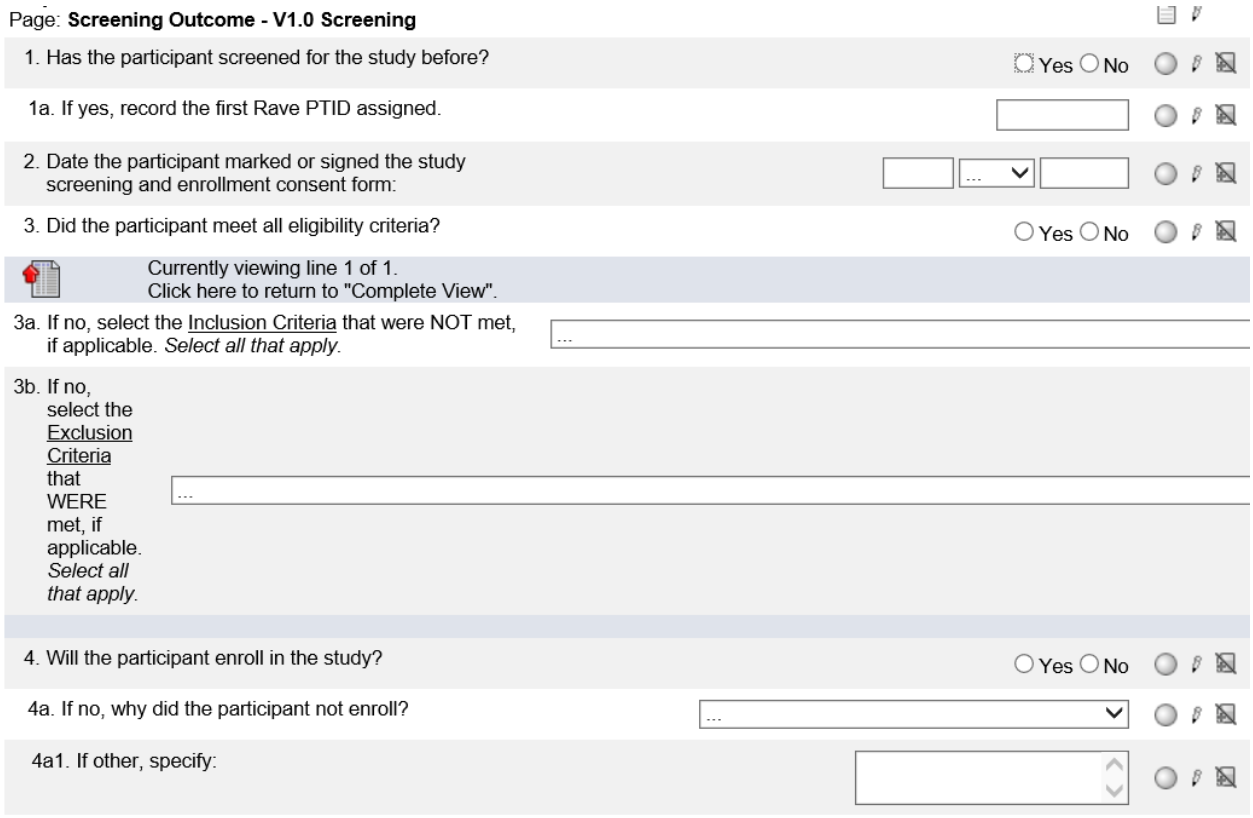
Field	Instructions
Lab	• **Select the site name from the drop-down menu to populate local lab reference ranges (and units) in the lab results section**. • If local lab is not listed under "Lab" contact the SCHARP CDM.
Test Results	• Enter the result of the specified test (bottom of form) in the standard units of measurement used for this study (see below). • If results from the local lab are not reported in the standard units of measurement, the units will need to be converted using the Lab Conversion Tool on Atlas. • If test was not performed or the results were not reported, leave blank and record a comment in the query message box (if query fires). *For example, if ALT was not reported, leave the item blank and save the form. When a query fires record "not reported" in the query message box.* • If result is entered, ensure a severity grade for the result is entered.

Data Formats and Units of Measurement

Field	Data Format Requirements	Unit Requirements
ALT (SGPT)	6.2	U/L
Total bilirubin	5.2	mg/dL

Field	Instructions
Was a sample collected for testing?	• If "No" is selected, leave remaining items on the form blank.
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.

SCREENING OUTCOME



Purpose

This form is used to document details of a participant's Screening Visit and their eligibility to enroll into HPTN084.

General Instructions

Complete this form for each participant who completed a Screening Visit, regardless if they enrolled into the study.

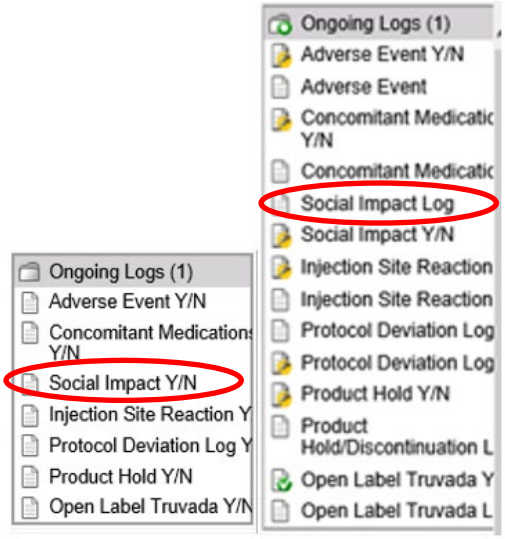
Item-specific Instructions

Field	Instructions
Has the participant screened for the study before?	• Select "Yes" or "No". • See protocol section 5.1 for more information on re-screening.
If yes, record the first Rave PTID assigned.	• Complete this item only if "Has the participant screened for the study before" if "Yes".

Field	Instructions
Date the participant marked or signed the study screening and enrollment consent form:	• A complete date is required.
Did the participant meet all eligibility criteria?	• Select "Yes" or "No".
If no, select the Inclusion Criteria that were NOT met, if applicable	• Select all applicable inclusion criteria that were not met. • To add a new criterion, first save the form. Then navigate back to the form and select "add a new Log line". Record the additional reason.
If no, select the Inclusion /Exclusion Criteria that were NOT met, if applicable	• Select all applicable exclusion criteria that were met. • To add a new criterion, first save the form. Then navigate back to the form and select "add a new Log line". Record the additional reason.
Will the participant enroll in the study?	• If the participant is eligible and willing at the Screening Visit to move on to the Enrollment Visit, select "Yes". If the participant is not eligible or willing at the Screening Visit to move on to the Enrollment Visit, select "No". • If "Yes" is selected at the Screening Visit but, later, the participant does not end up enrolling in the study, update the response to this item from "Yes" to "No" and record the reason why the participant did not enroll in the next item (item 4a).
If no, why did the participant not enroll?	• If "Will the participant enroll in the study?" is "No", this item must be completed. If "Will the participant enroll in the study?" is "Yes", leave this item blank. • If the participant did not enroll because of one of the inclusion or exclusion criteria recorded in item 3, select "Not eligible"; do not select "Other" and then record the inclusion criteria that was not met or the exclusion criteria that was met. • If "Other" is selected, record the reason for not enrolling in the "If other, specify" text box provided.

Field	Instructions
If other, specify:	• This item is only required if "Other" is selected for "If no, why did the participant not enroll". • Provide a concise explanation in the text box.

SOCIAL IMPACT Y/N



Purpose

This form is used to document if a social impact has occurred.

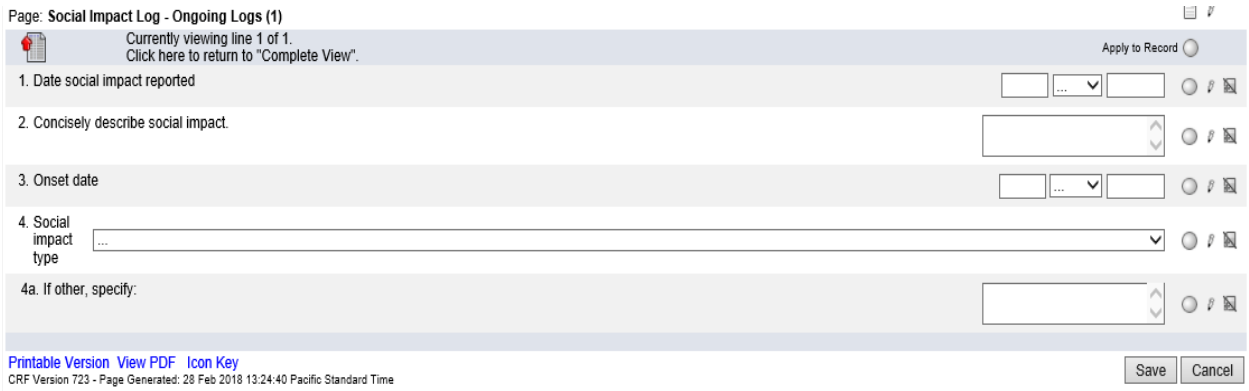
Generation Instructions

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?	• If "Yes" is selected, the Social Impact Log will appear in the Ongoing Logs folder and can then be completed.

SOCIAL IMPACT LOG



Purpose

This form is used to document information about reported social impacts.

General Instructions

Complete this form when a participant reports a social impact. A social impact is defined as a participant reported non-medical adverse consequence or benefit as a result of participation in the study. Refer to the SSP, section 10, for more information on reporting Social Impacts.

Item-specific Instructions

Field	Instructions
Date social impact reported	• A complete date is required.
Concisely describe social impact	• A maximum of 200 characters is allowed in this text field.
Onset date	• Enter the date on which the impact began/occurred. • A complete date is required.
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 the "If other, specify" text field provided.

SPECIMEN COLLECTION – BREAST MILK


Page: **Specimen Collection - Breast Milk - V87.0 - Step 4d - Week 2 PP (1)**

Were breast milk samples collected? *If no, end of form.*	Yes No
Date breast milk samples collected by site	
Specimen collection date	
Specimen collection time	:
Specimen collection method	Hand expression Pump
Was sample stored?	Stored Not stored
If "Not stored", record reason why sample was not stored (max. 200 characters).	

Purpose

This form is used to document collection and storage of breast milk for the Pregnancy and Infant Sub-study.

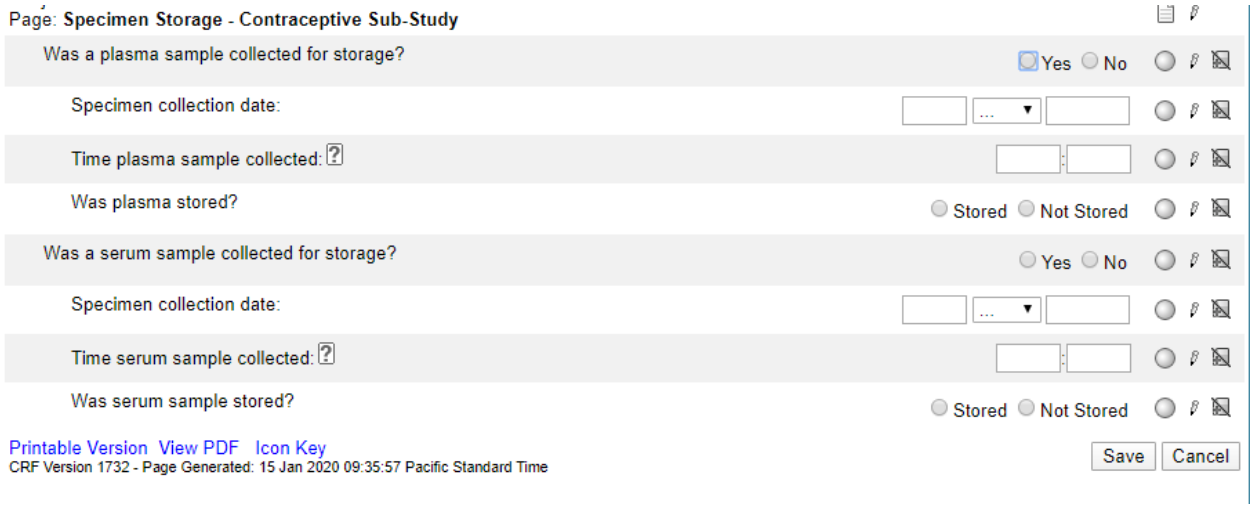
General Instructions

This form is found in the postpartum Pregnancy and Infant Sub-study visit folders.

Item-specific Instructions

Field	Instructions
Were breast milk samples collected?	• If "No", end of form.
Date breast milk samples collected by site	• Record the date that the specimen was received at the site. • A complete date is required.
Specimen collection date:	• Record the date that the specimen was collected. • A complete date is required.
Specimen collection time:	• Record the time the specimen was collected using a 24-hour clock.
Specimen collection method	• Indicate hand expression or pump
Was sample stored?	• Indicate if stored. • If "not stored", provide reason in text box.

SPECIMEN STORAGE – CONTRACEPTIVE SUB-STUDY



Purpose

This form is used to document collection and storage of plasma and serum samples if participant has consented to participate in the Contraceptive Sub-study.

General Instructions

This form is required only if participant consented to participate in Contraceptive Sub-study.

Item-specific Instructions

Field	Instructions
Was a plasma sample collected for storage?	• If "Was a plasma sample collected for storage?" is "No", skip to "Was a serum sample collected for storage?"
Specimen collection date:	• Record the date that the specimen was collected. • A complete date is required.
Time plasma sample collected:	• Record the time the specimen was collected using a 24-hour clock.
Was plasma stored?	• Select "Stored" or "Not Stored".

Field	Instructions
Was a serum sample collected for storage?	• If "Was a serum sample collected for storage?" is "No", leave the rest of the form blank.
Specimen collection date:	• Record the date that the specimen was collected. • A complete date is required.
Time serum sample collected:	• Record the time the specimen was collected using a 24-hour clock.
Was serum sample stored?	• Select "Stored" or "Not Stored".

STI TEST RESULTS

Page: **STI Test Results - V2.0 Day 0/Enrollment- S1 (1)**

Syphilis	
1. Was a sample collected for syphilis testing?	○ Yes ○ No
2. Date of collection:	...
3. Non-Treponemal test	○ Reactive ○ Non-reactive
4. Treponemal test	○ Non-reactive/Negative ○ Reactive/Positive ○ Not Done
5. Titer if indicated	
Or select if N/A	☐
GC/CT	
6. Was a urine sample collected for NAAT for GC/CT?	○ Yes ○ No
7. Date of collection:	...
8. N. gonorrhea – URINE	○ Positive ○ Negative
9. C. trachomatis – URINE	○ Positive ○ Negative
10. Was a vaginal swab collected for NAAT for GC/CT?	○ Yes ○ No
11. Date of collection:	...
12. N. gonorrhea – VAGINAL	○ Positive ○ Negative
13. C. trachomatis – VAGINAL	○ Positive ○ Negative
TV	
14. Was a sample collected for TV?	○ Yes ○ No
15. Date of collection:	...
16. Trichomonas vaginalis - Rapid Test	○ Negative ○ Positive ○ Invalid
Or select if not done	☐
17. Trichomonas vaginalis - Wet prep	○ Negative ○ Positive ○ Invalid
Or select if not done	☐

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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 clinically indicated during the study.

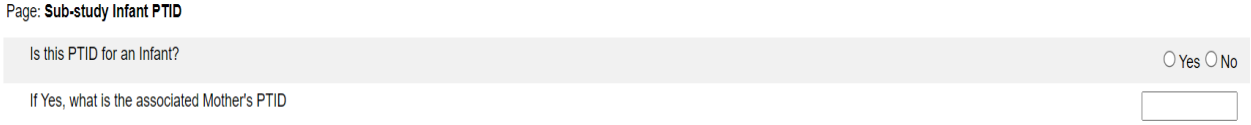
If an STI is diagnosed during screening, record the STI diagnosis on the Medical History form as a pre-existing condition.

Item-specific Instructions

Field	Instructions
Syphilis	
Was a sample collected for syphilis testing?	• If "No" is selected, leave items 2-5 blank (skip to item 6). If "Yes" is selected, provide a response for items 2-5.
Date of collection:	• A complete date is required.
Non-Treponemal test	• Select "Reactive or "Non-reactive". • This is a mandatory field and Treponemal test should be done first, followed by the Non-Treponemal test.
Treponemal test	• Select "Non-reactive/Negative", "Reactive/Positive" or "Not Done."
Titer if indicated	• Enter titer, if it is indicated, or mark the "N/A" box.
GC/CT	
Was a urine sample collected for NAAT for GC/CT?	• If "No" is selected, leave items 7-9 blank. If "Yes" is selected, provide a response for items 7-9.
Date of collection:	• A complete date is required.
N. gonorrhea – URINE	• Select "Positive" or "Negative".
C. trachomatis – URINE	• Select "Positive" or "Negative".
Was a vaginal sample collected for NAAT for GC/CT?	• If "No" is selected, leave items 11-13 blank. If "Yes" is selected, provide a response for items 11-13.
Date of collection:	• A complete date is required.

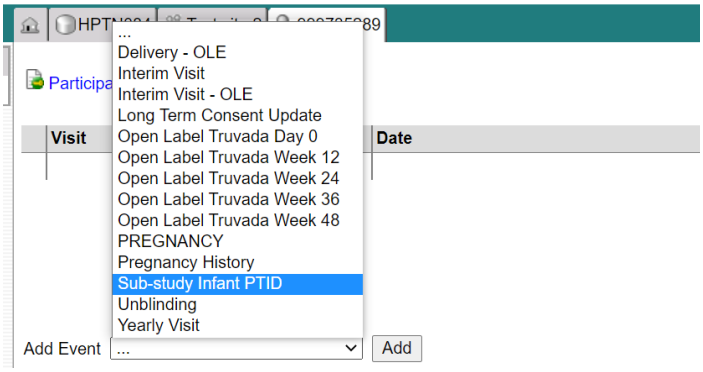
Field	Instructions
N. gonorrhea – VAGINAL	• Select "Positive" or "Negative".
C. trachomatis – VAGINAL	• Select "Positive" or "Negative".
TV	
Was a vaginal sample collected for TV?	• If "No" is selected, leave items 15-17 blank. If "Yes" is selected, provide a response for items 15-17.
Date of collection:	• A complete date is required.
Trichomonas vaginalis - Rapid Test	• Select "Negative", "Positive" or "Invalid" OR • Mark checkbox if "not done".
Trichomonas vaginalis - Wet prep	• Select "Negative", "Positive" or "Invalid" OR • Mark checkbox if "not done".

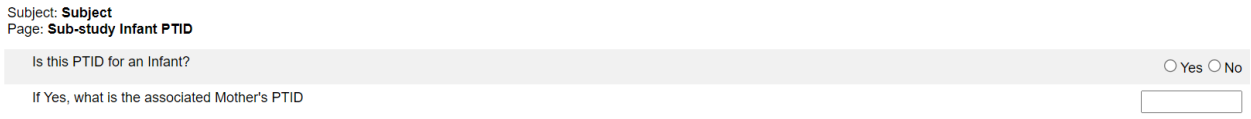
SUB-STUDY INFANT PTID



Purpose
This form is used to link the infant's PTID number to the mother's PTID.

General Instructions
Use the Add Event drop down menu in the Mother's casebook to add the Sub-study Infant PTID form.

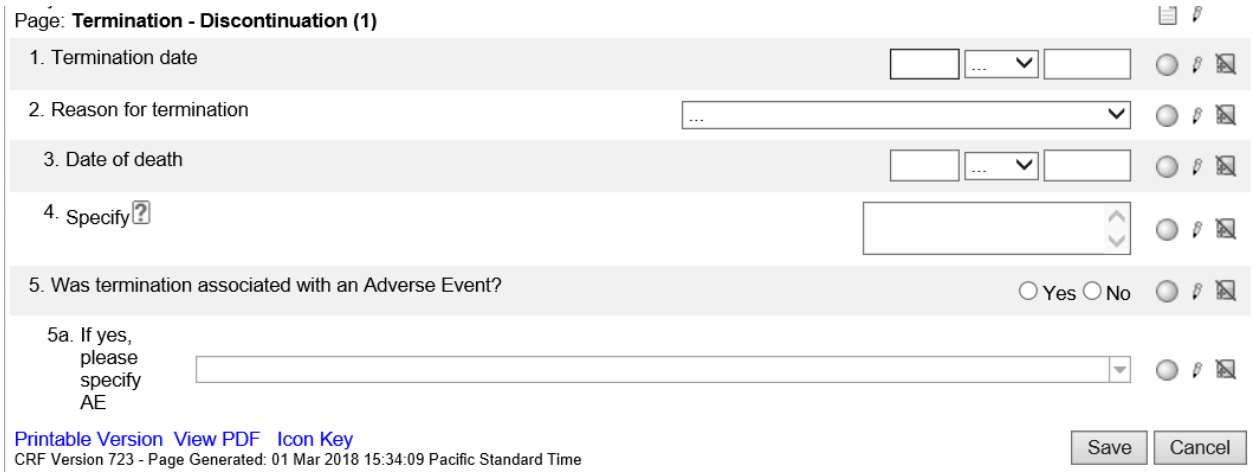




Item-specific Instructions

Field	Instructions
Is this PTID for an Infant?	• Ensure the PTID is for the *infant* and answer accordingly.
If Yes, what is the associated Mother's PTID	• Carefully record the ***Mother's 's PTID***. • This PTID entry will pair the mother's ptid to the nfant's PTID in the data.

TERMINATION



Purpose

This form is used to document a participant's termination from the study.

General Instructions

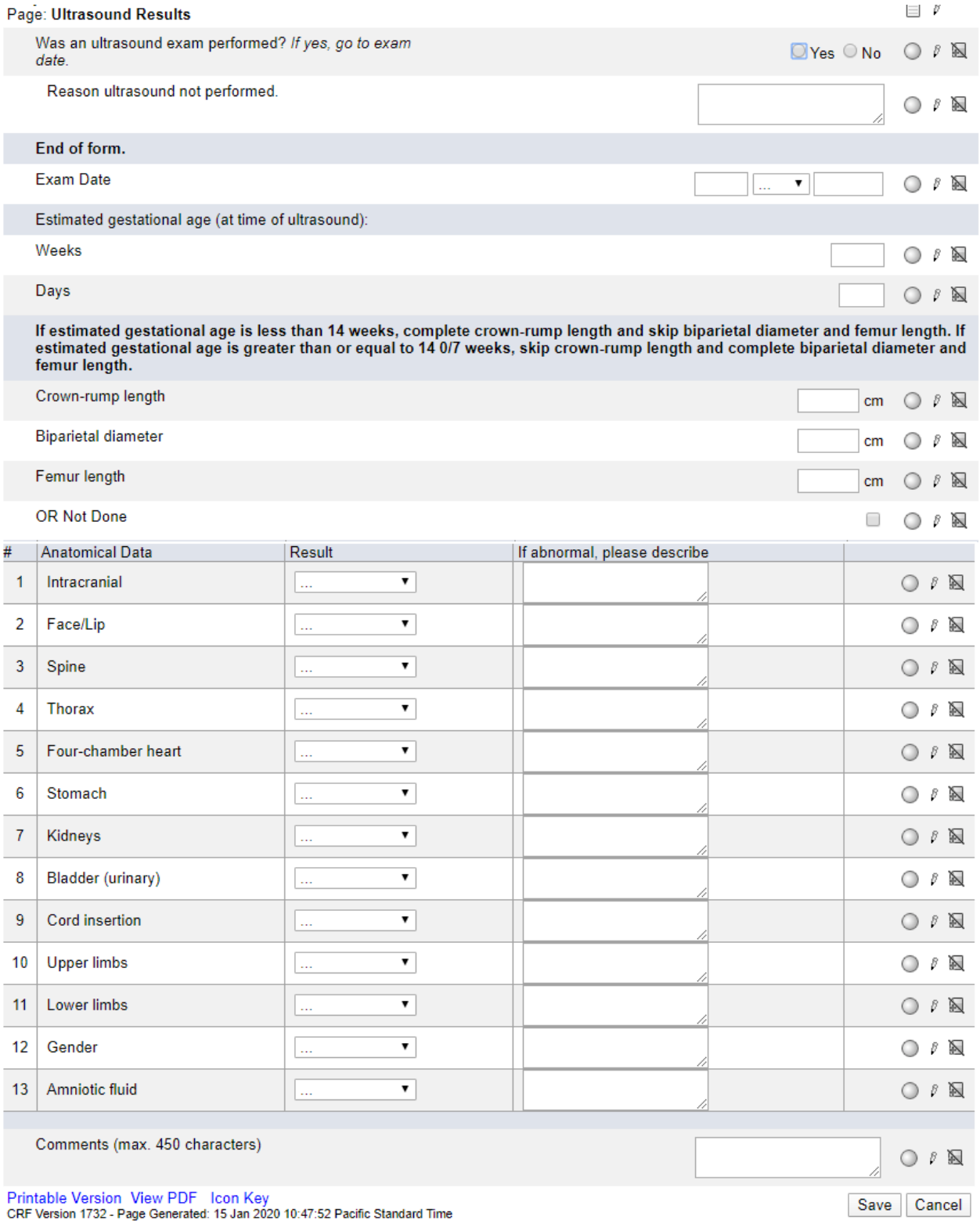
- Complete this form for each enrolled participant at either the scheduled exit/end of study visit or when the participant is confirmed to no longer be participating in the study.
- Every effort should be made to avoid terminating participants early. Sites should minimize, to the extent possible, terminating participants early due to lost to follow-up or relocation. Instead, Missed Visit forms can be completed during follow-up until the end of the study if needed.
- The Termination form is in the Discontinuations folder. This form and folder are automatically created when a participant is enrolled in the study.

Item-specific Instructions

Field	Instructions
Termination date	• Record the date the site determined that the participant was no longer in the study. • A complete date is required.
Reason for termination	• Select the appropriate reason from the drop-down menu. • Only mark "early study closure" when instructed by the CDM.

Date of death	• If "Reason for termination" is "Death", record date of death. Otherwise, leave this item blank. • At minimum, a month and year are required. If day is unknown, enter "UN" for the day.
Specify	• If "Death", "Participant refused further participation, specify", "Investigator decision, specify", or "Other, specify" are selected, record additional information in the "Specify" field. • Provide cause of death, if applicable and if available.
Was termination associated with an adverse event?	• Select "Yes" or "No".
If yes, please specify AE	• If "Was termination associated with an adverse event" is "Yes", 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.

ULTRASOUND RESULTS



Page: **Ultrasound Results**

Was an ultrasound exam performed? *If yes, go to exam date.* ☐ Yes ○ No

Reason ultrasound not performed.

End of form.

Exam Date ... ...

Estimated gestational age (at time of ultrasound):

Weeks

Days

If estimated gestational age is less than 14 weeks, complete crown-rump length and skip biparietal diameter and femur length. If estimated gestational age is greater than or equal to 14 0/7 weeks, skip crown-rump length and complete biparietal diameter and femur length.

Crown-rump length cm

Biparietal diameter cm

Femur length cm

OR Not Done ☐

#	Anatomical Data	Result	If abnormal, please describe
1	Intracranial	...	
2	Face/Lip	...	
3	Spine	...	
4	Thorax	...	
5	Four-chamber heart	...	
6	Stomach	...	
7	Kidneys	...	
8	Bladder (urinary)	...	
9	Cord insertion	...	
10	Upper limbs	...	
11	Lower limbs	...	
12	Gender	...	
13	Amniotic fluid	...	

Comments (max. 450 characters)

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Save Cancel

Purpose

CONFIDENTIAL DOCUMENT

This form is used to document ultrasound findings for pregnant participants who are referred to an obstetric specialist.

General Instructions
Complete this form as clinically indicated during the study.

Item-specific Instructions

Field	Instructions
Was an ultrasound exam performed?	• Select "Yes" or "No".
Reason ultrasound not performed.	• If "Was an ultrasound exam performed?" is "No", provide reason here.
Exam Date	• If an ultrasound was done, enter the date it was done. • A complete date is required.
Estimated gestational age (at time of ultrasound):	
Weeks	• Enter the number of weeks of the estimated gestational age at the time of the ultrasound.
Days	• Enter the number of days of the estimated gestational age at the time of the ultrasound.
Crown-rump length	• Complete if estimated gestational age is less than 14 weeks. • Skip this if estimated gestational age is greater than or equal to 14 0/7 weeks. • Enter measurement in centimeters.
Biparietal diameter	• Complete if estimated gestational age is greater than or equal to 14 0/7 weeks. • Skip this if estimated gestational age is less than 14 weeks. • Enter measurement in centimeters.
Femur length	• Complete if estimated gestational age is greater than or equal to 14 0/7 weeks. • Skip if estimated gestational age is less than 14 weeks. • Enter measurement in centimeters.

OR Not Done	• If femur length was not done, mark “OR Not Done.”
Anatomical Data #1-13 **Result**	• For each anatomical feature, select “Not visualized”, “Normal”, or “Abnormal” from drop-down list.
If abnormal, please describe	• If the result was “Abnormal” then provide a description here. • If the result was “Not Visualized” or “Normal”, leave blank.
Comments	• Provide additional comments regarding ultrasound exam results here if applicable. • Maximum allowed characters: 450

ULTRASOUND RESULTS – OLE

Page: **Ultrasound - OLE - V76.0 - Step 4d - Week 0 Pregnancy 1**

1. Was an ultrasound exam performed? If yes, go to exam date.	◉ Yes ○ No
1a. Reason ultrasound not performed.	
2 Exam Date	...
3. Number of fetuses observed on ultrasound	
Currently viewing line 1 of 1. Click here to return to "Complete View".	Apply to Recor
4. Estimated gestational age (at time of ultrasound) - Weeks	
5. Estimated gestational age (at time of ultrasound) - Days	
6. **If estimated gestational age is less than 14 weeks, complete crown-rump length and skip biparietal diameter and femur length (Mark "Or Not done/not collected") . If estimated gestational age is greater than or equal to 14 0/7 weeks, skip crown-rump length (Mark "Or Not done/not collected") and complete biparietal diameter and femur length.** Crown-rump length	cm
Or Not done/not collected	☐
7. Biparietal diameter	cm
Or Not done/not collected	☐
8. Femur length	cm
Or Not done/not collected	☐
9. Intracranial Result	...
If abnormal, please describe	
10. Face/Lip Result	...
If abnormal, please describe	
11. Spine Result	...
If abnormal, please describe	
12. Thorax Result	...
If abnormal, please describe	
13. Four-chamber heart Result	...
If abnormal, please describe	
14. Stomach Result	...

Purpose

This form is used to document ultrasound results in the OLE portion of the study.

General Instructions

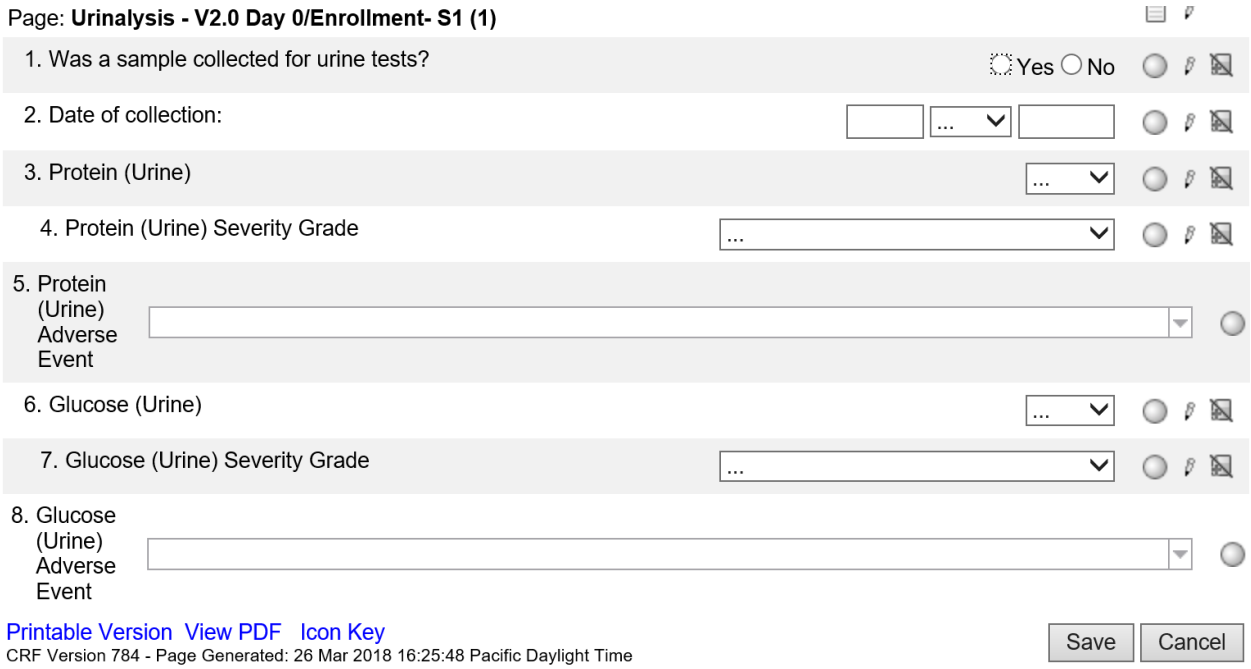
This form is populated from the Additional Procedures – OLE form and is added to the respective visit when selected.

Item-specific Instructions

Field	Instructions
Was an ultrasound exam performed?	• Select “Yes” or “No”.
Reason ultrasound not performed.	• If “Was an ultrasound exam performed?” is “No”, provide reason here.
Exam Date	• If an ultrasound was done, enter the date it was done. • A complete date is required.
Number of fetuses observed on ultrasound	• Record the number identified and enter a log line for each fetus.
Estimated gestational age (at time of ultrasound) - Weeks	• Enter the number of weeks of the estimated gestational age at the time of the ultrasound.

Estimated gestational age (at time of ultrasound) - Days	• Enter the number of days of the estimated gestational age at the time of the ultrasound.
Crown-rump length	• Complete if estimated gestational age is less than 14 weeks. • Skip this if estimated gestational age is greater than or equal to 14 0/7 weeks and mark Not done/Not collected. • Enter measurement in centimeters.
Biparietal diameter	• Complete if estimated gestational age is greater than or equal to 14 0/7 weeks. • Skip this if estimated gestational age is less than 14 weeks and mark Not done/Not collected. • Enter measurement in centimeters.
Femur length	• Complete if estimated gestational age is greater than or equal to 14 0/7 weeks. • Skip if estimated gestational age is less than 14 weeks and mark Not done/Not collected. • Enter measurement in centimeters.
Anatomical Data #9-21 **Result**	• For each anatomical feature, select “Not visualized”, “Normal”, or “Abnormal” from drop-down list.
If abnormal, please describe	• If the result was “Abnormal” then provide a description here. • If the result was “Not Visualized” or “Normal”, leave blank.
Comments	• Provide additional comments regarding ultrasound exam results here if applicable. • Maximum allowed characters: 450

URINALYSIS



Purpose

This form is used to document the participant's urinalysis test results.

General Information/Instructions

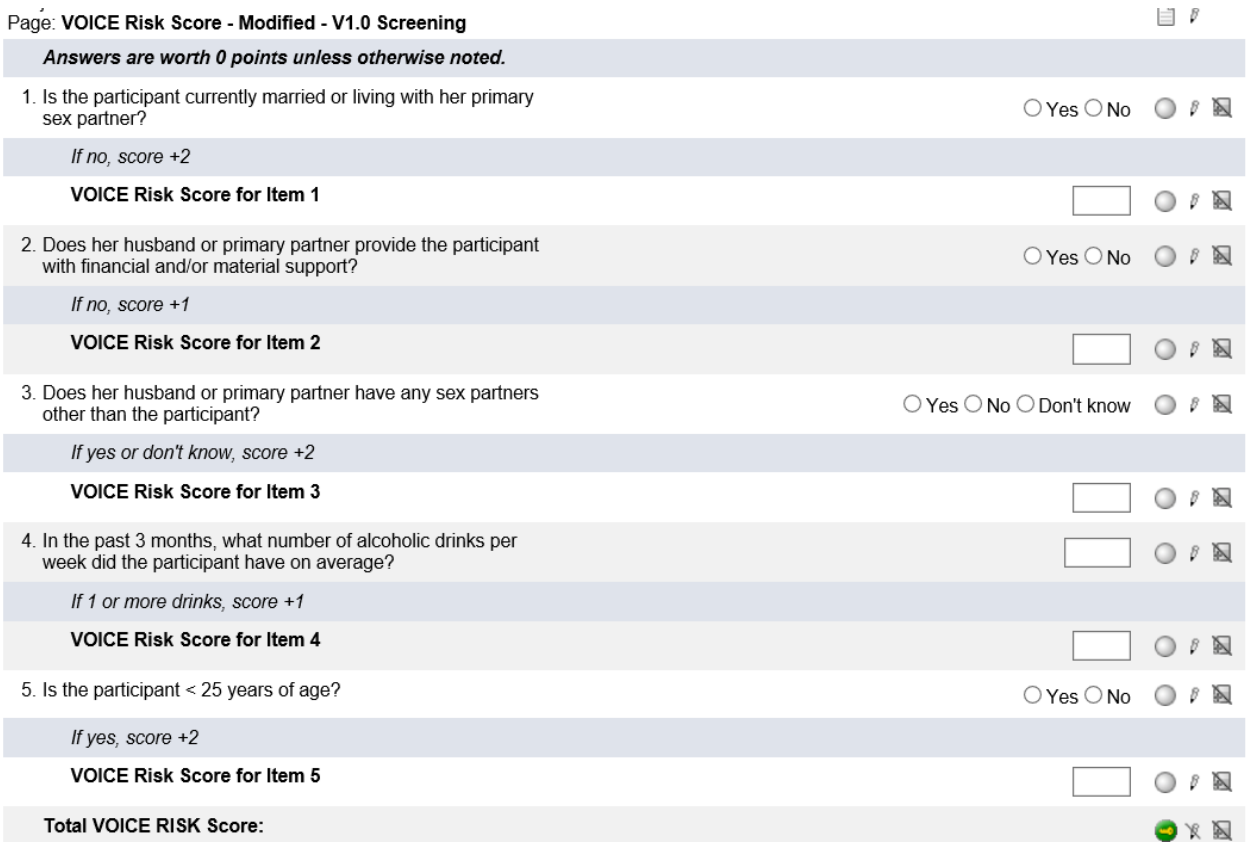
Complete this form at required protocol visits and as clinically indicated during the study.

Item Specific Instructions

Field	Instructions
Was a sample collected for urine tests?	• If "No" is selected, leave the remaining items on the form blank.
Date of collection	• Enter the date the specimen was collected. • A complete date is required.
Protein (Urine)	• Select the applicable result from the dropdown menu.
Protein (Urine) 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.

Field	Instructions
Protein (Urine) 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 Urinalysis form.
Glucose (Urine)	• Select the applicable result from the dropdown menu.
Glucose (Urine) 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.
Glucose (Urine) 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 Urinalysis form.

VOICE RISK SCORE- MODIFIED



Page: **VOICE Risk Score - Modified - V1.0 Screening**	
Answers are worth 0 points unless otherwise noted.	
1. Is the participant currently married or living with her primary sex partner?	○ Yes ○ No
If no, score +2	
VOICE Risk Score for Item 1	
2. Does her husband or primary partner provide the participant with financial and/or material support?	○ Yes ○ No
If no, score +1	
VOICE Risk Score for Item 2	
3. Does her husband or primary partner have any sex partners other than the participant?	○ Yes ○ No ○ Don't know
If yes or don't know, score +2	
VOICE Risk Score for Item 3	
4. In the past 3 months, what number of alcoholic drinks per week did the participant have on average?	
If 1 or more drinks, score +1	
VOICE Risk Score for Item 4	
5. Is the participant < 25 years of age?	○ Yes ○ No
If yes, score +2	
VOICE Risk Score for Item 5	
Total VOICE RISK Score:	

Purpose

This form is used to document the participant's Voice Risk Score at Screening. The total score is used to determine a participant's eligibility in the study.

General Instructions

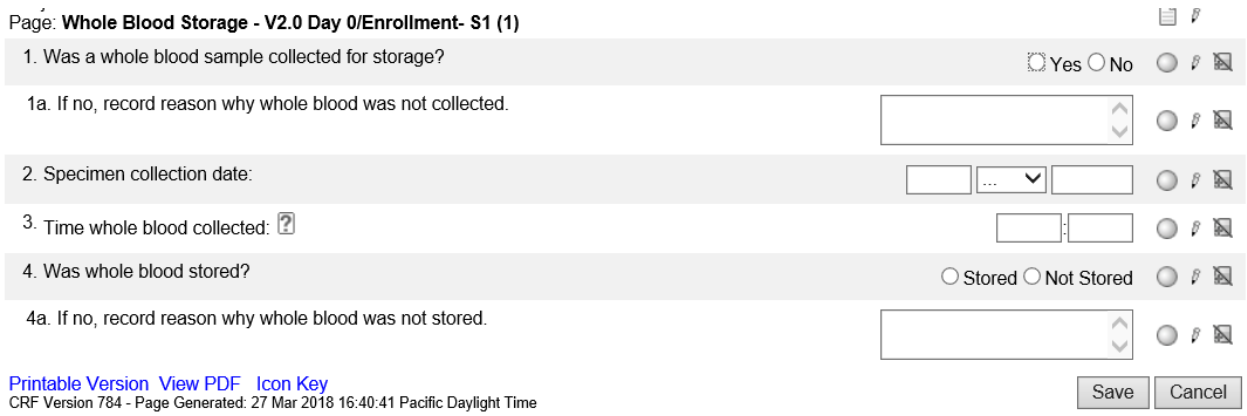
Complete this form at Screening. Answers are worth 0 points unless otherwise instructed on the form. Once the forms are saved, Rave will calculate the total score at the bottom of the form. **Remember: A participant must have a Total Voice Risk Score >4 to be considered eligible for the study per Protocol V2.0.**

Item-specific Instructions

Field	Instructions
1. Is the participant currently married or living with her primary sex partner?	• If "No", enter "2" in **VOICE Risk Score for item 1**. • If "Yes" enter "0" in **VOICE Risk Score for item 1**.

Field	Instructions
2. Does her husband or primary partner provide the participant with financial and/or material support?	• If "No", enter "1" in **VOICE Risk Score for item 2**. • If "Yes", enter "0" in **VOICE Risk Score for item 2**.
3. Does her husband or primary partner have any sex partners other than the participant?	• If "Yes" or "Don't know", enter "2" in **VOICE Risk Score for item 3**. • If "No" enter "0" in **VOICE Risk Score for item 3**.
4. In the past 3 months, what number of alcoholic drinks per week did the participant have on average?	• If 1 or more drink, enter "1" in **VOICE Risk Score for item 4**. • If 0 drinks, enter "0" in **VOICE Risk Score for item 4**.
5. Is the participant < 25 years of age?	• If "Yes", enter "2" in **VOICE Risk Score for item 5**. • If "No", enter "0" in **VOICE Risk Score for item 5**.
Total VOICE RISK Score	• Data entry is not required. • Rave will calculate the total score once all questions have been answered and the form has been saved.

WHOLE BLOOD STORAGE



Purpose

This form is used to document collection and storage of whole blood specimens.

General Instructions

Complete this form at all protocol-specified visits.

Item-specific Instructions

Field	Instructions
Was a whole blood sample collected for storage?	• If "No" is selected, provide the reason why whole blood was not collected in the text box provided. Leave the remaining items blank.
Specimen collection date	• Record the date that the specimen was collected. • A complete date is required.
Time whole blood collected	• Record the time the specimen was collected using a 24-hour clock.
Was whole blood stored?	• If "Not Stored" is selected, record the reason why in the text box provided (item 4a).

VERSION HISTORY

VERSION NUMBER	DATE	DETAILS OF CHANGES
Version 1.0	06/12/2018	Original signed version
Version 2.0	07/19/2018	Form-level instructions added for new CRFs: • Date of Visit – Yearly • Early Unblinding • Pill Dispensation – Step 2 and 3 Additional clarifying instructions added for sections: • Grading local laboratory results • Electronic signatures • AE log • CD-4 Viral Load Results • Concomitant Medications Log • HIV Test Results • Liver Function Tests • Missed Visit • Pregnancy Outcome • Social Impact Y/N
Version 3.0	01/24/2020	New CRFs and instructions added: • Contraception • HIV Supplemental Results • Plasma Storage -Contraceptive Sub-study • Specimen Storage – Contraceptive Sub-study Form-level instructions updated/added for these existing CRFs: • Date of Visit - Step 1 • Date of Visit – Step 2 • Date of Visit – Step 3 • Date of Visit – HIV • Date of Visit – Yearly Visit • Date of Visit - Pregnancy • Date of Visit – Open Label Truvada • Ultrasound Results • Cell Pellet Storage • Pregnancy Outcome Log • Cell Dispensation – Step 2 and 3 Additional clarifying guidelines are added for: • HIV Test Results • Plasma Storage • Concomitant Medications Log

Version 4.0	1/24/22	New CRFs and instructions added: • Product Choice - OLE • Date of Visit - OLE • Interim Visit Summary – OLE • Additional Procedures – OLE • Contraception –OLE • Long Term Consent Update • Product Hold – OLE • Product Hold – OLE Y/N • Pregnancy Test Results-OLE • Pregnancy Report-OLE • Pregnancy Outcome Log – OLE • Ultrasound – OLE • Consent - Pregnancy Infant Sub-study • Date of Visit - Pregnancy OLE • Sub-study Infant PTID • Infant Specimen Collection - Blood (Plasma) • Specimen Collection - Breast Milk • Infant Breastmilk Feeding Assessment • Adverse Event - Infant Y/N • Adverse Event - Infant
Version 5.0	X/XX/XX	New CRFs and instructions added: • Log Revisions • Infant HIV Testing • Infant Dried Blood Storage Updated screenshot for Adverse Event – Infant Updated screenshot for Chemistry CRF