CRF Completion Guidelines

HPTN 094

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CRF Completion Guidelines

The following instructions are study-specific data completion guidelines intended to assist site staff when completing electronic case report forms (eCRFs) and paper case report forms (CRFs). Detailed guidance on general data collection, entry, navigation and general use of Medidata Rave is provided in the Medidata Rave Electronic Data Capture (EDC) Training Manual, which is found on the HPTN 094 Protocol page: https://www.hptn.org/research/studies/190

General Guidelines

- The Participant ID is generated by Rave EDC as a 9-digit field, starting with the 3-digit site number followed by a randomly assigned 5-digit participant number, and 1-digit check number.
- All data entered in Rave must match the data on any source documents/paper CRFs.
- Complete all required data fields. Ensure that all entries are in English and are accurate, consistent, complete and medically logical.
- If “Other” is chosen as a response, further details must be provided by responding to the “If “Other”, specify” field.
- Text box fields have character limits. Text exceeding the limit will not be saved and a “Non-conformant” icon will appear.
- Visit dates must be complete and in chronological order according to the protocol.
- Most date fields must be entered as Day/Month/Year (dd/mmm/yyyy) (e.g., 01 NOV 2017). Exceptions are detailed in specific form sections where applicable.
- Drop-down menus are available for many fields. Use these menus, when available, to select the appropriate response.
- Avoid using abbreviations, symbols or special characters.
- Hitting the return or enter key in text fields may prematurely save the form and should not be used as a way to navigate form or add a line break.
- If a scheduled visit is missed, mark “no” on “Did the participant complete this visit?” on the Date of Visit form. This will add the Missed Visit form to the visit folder for completion.
- Log forms allow you to make multiple entries over the course of the study. All entries may be viewed at the same time in “Complete View”. Individual entries may be viewed in “Portrait View” for ease of entry. The following log forms for this study are available in the Ongoing Logs folder:
    - Antiretroviral Treatment Regimen
    - Medical History
    - Medication for Opioid Use Disorder
    - Navigation Session
    - Pre-exposure Prophylaxis
    - Protocol Deviations
    - Serious Adverse Event
    - Specimen Collection

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

Add Event

- The **Add Event** drop-down menu can add select forms and visit folders to a participant's casebook.
- To add a form or folder to a participant's casebook: navigate to the subject level page, select the event from the Add Event drop-down list, then click the "Add" button.
- The following forms and/or folders for this study are available in the Add Event drop-down menu:
    - **Clinical Care Visit**
        - By selecting "Clinical Care Visit" from the Add Event drop-down menu, a Clinical Care Visit folder will appear in the participant's casebook.
        - Open the Clinical Care Visit folder to access the Clinical Care Visit form. On the Clinical Care Visit form, select the forms that were completed at the Clinical Care Visit.
    - **Interim Visit**
        - By selecting "Interim Visit" from the Add Event drop-down menu, an Interim Visit folder will appear in the participant's casebook.
        - Open the Interim Visit folder to access the Interim Visit form. On the Interim Visit form, select the forms that were completed at the interim visit. The selected forms will then load in the folder.
    - **Pregnancy**
        - By selecting "Pregnancy" from the Add Event drop-down menu, a Pregnancy folder will appear in the participant's casebook.
        - Open the Pregnancy folder to access the Pregnancy Report and Pregnancy Outcome forms.
    - **Outside HIV Test**
        - By selecting "Outside HIV Test" from the Add Event drop-down menu, an Outside HIV Test folder will appear in the participant's casebook.
        - Open the Outside HIV Test folder to access the HIV Test Results form.
        - This folder is used to collect data from HIV confirmatory tests that were done by outside providers and are being used to confirmation of HIV status at enrollment.
- Please see the form specific instructions for further guidance.

Loading Forms in Visit Folders

- Forms are added to visit folders in a participant's casebook based on specific form responses. Below are a few key examples.
  - **Example 1**: Date of Visit form
    - If the question "Did the participant complete this visit?" is marked "No", the Missed Visit form will be added to the visit folder and the required forms for that visit will not appear in the visit folder.
    - To add a form to the visit folder, mark the appropriate check box under "Additional Procedures/Forms". Some forms will not be added to the visit folders. They are available in either the Ongoing Logs or Discontinuation folder or will need to be added using the Add Event drop down menu.
  - **Example 2**: Interim Visit form
    - To add a form to the interim visit folder, mark the appropriate check box under "Forms Completed at Interim Visit". Some forms will not be added to the visit folders. They are available in either the Ongoing Logs or Discontinuation folder or will need to be added using the Add Event drop down menu.

Loading of Folders in Participant Casebook

- Medidata Rave will add folders to a participant's casebook based on how certain forms are completed. See Table 1 for actions required to add folders to a participant's casebook.

Table 1. Folder Dynamics

Folder	Action Required to Add Folder
V1.0 – Screening Ongoing Logs	Save Participant Identifier form.
V2.0 – Day 0/Enrollment V3.0 Discontinuation	Randomization
V4.0	• Select "No" for "Did the participant exit/terminate the study at this visit?" on the Date of Visit form in the V3.0 visit folder.

Dynamic Search Lists

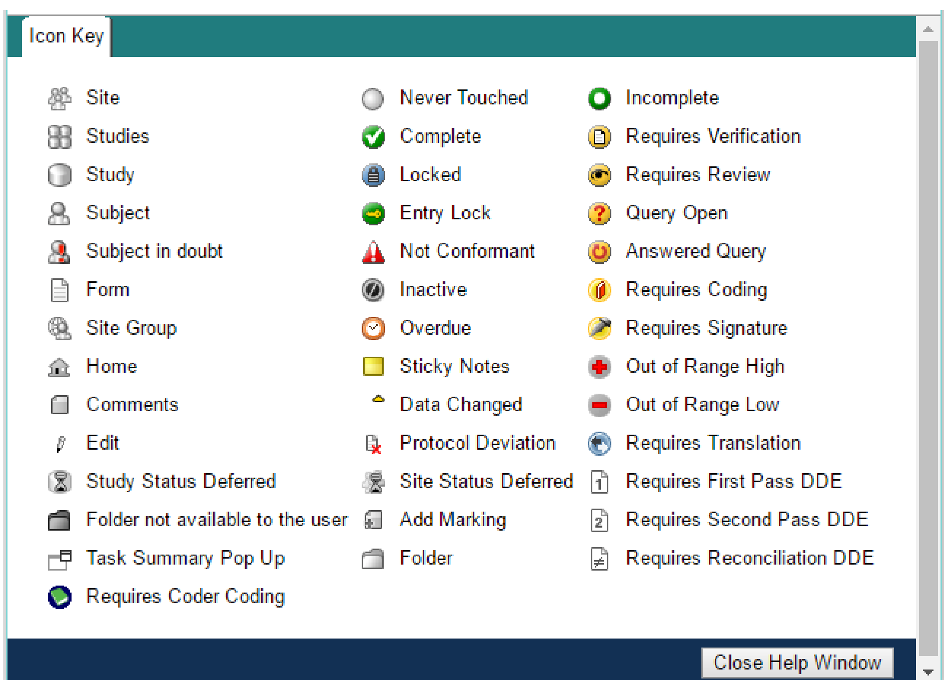
- Some forms have data fields with dynamic drop-down lists of available options. Options are populated by corresponding log form entries.
- Dynamic drop-down lists will be blank until entries are made and saved in the corresponding log form.
- Your selection in the dynamic search list can be deleted if entered in error.
- Changing the original log data or inactivating a log form entry that has been selected for a dynamic search list field will make that field non-conformant. To resolve the non-conformant data, make a new selection in the dynamic search list.
- For Example:
  - An AE of '*FEVER*' started on 05DEC2017 is reported on the Adverse Events log form.
  - A medication was used for this AE and is entered on the Concomitant Medication form.

- The applicable AE is linked to this medication by selecting it from the dynamic search list on the Concomitant Medication log entry.
- The start date for AE *'FEVER'* is corrected to 06DEC2017 on the Adverse Events log form.
- The selection from the dynamic search list on the Concomitant Medication log entry becomes non-conformant.
- Re-select the AE '*FEVER*' from the dynamic search list with the corrected start date to resolve the non-conformant data.

Icon Key

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

Figure 1. Icon Key

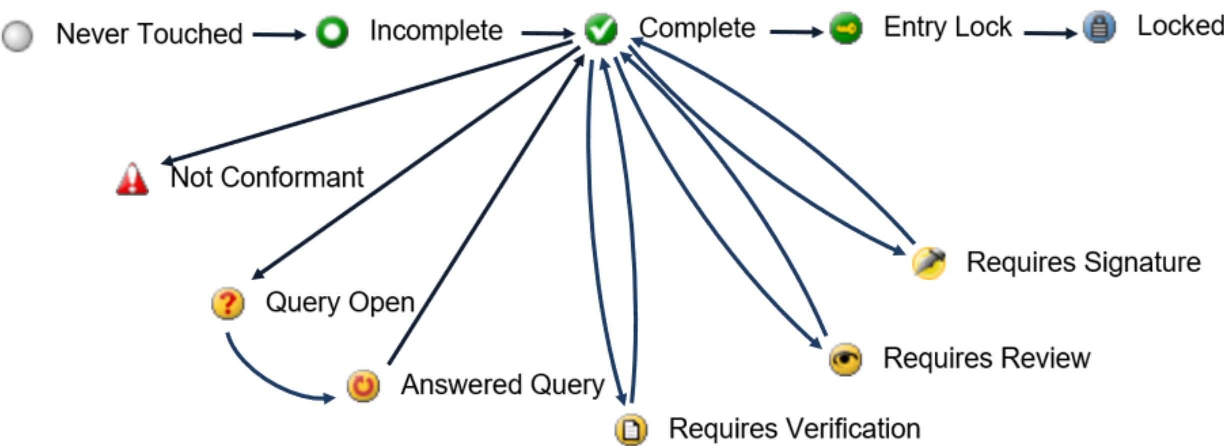


Icon Progression

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

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

Figure 2. Icon Progression



Task Summary

At the site level, the **Task Summary** displays the participants with outstanding tasks that need site review (see Figure 3). For example, click on "Open Queries" to expand the list of participants with open queries (see Figure 4). Click on a PTID to open the participant's casebook.

Figure 3. Site-Level Task Summary

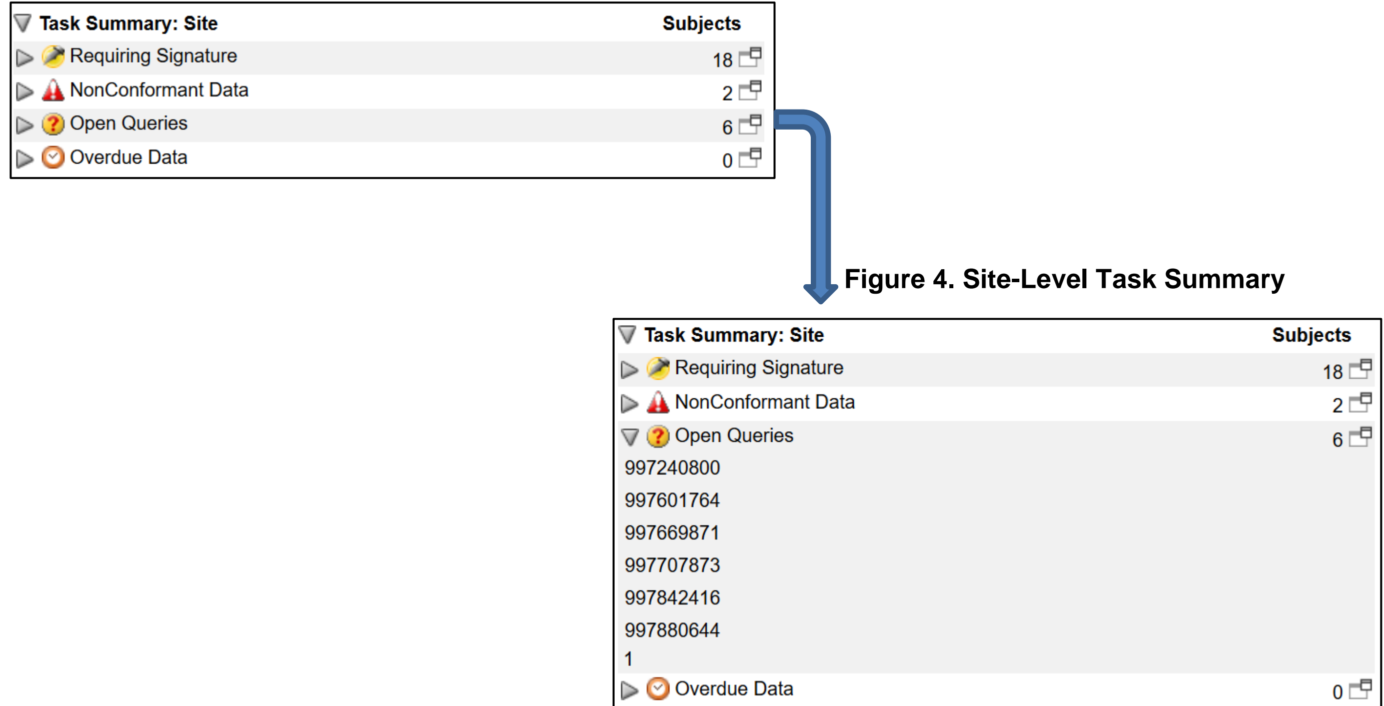
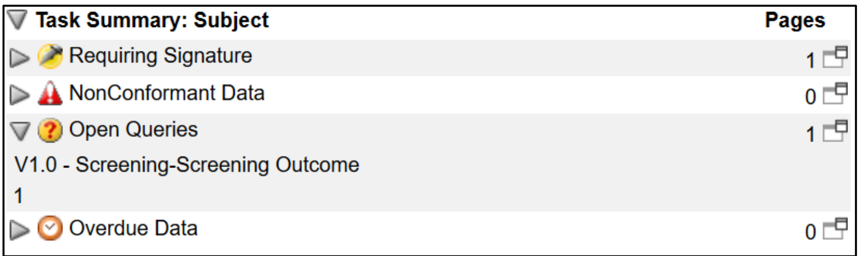


Figure 4. Site-Level Task Summary

At the subject level, the Task Summary displays the forms that need site review. In Figure 5 below, there is one open query for this participant on the Screening Outcome form at V1.0 – Screening. Click on this form in the expanded task summary view to navigate to the open query.

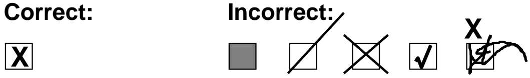
Figure 5. Subject-Level Task Summary



General Guidelines – Paper CRF Completion

CRF PDFs are generated from Rave and posted on the protocol webpage. When completing a CRF, refer to form specific instructions in sections below.

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



Recording Dates – Rave Form and/or Paper CRF

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

Month	Abbreviation	Month	Abbreviation
January	JAN	July	JUL
February	FEB	August	AUG
March	MAR	September	SEP
April	APR	October	OCT

May	MAY	November	NOV
June	JUN	December	DEC

For example, record September 20, 2016 as: 20 Sep 2016

Recording Time - Rave Form and/or Paper CRF

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

The following chart shows equivalencies between the 12- and 24-hour clocks:

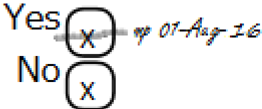
12-hour clock (a.m.)	24-hour clock
Midnight	00:00
1:00 a.m.	01:00
2:00 a.m.	02:00
3:00 a.m.	03:00
4:00 a.m.	04:00
5:00 a.m.	05:00
6:00 a.m.	06:00
7:00 a.m.	07:00
8:00 a.m.	08:00
9:00 a.m.	09:00
10:00 a.m.	10:00
11:00 a.m.	11:00

12-hour clock (p.m.)	24-hour clock
Noon	12:00
1:00 p.m.	13:00
2:00 p.m.	14:00
3:00 p.m.	15:00
4:00 p.m.	16:00
5:00 p.m.	17:00
6:00 p.m.	18:00
7:00 p.m.	19:00
8:00 p.m.	20:00
9:00 p.m.	21:00
10:00 p.m.	22:00
11:00 p.m.	23:00

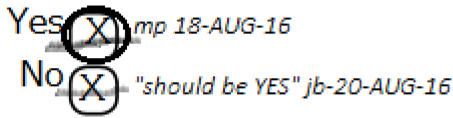
For example, record 2:25 p.m. as: 14 25 24-hour clock

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

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



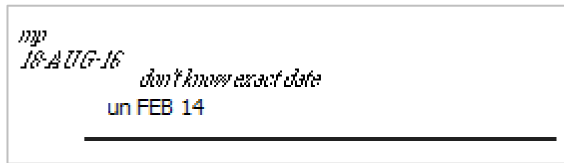
  - If the correct answer has previously been crossed out, do the following:
    - circle the correct response
    - write an explanation in the white space near the response
    - initial and date all corrections as shown below:



- Use the standards below when changing, clarifying, or amending data in Rave:
  - Data previously submitted in an eCRF data field can be updated and resubmitted unless the field is locked.
  - To edit a data field, click on the pencil icon to the right of the field.
  - To edit all data fields on a form, click the pencil icon at the top right of the form. **This is the best method to use if multiple fields need to be edited.**
  - Enter the updated data.
  - Select a reason for the data change from the dropdown menu.
  - Click “Save” at the bottom of the form to save the changes.
  - Otherwise, click “Cancel” to reset the form with the last saved data.
  - Updated data fields will be marked with a delta icon:

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

- Complete dates are required for most date fields unless specified in form specific instructions below.
- On paper CRFs, if a date is unknown, unavailable, or if the participant refuses to answer, draw a single horizontal line through the applicable question and initial and date. It is helpful to write "don't know," "refuses to answer," "UNK" (unknown), "N/A" (not applicable), or "REF" (refused) near the fields.
    - For example, when recording a date, if the exact day is not known, write "un" to designate the "dd" (or date) and write "don't know" next to the response, as shown below.



    - Initials and date are required for any data that are refused, missing, unknown, or not applicable, regardless of whether they are marked as such during the initial form completion, or as an update to the form.
- In Rave, where the data are missing or unknown, enter "UN" for the day and/or select 'UNK' from the drop-down list for the month.

Form-Specific Instructions

Antiretroviral Treatment Regimen

Purpose:
This form documents all Antiretroviral Treatments (ART) that is used by the participant during the study.

General Instructions:

- Complete one log line for each reported ART medication.
- Add additional log lines by clicking “Add a new Log line”.
- At each scheduled visit:
    - Update “Stop date” if previously reported medication was discontinued by the participant.
    - Enter any new medications on a new log line.
    - If participant is not currently taking medication, add a new log line and answer the first two questions.

Field-specific Instructions:

Field	Instructions
Is the participant currently taking ART?	• If “Yes”, skip to “Medication” and answer the following items regarding the current medication: ○ Medication ○ Dose ○ Dose units ○ Frequency ○ Route ○ How was ART obtained ○ Date started If “No”, answer “Since the previous visit has the participant taken ART?”
Since the previous visit has the participant taken ART? (At Enrollment visit ask if the participant has ever taken ART)	• If “Yes”, answer the following items regarding past medication: ○ Medication ○ Dose ○ Dose units ○ Frequency ○ Route ○ How was ART obtained ○ Date started ○ Date stopped ○ Stop/Refusal Code 1 • If “No”, go to “Stop/Refusal Code 1” and select reason participant did not take medication.
Date Started	At least year is required.
Date Stopped Or Continuing at end of study	• If the participant discontinued a medication that was reported on the log, enter the stop date. At least year is required. • If the participant terminates but is continuing the medication after termination (to the best of the site’s knowledge), leave “Date Stopped” blank and mark “Continuing at end of study”.

Stop/Refusal Code 1 Stop/Refusal Code 2 Stop/Refusal Code 3	Enter up to 3 reasons why the participant discontinued a medication or refused to start a medication.

Behavioral Questionnaire

Purpose:
This form is used to document information about a participant's life, beliefs and behavior.

General Instructions:
This is an interviewer-administered form. Read each question aloud and record the participant's response.

These questions ask the participant to provide sensitive information. To increase honest and accurate responses, it is important to stress that all information will be kept private and confidential.

CASI Tracking

Purpose:
This form is used to document the completion of required ACASI questionnaires.

General Instructions:
Complete this form when a participant completes am ACASI questionnaire.

Field-specific Instructions:

Field	Instructions
CASI collection date	Enter the data the participant completed the ACASI questionnaire.
CASI ID	• Enter the participant's CASI ID. • Each site has a list of CASI ID's to assign to participants. • Each participant will have one CASI ID for the course of the study.

CD4 Test Results/Viral Load

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

Field-specific Instructions:

Field	Instructions
Was a sample collected for absolute CD4+ count?	If “No”, leave the rest of the CD4 items blank and go to the HIV RNA section.
Specimen collection date	Enter the date the sample was collected for CD4 count.
Absolute CD4+ Or Unable to analyze	• Enter the absolute CD4 in units of “cells/mm^3”. • If sample was unable to be analyzed, leave “Absolute CD4+ blank and mark “Unable to analyze”.
Was HIV RNA PCR testing completed?	If “No” is selected, end of form.
Specimen collection date	Enter the date the sample was collected for HIV RNA PCR testing.
HIV RNA viral load result	• Enter the HIV RNA PCR value in “viral copies/mL”. • A maximum of nine digits is allowed.
HIV RNA PCR target detected, under the lower limit of quantification	If a lab result says “Detected, under lower limit of quantification”, mark this box. Otherwise, leave blank.
Lower limit of quantification	If a lab result says “Detected, under lower limit of quantification”, enter the lower limit of quantification. Otherwise, leave blank.
HIV RNA PCR target detected, above the upper limit of quantification	If a lab result says “Detected, greater than the upper limit of quantification”, mark this box. Otherwise, leave blank.
Upper limit of quantification	If a lab result says “Detected, greater than the upper limit of quantification”, enter the upper limit of quantification. Otherwise, leave blank.
Target not detected	If a lab result says “HIV-1 RNA target not detected”, mark this box. Otherwise, leave blank.

Chemistry Panel

Purpose:
This form documents participant’s local lab test results/values.

General Instructions:
Select your local laboratory from the drop-down list at the top of the form. This is required to populate the appropriate reference ranges for your site.

NOTE: Enter the severity grade for each lab result/value in the top section of the form. Enter the lab result/value in the bottom section of the form.

Field-specific Instructions:

Field	**Instructions**
Specimen collection date	Record the date that the specimen was *collected*, not the date results were reported or recorded on the form.
Severity grade	• Select laboratory value severity grade according to the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events*, most current version. • Select "Not gradable" for a lab result/value that does not meet grading criteria.

Clinical Care Visit

Purpose:
This form is used to summarize information from each participant at a Clinical Care visit and to record all procedures or assessments the participant received at any Clinical Care visit.

General Instructions:
- This form is required for each Clinical Care visit completed for a participant.
- Use the "Add Event" feature to dynamically create the Clinical Care Visit folder, which will add an Clinical Care Visit eCRF to the participant's casebook within the applicable Clinical Care Visit folder.

Field-specific Instructions:

Field	Instructions
Clinical care visit code	Clinical care visits are numbered as follows: • First Visit = 201.0 • Second Visit = 202.0 • Third Visit = 203.0 • Etc.
What is/are the reason(s) for this clinical care visit?	Mark at least one reason for the clinical care visit.
Forms completed at clinical care visit.	Select the forms needed for the clinical care visit. The selected forms will load into the clinical care visit folder upon saving.

Couple Tracking

Purpose:
This form is used to link sexually intimate partners who both enroll in the study.

General Instructions:
1) Ask the participant if they have any sexual partners who are also enrolling in the study. Inform them that is not exclusionary, but will be documented for interpreting results.

2) Explain to participants with sexual partners enrolled, that they may be randomized to a different arm than their partner. (e.g. “You may be getting free drug on the van for the first 5 months while your partner has to go to the community clinic, or vice versa.”)
3) Explain to participants why participants in the active arm should not share their meds with their partner in the control arm. (e.g. “It will negatively affect the research because neither partner will be getting what is expected. Also, if two people split one person’s MOUD, ART or PrEP, the drugs won’t be effective for either partner and (for ART) can even cause resistance.”)

NOTE:

- If the participant is in a sexual relationship with more than one other person enrolling/enrolled in the study, complete a separate Couples Tracking form for each of their partners
- Only collect data for sexual partners, not partners who participants share drugs with, share a home with, etc.

Field-specific Instructions:

Field	Instructions
Does the participant have a sexually intimate partner who is enrolling in the trial?	If “No”, end of form.
PTID of partner	Enter the 9 digit PTID of the partner.
Mark if a second Couple Tracking eCRF is needed for this participant	Mark this box to add another Couple Tracking form to the participant’s casebook in the even that the participant has more than one sexually intimate partner also enrolled in the study.

Current Medication Use

Purpose:
This form documents the participant’s current use of medications (ART, PrEP, and MOUD) and their use between study visits.

General Instructions:
Complete this form at weeks 26 and 52.

- Document all use of medications since enrollment at the week 26 visit.
- Document all use of medications since the week 26 visit at the week 52 visit
- If the week 26 visit is missed, document all use of medications since enrollment at the week 52 visit.

Date of Visit

Purpose:
This form is used to load visit folders in participant’s casebook according to the study visit schedule.

Field-Specific Instructions:

Field	Instructions
Did the participant complete this visit?	• Select “Yes” if the participant completed all or part of the visit. • If “Yes” is selected, the required forms associated with the visit will load in the visit folder. • If “No” is selected, only the **Missed Visit** form will be added to the visit folder. Complete the Missed Visit form.
Visit date	Use the date the first assessment associated with this visit was completed. If the visit reflects data collected across multiple days, enter the date of the earliest collection.
Did the participant exit/terminate the study at this visit?	If “Yes” is marked, complete the **Termination** form within the Discontinuation folder.
Additional Procedures/Forms	• If needed, select the procedure(s) from the list and save the form in order to add the applicable form(s) to the visit folder. Refer to the Schedule of Forms to select procedures that are allowed at each visit. • **Do not select procedures/forms that are already in the folder for that visit**.

Demographics

Purpose:
This form documents a participant’s demographic information.

General Instructions:
Complete and submit this form for participants who have signed a study-specific consent form, regardless of if they enroll in the study or not. If the participant does not understand the question, read the response options to the participant. Responses should reflect the participant’s status at screening, and should not be changed after screening unless correction is needed. If the participant is found to be ineligible prior to the collection of all demographic data, enter all available data and respond to system queries with “Not Collected”.

Field-specific Instructions:

Field	Instructions
Date of birth	If the entire date of birth is unknown, record participant’s best estimate. At a minimum year is required.
Age	The age field is calculated automatically based on the “Date of birth” field and the “Informed consent date” field on the Informed Consent form. No data entry is required.
Sex at birth	This is the sex that the participant was assigned at birth.
Ethnicity	Record the participant’s ethnicity based on self-definition.

Field	Instructions

Race	• Record the participant's race based on self-definition.
	• The race categories are based on the US census:
	  ○ **American Indian or Alaska Native:** A person having origins in any of the original peoples of North and South America (including Central America) and who maintains tribal affiliation or community attachment.
	  ○ **Asian:** A person having origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent including, for example, Cambodia, China, India, Japan, Korea, Malaysia, Pakistan, the Philippine Islands, Thailand, and Vietnam.
	  ○ **Native Hawaiian or Other Pacific Islander:** A person having origins in any of the original peoples of Hawaii, Guam, Samoa, or other Pacific Islands.
	  ○ **Black or African American:** A person having origins in any of the Black racial groups of Africa.
	  ○ **White:** A person having origins in any of the original peoples of Europe, the Middle East, or North Africa.

Gender	• This response must be self-reported by the participant.
	• Site staff are encouraged to document in chart notes if the participant, during study participation, prefers to be referred to by a specific pronoun or gender.
	• Gender is the social part of being male or female, and related to self-identity. Below are descriptions of each gender category:
	  ○ Gender nonconforming/Gender variant: A person whose gender expression is different than gender norms and does not "fit" the man/woman categories, regardless of their gender identity or sexual orientation.
	  ○ Genderqueer:
	  ○ Man: A person who identifies their gender as male.
	  ○ Transgender Man (also known as trans man): A person who was assigned female sex at birth, but whose gender identity is male or trans*male.
	  ○ Transgender Woman (also known as trans woman): A person who was assigned male sex at birth, but whose gender identity is female or trans*female.
	  ○ Woman: A person who identifies their gender as female.
	  ○ Additional identity, please specify: Record any additional gender reported by the participant.
	  ○ Decline to answer.

Field	Instructions
How do you define your sexual orientation?	Below are descriptions of each sexual orientation: • Bisexual: A person attracted to both the same and different gender(s) than oneself. • Gay/Lesbian/Homosexual: A person attracted to the same gender as oneself. • Queer: An umbrella term for a person from sexual and gender minorities who are not heterosexual. • Two spirit: A person who identifies as having both a masculine and a feminine spirit and is used by some Indigenous people to describe their sexual, gender and/or spiritual identity. • Straight/Heterosexual: A person attracted to a different gender than oneself. • Additional identity: Record any additional sexual orientation reported by the participant. Record what the participant reports in the "If "Additional identity", specify:" field. • Not sure • Prefer not to answer

Hematology

Purpose: This form documents participant's local lab test results.

General Instructions:
Select your local laboratory from the drop-down list at the top of the form. This is required to populate the appropriate reference ranges for your site.

NOTE: The fields for lab analyte values (for example: WBC) are located at the bottom of form.

Field-specific Instructions:

Field	Instructions
Collection date	Record the date that the specimen was *collected*, not the date results were reported or recorded on the form.
Severity grade	• Select laboratory value severity grade according to the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events*, most current version. • Select "Not gradable" for a value that does not meet grading criteria.

Hepatitis Test

Purpose:
This form documents a hepatitis test results.

General Instructions:
For each test type, select one of:

- Not done
- Not detected/Negative

- Positive/Reactive
- Invalid
- Indeterminate

HIV Test Results

Purpose:
This form is used to document HIV testing results.

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

Field-specific Instructions:

Field	Instructions
Was HIV testing performed?	Select “Yes” if at least one of HIV Raid Testing or HIV Laboratory Testing was performed. Select “No” if no HIV testing was performed.
Where was HIV testing performed?	Record whether the specimen used for HIV testing was collected on the van or if the HIV test results are from an outside source such as another clinic or doctor’s office.
HIV Rapid 1 specimen collection date	If HIV Rapid 1 testing was performed, record the date the sample was collected for rapid testing.
HIV Rapid 1	Select “Not done” if HIV Rapid testing was not performed, otherwise, record the testing outcome.
HIV laboratory based testing specimen collection date	If HIV laboratory based testing was performed, record the date the sample was collected for laboratory based testing.
HIV EIA or CMIA	Select “Not done” if HIV EIA CMIA testing was not performed, otherwise, record the testing outcome.
HIV 1/2 Discriminatory Assay Result	Select “Not done” if HIV 1/2 Discriminatory Assay testing was not performed. Select “Assay result not provided” if the laboratory did not provide the assay results. Otherwise, record the testing outcome.
HIV-1 RNA	Select “Not done” if HIV-1 RNA testing was not performed, otherwise, record the testing outcome.
Final HIV status	Select “Additional testing needed” if a rapid test was performed but laboratory based testing was not performed, otherwise, record the testing outcome.

Informed Consent

Purpose:
This form documents the date the participant signed the Informed Consent form.

General Instructions:

- Complete and submit this form for participants who have signed a study-specific consent form, regardless if they enroll in the study.
- Add a log line for each additional consent form that is signed. Examples: participant signed partial consents on different dates (i.e. enrollment consent on one day and long term specimen storage on another), participant transferred to a new site and signed a consent at the receiving site, a new version of the protocol requires a new consent to be signed by the participant.

Field-specific Instructions:

Field	Instructions
Date initial informed consent signed	Record the date participant signed the initial informed consent form. A complete date is required.
Initial informed consent version	Record the version of consent that was signed by the participant.
Types of consents signed on this date	Mark the types of consent signed on the initial signing date
Additional Informed Consents	• Complete a log line for each additional informed consent that the participant signs. • After the first log line is saved, the add log line option will appear.

Interim HIV Test

Purpose:
This form is for any time a participant or clinician requests an interim HIV test at the site. **Complete this form for HIV tests performed at an HPTN-approved lab only.**

General Instructions:
Available by checkbox on the Date of Visit form and Interim Visit form.

Field-Specific Instructions:

Field	Instructions
Missed regularly scheduled visit	Participant missed a regularly scheduled visit and the participant or clinician feels HIV testing is warranted.
Redraw requested	An HIV test was done previously, but a re-test is requested.
Recent or possible exposure	• Review each item under "Recent and possible exposure" with the participant and mark all items that apply. • If applicable, mark "Other" for possible exposures that are not listed and describe them in the "Other, specify" box. • **NOTE:** Sexual contact refers to penetrative penile-vaginal sex (when a penis is put into the vagina) or penetrative penile-anal sex (when a penis is put into the anus. Anus refers to the hole that feces pass through.

Interim Visit

Purpose:
This form is used to summarize information from each participant at an interim visit and to record all procedures or assessments the participant received at any interim study visit.

General Instructions:

- This form is required for each interim visit completed for a participant.
- Use the "Add Event" feature to dynamically create the Interim Visit folder, which will add an Interim Visit Summary eCRF to the participant's casebook within the applicable Interim Visit folder.
- NOTE: Interim visits that do not result in study data should not be entered into the database. For example, if the participant comes into the clinic just to receive lab results, the visit resulted in no study data, so no interim visit should be entered in the database.

Field-specific Instructions:

Field	Instructions
Interim visit code	Interim visits are numbered in sequential order referring to the last visit completed. For example, if the last scheduled visit was V3.0, the first interim visit that occurs between V3.0 and V4.0 would be coded "3.01". If the participant came in for another interim visit between visits 3.0 and 4.0, it would be coded "3.02".
What is/are the reason(s) for this interim visit?	Mark at least one reason for the interim visit.
Forms completed at interim visit.	Select the forms needed for the interim visit. The selected forms will load into the interim visit folder upon saving.

Medical History Y/N

Purpose:
This form is used to trigger the Medical History log.

General Instructions:
This form is in the "Ongoing Logs" folder and is only completed once, at the time the first medical history condition/event is reported or at the end of screening if no medical history conditions/events are reported.

Field-specific Instructions:

Field	Instructions
Does the participant have any medical history to report?	• If "Yes" is selected, the **Medical History** log is added to the "Ongoing Logs" folder. • At the end of screening, mark "No" if no medical history was reported.

Medical History

Purpose:
This form documents a snapshot of the participant's medical history at enrollment.

General Instructions:
- Record only medical conditions/events experienced up to enrollment.
- Include current medical conditions/events and any ongoing conditions such as mental illness, alcoholism, drug abuse, and chronic conditions (controlled or not controlled by medication).
- Complete one log line for each medical history condition/event.
- Add additional log lines by clicking "Add a new Log line".
- If a participant recalls additional medical history after enrollment, update the **Medical History** log by adding a new log line.
- Do not update existing log lines after the Enrollment Visit.

Field-specific Instructions:

Field	Instructions
Description of medical history condition/event	Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, record each symptom as a separate entry on the Medical History log. 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."
Is condition/event gradable?	Mark "Yes" if the condition is active at the time of enrollment **AND** meets grading criteria per *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events*, most current version. Mark "No" if the condition is not active at the time of enrollment **OR** does not meet grading criteria per *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events*, most current version.

Field	Instructions
Severity grade	• Grade the severity according to the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events*. • Record the severity grade of the condition/event at the time of enrollment. ○ Example: left ankle sprain that was initially grade 3 (severe) during screening, but grade 1 (mild) upon enrollment, to be reported as grade 1 (mild). • If the severity grade has increased or decreased in severity or frequency during the study AE reporting period, then report the change as an AE. The Severity Grade should remain unchanged on the **Medical History** log. • If the severity grade increased or decreased **on or prior to** Enrollment, this should be updated on the **Medical History** log as needed. • If the condition/event improves in severity or resolves during the study, the Severity Grade should remain unchanged on the **Medical History** log.
Start date of medical history condition/event	• If the participant is unable to recall the date, obtain participant's best estimate. • At a minimum, the year is required. If the date is within the same year as study enrollment, the month and year are both required. • If the condition is diagnosed due to an abnormal lab result, record the date on which the specimen was collected. If a specimen collection date is not available, record the date of onset of condition.
Is the condition ongoing?	Review and update conditions marked "ongoing" on or prior to Enrollment.
Date medical history condition/event ended/resolved	At a minimum year is required. • Record the date the medical condition was considered resolved. • For surgeries/procedures, record the date the surgery/procedure was completed. • If the condition resolves during the study, the Medical History form should not be updated with a resolution or end date for the medical condition

Medication for Opioid Use Disorder

Purpose:
This form documents all Medications for Opioid Use Disorder (MOUD) that is used by the participant during the study.

General Instructions:

- Complete one log line for each reported MOUD.
- Add additional log lines by clicking "Add a new Log line".
- At each scheduled visit:
  - Update "Stop date" if previously reported medication was discontinued by the participant.
  - Enter any new medications on a new log line.
  - If participant is not currently taking medication, add a new log line and answer the first two questions.
- Document induction periods of MOUD separately than the continuing use. To document the dose of MOUD prescribed during the induction period, the "date started" should be the first date of induction, the "date stopped" should be the last date of induction, and the dose should be the highest daily dose of MOUD provided during the induction period.

- When prescribing combination buprenorphine/naloxone product, the record the dose of the buprenorphine component only. Example: For an 8mg buprenorphine/2mg naloxone film, the dose recorded will be 8mg.

Field-specific Instructions:

Field	Instructions
Is the participant currently taking MOUD?	• If "Yes", skip to "Medication" and answer the following items regarding the current medication: ○ Medication ○ Dose ○ Dose units ○ Frequency ○ Route ○ How was MOUD obtained ○ Date started If "No", answer "Since the previous visit has the participant taken MOUD?"
Since the previous visit has the participant taken MOUD? (At Enrollment visit ask if the participant has ever taken MOUD)	• If "Yes", answer the following items regarding past medication: ○ Medication ○ Dose ○ Dose units ○ Frequency ○ Route ○ How was MOUD obtained ○ Date started ○ Date stopped ○ Stop/Refusal Code 1 • If "No", go to "Stop/Refusal Code 1" and select reason participant did not take medication.
Date Started	At least year is required.
Date Stopped Or Continuing at end of study	• If the participant discontinued a medication that was reported on the log, enter the stop date. At least year is required. • If the participant terminates but is continuing the medication after termination (to the best of the site's knowledge), leave "Date Stopped" blank and mark "Continuing at end of study".
Stop/Refusal Code 1 Stop/Refusal Code 2 Stop/Refusal Code 3	Enter up to 3 reasons why the participant discontinued a medication or refused to start a medication.

Missed Visit

Purpose:
This form documents that a required visit was missed and the reason for the missed visit.

General Instructions:
Complete when a participant misses a required visit according to the protocol. A Missed Visit form will be added to the visit folder if the response to "Did the participant complete this visit?" is "No" on the Date of Visit form.

Field-specific Instructions:

Field	Instructions
Target visit date	Record the visit **target** date specified in the protocol.
Reason visit was missed	• Select the reason that the participant missed the visit from the drop-down list. • If the reason that the participant missed the visit cannot be captured by one of the available options, select "Other".

Navigation Session Y/N

Purpose:
This form is used to trigger the Navigation Session log.

General Instructions:
This form is in the "Ongoing Logs" folder and is only completed once, at the time the first navigation session is reported or at the end of the study if no navigation sessions are reported.

Field-specific Instructions:

Field	Instructions
Did the participant have any navigation sessions during the study?	• If "Yes" is selected, the **Navigation Session** log is added to the "Ongoing Logs" folder. • At the end of screening, mark "No" if no navigation sessions were reported.

Navigation Session

Purpose:
This form is used to document navigation sessions.

General Instructions:
Complete this form after each navigation session.

OUD Test Results

Purpose:
This form is used to document testing for MOUD and substance use.

General Instructions:
For each substance listed, answer:

- Not done (If that substance was not tested for)
- Not detected/Negative
- Detected/Positive/Reactive
- Equivocal
- Invalid
- Indeterminate

Participant Identifier

Purpose:
This form generates a PTID for the participant. Complete this form first for each participant.

Field-specific Instructions:

Field	Instructions
Participant ID	• To add a participant to the study database, select the “Add Subject” link on the site-specific home page for the study. The Participant Identifier form will appear. • No data entry is required on this form. • Click the “Save” button at the bottom of the form. A pop-up box will appear to indicate that a participant has been added to the database. The participant’s home page will appear. • The PTID will appear on each form in the participant’s casebook.

Participant Receipt

Purpose:
This form documents when a transferred participant has signed informed consent at the receiving study site.

General Instructions:

- The participant will retain the PTID assigned by the original study site. **Do not assign a new PTID.**
- Receiving site will gain access to the participant’s electronic casebook after the transfer procedures are complete at the transferring site.
- The receiving site adds the Participant Receipt form to the visit folder by marking it on the Date of Visit form or Interim Visit form.
- The Participant Receipt form must be added to the same visit folder as the corresponding Participant Transfer form.

Participant Transfer

Purpose:
This form documents when a participant is permanently transferring to another study site.

General Instructions:
- The transferring site adds the Participant Transfer form to the appropriate visit folder by marking it on the Date of Visit form or Interim Visit form.
- For more information, refer to the Study-Specific Procedures (SSP) manual and/or Manual of Operations (MOP).

Field-specific Instructions:

Field	Instructions
Date participant's records were sent to receiving study site	Enter the date that the source documents were sent from the transferring site to the receiving site.

Pre-Exposure Prophylaxis

Purpose:
This form documents all Pre-Exposure Prophylaxis (PrEP) medication that is used by the participant during the study.

General Instructions:
- Complete one log line for each reported PrEP medication.
- Add additional log lines by clicking "Add a new Log line".
- At each scheduled visit:
  - Update "Stop date" if previously reported medication was discontinued by the participant.
  - Enter any new medications on a new log line.
  - If participant is not currently taking medication, add a new log line and answer the first two questions.

Field-specific Instructions:

Field	Instructions
Is the participant currently taking PrEP?	• If "Yes", skip to "Medication" and answer the following items regarding the current medication: ○ Medication ○ Dose ○ Dose units ○ Frequency ○ Route ○ How was PrEP obtained ○ Date started If "No", answer "Since the previous visit has the participant taken PrEP?"

Since the previous visit has the participant taken PrEP? (At Enrollment visit ask if the participant has ever taken PrEP)	• If "Yes", answer the following items regarding past medication: ○ Medication ○ Dose ○ Dose units ○ Frequency ○ Route ○ How was PrEP obtained ○ Date started ○ Date stopped ○ Stop/Refusal Code 1 • If "No", go to "Stop/Refusal Code 1" and select reason participant did not take medication.
Date Started	At least year is required.
Date Stopped Or Continuing at end of study	• If the participant discontinued a medication that was reported on the log, enter the stop date. At least year is required. • If the participant terminates but is continuing the medication after termination (to the best of the site's knowledge), leave "Date Stopped" blank and mark "Continuing at end of study".
Stop/Refusal Code 1 Stop/Refusal Code 2 Stop/Refusal Code 3	Enter up to 3 reasons why the participant discontinued a medication or refused to start a medication.

Pregnancy Outcome

Purpose:
This form documents a pregnancy outcome.

General Instructions:
- This form is required for each reported pregnancy or positive pregnancy test.
- Use the "Add Event" feature to dynamically create the "Pregnancy" folder, which will add a Pregnancy Outcome eCRF to the participant's casebook within the Pregnancy folder.

Field-specific Instructions:

Field	**Instructions**
How many pregnancy outcomes resulted from this reported pregnancy?	A pregnancy outcome can be an infant or fetus. If the pregnancy results in two or more outcomes, complete a Pregnancy Outcome log line for each outcome.
Specify outcome	Refer to the protocol and applicable version of the *Manual for Expedited Reporting of Adverse Events to DAIDS* to evaluate if the

Field	Instructions
	outcome or any maternal complications meet AE and/or EAE reporting requirements.
Were any fetal/infant congenital anomalies identified?	• If "Yes", report as an adverse event with "Congenital anomaly in offspring" as the adverse event. Record "Outcome date" on this form as the AE "Onset date" and note the specific anomaly in "Comments". • Refer to the protocol and applicable version of the *Manual for Expedited Reporting of Adverse Events to DAIDS* to evaluate if the outcome or any maternal complications meet AE and/or EAE reporting requirements.

Pregnancy Report

Purpose:
This form is used to document pregnancies that occur between study enrollment and termination.

General Instructions:

- This form is required for each reported pregnancy or positive pregnancy test.
- Use the "Add Event" feature to dynamically create the "Pregnancy" folder, which will add a Pregnancy Report eCRF to the participant's casebook within the Pregnancy folder.

Field-specific Instructions:

Field	Instructions
Date of onset of last menstrual period	Record best estimate if date not known.

Pregnancy Test Results

Purpose:
This form documents pregnancy test results.

Field-specific Instructions:

Field	Instructions
Was a pregnancy test done?	If "No" end of form.
Collection time	Defined as time the sample was taken.
Pregnancy test result	If participant is pregnant (tests positive): • Complete **Pregnancy Report** form • Complete **Pregnancy Outcome** form

Protocol Deviation

Purpose:
This form documents and reports protocol deviations identified for study participants.

General Information/Instructions:
- Complete one log line for each protocol deviation.
- Add additional log lines by clicking "Add a new Log line".
- Refer to the Protocol Deviations and Critical Events MOP section for further guidance.
- Consult the **HPTN Clinical Research Manager** (CRM) as needed to confirm whether the event qualifies as a protocol deviation.

Item-specific Instructions:

Field	Instructions
Site awareness date	Record the date the site became aware of the deviation. (Example: The date the site discovered the deviation, the date the monitor notified the site of a deviation, etc.)
Deviation date	Record the date the deviation occurred (start date). (Example: The date of procedures conducted outside of the visit window, the date a participant was inappropriately enrolled, etc.)
Type of deviation	• Record the applicable deviation by selecting from the list of available options. • Record "other" and specify in space provided if none of the listed options match. • Please see table below for a listing and description of incident types.
Deviation reported by	Enter name of staff member that reported the deviation

REPORTABLE INCIDENT LIST	
Deviation Type	**Description/Examples**
Inappropriate enrollment	The participant enrolled and not all eligibility requirements were met.
Failure to follow randomization or blinding procedures	Includes instances where randomization procedures were not followed by site staff, or product blinding procedures were not followed by pharmacy staff.
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.
Improper SAE	A SAE is not followed per protocol. For example, a clinical finding/lab result is not re-assessed as outlined in the protocol.

Unreported SAE	Site staff became aware of a SAE but did not report it per protocol requirements.
Breach of confidentiality	Includes potential and actual cases where participant confidentiality was breached. For example, a staff member put a participant's name on a case report form.
Physical assessment deviation	Includes when a protocol-specified exam or assessment was not performed.
Lab assessment deviation	Includes when a protocol-specified safety lab or necessary follow-up laboratory test was not collected or reported to the participant (e.g. HIV testing).
Staff performing duties that they are not qualified to perform	Includes any instances when any study procedure, including clinical and administrative procedures, was completed by a staff member who is not adequately qualified AND delegated to perform the procedure.
Use of non-IRB/EC-approved materials	Includes use of ANY study-related material that has not received IRB or EC approval for use per site requirements.
Informed consent process deviation	Includes failure to accurately execute and/or document any part of the informed consent process.

Prior Medication Use

Purpose:
This form documents the participant's full history of medication use (ART, PrEP, and MOUD).

General Instructions:
Complete this form at enrollment. Check off every medication that the participant has used prior to enrolling into the study.

Randomization

Purpose:
This form generates the participant's treatment assignment in Medidata RTSM.

Field-specific Instructions:

Field	Instructions
Is the participant ready to be randomized?	• Respond "Yes" and save the form to randomize the participant. When a participant is successfully randomized, the below text will appear on the eCRF: Subject: **998130659** Page: **Randomization - V2.0 - Day 0/Enrollment (1)** Is the participant ready to be randomized? Subject successfully randomized. • If successful, the participant is assigned to a treatment arm. • If randomization was not successful, this message will not appear. • For additional guidance please refer to the Randomization SSP.

Receipt of Community Services

Purpose:
This form is used to document participant's successful transfer all care to existing facilities in the community.

General Instructions:
Complete for all participants at week 26 and 52.

Field-specific Instructions:

Field	Instructions
At the 26 week/52 week visit, was the participant receiving ART from a provider in the community?	Leave blank for participants who did not test positive for HIV during the first 26 weeks of the study
At 26 week/52 week visit, was the participant receiving PrEP from a provider in the community?	Leave blank for participants who tested positive for HIV during the first 26 weeks of the study

Screening and Enrollment

Purpose:
This form is used to document the participant's enrollment status after screening.

General Instructions:

- Complete for all participants who have signed a study-specific informed consent form, regardless if they enroll in the study or not.

- Create a new PTID for each screening attempt.

Field-Specific Instructions:

Field	Instructions
Enter the first RAVE PTID assigned	If the participant has screened previous, enter the PTID that was assigned for the previous screening attempt.
Eligibility status	• Eligible and enrolled: Participant met all eligibility criteria and enrolled in the study. • Eligible/Not enrolled: Participant met all eligibility criteria but did not enroll in the study. • Ineligible: Participant did not meet eligibility criteria. • Incomplete screening: One or more eligibility criteria was not assessed.
Enrollment date	• A complete date is required. Enrollment date is the date the participant was randomized. • If enrolled and “Enrollment date” is entered, no further data is required for this form.
Study arm	This field auto-populate after randomization. No data entry is required.
Date participant was found "Eligible/Not Enrolled" or "Ineligible"	Enter the date the site determined the participant would not enroll.
Select reason(s) why participant is "Eligible/Not Enrolled" or "Ineligible".	• If participant was eligible but did not enroll in the study or is deemed “Ineligible”, select the reason from the drop down menu. • If there is more than one reason, click on the “Add a new Log line” and select the other reason(s). You can add as many log lines as necessary.

Serious Adverse Event Y/N

Purpose:
This form is used to trigger the Serious Adverse Event log.

General Instructions:
This form is in the “Ongoing Logs” folder and is only completed once, at the time the first adverse event is reported or at the end of the study if no adverse events are reported.

Field-specific Instructions:

Field	Instructions
Has the participant experienced a serious adverse event during the study?	• If “Yes” is selected, the **Serious Adverse Event** log is added to the Ongoing Logs folder. • At the end of study participation, mark “No” if no serious adverse events have occurred.

Serious Adverse Event

Purpose:
This form documents Serious Adverse Events (SAEs) reported by the participant or clinically observed as defined by the protocol.

General Instructions:

- Complete one log line for each serious adverse event.
- Add additional log lines by clicking “Add a new log line”.
- Only list conditions that start on or after enrollment date, otherwise record as medical history.
- Record increases in severity/frequency as new events with corresponding start/stop dates.
- Serious adverse events should be reassessed and updated as applicable. For example, when a SAE resolves, the status/outcome should be updated.

Field-specific Instructions:

Field	Instructions
Serious adverse event (SAE)	• Describe the SAE using medical terminology. • Record a diagnosis/anatomical location if available. • For lab abnormalities, format is (increased/decreased [test name]).
Onset date	At minimum, month and year are required. Record one of the following, as appropriate: • The date on which the participant reports first experiencing the SAE. • If the SAE is discovered during a study visit, record the date of the study visit. • If the SAE is an abnormal lab result, record the date on which the specimen was collected.
If "No", outcome date	At minimum, month and year are required. Record one of the following as appropriate: • The date on which the participant no longer experienced the SAE. • The date of the study visit or specimen collection at which the change in status/outcome is first noted.
Severity grade	Record the severity grade using the most current version of the *Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events* (including relevant appendices/addendums). • Grade 1 (Mild) • Grade 2 (Moderate) • Grade 3 (Severe) • Grade 4 (Potentially life-threatening) • Grade 5 (Death)

Field	Instructions
Status/Outcome	• ***Recovered/Resolved:*** SAE is no longer present or returned to the pre-enrollment severity/frequency. If a participant is taking a medication to control an SAE that arose during study participation, it is not considered resolved. • ***Recovering/Resolving:*** AE is continuing and has not yet resolved or returned to baseline severity/frequency. • ***Recovered/Resolved with sequelae:*** Participant has recovered from the SAE, but with remaining effects or impairment. • ***Not recovered/Not resolved:*** The participant has not recovered and the SAE is not resolved at the time of study termination. • ***Fatal:*** Severity of this SAE is Grade 5 (Death). Update any other SAEs continuing at the time of death to "Not recovered/Not resolved." • ***Severity/Frequency increased:*** SAE increases in severity or frequency after it has been reported on the SAE Log: o On the original SAE log line, update the "Status/Outcome" field to "Severity/Frequency increased." Record the date of increase in the "Outcome date" field. o Add a new log line to report the increase in severity or frequency. For this new SAE, the "Onset date" will be the date that the severity or frequency increased. o Update SAE form if applicable. Note: Do not record decreases in severity as a new SAE. Instead, update the "Status/Outcome" field on the original SAE log line to "Recovering/Resolving."
Relationship to study product	Mark the assessment of the relationship between the SAE and the study product. • "Related" - reasonable possibility that the SAE may be related to the study product. • "Not related" - not a reasonable possibility that theS AE is related to the study product. Record pertinent details for relationship assessment in "Comments". For more information, refer to the *Manual for Expedited Reporting of Adverse Events to DAIDS,* most current version.
EAE number	If reported as an EAE, provide the EAE number and complete any subsequent updates to this form on the applicable EAE form.
Comments	• Record pertinent details for relationship assessments. • Record pertinent clinical information.

Social Impact Y/N

Purpose:
This form is used to trigger the Social Impact log.

General Instructions:
This form is in the "Ongoing Logs" folder and is only completed once, at the time the first social impact is reported.

Field-specific Instructions:

Field	Instructions
Has the participant experienced any social impacts related to study participation?	• If "Yes" is selected, then the **Social Impact** log loads in the "Ongoing Logs" folder. • At the end of study participation, mark "No" if no social impacts have occurred.

Social Impact

Purpose:
This form documents social impacts reported by the participant as defined by the protocol.

General Instructions:
- Complete one log line for each reported social impact associated with study participation.
- Add additional log lines by clicking "Add a new Log line".

Field-specific Instructions:

Field	Instructions
Onset date	Record the date the social impact first started.
Reported at Visit Code	Record the visit number at which the social impact was reported. If a participant reports a social impact outside of a regularly scheduled visit, code as an interim visit.
Social Impact	Record the applicable social impact by selecting from the list of available options. See table below for the list and description of social impacts.
What impact has this situation had on the participant's quality of life?	Assess the impact of the social harm on the participant's quality of life based on participant self-report.
Record current status	Update this field at subsequent visits as needed.

Specimen Collection

Purpose:
This form documents research specimen collection.

General Instructions:
Do not use this form to document any local lab specimens. Use this form only to document the collection of research specimens that will be sent to the site processing lab.

Field-specific Instructions:

Field	Instructions
Plasma; Dried Blood Spot for PK; Serum; Urine	For each type of specimen, answer all questions on the log line.

STI/GTI Test Results

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.

Field-specific Instructions:

Field	Instructions
Specimen Collection date	• Record the date that the specimen was collected, NOT the date the result was reported or recorded on the form for this visit. A complete date is required. • If specimens were collected on multiple dates, mark "Mark if a new STI/GTI Test Results eCRF is required to complete specimen collection requirements for this visit." at the bottom of the form to add another form for the next date that specimens were collected.
Syphilis Testing Not done/ Not collected	• Mark this box if no syphilis testing was completed • Leave the rest of the syphilis section blank and go to "N. Gonorrhea and C. Trachomatis"
Treponemal Non-Treponemal Second Treponemal test	For each test, select one of: • Not done • Not detected/Negative • Positive/Reactive • Invalid • Indeterminate
N. gonorrhea and C. trachomatis	For each test in the N. gonorrhea and C. trachomatis field, mark: • Not done • Not detected/Negative • Positive/Reactive • Invalid • Indeterminate

Field	Instructions
Mark if a new STI/GTI Test Results eCRF is required to complete specimen collection requirements for this visit.	Mark this box to add another STI/GTI Test Results eCRF to the visit folder. A second eCRF should be used if specimens were collected on separate dates for STI/GTI testing or any tests were repeated within the visit window.

Study Co-Enrollment

Purpose:
This form documents participant's co-enrollment in another interventional research study.

Field-specific Instructions:

Field	Instructions
Has this participant enrolled in another interventional research study since enrolling in HPTN 094?	Answer "Yes" if since the time of enrollment, the participant newly enrolled in another interventional research study.

Study Termination

Purpose:
This form documents participant's termination from the study.

General Instructions:

- Complete once for every participant at the time of early study termination or at the final study visit.
- This form is in the Discontinuation folder.

Field-specific Instructions:

Field	Instructions
Primary reason for completion/discontinuation	• Scheduled exit visit/end of study: Select this reason if the participant has completed all protocol required visits. • Early study closure: Only select this reason when instructed by SCHARP.

Change History

Summary of Changes to Study DMP

Version		Affected Section(s) or Form(s)	Summary of Revisions
Number	Date		
1.0	15Apr2021		Original CCG's
1.1	10May2021	Couple Tracking Social Impact Y/N Social Impact	Added 3 forms to study
1.2	18Aug2021	Receipt of Community Services Study Co-Enrollment	Added 2 forms to study
1.3	23Sep2021	Medication for Opioid Use Disorder	Added further instructions for recording induction periods and combination buprenorphine/naloxone dose
1.4	23Jun2023	Current Medication Use Prior Medication Use	Added 2 forms to study