



HPTN CRF Completion Guidelines
HPTN 096

Approved



CRF Completion Guidelines

Protocol Name:	<i>Getting to Zero among Highest HIV Incidence (HHI) Men who have Sex with Men (MSM) in the American South: Testing an Integrated Strategy</i>
Protocol Number:	<i>HPTN 096</i>
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Definition and Abbreviations

Term / Abbreviation	Definition
AE/SAE	Adverse Event/Serious Adverse Event; any untoward medical occurrence that meets reporting criteria as defined in the protocol.
CASI	Computer Assisted Self-Interview; format of participant-driven survey administration via private computer interface. This format is designed to minimize interviewer influence on sensitive responses via confidential, direct entry of self-report data.
CDM/LCDM	Clinical Data Manager/Lead Clinical Data Manager
CRF/eCRF	Case Report Form / Electronic Case Report Form; A tool used to collect data from each participant.
CRM	Clinical Research Manager
DAIDS	Division of AIDS; develops and implements the national research agenda to address the HIV/AIDS epidemic. DAIDS supports a global research portfolio on HIV/AIDS, its related co-infections, and co-morbidities.
EAE	Expedited Adverse Event; an adverse event that must be reported in an expedited manner to DAIDS to fulfill its regulatory obligations as a sponsor.
eCOA	Electronic Clinical Outcomes Assessment; a Medidata module that enables participants to submit study data using an iOS or Android app.
EDC/RCC	Electronic Data Capture; A computerized system designed for the collection of clinical data in electronic format for use in clinical trials.
GCP	Good Clinical Practices; a standard for the design, conduct, performance, monitoring, auditing, recording, analysis, and reporting of clinical studies that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of study participants are protected.
ICH	International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use; an initiative that brings together regulatory authorities and pharmaceutical industry to discuss scientific and technical aspects of pharmaceutical product development and registration.

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Term / Abbreviation	Definition
IoR	Investigator of Record; responsible for supervising the conduct of the study and documenting the accuracy of eCRFs by applying their electronic signature.
MOP	Manual of Procedures; the HPTN MOP describes the structure; operating policies; roles and responsibilities of entities and individuals within the HPTN; protocol development and approval processes; standardized study operations procedures; data and specimen collection and processing procedures; and quality management, monitoring and evaluation of trials conducted by the HPTN.
OMB	Office of Management and Budget; office of the United States government that oversees the performance of federal agencies and administers the federal budget. Produces the Standards for the Classification of Federal Data on Race and Ethnicity.
Participant Casebook	Each individual participant's data within an EDC system.
PI	Principal Investigator; see IoR.
PTID	Participant Identifier; a study-specific numerical identifier assigned to each participant.
RTSM	Randomization and Trial Supply Management; Medidata module that randomly assigns participants to treatment groups.
SSP	Study Specific Procedure; a document developed for each study that provides detailed and standardized instructions for conducting protocol-specified procedures.

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 REDCap Cloud (RCC) is provided in the Study Specific Procedures (SSP), which is found on the HPTN 096 study page:

<https://www.hptn096.org/hcf/>

General Guidelines

- The Participant ID is generated by RCC and is unique to each site.
- All data entered in RCC must match the data on any source documents/paper CRFs.

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- 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 system generated error will appear.
- Visit dates must be complete and in chronological order according to the protocol.
- Most date fields require a complete date and 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.
- Log forms allow you to make multiple entries over the course of the cross-sectional assessments. The following CRFs are log forms for this study:
 - STI Diagnosis Log
 - ART Medication Log
 - HIV RNA Results Log
 - Retention In Care Log
 - PrEP Log
 - Medical Visits Log
- There 2 logs that are applicable to the entire HPTN 096 study and used for multiple components, not just the cross-sectional assessment. Those logs can be found in the site “Study Logs” and located in a single PTID (there are no other PTIDs for this site):
 - Social Harms
 - Protocol Deviations
- 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 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.

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- 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 have 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.

Loading Forms in Visit Folders

- Forms are added to visit folders in a participant's casebook based on specific responses on the Enrollment CRF. Below are a few key examples.
 - **Example:** Not Living with HIV
 - If the question "What is the Participant's current HIV status" is marked "Not Living with HIV", forms will be added to the visit folder for completion.

General Guidelines – Paper CRF Completion

CRF PDFs are generated from RCC 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.
 - NA 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.

Recording Dates – RCC 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 and "yyyy" represents the four digits of the year.
- Month abbreviations are shown below. In RCC EDC, these abbreviations are in a drop-down list in the month field.

Month	Abbreviation	Month	Abbreviation
January	Jan	July	Jul

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February	Feb	August	Aug
March	Mar	September	Sep
April	Apr	October	Oct
May	May	November	Nov
June	Jun	December	Dec

For example, record September 20, 2016 as:

Recording Time - RCC 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	12-hour clock (p.m.)	24-hour clock
Midnight	00:00	Noon	12:00
1:00 a.m.	01:00	1:00 p.m.	13:00
2:00 a.m.	02:00	2:00 p.m.	14:00
3:00 a.m.	03:00	3:00 p.m.	15:00
4:00 a.m.	04:00	4:00 p.m.	16:00
5:00 a.m.	05:00	5:00 p.m.	17:00
6:00 a.m.	06:00	6:00 p.m.	18:00
7:00 a.m.	07:00	7:00 p.m.	19:00
8:00 a.m.	08:00	8:00 p.m.	20:00
9:00 a.m.	09:00	9:00 p.m.	21:00
10:00 a.m.	10:00	10:00 p.m.	22:00
11:00 a.m.	11:00	11:00 p.m.	23:00

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

24-hour clock

Data Corrections and Additions - RCC 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 RCC.
- 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:

Yes ~~mp 01-Aug-16~~
 No

- 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:


Yes ~~mp 18-AUG-16~~
 No "should be YES" jb-20-AUG-16

- Use the standards below when changing, clarifying, or amending data in RCC:
 - 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.

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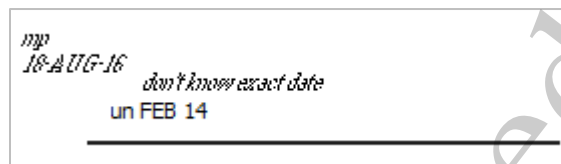
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- Click “Save” at the bottom of the form to save the changes.
- Otherwise, click “Cancel” to reset the form with the last saved data.
- Updated data fields will be marked with a delta icon: 

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

UN	Jul	2017	UN	UNK	2015
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Form-Specific Instructions

Enrollment

Purpose:

This form is used to enroll the participant and trigger the correct set of forms for their cohort.

General Instructions:

Complete this form first after subject creation as it will determine the cohort of the participant and populate the correct set of forms to be entered. This form is required for all participants.

Field-specific Instructions:

Field	Instructions
Screening ID	Enter the Screening ID the site used to screen the participant.
Date of Enrollment	Select the date of enrollment
Timepoint	Select the correct timepoint for enrollment.
Questions 1-7	Select "Yes" or "No" for each question. <i>Please note that these are also eligibility criteria. If "No" is selected for any of these questions, please contact FHI to confirm if the participant can be enrolled before you proceed.</i>
Confirm that the participant meets all eligibility criteria	Check the box to confirm eligibility. <i>If the participant is not eligible, do not enroll or complete the form.</i>
What is the Participant's current HIV status?	Select one of these options: <ul style="list-style-type: none"> • "Living with HIV" if the participant has tested positive for HIV. • "Not living with HIV" if the participant has not tested positive for HIV.
What is the participant's care history at this facility?	Only for participants "Living with HIV" Select one of these options: <ul style="list-style-type: none"> • "In Care: Has a medical visit within the past 6 months (Excluding this healthcare visit)" • "Gap in Service/New Client: Has not had a medical visit within the past 6 months (Excluding this healthcare visit)"
What is the Participant's current PrEP usage?	Only for participants "Not living with HIV" Select one of these options: <ul style="list-style-type: none"> • "Received or has an existing PrEP prescription at this healthcare visit"

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	<ul style="list-style-type: none"> “Did not receive or does not have an existing PrEP prescription at this healthcare visit”
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Informed Consent

Purpose:

This form is used to confirm consent of the participant for either the treatment or prevention surveys.

General Instructions:

Site staff may read the informed consent language to the participants or have them read it themselves. Once that is done, select either “Yes, I agree” or “No, I don’t agree” to complete the form. The participant must agree to complete the survey before the actual survey will populate depending on their response on the Enrollment form. If they do not agree, do not proceed with enrollment.

After this form is complete, please note that you may need to refresh or reload the CRF summary page in order to see the additional set of forms for each cohort.

Healthcare Facility Visit

Purpose:

This form documents the participant’s first medical visit at this facility.

General Instructions:

Enter/select the date of the participant’s first medical visit at this facility. If the date is unknown, check the box for unknown. Only complete one or the other, do not complete both the date and the unknown checkbox. This form is required for all participants.

STI Diagnosis Log

Purpose:

This form documents all STI diagnoses and test results in the past 12 months. This form is required for all participants.

General Instructions:

- Complete one log line for each STI diagnosis.
- Add additional log lines by clicking “+ Add” in the upper right corner of the table.

Field-specific Instructions:

Field	Instructions
Are STI test results available in participant’s chart within the past 12 months?	Select “Yes” or “No” if test results are available within the past 12 months. <i>If “Yes”, complete the rest of the fields on the log form.</i>
STI test date	Enter/select the date of the STI test.

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STI test performed	Select the STI test performed from the dropdown list: Test options: Herpes Simplex Virus 1 (HSV-1), Herpes Simplex Virus 2 (HSV-2), Chlamydia, Gonorrhea, Hepatitis A, Hepatitis B, Hepatitis C, Syphilis, Trichomoniasis, HPV, Mpox, Other
If “Other”, specify	If “Other” was selected for the test performed, enter in the STI test.
STI Test Result	Select the test result from the options. <ul style="list-style-type: none"> • Not detected/Negative • Positive/Reactive • Invalid (e.g. something wrong with the test) • Indeterminate

HIV Diagnosis

Purpose:

This form documents the approximate date of first HIV diagnosis for the participant. This is only required for participants in the “Living with HIV” cohort.

General Instructions:

Enter the month and year of the participant’s first HIV diagnosis. If the date is unknown, please use their best guess. If only the season is known, use the beginning of the season (e.g. “summer”, enter June).

ART Medication Log

Purpose:

This form documents any ART medications prescribed and refilled by the participant in the past 12 months. This form is required for participants in the “Living with HIV” cohort.

General Instructions:

- Complete one log line for each ART medication.
- Add additional log lines by clicking “+ Add” in the upper right corner of the table.

Field-specific Instructions:

Field	Instructions
Has any ART medication been initially prescribed or refilled in the last year?	Select “Yes” or “No”. <i>If “Yes”, complete the rest of the fields on the log form.</i>
Medication name	Select the medication name from the dropdown list. If the medication is not listed, select “Other”.

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Field	Instructions
If "Other", specify	If "Other" is selected for "medication name", enter in the medication name.
Date of initial prescription or refill	Enter/Select the date of the prescription or refill. <i>If they were already on ART prior to visiting this facility, enter the initial prescription at your site.</i>
Is this medication part of the participant's current ART regimen?	Select "Yes" or "No" if the medication is part of their current ART regimen.

HIV RNA Results Log

Purpose:

This form documents HIV RNA viral load data within the past 12 months. This form is required for participants in the "Living with HIV" cohort.

General Instructions:

- Complete one log line for each HIV RNA viral load result.
- Add additional log lines by clicking "+ Add" in the upper right corner of the table.

Field-specific Instructions:

Field	Instructions
Are HIV RNA viral load results available in the participant's chart from within the past 12 months?	Select "Yes" or "No" if RNA viral load results are available within the last 12 months. <i>If "Yes", complete the rest of the fields on the log form.</i>
HIV RNA specimen collection date	Enter the date the sample was collected. (Do not enter the date results were received)

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HIV RNA Result	<p>Select one of the following options:</p> <ul style="list-style-type: none"> • Reportable viral load • Not Detected • Detected, under LLOQ • Detected, greater than ULOQ <p><i>For the Lower Limit of Quantification (LLOQ) and Upper Limit of Quantification (ULOQ) use the following:</i></p> <p>LLOQ: <20</p> <p>ULOQ: >10,000,000</p>
Operator	<p>Select one of the following options if “Reportable Viral Load” was selected for HIV RNA Result</p> <ul style="list-style-type: none"> • > (greater than) • < (less than) • = (equal to)
Viral Copies/mL	<p>If “Reportable Viral Load” was selected for HIV RNA Result, enter the HIV RNA PCR value in “viral copies/mL”</p>

Retention in Care Log

Purpose:

This form documents all of the participant’s medical visits within the last 12 months. This form is required for participants in the “Living with HIV” cohort.

General Instructions:

- Complete one log line for each medical visit.
- Add additional log lines by clicking “+ Add” in the upper right corner of the table.

Field	Instructions
Date of medical visit at enrollment	Enter/select the date of visit for enrollment in this study.
Are prior medical visits available in the participant’s chart?	<p>Select “Yes” or “No” if there are prior medical visits available within the last 12 months.</p> <p><i>If “Yes”, complete the rest of the fields on the log form.</i></p>

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Date of prior medical visit	Enter the date of the medical visit.
Primary reason for visit	Select one of the following options: <ul style="list-style-type: none"> • Initial HIV test (brand new) • HIV Follow-up Visit • STI Visit • Non-HIV prevention/STI-related Visit • Other
If "Other", specify	If "Other" is selected, enter in the reason for the visit.

HIV Test

Purpose:

This form documents participant's most recent HIV test.

General Instructions:

Enter the date and results of the most recent HIV test for the participant. This is required for all participants.

Field-specific Instructions:

Field	Instructions
Are HIV test results available in participant's chart?	Select "Yes" or "No" if there is a previous HIV test result. <i>If "Yes", complete the rest of the fields on the log form.</i>
Date of most recent HIV Test	Enter/Select the date of collection for the most recent HIV Test.
What is the confirmed result of this HIV test?	Select the result: <ul style="list-style-type: none"> • HIV-negative • HIV-positive

PrEP Log

Purpose:

This form documents all of the participant's pre-exposure prophylaxis (PrEP) prescriptions within the last 12 months. This form is required for participants in the "Not living with HIV" cohort.

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**General Instructions:**

- Complete one log line for each PrEP prescription.
- Add additional log lines by clicking "+ Add" in the upper right corner of the table.

Field	Instructions
Are PrEP prescriptions available in the participant's chart?	Select "Yes" or "No" if there are prior PrEP prescriptions. <i>If "Yes", complete the rest of the fields on the log form.</i>
Medication name	Select the medication from the list of options: <ul style="list-style-type: none"> • Descovy • Truvada • Apretude • Long-acting lenacapivir • Other
If "Other", please specify	If "Other" is selected, enter in the medication name.
Date started	Enter the date the participant started taking the medication.
Date stopped	Enter the date the participant stopped taking the medication. If currently taking it, leave this field blank.
Currently taking this prescription (as noted in chart)	If the participant is currently taking the medication, check this box.
Number of refills	Enter the number of available refills as noted on the prescription.

Medical Visits Log**Purpose:**

This form documents all of the participant's medical visits within the last 12 months. This form is required for participants in the "Not living with HIV" cohort.

General Instructions:

- Complete one log line for each medical visit.
- Add additional log lines by clicking "+ Add" in the upper right corner of the table.

Field-Specific Instructions:**CONFIDENTIAL DOCUMENT**

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Field	Instructions
Today's date	Enter/select the date of visit for enrollment in this study.
Are prior medical visits available in the participant's chart?	Select "Yes" or "No" if there are prior medical visits available within the last 12 months. <i>If "Yes", complete the rest of the fields on the log form.</i>
Date of prior medical visit	Enter the date of the medical visit.
Primary reason for visit	Select one of the following options: <ul style="list-style-type: none"> • PrEP initiation/Follow-up Visit • HIV Test Visit • STI Visit • Non-HIV prevention/STI-related Visit • Other
If "Other", specify	If "Other" is selected, enter in the reason for the visit.

Social Harms Log

Purpose:

This form is used to document any social harms reported for HPTN 096 from any component of the study.

General Instructions:

- This form is used for all components of the HPTN 096 study and is housed in site "Study Logs" and added to a single, dummy PTID.
- There is only 1 PTID for this site which will be used for all social harm entries.
- Navigate to the Social Harms Log, but clicking on the PTID and clicking on "Study Logs".
- Click on "Social Harms Log" to open the form.
- Complete one log line for each social harm.
- Add additional log lines by clicking "+ Add" in the upper right corner of the table.

Field-specific Instructions:

Field	Instructions
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Which study component is reporting the social harm?	<p>Select one of the following options:</p> <ul style="list-style-type: none"> • Participant in the cross-sectional assessment • PHASE • Health Access • Peer Support • Social Media
Participant ID (If no PTID, please leave blank)	<p>Enter the participant ID (PTID) from the study component which they belong to.</p> <p><i>If there is no PTID, leave blank.</i></p>
Form completion date	Enter the date that the log entry was completed.
Study community:	If applicable, enter the study community.
Staff member initials	Enter the initials of the staff member who reported the social harm.
Date social harm reported to study staff	Enter the date the study staff member was made aware of the social harm.
Concisely describe the social impact	Describe the social harm.
Onset date	Enter the date the social harm took place or began.
Please select the social impact	<p>Select an option from the dropdown menu:</p> <ul style="list-style-type: none"> • Personal Relationships - Had any negative experiences with family, friends, significant others, or sex partners • Travel/Immigration - Had problems obtaining formal permission to travel to or enter another country, such as being denied a visa, or had a problem with immigration/naturalization. • Employment - Been turned down for a job, lost a job, study visits interfering with work/work performance or experienced other problems at work. • Education - Been turned down by an educational program, told to leave an educational program, study visits interfering with school attendance/performance, or experienced other problems at school • Medical/Dental - Been told you have an HIV test by a health care provider, been refused medical or dental treatment or treated negatively by a health care provider. • Health Insurance - Lost health insurance, had a problem getting new health insurance, or experienced other problems related to health insurance.

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	<ul style="list-style-type: none"> Life Insurance/Funeral coverage - Lost your life insurance policy or funeral cover policy, had a problem getting new life insurance policy or funeral cover policy, or experienced other problems related to life insurance policy or funeral cover policy. Housing - Had trouble getting or keeping housing, had negative experience with landlord, or had other problems related to housing. Military/Other Government Agency - Had a problem with the military or any other government agencies Other - Had other problems not covered in the list above <p><i>Choose "Other" for any medically-related adverse events affiliated with the blood draw, e.g., fainting, severe bruising, etc.</i></p>
If "Other", please specify	If "Other" is selected, enter in the social harm.

Protocol Deviations Log

Purpose:

This form is used to document any protocol deviations reported for HPTN 096 from any component of the study.

General Instructions:

- This form is used for all components of the HPTN 096 study and is housed in site "Study Logs" and added to a single, dummy PTID.
- There is only 1 PTID for this site which will be used for all protocol deviations entries.
- Navigate to the Protocol Deviations Log, but clicking on the PTID and clicking on "Study Logs".
- Click on "Protocol Deviations Log" to open the form.
- Complete one log line for each protocol deviation.
- Add additional log lines by clicking "+ Add" in the upper right corner of the table.

Field-specific Instructions:

Field	Instructions
Which study component is reporting the protocol deviation?	Select one of the following options: <ul style="list-style-type: none"> Participant in the cross-sectional assessment PHASE Health Access Peer Support Social Media
Participant ID (If no PTID, please leave blank)	Enter the participant ID (PTID) from the study component which they belong to. <i>If there is no PTID, leave blank.</i>

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Date of site awareness	Enter the date the study staff member was made aware of the protocol deviation.
Deviation start date	Enter the date the deviation occurred or began.
Deviation stop date	Enter the date the deviation ended or stopped.
Provide a description of the deviation	Concisely describe the deviation.
Has or will this deviation be reported to single IRB (Advarra)?	Select "Yes" or "No" if the deviation will be reported to the IRB.
Deviation category	Select an option from the dropdown menu: <ul style="list-style-type: none"> • Survey not completed • Did not meet eligibility criteria • Conduct of non-protocol procedure • Breach of confidentiality • Staff performing duties that they are not qualified or delegated to perform • Use of non-IRB/EC-approved materials • IRB, ethics, or regulatory review deviation • Other
If deviation category is "Eligibility criteria" indicate the category not met	Selection which criteria was not met: <ul style="list-style-type: none"> • Inclusion criteria • Exclusion criteria
Protocol version to which the participant enrolled	Enter the study protocol version when the participant enrolled.
Which criteria did the participant not meet	Select an option from the dropdown menu: <ul style="list-style-type: none"> • 17 years of age or younger • Does not self-identify as a man • Does not self-report a lifetime history of anal sex with another man • Not determined to be HHI within the community • Not willing or able to provide consent to participate in the study • Does not have a medical visit scheduled at a PHASE facility during the sampling period • No enrollment slot available • Withdrew consent to participate in the study • Has a condition that would make participation unsafe, complicate interpretation of outcome data, or interfere with achieving study objectives

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	<ul style="list-style-type: none"> • IoR determination • Other
If “Other”, please specify	If “Other” is selected, enter the protocol deviation.
<p><i>For Peer Support Only</i></p> <p>Which criteria did the participant not meet:</p>	<p><i>Only applicable to Peer Support component</i></p> <p>Select an option from the dropdown menu:</p> <ul style="list-style-type: none"> • 14 years of age or younger • Does not self-identify as a man • Does not self-report a lifetime history of anal sex with another man • Not determined to be HHI within the community • Not willing or able to provide consent to participate in the study • Does not live in one of the selected study communities • No enrollment slot available • Withdrew consent to participate in the study • Has a condition that would make participation unsafe, complicate interpretation of outcome data, or interfere with achieving study objectives • IoR determination • Other
If “Other”, please specify	If “Other” is selected, enter the protocol deviation.

Change History

Summary of Changes to Study CCGs

Version		Affected Section(s) or Form(s)	Summary of Revisions
Number	Date		
1.0	06NOV2025	N/A	Initial
2.0	Date of last signature	HIV RNA Results Log, Protocol Deviations	HIV RNA Results Log: LLOQ and ULOQ guidance added; Protocol Deviations: Peer support age eligibility criteria updated, Deviation category “AE/SAE/EAE reporting deviation” removed.

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Signature Page for SCHARP-TMF-156159 v1.0

Reason for signing: Approved	Name: Paul Butler Role: I reviewed and approved the document. Date of signature: 15-Jan-2026 17:21:42 GMT+0000
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Reason for signing: Approved	Name: Jiayan Liu Role: I reviewed and approved the document. Date of signature: 15-Jan-2026 17:49:39 GMT+0000
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Signature Page for SCHARP-TMF-156159 v1.0

Approved