



(HPTN 082) DF/Net 083

(AC-1) 148

Visit Code .

Participant ID:

- -

Site Number Participant Number Chk

Form Completion Date:

/ /

dd MMM yy

Adherence Counseling, page 1 of 2

1 Counseling Session: #1 #3 #5
 #2 #4 #6

2 Is the participant randomized to receive drug level feedback? yes no → *If no, go to item 3.*

2a. Are tenofovir levels available for counseling? yes no → *If no, go to item 3.*

2a1. What is the TFV-DP level? . *fmol/punch* OR BLQ

2a2. For counseling, which category does the TFV-DP level correspond to?
 Green
 Yellow
 Red

3 Indicate which topics were covered during this session: *Mark all that apply.*

| | |
|--|---|
| <input type="checkbox"/> Adherence goal setting | <input type="checkbox"/> Planning for future PrEP use |
| <input type="checkbox"/> Adherence reminder strategies | <input type="checkbox"/> Pregnancy decision making |
| <input type="checkbox"/> Barriers to adherence | <input type="checkbox"/> PrEP education |
| <input type="checkbox"/> Communication skills | <input type="checkbox"/> Problem solving |
| <input type="checkbox"/> Coping with stress | <input type="checkbox"/> Relaxation and wellness |
| <input type="checkbox"/> Disclosing PrEP use to others | <input type="checkbox"/> Role-Play practice and Application of skills |
| <input type="checkbox"/> Healthy sexuality | <input type="checkbox"/> Social support |
| <input type="checkbox"/> Homework assignment | <input type="checkbox"/> Other, specify: _____ |

Purpose: This form is used to document adherence counseling sessions that occur with participants who choose to accept PrEP.

General Instructions: Transmit this form for any PrEP acceptor at any visit where adherence counseling is conducted.

Item-specific Instructions:

| | |
|-----------------|---|
| Item 1 | Mark the counseling session as listed in the counseling manual. |
| Item 2a1 | Enter the TFV-DP result as used at the time of counseling. Do not correct this value on the CRF if later laboratory results indicate a different TFV-DP level for this visit. If the result is greater than the upper limit of laboratory reporting, e.g. > 1031.5 fmol/punch, please record 9999.9 in this field. |



(HPTN 082) DF/Net 083

(AC-2) 149

Visit Code .

Participant ID:

- -
Site Number Participant Number Chk

Adherence Counseling, page 2 of 2

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

| | |
|--|--|
| <input type="checkbox"/> Barriers to return for study visits (e.g. money or time) | <input type="checkbox"/> Negative reactions (family, friends, partner) |
| <input type="checkbox"/> Disruption in routine (for example travel away from home) | <input type="checkbox"/> Partying/drugs/alcohol |
| <input type="checkbox"/> Forgetting/no dose available | <input type="checkbox"/> School commitments (classes or exams) |
| <input type="checkbox"/> Job Commitments | <input type="checkbox"/> Side effects |
| <input type="checkbox"/> Lack of privacy | <input type="checkbox"/> Other, specify: _____ |
| <input type="checkbox"/> Medication side effects | <input type="checkbox"/> None could be identified |

5 Indicate which adherence strategies/facilitators were explored during this session: *Mark all that apply or "None could be identified"*

| | |
|---|--|
| <input type="checkbox"/> Commitment protecting self or others | <input type="checkbox"/> Social support (family, friends, partners, fellow participants) |
| <input type="checkbox"/> Match with routine/event | <input type="checkbox"/> Stress management |
| <input type="checkbox"/> Memory aids/tools (e.g. calendar, alarm) | <input type="checkbox"/> Other, specify: _____ |
| <input type="checkbox"/> Mobile/carry tool (e.g. pill boxes) | <input type="checkbox"/> None could be identified |

6 Were there any unexpected problems in the session? *yes* *no* → *If no, end of form.*

6a. If yes, please explain what happened and how you handled the problem: _____

Comments:

No additional instructions.



(HPTN 082) DF/Net 083

(AE) 460

Note: Number pages sequentially (001, 002, 003) for each participant.

Page #

Participant ID:

- -
 Site Number Participant Number Chk

Date reported to site:

dd MMM yy

Adverse Experience Log

| | | | |
|-----------|--|----------|--|
| 1 | Adverse Experience: <i>Record diagnosis if available. Include anatomical location, if applicable.</i> | | |
| 2 | Onset date: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> dd MMM yy | 3 | At which visit was this AE first reported? <input type="text"/> <input type="text"/> . <input type="text"/> visit code |
| 4 | Severity: <input type="checkbox"/> grade 1—mild <input type="checkbox"/> grade 2—moderate <input type="checkbox"/> grade 3—severe <input type="checkbox"/> grade 4—potentially life-threatening <input type="checkbox"/> grade 5—death | | |
| 5 | Relationship to study product: <input type="checkbox"/> related <input type="checkbox"/> not related <i>If not related, record rationale or alternative etiology in Comments.</i> | | |
| 6 | Study product administration <input type="checkbox"/> no change <input type="checkbox"/> held <input type="checkbox"/> permanently discontinued <input type="checkbox"/> N/A | | |
| 7 | Status or Outcome of AE <input type="checkbox"/> continuing <input type="checkbox"/> resolved <input type="checkbox"/> death <input type="checkbox"/> severity/frequency increased (report as new AE) <input type="checkbox"/> continuing at end of study <div style="display: flex; align-items: center; margin-top: 10px;"> <div style="border: 1px solid black; padding: 5px; margin-right: 10px;"> If none, go to item 9. </div> <div style="font-size: 2em;">→</div> <div style="margin-left: 10px;"> 7a. Status/Outcome Date (<i>Leave blank if item 7 is "continuing" or "continuing at end of study."</i>) <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> dd MMM yy </div> </div> <div style="margin-top: 10px;"> 7b. If severity/frequency increased, record the new AE page #: <input type="text"/> <input type="text"/> <input type="text"/> AE page # </div> | | |
| 8 | Treatment <i>Mark "none" or all that apply.</i> <input type="checkbox"/> none <input type="checkbox"/> procedure/surgery <i>Comment below.</i> <input type="checkbox"/> new/prolonged hospitalization <i>Comment below.</i> <input type="checkbox"/> medication(s) <i>(Report on CM)</i> <input type="checkbox"/> other, specify _____ <i>Comment below.</i> CM Page # <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | | |
| 9 | Is this an SAE according to ICH guidelines? <input type="checkbox"/> yes <input type="checkbox"/> no | | |
| 10 | Has or will this AE be reported as an EAE? <input type="checkbox"/> yes <input type="checkbox"/> no | | |

Comments:

Purpose: This form is used to document any Adverse Experience (AE) reported by the participant or clinically observed as defined by the protocol.

General Instructions: Record any Adverse Experience (AE) reported by the participant or clinically observed as defined by the protocol. Do not record a condition as an AE if it existed at enrollment as a pre-existing condition, unless it increases in severity or frequency. If a cluster of symptoms reported on separate Adverse Experience Log pages is later attributed to a single diagnosis, change the earliest reported symptom to the final diagnosis. In addition, mark the AE Log pages for the other symptoms with the words "Delete due to diagnosis on AE page #" (specify page number of diagnosis AE). HIV-1 infection should not be reported on this form. Transmit this form to DataFax each time an AE is reported or when new information is obtained.

Item-specific Instructions:

| | |
|-----------------------|--|
| Page # | Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any AE Log pages after transmitting, unless instructed by the Data Manager. |
| Item 1 | Enter the condition, diagnosis, sign, or symptom, as applicable, e.g., "urinary tract infection" (no abbreviations should be used on the CRF). List only one AE per CRF. Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded on a separate page of the AE 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." |
| Item 2 | At minimum, month and year are required. Record one of the following, as appropriate: the date on which the participant reports first experiencing the AE; if the AE is discovered during the study visit exam, record the date of the study visit exam; if the AE is an abnormal lab result, record the date on which the specimen was collected. |
| Item 4 | To grade the severity of an AE, consult the <i>Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events</i> . |
| Item 5 | Mark the assessment of the relationship between the AE and the study agent. Mark "related" if there is a reasonable possibility that the AE may be related to the study agent. Mark "not related" if there is not a reasonable possibility that the AE is related to the study agent. If not related, record rationale or alternative etiology in Comments. For more information, refer to the <i>Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2</i> . |
| Item 6 | no change: Mark if the participant is expected to continue to use study product and the AE does NOT result in a study product hold or permanent discontinuation. held: Mark if the AE results in a study product hold. If multiple AEs are reported at the same visit, mark "held" for the AE(s) that contributed to the product hold. permanently discontinued: Mark if the AE results in permanent discontinuation of study product. If multiple AEs are reported at the same visit, mark "permanently discontinued" for the AE(s) that contributed to the permanent discontinuation. N/A (not applicable): Mark if the AE occurred after the participant had completed all administration of the study product, if the participant never began the study product, if the study product is held or permanently discontinued for a different AE or other reason, or if the AE is grade 5-death. |
| Item 7 | continuing: AE is continuing at the time it is reported. resolved: Condition is no longer present, or returned to the pre-enrollment severity/frequency. If a participant is taking a medication to control an AE that arose during study participation, it is not considered resolved. death: Mark only if the severity of this AE is grade 5. Any other AEs continuing at the time of death should be changed to "continuing at end of study participation." severity/frequency increased: If an AE increases in severity or frequency after it has been reported on the AE Log, line through the "continuing" box previously marked and mark "severity/frequency increased." Record the date of increase in the "Status/Outcome Date." Report the increase in severity or frequency as a new AE and record new AE Page # in space provided. If a new AE Page # is completed, an AE Log page with corresponding AE number must be received. For this new AE, the "Onset Date" will be the date that the severity or frequency increased. Update EAE form if applicable. Note that decreases in severity should not be recorded as new AEs. continuing at end of study participation: Mark this box whenever an AE is continuing at the time of participant study termination. |
| Item 7a | At minimum, month and year are required. Record one of the following as appropriate: the date on which the participant no longer experienced the AE, or the date of the study visit or specimen collection at which the change in status/outcome is first noted. |
| Item 8 | Indicate all treatments administered for this AE, including treatment provided by a health care professional and participant self-treatment. Do not indicate treatments that were clinically indicated or prescribed but not administered. If Concomitant Medication Log (CM) Page # completed, a Concomitant Medication Log page with corresponding AE number must be received. If only one CM Page # recorded, line through unused box to confirm that it was left blank intentionally. |
| Items 9 and 10 | For questions about ICH guidelines and EAE reporting, refer to the <i>Manual for Expedited Reporting of Adverse Events to DAIDS, Version 2</i> . |



(HPTN 082) DF/Net 083

(CDV) 179

Visit Code .

Participant ID:

- -
Site Number Participant Number Chk

Initial Specimen Collection Date:

dd MMM yy

CD4+/Viral Load Results

| | | | | |
|---|---------------------------|--|--|--|
| 1 | Absolute CD4+ | <input type="checkbox"/> Not done/ Not collected <input type="checkbox"/> Unable to analyze | Alternate Collection Date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i> | cells/mm ³ |
| | | | | |
| 2 | HIV RNA PCR | <input type="checkbox"/> Not done/ Not collected | Alternate Collection Date <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i> | |
| | 2a. HIV RNA PCR (plasma): | < <input type="checkbox"/> = <input type="checkbox"/> > <input type="checkbox"/> | viral copies/mL <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | OR <input type="checkbox"/> Undetectable |
| | 2b. RNA PCR kit code: | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | kit code | |

Comments:

Item-specific Instructions:

| Initial Specimen Collection Date | Record the date that the first specimen(s) was collected (not the date results were reported or recorded on the form) for this visit. A complete date is required. | | | | |
|---|---|-------------|------|------------------------|------|
| Not done/Not collected | Mark this box in the event that a specimen was not collected, or if the specimen was collected but a result is not available due to specimen loss or damage. For every test, either the "Not done/Not collected" box has to be marked or a test result has to be entered. If "Not done/Not collected" is marked, provide an explanation in the Comments. | | | | |
| Alternate Collection Date | This date is to be completed ONLY if the specimen was collected after the Initial Specimen Collection Date for this same visit. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required. | | | | |
| Results Reporting | <ul style="list-style-type: none"> • If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results box(es), provide initials and date, and write an explanation in Comments. • If the site lab does not produce test results in the units used on this CRF, the results must be converted before the laboratory CRF is transmitted to DataFax. • It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the CRF. If the site lab does not produce test results in the units used on this form, first perform the conversion, then round the converted result if necessary. | | | | |
| Item 2a | Mark the less than (<), equal to (=), or greater than (>) box as appropriate and record the value. For example, if the value is 3100 copies, mark the equal to (=) box and record "00003100" as the value. If the value reported is <400 copies, mark the less than (<) box and record "00000400" as the value. | | | | |
| Item 2b | Record the kit code from the table below. If a test kit being used at your site is not listed, contact the SCHARP Clinical Data Manager for a new code. <table border="1" data-bbox="435 1325 1284 1438"> <thead> <tr> <th>RNA PCR KIT</th> <th>Code</th> </tr> </thead> <tbody> <tr> <td>Abbott m2000 Real-time</td> <td>0406</td> </tr> </tbody> </table> | RNA PCR KIT | Code | Abbott m2000 Real-time | 0406 |
| RNA PCR KIT | Code | | | | |
| Abbott m2000 Real-time | 0406 | | | | |



(HPTN 082) DF/Net 083

(CM) 423

Note: Number pages sequentially (01, 02, 03) for each participant.

Page #

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|---|--|---------------------------|--|--|--|--|--|------------|--|--|--|--------------------|--|--|---------------------------|--|--|--|--|--|------------|--|--|---|--|---|---|---|-----------------------------------|--|
| <p>Participant ID:</p> <table style="width:100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 10%; text-align: center;"> </td> <td style="border: 1px solid black; width: 10%; text-align: center;"> </td> <td style="border: 1px solid black; width: 10%; text-align: center;"> </td> <td style="border: 1px solid black; width: 10%; text-align: center;"> </td> <td style="border: 1px solid black; width: 10%; text-align: center;"> </td> <td style="border: 1px solid black; width: 10%; text-align: center;"> </td> <td style="border: 1px solid black; width: 10%; text-align: center;"> </td> <td style="border: 1px solid black; width: 10%; text-align: center;"> </td> <td style="border: 1px solid black; width: 10%; text-align: center;"> </td> <td style="border: 1px solid black; width: 10%; text-align: center;"> </td> <td style="border: 1px solid black; width: 10%; text-align: center;"> </td> <td style="border: 1px solid black; width: 10%; text-align: center;"> </td> </tr> <tr> <td colspan="3" style="text-align: center;"><i>Site Number</i></td> <td colspan="6" style="text-align: center;"><i>Participant Number</i></td> <td colspan="3" style="text-align: center;"><i>Chk</i></td> </tr> </table> | | | | | | | | | | | | | <i>Site Number</i> | | | <i>Participant Number</i> | | | | | | <i>Chk</i> | | | <table style="width:100%; border-collapse: collapse;"> <tr> <td style="width:50%; border: 1px solid black; padding: 2px;"> <input type="checkbox"/> No medications taken at Screening/Enrollment. </td> <td style="width:50%; border: 1px solid black; padding: 2px;"> <i>Staff Initials/</i> <i>Date</i> _____ </td> </tr> <tr> <td style="border: 1px solid black; padding: 2px;"> <input type="checkbox"/> No medications taken throughout study. </td> <td style="border: 1px solid black; padding: 2px;"> <i>Staff Initials/</i> <i>Date</i> _____ </td> </tr> <tr> <td colspan="2" style="border: 1px solid black; padding: 2px;"> End of form. Transmit to DataFax. </td> </tr> </table> | <input type="checkbox"/> No medications taken at Screening/Enrollment. | <i>Staff Initials/</i> <i>Date</i> _____ | <input type="checkbox"/> No medications taken throughout study. | <i>Staff Initials/</i> <i>Date</i> _____ | End of form. Transmit to DataFax. | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <i>Site Number</i> | | | <i>Participant Number</i> | | | | | | <i>Chk</i> | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> No medications taken at Screening/Enrollment. | <i>Staff Initials/</i> <i>Date</i> _____ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <input type="checkbox"/> No medications taken throughout study. | <i>Staff Initials/</i> <i>Date</i> _____ | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| End of form. Transmit to DataFax. | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

Concomitant Medications Log

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|--|--------------------------|--|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------------|--------------------------------|------------|-----------|---|--|---|--|--|--|--|-----------|------------|-----------|------------|-----------|--|--|--|-------------------|--|-----|----|-----|-----|------|-----|-----|----------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------------|----|----|----|-----|-----|-----|-----|----|----------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------------|
| 1 | <p>Medication Name</p> | <p>Staff Initials/ Log Entry Date</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>Indication</p> | | <p>Taken for a reported AE? <input type="checkbox"/> yes <input type="checkbox"/> no</p> <p style="text-align: center;">↓</p> <p>AE Log page(s)</p> <table style="width:100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 25px; height: 20px;"> </td> <td style="border: 1px solid black; width: 25px; height: 20px;"> </td> <td style="border: 1px solid black; width: 25px; height: 20px;"> </td> <td style="border: 1px solid black; width: 25px; height: 20px;"> </td> </tr> <tr> <td style="border: 1px solid black; width: 25px; height: 20px;"> </td> <td style="border: 1px solid black; width: 25px; height: 20px;"> </td> <td style="border: 1px solid black; width: 25px; height: 20px;"> </td> <td style="border: 1px solid black; width: 25px; height: 20px;"> </td> </tr> </table> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <table style="width:100%; border-collapse: collapse;"> <tr> <td style="width:50%; border: 1px solid black; padding: 2px;"> <p>Date Started</p> <table style="width:100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"> </td> <td style="border: 1px solid black; width: 20px; height: 20px;"> </td> <td style="border: 1px solid black; width: 20px; height: 20px;"> </td> <td style="border: 1px solid black; width: 20px; height: 20px;"> </td> <td style="border: 1px solid black; width: 20px; height: 20px;"> </td> </tr> <tr> <td style="text-align: center;"><i>dd</i></td> <td style="text-align: center;"><i>MMM</i></td> <td style="text-align: center;"><i>yy</i></td> <td colspan="2"></td> </tr> </table> </td> <td style="width:50%; border: 1px solid black; padding: 2px;"> <p>Date Stopped</p> <table style="width:100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 20px; height: 20px;"> </td> <td style="border: 1px solid black; 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| 2 | <p>Medication Name</p> | <p>Staff Initials/ Log Entry Date</p> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| <p>Indication</p> | | <p>Taken for a reported AE? <input type="checkbox"/> yes <input type="checkbox"/> no</p> <p style="text-align: center;">↓</p> <p>AE Log page(s)</p> <table style="width:100%; border-collapse: collapse;"> <tr> <td style="border: 1px solid black; width: 25px; height: 20px;"> </td> <td style="border: 1px solid black; width: 25px; height: 20px;"> </td> <td style="border: 1px solid black; width: 25px; height: 20px;"> </td> <td style="border: 1px solid black; width: 25px; height: 20px;"> </td> </tr> <tr> <td style="border: 1px solid black; width: 25px; height: 20px;"> </td> <td style="border: 1px solid black; width: 25px; height: 20px;"> </td> <td style="border: 1px solid black; width: 25px; height: 20px;"> </td> <td style="border: 1px solid black; width: 25px; height: 20px;"> </td> </tr> </table> | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
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Purpose:

This form will be used to document only concomitant medications contraindicated for Truvada and medications used for the treatment of AEs that occur during study participation. See protocol section 4.6.8.

General Instructions:

When to transmit this form:

- once the participant has enrolled in the study;
- when pages have been updated or additional Log pages have been completed (only transmit updated or new pages);
- when the participant has completed study participation
- when instructed by Data Manager

Item-specific Instructions:

| | |
|--|---|
| Page # | Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Concomitant Medications Log pages after transmitting, unless instructed by the Data Manager. |
| No medications taken at Screening/ Enrollment | Mark this box if no medications were taken by the participant from Screening through the Enrollment visit. This box should only be marked on Page 01. |
| No medications taken throughout study | Mark this box at the Termination visit if no medications were taken by the participant throughout the entire study. |
| Medication Name | Record generic name of medication. For combination generic medications, record the first three main active ingredients, if applicable. |
| Indication | For health supplements, such as multivitamins, record "general health." For preventive medications, record "prevention of [insert condition]" (e.g., for flu shot, record "prevention of influenza"). |
| Date Started | If the participant is unable to recall the exact date, obtain participant's best estimate. At a minimum, the year is required. |
| Date Stopped | At the participant's Termination visit, the "Date Stopped" must be recorded for each medication OR the "Continuing at end of study" box must be marked. At a minimum, the month and year are required. |
| Frequency | Below is a list of common frequency abbreviations: prn: as needed qd: every day tid: three times daily qhs: at bedtime once: one time bid: twice daily qid: four times daily other specify: alternative dosing schedules |
| Dose/Units | If the participant does not know the dose or units, draw a single line through the blank response box and initial and date. For prescription combination medications, record the dosage of first three main active ingredients. For multivitamin tablets or liquids, record number of tablets or liquid measurement (e.g., one tablespoon). |
| Route | Below is a list of common route abbreviations: PO: oral IV: intravenous IHL: inhaled REC: rectal other, specify: IM: intramuscular TOP: topical VAG: vaginal SC: subcutaneous alternative routes |



(HPTN 082) DF/Net 083

(DEM-1) 001

Participant ID:

- -
Site Number Participant Number Chk

Form Completion Date:

/ /
dd MMM yy

Demographics, page 1 of 2

1 What is the participant's date of birth? / / **OR** If unknown, record age: Years
dd MMM yy

2 Sex at birth?
 Male
 Female
 Intersex

3 Gender: *Mark all that apply.*
 3a. Male
 3b. Female
 3c. Transgender male (female to male)
 3d. Transgender female (male to female)
 3e. Gender Queer
 3f. Gender variant or gender non-conforming
 3g. Self-identify, specify: _____
 3h. No answer

4 Sexual orientation: *Mark only one.*
 Straight/heterosexual
 MSM/WSW/Gay/Lesbian/Homosexual
 Bisexual
 Queer
 Not sure
 Other, specify: _____
 No answer

Purpose: This form is used to collect a participant's demographic information.

General Information/Instructions: This form is transmitted to DataFax only if a participant enrolls in the study.

Item-specific Instructions:

| | |
|----------------------|--|
| Item 1 | If any portion of the date of birth is unknown, record age at time of screening. If age is unknown, record the participant's best estimate of her age. Do not complete both answers. |
| Items 3 and 4 | These items must be based on self-report. |

No additional instructions.



(HPTN 082) DF/Net 083

(ENR) 124

Participant ID:

- -
Site Number Participant Number Chk

Enrollment Date:

dd MMM yy

Enrollment

| | |
|----------|--|
| 1 | Did the participant agree to have leftover blood stored and used for future post-study testing? <input type="checkbox"/> yes <input type="checkbox"/> no |
| 2 | Did the participant accept PrEP? <input type="checkbox"/> yes <input type="checkbox"/> no → <i>If no, end of form.</i> ↙ <i>If yes, complete Randomization form.</i> |
| | 2a. Has the participant been entered into the HPTN 082 SMS Platform? <input type="checkbox"/> yes <input type="checkbox"/> no ↙ <i>If yes, end of form.</i> |
| | 2a1. Why was the participant <u>not</u> entered into the SMS Platform? <input type="checkbox"/> The participant declined messaging <input type="checkbox"/> Other, specify: _____ |

Purpose: This form is used to document a participant's enrollment into the study.

Item-specific Instructions:

| | |
|---------------|---|
| Item 1 | This item refers to any blood specimens remaining after study completion, not including study-related plasma storage. |
|---------------|---|



(HPTN 082) DF/Net 083

(FP) 155

Visit Code .

Participant ID:

- -

Site Number Participant Number Chk

Form Completion Date:

/ /

dd MMM yy

Family Planning

1 What method(s) of contraception/family planning is the participant using? *Mark "None" or all that apply.*

- 1a. None → *End of form.*
- 1b. Vaginal ring
- 1c. Intrauterine device (IUD)—copper
- 1d. Intrauterine device (IUD)—hormone
- 1e. Oral contraceptive/birth control pills
- 1f. Injectable contraceptives (such as Depo-Provera)
- 1g. (Ortho Evra) The Patch
- 1h. Implants
- 1i. Sterilization (tubal ligation/hysterectomy/laparoscopy/other surgical procedure that causes sterilization)
- 1j. Sex with partner who had a vasectomy
- 1k. Diaphragm
- 1l. Sponge
- 1m. Female condoms
- 1n. Male condoms
- 1o. Natural methods such as the withdrawal or rhythm method

Purpose: This form is used to document the methods of contraception/family planning used by study participants.

General Information/Instructions: Transmit this form at Enrollment and at all study visits except for the final visit.



(HPTN 082) DF/Net 083

(FUV-1) 133

Visit Code .

Participant ID:

- -
Site Number Participant Number Chk

Visit Date:

/ /
dd MMM yy

Follow-up Visit, page 1 of 2

1 Is this an interim visit? yes no → If no, go to item 2.

1a. Reason for interim visit. *Mark all that apply.*

- | | |
|--|---|
| <input type="checkbox"/> 1a1. Report difficulty with adherence | <input type="checkbox"/> 1a6. Repeat laboratory work including HIV confirmatory testing |
| <input type="checkbox"/> 1a2. Report new symptoms | <input type="checkbox"/> 1a7. Repeat specimen or fluid collection |
| <input type="checkbox"/> 1a3. Report a social impact | <input type="checkbox"/> 1a8. HBV vaccination |
| <input type="checkbox"/> 1a4. HIV lab testing | <input type="checkbox"/> 1a9. STI treatment |
| <input type="checkbox"/> 1a5. Pregnancy testing | <input type="checkbox"/> 1a10. Other, specify: _____ |
| | <input type="checkbox"/> 1a11. Late PrEP request or acceptance |

1b. Besides this form, what other forms were completed at this visit? *Mark all that apply.*

- | | |
|--|---|
| <input type="checkbox"/> 1b1. Adherence Counseling | <input type="checkbox"/> 1b8. Local Laboratory Results |
| <input type="checkbox"/> 1b2. Adverse Experience Log | <input type="checkbox"/> 1b9. Hepatitis B Test Results |
| <input type="checkbox"/> 1b3. Social Impact Log | <input type="checkbox"/> 1b10. Specimen Storage |
| <input type="checkbox"/> 1b4. Product Hold/Discontinuation Log | <input type="checkbox"/> 1b11. Pregnancy Report and History |
| <input type="checkbox"/> 1b5. Concomitant Medications Log | <input type="checkbox"/> 1b12. Pregnancy Outcome |
| <input type="checkbox"/> 1b6. HIV Test Results | <input type="checkbox"/> 1b13. Other, specify: _____ |
| <input type="checkbox"/> 1b7. CD4+/Viral Load Results | <input type="checkbox"/> 1b14. Randomization |

2 Is this an early termination visit? yes no → If yes, complete Termination form.

3 At this visit, how many **new** Adverse Experiences (AEs) have been reported? # new AEs
 Complete a separate AE Log page for each AE. If none, enter 00.

4 At this visit, how many **new** Social Impacts have been reported? # new Impacts
 Complete a separate Social Impact Log page for each event. If none, enter 00.

Comments:

Purpose: This form is used to summarize information from each participant visit.

General Instructions: Submit this form for any scheduled or interim follow-up visits. Any other forms completed for this visit must have the same Visit Code as this Follow-up Visit form.

If this visit is for a late PrEP request, please wait to submit this form until the participant has returned to complete all required procedures and received drug or until the visit window has closed following her request to start PrEP, whichever occurs first.

Item-specific Instructions:

| | |
|----------------|--|
| Item 1a | Mark the reason for this interim visit. If the participant has returned to request or accept PrEP medication, select "Late PrEP request or acceptance." If the participant requests and accepts PrEP within the same visit window, you may code this as a split visit. |
| Item 1b | Mark the newly completed forms (in addition to this form) that are being transmitted for the interim visit/contact. If "other, specify" is marked, record the form acronym(s) in the space provided. |



(HPTN 082) DF/Net 083

(FUV-2) 134

Visit Code .

Participant ID:

- -
Site Number Participant Number Chk

Follow-up Visit, page 2 of 2

| | | | |
|----------|---|---|--|
| 5 | At this visit how many new product holds or discontinuations have been initiated? | # new holds <input type="text"/> <input type="text"/> | Complete a separate Product Hold/Discontinuation Log page for each hold or discontinuation. If none, enter 00. |
| 6 | Did the participant complete the CASI questionnaire at this visit? | <input type="checkbox"/> yes <input type="checkbox"/> no | → If no, specify reason in the Comments. |
| 7 | Was a pregnancy test done at this visit? | <input type="checkbox"/> yes <input type="checkbox"/> no | → If no, specify reason in the Comments. Go to item 8. |
| | 7a. Pregnancy test result: | <input type="checkbox"/> negative <input type="checkbox"/> positive | → If newly positive, complete Pregnancy Report and History form, and Product Hold/Discontinuation Log. |
| 8 | Has the participant attended the adherence club since her last visit? | <input type="checkbox"/> yes <input type="checkbox"/> no | → If no, go to instructions above item 9. |
| | 8a. How many club events has she attended? | # events <input type="text"/> <input type="text"/> | |

Participants who received PrEP medication at any previous visit, end of form.

| | | | |
|-----------|--|---|---|
| 9 | Did the participant request to initiate PrEP at this visit? | <input type="checkbox"/> yes <input type="checkbox"/> no | |
| 10 | Did the participant accept PrEP at this visit? | <input type="checkbox"/> yes <input type="checkbox"/> no | → If no, end of form. → If yes, complete Randomization form. Continue to item 10a. |
| | 10a. Has the participant been entered into the HPTN 082 SMS Platform? | <input type="checkbox"/> yes <input type="checkbox"/> no | → If yes, end of form. |
| | 10a1. Why was the participant <u>not</u> entered into the HPTN 082 SMS Platform? | <input type="checkbox"/> The participant declined messaging <input type="checkbox"/> Other, specify: _____ | |

Comments:

Item-specific Instructions:

| | |
|----------------|---|
| Item 9 | Mark "Yes" on the date of the participant's initial request. Mark "No" if she is returning to complete PrEP acceptance, but requested PrEP at a previous visit. |
| Item 10 | Mark "Yes" when the participant receives PrEP medication. Mark "No" if she has not yet received medication at the close of the current visit window, i.e. she has not returned to receive drug, no longer wants to accept PrEP, or if CrCl or HIV results are still pending. |



(HPTN 082) DF/Net 083

(HBT) 040

Visit Code .

Participant ID:

- -

Site Number Participant Number Chk

Initial Specimen Collection Date:

dd MMM yy

Hepatitis B Test Results

1 Hepatitis B

Alternate Collection Date

dd MMM yy

1a. Hepatitis B Surface Antigen (Hbs Ag):

negative

positive



If positive during follow-up, complete Product Hold/Discontinuation Log and Adverse Experience Log.

1b. Hepatitis B Surface Antibody:

negative

positive



If positive during follow-up, complete Product Hold/Discontinuation Log and Adverse Experience Log.

2 Did the participant initiate the Hepatitis B vaccination Series?

yes

no

N/A

Comments:

Purpose:

This form is used to document local laboratory Hepatitis B test results.

General Instructions:

During screening, if the participant has laboratory-confirmed Hepatitis B infection, the participant is ineligible and this form should not be transmitted to DataFax.

During study follow-up, complete and submit this form if a participant has laboratory-confirmed Hepatitis B infection. Also report the infection on the **Adverse Experience (AE) Log**.

Item-specific Instructions:

| | |
|------------------------------------|--|
| Initial Specimen Collection | Record the date that the first specimen(s) was collected (NOT the date results were reported or recorded on the form) for this visit. |
| Alternate Collection Date | This date is to be completed ONLY if the specimen was collected after the Initial Specimen Collection Date for this same visit. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required. |
| Item 2 | If item 2 is marked "yes", record each Hepatitis B vaccination on the Concomitant Medications Log . |



(HPTN 082) DF/Net 083

(HTR-1) 178

Visit Code .

Participant ID:

- -
Site Number Participant Number Chk

HIV Test Results, page 1 of 2

| | | | | |
|----------|--------------------------------|--|--|---|
| 1 | HIV TEST RESULTS | Not collected <input type="checkbox"/> | Specimen #1 Collection Date | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i> |
| | 1a. HIV Rapid Test 1 Kit Code: | Not done <input type="checkbox"/> | Kit code <input type="text"/> <input type="text"/> | 1a1. HIV Rapid 1: <input type="checkbox"/> Non-reactive <input type="checkbox"/> Reactive |
| | 1b. HIV Rapid Test 2 Kit Code: | <input type="checkbox"/> | <input type="text"/> <input type="text"/> | 1b1. HIV Rapid 2: <input type="checkbox"/> <input type="checkbox"/> |
| | 1c. HIV EIA Test Kit Code: | <input type="checkbox"/> | <input type="text"/> <input type="text"/> | 1c1. HIV EIA: <input type="checkbox"/> <input type="checkbox"/> |
| | 1d. HIV-1 RNA Qualitative: | Not done <input type="checkbox"/> | Non-reactive <input type="checkbox"/> Reactive <input type="checkbox"/> | |
| | 1e. HIV-1 RNA PCR: | Not done <input type="checkbox"/> | Kit code <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | |
| | 1f. HIV RNA PCR (plasma): | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | viral copies/mL <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | Undetectable OR <input type="checkbox"/> |

| | | | | | |
|----------|--------------------------------|--|--|---|---|
| 2 | HIV TEST RESULTS | Not collected <input type="checkbox"/> | Specimen #2 Collection Date | <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>dd MMM yy</i> | Visit Code <input type="text"/> <input type="text"/> . <input type="text"/> |
| | 2a. HIV Rapid Test 1 Kit Code: | Not done <input type="checkbox"/> | Kit code <input type="text"/> <input type="text"/> | 2a1. HIV Rapid 1: <input type="checkbox"/> Non-reactive <input type="checkbox"/> Reactive | |
| | 2b. HIV Rapid Test 2 Kit Code: | <input type="checkbox"/> | <input type="text"/> <input type="text"/> | 2b1. HIV Rapid 2: <input type="checkbox"/> <input type="checkbox"/> | |
| | 2c. HIV EIA Test Kit Code: | <input type="checkbox"/> | <input type="text"/> <input type="text"/> | 2c1. HIV EIA: <input type="checkbox"/> <input type="checkbox"/> | |
| | 2d. HIV-1 RNA Qualitative: | Not done <input type="checkbox"/> | Non-reactive <input type="checkbox"/> Reactive <input type="checkbox"/> | | |
| | 2e. HIV-1 RNA PCR: | Not done <input type="checkbox"/> | Kit code <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | | |
| | 2f. HIV RNA PCR (plasma): | <input type="checkbox"/> <input type="checkbox"/> <input type="checkbox"/> | viral copies/mL <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | Undetectable OR <input type="checkbox"/> | |

Comments:

Purpose: The **HIV Test Results** CRF documents the results of HIV testing performed at the site at scheduled and interim visits.

General Information and Instructions:

- Record test results on this form as they become available from the local lab. Transmit this form to DataFax when the first test results are available and recorded. Do not wait to transmit this form until confirmatory testing has been completed.
- If HIV infection is suspected or confirmed during follow-up, complete a **Product Hold/Discontinuation Log**. Complete Final Status as available at the time of submission.
- If determination of final HIV status is pending confirmatory testing, mark "Additional testing required." Correct this field on resubmission, as additional results allow determination.

Item-specific Instructions:

| | |
|----------------------------------|---|
| Visit Code: | Complete the form visit code at the time of initial testing, as required per protocol or clinical necessity. If confirmatory testing is required, record each additional visit code for subsequent specimen collections in the area for each sample. |
| Specimen Collection Date: | Record the date that the specimen(s) was collected (NOT the date results were reported or recorded on the form) for this visit. Complete date is required. |
| Not Collected: | If samples 2 through 4 were not collected at all, mark the "Not collected" box next to the Specimen Collection Date field. Do not mark any other boxes in the area for that sample. If the "Not collected" box is marked at a visit where that sample is required by the protocol, record the reason(s) why it was not collected in the Comments. |
| Not done: | For each test, mark either the "Not done" box, or enter a test result. If the "Not done" box is marked at a visit where that is required by the protocol, record the reason in Comments. |
| Kit code: | <ul style="list-style-type: none"> Refer to Atlas for kit codes. If a test kit being used at your site is not listed, contact SCHARP Clinical Data Manager for a new code. Rapid tests on oral transudate are not allowed per protocol. |
| Items 1b and 2b: | A second Rapid Test is performed if required per site's standard operating procedures. |
| Items 1f and 2f: | Mark the less than (<), equal to (=), or greater than (>) box as appropriate and record the value. For example, if the value is 3100 copies, mark the equal to (=) box and record "00003100" as the value. If the value reported is <400 copies, mark the less than (<) box and record "00000400" as the value. |

No additional instructions.



(HPTN 082) DF/Net 083

(LLR) 152

Visit Code

Participant ID:

- -
Site Number Participant Number Chk

Initial Specimen Collection Date:

dd MMM yy

Local Laboratory Results

1 PHYSICAL:

1a. Height: cm *Height is required at Screening only. Otherwise, leave blank.*
 1b. Weight: . kg OR Not done

2 RENAL FUNCTION:

Not done **Alternate Collection Date**
dd MMM yy

2a. Creatinine: . mg/dL OR . μmol/L Severity Grade *If applicable* AE Log *Page #* OR Not reportable *as an AE*

2b. Calculated Creatinine Clearance: . mL/min OR

3 SYPHILIS SCREENING TEST:

Alternate Collection Date
dd MMM yy

3a. Treponemal test: Not done Non-reactive Reactive
 3b. Non-Treponemal test:
 3c. Titer (if indicated): 1: OR N/A

4 OTHER STI TESTS:

4a. N. gonorrhea: Not done/Not collected **Alternate Collection Date**
dd MMM yy Negative Positive Invalid Result

4b. C. trachomatis:
dd MMM yy

4c. T. vaginalis:
dd MMM yy Negative Positive

Comments:

Purpose:

This form is used to document local laboratory test results of specimens collected as part of the study.

General Information/Instructions:

Record test results on this form as they become available from the local laboratory. Transmit this form to DataFax when results for all collected specimens are available and recorded.

Item-specific Instructions:

| | |
|--|---|
| | At the Enrollment Visit, report gradable lab results on the Pre-existing Conditions form; do not complete an AE for abnormal lab results found at enrollment. |
| Initial Specimen Collection Date: | Record the date that the first specimen(s) was collected (not the date results were reported or recorded on the form) for this visit. A complete date is required. |
| Alternate Collection Date: | This date is to be completed ONLY if the specimen was collected after the Initial Specimen Collection Date for this same visit. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required. |
| Results Reporting: | <ul style="list-style-type: none"> • If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results box(es), provide initials and date, and write an explanation in Comments. • If the site lab does not produce test results in the units used on this form, the results must be converted before the laboratory CRF is faxed to DataFax. • It may be necessary to round the result reported by the lab up or down to the level of precision allowed on the CRF. For example, a lab-reported hemoglobin value of 11.06 g/dL would be recorded as 11.1 g/dL. <ul style="list-style-type: none"> - If the site lab does not produce test results in the units used on this form, <i>first</i> perform the conversion, then round the converted result if necessary. |
| AE Severity Grade: | <ul style="list-style-type: none"> • If any abnormal laboratory values meet the criteria for severity grade 1 or greater, according to the appropriate <i>DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events</i>, record the grade in the appropriate box next to the results. • Always compare the severity grade range to the value that was recorded on the CRF (not the lab-reported value). • When working with calculated severity grade ranges (e.g., 1.1–1.5 times the site lab upper limit of normal), the calculated range may have more significant digits than the lab result. <ul style="list-style-type: none"> - Treat all missing digits in the lab value as zeros. - If the lab value falls between two calculated severity grade ranges, assign it the higher grade. |
| AE Log Page #: | Record the page number of the AE Log which is most closely associated with the abnormal lab value. |
| Not reportable as an AE: | Only mark this response if the lab value is gradable according to the appropriate <i>DAIDS Table for Grading the Severity of Adult and Pediatric Adverse Events</i> , but is not reportable as an AE. This includes pre-existing conditions and abnormal lab values that do not meet protocol-specific AE reporting requirements. |
| Not done/Not collected: | For every test, mark either "Not done/Not collected" or enter a test result. If "Not done/Not collected" is marked, provide an explanation in Comments on page 3. |
| Repeat Local Laboratory Tests: | <p>Sometimes it is necessary to repeat a local lab test.</p> <ul style="list-style-type: none"> • For a repeat test of the same sample, record only the results considered the most accurate. If a first result was already recorded and faxed to DataFax, but the second result is considered more accurate, amend the form to reflect the second result by drawing a line through the first result and writing the second result on the form. Initial and date the change, and re-transmit the amended form to DataFax. • For a repeat test using a different sample (e.g., a blood re-draw for a repeat CBC), record the repeat test results on a new form. If the new sample is collected at an unscheduled visit, use an interim visit code. If the new sample is collected at a future scheduled study visit, use that scheduled study visit code. Fax new form to DataFax. |



(HPTN 082) DF/Net 083

(MV) 463

Visit Code .

Participant ID:

- -
Site Number Participant Number Chk

Form Completion Date:

dd MMM yy

Missed Visit

1 Target Visit Date:
dd MMM yy

- 2 Reason visit was missed. *Mark only one.*
- 2a. Unable to contact participant
 - 2b. Unable to schedule appointment(s) within target window
 - 2c. Participant refused visit
 - 2d. Participant incarcerated
 - 2e. Participant admitted to a health care facility
 - 2f. Participant withdrew from the study → Complete Termination form.
 - 2g. Participant deceased → Complete Termination form and Adverse Experience Log.
 - 2h. Other, specify: _____

Comments:

Purpose: Complete this form whenever an enrolled participant misses a required visit according to the visit window outlined in the protocol or Study-specific Procedures (SSP).

General Information and Instructions: If the QC Report indicates that a visit is overdue, confirm that the visit was missed before completing a **Missed Visit** form. Transmit this form when it is determined that a visit has been missed and cannot be completed within the visit window. Record the Visit Code of the visit that was missed. Record the date that the form was completed. This will not necessarily be the date of the missed visit.

Item-specific Instructions:

| | |
|---------------|---|
| Item 1 | Record the target date of the visit. A complete date is required. |
| Item 2 | Record the reason the participant missed the visit. |

General Instructions:

- Complete this form when a transferred participant has provided informed consent at the receiving study clinic/site.
- The **Participant Receipt** form is completed by the receiving site (the site at which the participant will be continuing his or her study visits).
- For more information on Participant Transfer and Receipt, refer to the protocol, Study-specific Procedures (SSP), and/or Manual of Operations (MOP).

Item-specific Instructions:

| | |
|-----------------------|--|
| Participant ID | Do not assign a new Participant ID. Record the Participant ID assigned by the original study site. |
| Item 3 | A complete date is required. |



(HPTN 082) DF/Net 083

(PT) 465

Participant ID:

| | | | | | | | | | |
|----------------------|----------------------|----------------------|---|---------------------------|----------------------|----------------------|----------------------|---|----------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> | - | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | - | <input type="text"/> |
| <i>Site Number</i> | | | | <i>Participant Number</i> | | | | | <i>Chk</i> |

Form Completion Date:

| | | | | | |
|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| <i>dd</i> | | <i>MMM</i> | | <i>yy</i> | |

Participant Transfer

1 Name of transferring study site: _____

2 Name of receiving study site: _____

3 Visit Code of last completed contact with participant: . *visit code*

4 Date participant records were sent to receiving study site: *dd* *MMM* *yy*

Comments:

General Instructions:

- Complete this form when a participant is transferring to another study clinic/site.
- The **Participant Transfer** form is completed by the transferring site (the site that the participant is leaving).
- For more information on Participant Transfer and Receipt, refer to the protocol, Study-specific Procedures (SSP), and/or Manual of Operations (MOP).

Item-specific Instructions:

| | |
|---------------|------------------------------|
| Item 4 | A complete date is required. |
|---------------|------------------------------|



(HPTN 082) DF/Net 083

(PRE) 012

Note: Number pages sequentially (01, 02, 03) for each participant.

Page #

Participant ID:

- -
Site Number Participant Number Chk

No pre-existing conditions reported or observed.

Staff Initials/Date _____

End of form. Transmit to DataFax.

Pre-Existing Conditions

| | | | |
|---|-----------|--|---|
| 1 | Condition | Onset Date MMM yy <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | Staff Initials/Date |
| | Comments | Ongoing at Enrollment? yes no <input type="checkbox"/> <input type="checkbox"/> | Severity Grade not gradable <input type="checkbox"/> OR <input type="checkbox"/> |
| 2 | Condition | Onset Date MMM yy <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | Staff Initials/Date |
| | Comments | Ongoing at Enrollment? yes no <input type="checkbox"/> <input type="checkbox"/> | Severity Grade not gradable <input type="checkbox"/> OR <input type="checkbox"/> |
| 3 | Condition | Onset Date MMM yy <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | Staff Initials/Date |
| | Comments | Ongoing at Enrollment? yes no <input type="checkbox"/> <input type="checkbox"/> | Severity Grade not gradable <input type="checkbox"/> OR <input type="checkbox"/> |
| 4 | Condition | Onset Date MMM yy <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> | Staff Initials/Date |
| | Comments | Ongoing at Enrollment? yes no <input type="checkbox"/> <input type="checkbox"/> | Severity Grade not gradable <input type="checkbox"/> OR <input type="checkbox"/> |

Purpose:

The Pre-existing Conditions form serves as the “starting point” or baseline from which study clinicians must determine whether conditions identified during follow-up are adverse events (AEs).

General Instructions:

- At the Screening Visit, record relevant baseline medical history. This includes conditions and symptoms reported by the participant as well as any conditions identified via physical exam or laboratory testing. This includes, but is not limited to, history of hospitalizations, surgeries, allergies, any condition that required prescription or chronic medication (that is, more than 2 weeks in duration), and acute conditions ongoing at screening and/or that occur between screening and enrollment.
- At the Enrollment Visit, review and update as needed.
- Do record pre-existing conditions if identified during follow-up. Add a chart note to explain why the PRE entry was added after Enrollment.

Item-specific Instructions:

| | |
|-------------------------------|--|
| Page | Number pages sequentially throughout the study, starting with “01.” Do not repeat page numbers. Do not renumber any Pre-existing Conditions pages after transmitting, unless instructed by Data Manager. |
| Condition | Whenever possible, provide a diagnosis instead of listing a cluster of symptoms. If no diagnosis is identified, each symptom must be recorded as a separate entry on the Pre-existing Conditions form. If an abnormal lab value is reported, record the lab assay with the direction (i.e., increased or decreased) of the abnormality. For example, “decreased hematocrit” or “increased ALT.” |
| Onset Date | If the participant is unable to recall the date, obtain participant’s best estimate. At a minimum, the year is required. If the condition is diagnosed due to an abnormal lab result, record the date on which the specimen was collected. |
| Comments | This field is optional. Use it to record any additional relevant information about the condition, including any associated signs/symptoms. |
| Ongoing at Enrollment? | Mark “yes” for chronic conditions, as well as any other conditions, ongoing at the Enrollment Visit. If a condition resolves or increases in severity or frequency after the Enrollment Visit, document this in chart notes and/or another document other than this form. |
| Severity Grade | For each condition, grade the severity according to the <i>Division of AIDS (DAIDS) Table for Grading the Severity of Adult and Pediatric Adverse Events</i> (Version 2.0). If a condition is not gradable, mark “not gradable”. Review and update as needed for conditions ongoing at the Enrollment Visit. |



(HPTN 082) DF/Net 083

(PO) 441

Visit Code .

Participant ID:

- -
Site Number Participant Number Chk

Outcome unobtainable
 → End of form.

Pregnancy Outcome

1 How many pregnancy outcomes resulted from the reported pregnancy?

2 OUTCOME #1

2a. Outcome Date

dd MMM yy

2b. Specify outcome *Mark only one.*

full-term live birth (≥ 37 weeks) → 2b1. Method C-section
 premature live birth (< 37 weeks) → vaginal
 spontaneous fetal death and/or still birth (≥ 20 weeks)
 spontaneous abortion (< 20 weeks)
 ectopic pregnancy
 therapeutic/elective abortion

2c. Were any fetal/infant congenital anomalies identified?

yes no not assessed
 → If yes, complete AE Log and EAE Reporting form.

If only one outcome, end of form.

3 OUTCOME #2

3a. Outcome Date

dd MMM yy

3b. Specify outcome *Mark only one.*

full-term live birth (≥ 37 weeks) → 3b1. Method C-section
 premature live birth (< 37 weeks) → vaginal
 spontaneous fetal death and/or still birth (≥ 20 weeks)
 spontaneous abortion (< 20 weeks)
 ectopic pregnancy
 therapeutic/elective abortion

3c. Were any fetal/infant congenital anomalies identified?

yes no not assessed
 → If yes, complete AE Log and EAE Reporting form.

Comments:

Purpose: This form is used to report the pregnancy outcome(s) of a pregnancy reported post-enrollment.

General Instructions:

- Complete this form when information about a pregnancy outcome becomes available to study staff or when it is determined that the outcome is unobtainable. A **Pregnancy Outcome** form is required for each **Pregnancy Report and History** form that is completed for a participant.
- A pregnancy outcome can be an infant or a fetus. The conception of twins should result in reporting of two outcomes. If a pregnancy results in more than two outcomes, contact SDMC Clinical Data Manager for guidance on how to complete this form.

Item-specific Instructions:

| | |
|-----------------------------|--|
| Visit Code | Record the visit code of the participant's corresponding Pregnancy Report and History form. |
| Outcome unobtainable | If it is determined that an outcome is unobtainable (i.e., the participant refuses further contact), mark "Outcome unobtainable" at the top of the page and transmit to DataFax. Note the rationale in Comments. |
| Items 2b and 3b | Refer to the protocol and applicable version of the <i>Manual for Expedited Reporting of Adverse Events</i> to DAIDS to evaluate if the outcome or any maternal complications, as a result of the pregnancy outcome, meets AE and/or EAE reporting requirements. If prior to study termination, a therapeutic/elective abortion is performed due to a pregnancy complication, the pregnancy complication should be reported on an Adverse Event Log (AE) , with "procedure/surgery" marked under item 8, "Treatment." |
| Items 2c and 3c | If prior to study termination, a woman on study has a baby with a congenital anomaly/birth defect and the infant does not have his/her own participant ID, report the event on an Adverse Event Log (AE) . On the AE Log , record "Congenital Anomaly in Offspring" on Item 1, record the Outcome Date as the Onset Date, and note the specific anomaly in Comments. Also transmit an Expedited Adverse Event Reporting form (EAE). |



(HPTN 082) DF/Net 083

(PR) 440

Visit Code .

Participant ID:

- -
Site Number Participant Number Chk

Pregnancy Report & History

1 Date of onset of last menstrual period
dd MMM yy

2 Estimated date of delivery
dd MMM yy

3 Has the participant ever been pregnant before? yes no → If no, end of form.

3a. Is this the participant's first pregnancy since enrollment in this study? yes no → If no, end of form.

3a1. Number of full-term live births (≥ 37 weeks)

3a2. Number of premature live births (< 37 weeks)

3a3. Number of spontaneous fetal deaths and/or still births (≥ 20 weeks)

3a4. Number of spontaneous abortions (< 20 weeks)

3a5. Number of therapeutic/elective abortions

3a6. Number of ectopic pregnancies

4 Does the participant have a history of pregnancy complications or fetal/infant congenital anomalies before study enrollment? yes no
 → If yes, document in participant's records.

Comments:

General Instructions:

Complete this form when reporting a pregnancy of a study participant post-enrollment through termination. Record the visit code of the visit at which study staff became aware that the participant is/was pregnant.

Item-specific Instructions:

| | |
|---------------|--|
| Item 1 | A complete date is required. Record best estimate if date not known. |
| Item 2 | A complete date is required. |

Purpose: This log is used to document temporary holds and early permanent discontinuations of study product use.

General Information and Instructions:

This form is completed each time the study product is temporarily held or permanently discontinued, for either clinical reasons or participant preference.

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

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

In the case of temporary product holds, do not wait for information about product resumption to transmit the log page—transmit the log to DataFax as soon as items 1–4 are completed and re-transmit the page once item 5 has been completed.

Item-specific Instructions:

| | |
|------------------------|---|
| Page | Number pages sequentially throughout the study, starting with 01. Do not repeat page numbers. Do not renumber any Product Hold/Discontinuation Log pages after transmitting, unless instructed by the Data Manager. |
| Items 3a and 3b | Complete only item 3a or item 3b; do not complete both. If product is being held or discontinued due to an adverse experience, record the page number of the AE Log documenting the product hold or permanent discontinuation. |
| Item 4 | Record the date the participant last used study product. Use a best estimate if the actual date cannot be determined. |
| Item 5 | Complete this item once study staff has determined that the participant can resume study product use or has determined that the participant is permanently discontinued from study product use. Mark “yes” if study staff instructed the participant to resume use of study product. Mark “no (permanently discontinued)” if the participant was permanently discontinued from study product use. If the reason for the product hold, as recorded in item 3, has resolved but there is a concurrent reason for continuing the product hold, mark “no (continuing for another reason)”. |
| Item 5a | If study product use will resume, record the date the participant resumed dosing and the visit code at which it was decided to resume. |

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

General Information and Instructions:

- Consult HPTN 082 Management Group (082mgmt@hptn.org) to confirm whether the event qualifies as a reportable deviation.
- After confirmed, complete this form each time a protocol deviation is identified.
- Reportable protocol deviations are defined by the HPTN as individual incidents, trends or omissions that result in:
 - Significant added risk to the participant
 - Non-adherence to significant protocol requirements
 - Significant non-adherence to GCP
- If a deviation needs to be reported but is not associated with a participant (for example, necessary test kits are not available on site), use a PTID that follows the format below on the PDL CRF:
 - XXX-00000-0
 - Enter your site DataFax ID number in the first 3 digits followed by zeros. Assign page numbers sequentially when completing new PDLs using this PTID.

Item-specific Instructions:

| | |
|---------------|--|
| Page | Number pages sequentially for each participant, starting with 01. Do not re-assign page numbers if a form is marked for deletion. |
| Item 2 | Record the date the event occurred (start date). |
| Item 5 | Record the two-digit category code that best describes the type of deviation. Use "99" (other) if none of the listed categories match. Describe the specifics of the deviation in item 6. |
| Item 6 | Briefly describe the specific details of the deviation. |
| Item 9 | Record name of site staff person who completed the form. |
| Code | Description |
| 01 | Inappropriate enrollment: The participant enrolled and not all eligibility requirements were met. |
| 02 | Failure to follow trial randomization or blinding procedures: Include instances where randomization procedures were not followed by site staff. |
| 03 | Study product management deviation: Site staff did not instruct the participant to hold, permanently discontinue, or resume study product use per protocol requirements. |
| 04 | Study product dispensing error: The wrong study product was dispensed to a participant, or study product was dispensed to a participant on product hold. |
| 05 | 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. |
| 06 | Breach of confidentiality: Include potential and actual cases where participant confidentiality is breached. For example, a staff member puts a participant's name on a case report form. |
| 07 | Physical assessment deviation: Examples include a protocol-specified exam or assessment consistently not being performed (a single missed exam during one participant visit would not be considered a reportable protocol deviation). |
| 08 | Lab assessment deviation: Examples include a protocol-specified laboratory assay consistently not being performed (a single missed assay during one participant visit would not be considered a reportable protocol deviation). |
| 09 | Use of non-IRB/EC-approved materials: Examples include use of ANY study-related material that has not received IRB or EC approval for use per site requirements. |
| 10 | Informed assent/consent process deviation: Examples include failure to accurately execute and/or document any part of the informed consent process. |
| 99 | Other |



(HPTN 082) DF/Net 083

(RAN) 070

Participant ID:

| | | | | | | | | | | | |
|----------------------|----------------------|----------------------|---|---------------------------|----------------------|----------------------|----------------------|----------------------|---|----------------------|------------|
| <input type="text"/> | <input type="text"/> | <input type="text"/> | - | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | - | <input type="text"/> | |
| <i>Site Number</i> | | | | <i>Participant Number</i> | | | | | | | <i>Chk</i> |

Randomization

| | | | | | | | |
|---|------------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| 1 | Date of randomization: | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> | <input type="text"/> |
| | | <i>dd</i> | <i>MMM</i> | <i>yy</i> | | | |

| | | |
|---|--|---|
| 2 | To which study arm was the participant randomized? | <input type="checkbox"/> Standard adherence support |
| | | <input type="checkbox"/> Enhanced adherence support |

Comments:

Purpose: This form is used to document a participant's randomization assignment.



(HPTN 082) DF/Net 083

(SO) 006

Participant ID:

- -
Site Number Participant Number Chk

Screening Date:

dd MMM yy

Screening Outcome

1 Has the participant previously screened for this study? yes no
 If yes, record PTID assigned at that time:
Site Number Participant Number Chk

2 Did the participant enroll in the study? yes no
 If yes, end of form.

3 Why was the participant not enrolled in the study? *Mark all that apply.*

| | |
|---|--|
| <input type="checkbox"/> Not female at birth | <input type="checkbox"/> Completion of PEP regimen within 4 weeks prior to screening |
| <input type="checkbox"/> Younger than 16 or older than 25 | <input type="checkbox"/> Has a health condition that may interfere with participation |
| <input type="checkbox"/> In the month prior to screening, no vaginal or anal intercourse reported | <input type="checkbox"/> Pregnant or planning to become pregnant during the next 12 months |
| <input type="checkbox"/> Score <5 on VOICE risk score tool | <input type="checkbox"/> Current active and serious infections which could interfere with study participation |
| <input type="checkbox"/> Not interested in PrEP | <input type="checkbox"/> Hepatitis B (HBV) seropositive or unwilling to accept vaccination if HBV seronegative |
| <input type="checkbox"/> Lacks mobile phone access or SMS capacity | <input type="checkbox"/> Reactive or positive HIV test result |
| <input type="checkbox"/> Planning to relocate or absences >4 weeks required in the next 12 months | <input type="checkbox"/> Signs or symptoms of acute HIV infections |
| <input type="checkbox"/> Reported PrEP use within the last 12 months | <input type="checkbox"/> Abnormal kidney function tests |
| <input type="checkbox"/> Participation in another clinical trial using investigational agents | <input type="checkbox"/> Allergy/sensitivity to the study drug or its components |
| <input type="checkbox"/> Prior participation in the active arm of an HIV vaccine trial | <input type="checkbox"/> Receiving therapy with other investigational agents or agents which may inhibit or compete for elimination via active renal tubular secretion |
| <input type="checkbox"/> Current use of ARV drugs for post-exposure prophylaxis (PEP) | <input type="checkbox"/> Other, specify: _____ |
| | <input type="checkbox"/> Unable to complete Enrollment Visit within 45 days of blood collection at Screening Visit. |

Comments:

Purpose: This form is used to collect reasons why a participant who screens for this study is not enrolled.

General Information/Instructions: Complete and transmit this form to DataFax for all participants who screen for this study regardless if they enroll.

Item-specific Instructions:

| | |
|----------------|--|
| Item 1 | If a participant screens a second time for the study, please assign a new PTID and administer the screening CASI using the new PTID. |
| Item 1a | Record the first PTID assigned to the participant during previous screening. |

Purpose: This form is used to track follow-up that occurs as a result of participant interaction or non-response with the study SMS system.

General Instructions:

If additional study data is collected as a result of this contact, complete **Follow-up Visit** Form (Interim Visit) and any other required CRFs. These may include: **Adverse Event Log, HIV Test Results, Local Laboratory Results, Social Impact Log**, or other forms as appropriate.

Item-specific Instructions:

| | |
|---------------|---|
| Item 6 | Select the main cause of outreach, as indicated in Item 2 response. For example, when non-response triggers follow-up: select "Participant forgot to respond to SMS" if the participant forgot to respond to her weekly check-in text within the specified window. If the participant was out of phone credit, did not have access to her phone, etc., select "Participant could not respond to SMS." |
|---------------|---|

Purpose: Complete this form when recording the occurrence and resolution of social impacts reported spontaneously at any time during the study.

General Information/Instructions: Social impacts are events that the participant thinks are related to participation in this study.

Item-specific Instructions:

| | |
|---------------|---|
| Item 4 | Use the following definitions to code the social impact. |
| Code | Description |
| 01 | Personal Relationships: Had negative experiences with family, friends, significant others, or sex partners. |
| 02 | 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. |
| 03 | Employment: Been turned down for a new job, lost a job, or experienced other problems at work. |
| 04 | Education: Been turned down by an educational program, told to leave an educational program, or experienced other problems at school. |
| 05 | Medical/Dental: Been refused medical or dental treatment, or treated negatively by a health care provider. |
| 06 | Health Insurance: Lost health insurance, had a problem getting new health insurance, or experienced other problems related to health insurance. |
| 07 | Life Insurance: Lost life insurance, had a problem getting new life insurance, or experienced other problems related to life insurance. |
| 08 | Housing: Had trouble getting or keeping housing, or had other problems related to housing. |
| 09 | Military/Other Government Agency: Had a problem with the military or any other government agencies. |
| 10 | Other: Had other problems not covered in the codes above. |
| 11 | Personal relationships benefit: Had positive experiences with family, friends, significant others, or sex partners. |
| 12 | Emotional benefit: Experienced improved feelings about circumstances or abilities, or experienced positive change in mood. |
| 13 | Medical care benefit: Had improved access or quality of medical or dental treatment, or treated positively by a health care provider. |
| 14 | Counseling benefit: Had improved access to counseling, or experienced benefit from topics or techniques discussed during counseling. |
| 15 | Other benefit: Had other benefits not covered in the codes above. |



(HPTN 082) DF/Net 083

(SS) 230

Visit Code .

Participant ID:

- -
Site Number Participant Number Chk

Initial Specimen Collection Date:

dd MMM yy

Specimen Storage

1 Plasma

Alternate Collection Date

dd MMM yy

Time Collected

:
hr min
(24-hour clock)

stored not stored not collected not required

Reason not stored or not collected: _____

2 Dried blood spot (DBS)

Alternate Collection Date

dd MMM yy

Time Collected

:
hr min
(24-hour clock)

stored not stored not collected not required

Reason not stored or not collected: _____

Comments:

Purpose: This form is used to document the storage of specimens that will be tested at a lab other than the site local laboratory.

Item-specific Instructions:

| | |
|---|---|
| Initial Specimen Collection Date | Record the date that the first specimen(s) was collected for this visit. A complete date is required. |
| Alternate Collection Date | This date is to be completed only if the specimen was collected after the Initial Specimen Collection Date for the same visit. A specimen collected for the same visit but on a different day should be recorded on the same form only when obtained within the same visit window. A complete date is required. |
| Items 1–2 | <ul style="list-style-type: none"> • If a specimen was collected and stored, mark “stored.” • If a specimen was collected but not stored, mark “not stored.” • If a specimen was required to be collected and stored at this visit but was not collected, mark “not collected.” • If a specimen was not required to be collected and stored at this visit, mark “not required.” In addition, if a specimen WAS required but was NOT collected because the participant did not consent to long-term specimen storage of that sample, mark “not required.” • If a participant doesn’t consent for long-term plasma storage or dried blood spot specimen collection, mark the “not required” box. |

General Instructions:

This form is completed for every enrolled participant at either the scheduled exit/end of study visit or when the participant is no longer participating in the study.

Item-specific Instructions:

| | |
|-----------------|---|
| Item 1 | A complete date is required. |
| Item 2 | Mark only the primary reason for termination. |
| Item 2a | Only mark 2a if the participant completes the protocol-defined final visit. |
| Item 2b1 | If date is recorded, at a minimum, the month and year are required. |
| Item 2h | Only mark 2l when instructed. |
| Item 3a | Record the page number of the Adverse Event Log on which the AE was recorded. In situations where more than one AE is associated with termination, record the AE that most strongly influenced the decision to terminate. If termination is associated with a non-reportable AE, record the event on the "specify" line. |



(HPTN 082) DF/Net 083

(VRS) 130

Participant ID:

- -
Site Number Participant Number Chk

Form Completion Date:

dd MMM yy

VOICE Risk Score

| | | | |
|----------|--|--|---|
| 1 | Is the participant currently married or living with her primary sex partner? <i>Answers are worth 0 points unless otherwise noted.</i> | yes <input type="checkbox"/> no <input type="checkbox"/> → <i>If no, score +2</i> | VOICE Risk Score <input type="text"/> |
| 2 | Does her husband or primary partner provide the participant with financial and/or material support? <i>Answers are worth 0 points unless otherwise noted.</i> | yes <input type="checkbox"/> no <input type="checkbox"/> → <i>If no, score +1</i> | VOICE Risk Score <input type="text"/> |
| 3 | Does her husband or primary partner have any sex partners other than the participant? <i>Answers are worth 0 points unless otherwise noted.</i> | yes <input type="checkbox"/> no <input type="checkbox"/> don't know <input type="checkbox"/> → <i>If yes or don't know, score +2</i> | VOICE Risk Score <input type="text"/> |
| 4 | In the past 3 months, what number of alcoholic drinks per week did the participant have on average? <i>Answers are worth 0 points unless otherwise noted.</i> | # of drinks <input type="text"/> <input type="text"/> → <i>If 1 or more, score +1</i> | VOICE Risk Score <input type="text"/> |
| 5 | Does the participant have chlamydia, gonorrhea, trichomonas, or syphilis? <i>Answers are worth 0 points unless otherwise noted.</i> | yes <input type="checkbox"/> no <input type="checkbox"/> → <i>If yes, score +2</i> | VOICE Risk Score <input type="text"/> |
| 6 | Is the participant ≤ 25 years of age? <i>Answers are worth 0 points unless otherwise noted.</i> | yes <input checked="" type="checkbox"/> no <input type="checkbox"/> → <i>If yes, score +2</i> | VOICE Risk Score <input type="text" value="2"/> |
| 7 | Total VOICE RISK Score: _____ → | | <input type="text"/> <input type="text"/> |

Comments:

Purpose: This form is used to document the participant risk score according to the VOICE instrument.

General Instructions: This form is completed at screening and submitted for every participant, regardless of screening outcome.

Item-specific Instructions:

| | |
|---------------|--|
| Item 5 | Complete this item based on laboratory test results. |
| Item 7 | Sum scores for items 1 through 6. |