



**Purpose:** This form is used to collect participants' demographic information.

**General Information and Instructions:** This form is completed and faxed to DataFax only if the participant enrolls in the study.

**Item-specific Instructions:**

<b>Item 1</b>	If any portion of the date of birth is unknown, record age at time of enrollment. If age is unknown, record participant's estimate of their age. Do not complete both answers.
<b>Item 3</b>	This item must be self-reported by the participant. Site staff is encouraged to document in chart notes if the participant, during study participation, prefers to be referred to by a specific pronoun or gender.
<b>Items 4–6</b>	Record the participant's race or ethnic group based on self-definition.



Participant ID:

-       -   
*Site Number Participant Number Chk*

Screening Visit Date:

*dd MMM yy*

**Screening Outcome**

**1** Has the participant screened for the study before?  Yes  No *If yes, record the first Participant ID assigned:*    -       -   
*Site Number Participant Number Chk*

**2** Did the participant take the Screening Questionnaire at this visit?  Yes  No

**3** Did the participant enroll in the study?  Yes  No *If Yes, end of form.*

3a. Why didn't the participant enroll in the study? *Mark all that apply.*

- 3a1. Younger than 18 or older than 44 *Record age:*   *Years*
- 3a2. Unwilling to undergo HIV testing throughout the study and to receive those test results
- 3a3. Did not report at least one act of anal intercourse in the previous 3 months with another man
- 3a4. Not able to provide complete locator information for himself and at least 2 other personal contacts
- 3a5. Not planning to remain in the study area for at least 1 year
- 3a6. Unwilling to adhere to study procedures
- 3a7. Past or current participation in a biomedical and/or behavioral HIV/STI intervention or cohort study
- 3a8. HIV-infected and already on ART or in HIV care
- 3a9. Discordant HIV test results at Screening Visit
- 3a10. Discordant HIV test results between HIV tests done at Screening Visit and HIV tests done at Enrollment Visit
- 3a11. HIV positive and site has reached enrollment cap
- 3a12. Did not return for enrollment within 30 days
- 3a13. Withdrew consent
- 3a14. Any other reason or condition that, in the opinion of the IoR, would interfere with participation
- 3a15. Other, specify: \_\_\_\_\_

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

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



(HPTN 075) DF/Net 070

(SSS) 010

Participant ID:

			-						-		
Site Number				Participant Number							Chk

**Screening Specimen Storage**

1 Did the participant agree to have leftover samples from the Screening Visit stored?  Yes  No

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



(HPTN 075) DF/Net 070

(ENR) 124

Participant ID:

			-					-	
<i>Site Number</i>				<i>Participant Number</i>					<i>Chk</i>

Enrollment Date:

<i>dd</i>		<i>MMM</i>		<i>yy</i>	

**Enrollment**

- |          |   |                                     |   |
|----------|---|-------------------------------------|---|
| <b>1</b> | Did the participant consent to having blood stored and used for future testing? | <input type="checkbox"/> <i>Yes</i> | <input type="checkbox"/> <i>No</i>                                      |
| <b>2</b> | Did the participant consent to having urine stored and used for future testing? | <input type="checkbox"/> <i>Yes</i> | <input type="checkbox"/> <i>No</i>                                      |
| <b>3</b> | Did the participant consent to having swabs stored and used for future testing? | <input type="checkbox"/> <i>Yes</i> | <input type="checkbox"/> <i>No</i>                                      |
| <b>4</b> | Is the participant HIV-infected at enrollment?                                  | <input type="checkbox"/> <i>Yes</i> | <input type="checkbox"/> <i>No</i>                                      |
| <b>5</b> | Did the participant complete an Enrollment Questionnaire at this visit?         | <input type="checkbox"/> <i>Yes</i> | <input type="checkbox"/> <i>No</i> —————▶ <i>If No, specify reason:</i> |

*Comments:*

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**General Information and Instructions:** Complete this form once at the Enrollment Visit.

**Item-specific Instructions:**

<b>Items 1-3</b>	These items refer to storage of specimens for future post-study testing, not protocol required storage and testing.
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(HPTN 075) DF/Net 070

(FUV) 133

Visit Code   .

Participant ID:

-      -

*Site Number Participant Number Chk*

Visit Date:

*dd MMM yy*

**Follow-up Visit**

**1** Is this an interim visit?  *yes*  *no* —————▶ *If no go to item 2.*

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

- 1a1. Report a social impact
- 1a2. HIV lab testing
- 1a3. Lab testing other than HIV
- 1a4. Repeat laboratory work including HIV confirmatory testing
- 1a5. Other, specify: \_\_\_\_\_

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

- 1b1. HIV Test Results
- 1b2. Local Laboratory Results
- 1b3. CD4+/Viral Load Results
- 1b4. Sexually Transmitted Infections
- 1b5. Specimen Storage
- 1b6. Other, specify: \_\_\_\_\_

**2** Is this an early termination visit?  *Yes*  *No*  
 —————▶ *If yes, complete Termination form.*

**3** 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.*

**4** Did the participant complete a Follow-up Questionnaire at this visit?  *Yes*  *No* —————▶ *If No, specify reason:*  
 \_\_\_\_\_

*Comments:*

---

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

**Item-specific Instructions:**

<b>Item 1b</b>	Mark the newly completed forms (in addition to this form) that are being submitted for the interim visit/contact. If “other, specify” is marked, record the form acronym(s) in the space provided.
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Note: Number pages sequentially (01, 02, 03) for each participant.

Page #

Participant ID:

-       -

*Site Number Participant Number Chk*

**Social Impact Log**

1 Concisely describe social impact:

2 Onset date:

*dd MMM yy*

3 Reported at visit:   .

4 Social impact code:

**Social Impact Codes (see back for definitions)**

01 Personal Relationships	05 Medical/Dental	09 Military/Other Government Agency
02 Travel/Immigration	06 Health Insurance	10 Other
03 Employment	07 Life Insurance	
04 Education	08 Housing	

**Purpose:** Complete this form when recording the occurrence and resolution of adverse 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:**

<b>Item 4</b>	Use the following definitions to code the social impact.		
	Code		Definition
	<b>01</b>	Personal Relationships	Had negative experiences with family, friends, significant others, or sex partners.
	<b>02</b>	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.
	<b>03</b>	Employment	Been turned down for a new job, lost a job, or experienced other problems at work.
	<b>04</b>	Education	Been turned down by an educational program, told to leave an educational program, or experienced other problems at school.
	<b>05</b>	Medical/Dental	Been refused medical or dental treatment, or treated negatively by a health care provider.
	<b>06</b>	Health Insurance	Lost health insurance, had a problem getting new health insurance, or experienced other problems related to health insurance.
	<b>07</b>	Life Insurance	Lost life insurance, had a problem getting new life insurance, or experienced other problems related to life insurance.
	<b>08</b>	Housing	Had trouble getting or keeping housing, or had other problems related to housing.
	<b>09</b>	Military/Other Government Agency	Had a problem with the military or any other government agencies.
<b>10</b>	Other	Had other problems not covered in the codes above.	



(HPTN 075) DF/Net 070

(LLR-1) 152

Visit Code   .

Participant ID:

-      -   
*Site Number Participant Number Chk*

Initial Specimen Collection Date:

*dd MMM yy*

**Local Laboratory Results, page 1 of 2**

<b>1</b>	HEMOGRAM	<i>Not done/ Not collected</i> <input type="checkbox"/>	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>
	1a. Hemoglobin	<i>Not reported</i> <input type="checkbox"/>	<input type="text"/> <input type="text"/> . <input type="text"/> <i>g/dL</i>
	1b. Hematocrit	<input type="checkbox"/>	<input type="text"/> <input type="text"/> . <input type="text"/> %
	1c. MCV	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <i>fL</i>
	1d. Platelets	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <i>x 10<sup>3</sup>/mm<sup>3</sup></i>
	1e. WBC	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <i>x10<sup>3</sup>/mm<sup>3</sup></i>
	DIFFERENTIAL	<i>Not done</i> <input type="checkbox"/>	→ <i>If not done, go to item 2 on page 2.</i>
			Absolute Count <i>cells/mm<sup>3</sup></i>
	1f. Neutrophils	<i>Not reported</i> <input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	1g. Lymphocytes	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	1h. Monocytes	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	1i. Eosinophils	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	1j. Basophils	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	1k. Atypical lymphocytes	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
	1l. Other	<input type="checkbox"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <i>Specify: _____</i>

Comments:

**Purpose:** This form is used to collect results from tests performed by the site's local laboratory.

**Item-specific Instructions:**

<b>Initial Specimen Collection Date</b>	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.
<b>Alternate Collection Date</b>	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.
<b>Results Reporting</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• 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. Refer to Study Specific Procedures (SSP) for conversion instructions.</li> <li>• If the site lab does not report results to the same level of precision allowed on the CRF, record a zero (0) in the box(es) to the right of the decimal point. For example, a lab-reported hematocrit value of 30% would be recorded as 30.0%</li> <li>• 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. -- 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.</li> </ul>
<b>Not done/Not collected</b>	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.



Visit Code   .

Participant ID:

-      -   
*Site Number Participant Number Chk*

**Local Laboratory Results, page 2 of 2**

<b>2</b>	<p><b>URINE TESTS</b></p> <p><i>If Not done/Not collected, go to item 3.</i></p> <p>2a. Protein</p> <p>2b. Glucose</p>	<p><i>Not done/Not collected</i></p> <input type="checkbox"/>	<p><b>Alternate Collection Date</b></p> <p><input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p style="text-align: center;"><i>dd MMM yy</i></p>	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="text-align: center;"><i>neg</i></td> <td style="text-align: center;"><i>trace</i></td> <td style="text-align: center;"><i>1+</i></td> <td style="text-align: center;"><i>2+</i></td> <td style="text-align: center;"><i>3+</i></td> <td style="text-align: center;"><i>4+</i></td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> <tr> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>	<i>neg</i>	<i>trace</i>	<i>1+</i>	<i>2+</i>	<i>3+</i>	<i>4+</i>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>neg</i>	<i>trace</i>	<i>1+</i>	<i>2+</i>	<i>3+</i>	<i>4+</i>																	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																	
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>																	
<b>3</b>	<p><b>RENAL FUNCTION TESTS</b></p> <p>3a. Creatinine</p>	<p><i>Not done/Not collected</i></p> <input type="checkbox"/>	<p><b>Alternate Collection Date</b></p> <p><input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p style="text-align: center;"><i>dd MMM yy</i></p>	<p style="text-align: right;"><i>mg/dL</i></p> <p><input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/></p> <p style="text-align: center;"><b>OR</b></p> <p><input type="text"/> <input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/> <i>μmol/L</i></p>																		
<b>4</b>	<p><b>LIVER FUNCTION TESTS</b></p> <p>4a. AST (SGOT)</p> <p>4b. ALT (SGPT)</p> <p>4c. Total bilirubin</p>	<p><i>Not done/Not collected</i></p> <input type="checkbox"/>   <input type="checkbox"/>   <input type="checkbox"/>	<p><b>Alternate Collection Date</b></p> <p><input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p style="text-align: center;"><i>dd MMM yy</i></p>	<p style="text-align: right;"><i>U/L</i></p> <p><input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p style="text-align: right;"><i>U/L</i></p> <p><input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p style="text-align: right;"><i>mg/dL</i></p> <p><input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/></p>																		
<b>5</b>	<p><b>OTHER CHEMISTRIES</b></p> <p>5a. Phosphorus (phosphate)</p>	<p><i>Not done/Not collected</i></p> <input type="checkbox"/>	<p><b>Alternate Collection Date</b></p> <p><input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p style="text-align: center;"><i>dd MMM yy</i></p>	<p style="text-align: right;"><i>mg/dL</i></p> <p><input type="text"/> <input type="text"/> . <input type="text"/> <input type="text"/></p>																		

Comments:

**Item-specific Instructions:**

<b>Alternate Collection Date</b>	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.
<b>Results Reporting</b>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• 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. Refer to Study Specific Procedures (SSP) for conversion instructions.</li> <li>• If the site lab does not report results to the same level of precision allowed on the CRF, record a zero (0) in the box(es) to the right of the decimal point. For example, a lab-reported hematocrit value of 30% would be recorded as 30.0%</li> <li>• 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.        -- 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.</li> </ul>
<b>Not done/Not collected</b>	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.



(HPTN 075) DF/Net 070

(STI) 160

Visit Code   .

Participant ID:

-      -

*Site Number Participant Number Chk*

Initial Specimen Collection Date:

*dd MMM yy*

**Sexually Transmitted Infections**

<b>1</b>	<b>1 SYPHILIS SCREENING TEST</b>		<b>Alternate Collection Date</b>				
			<input type="text"/>	<input type="text"/>	<input type="text"/>		
			<i>dd</i>	<i>MMM</i>	<i>yy</i>		
			<i>Not done</i>	<i>Non-Reactive</i>	<i>Reactive</i>		
	1a. Treponemal test	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
	1b. Non-Treponemal test	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>			
	1c. Titer if indicated	<b>1:</b> <input type="text"/>	<i>OR</i>	<input type="checkbox"/>	<i>N/A</i>		
<b>2</b>	<b>2 N. gonorrhea – URINE</b>		<b>Alternate Collection Date</b>		<i>Negative</i>	<i>Positive</i>	
			<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
		<i>Not done/ Not collected</i>	<i>dd</i>	<i>MMM</i>	<i>yy</i>		
<b>3</b>	<b>3 C. trachomatis – URINE</b>		<b>Alternate Collection Date</b>		<i>Negative</i>	<i>Positive</i>	
			<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
		<i>Not done/ Not collected</i>	<i>dd</i>	<i>MMM</i>	<i>yy</i>		
<b>4</b>	<b>4 HEPATITIS B</b>		<b>Alternate Collection Date</b>				
			<input type="checkbox"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	
			<i>Not done/ Not collected</i>	<i>dd</i>	<i>MMM</i>	<i>yy</i>	
			<i>Negative</i>	<i>Positive</i>			
	4a. Hepatitis B Surface Antigen (HBsAg)	<input type="checkbox"/>	<input type="checkbox"/>				
	4b. Hepatitis B Surface Antibody (HBsAb)	<input type="checkbox"/>	<input type="checkbox"/>				
	4c. Hepatitis B Core Antibody (HBCoreAb)	<input type="checkbox"/>	<input type="checkbox"/>				

Comments:

**Item-specific Instructions:**

<b>Initial Specimen Collection Date</b>	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.
<b>Not done/Not collected</b>	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.
<b>Alternate Collection Date</b>	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.



Visit Code   .

Participant ID:

-      -   
*Site Number Participant Number Chk*

**HIV Test Results**

<b>1</b>	Not collected <input type="checkbox"/>	Specimen #1 Collection Date				
	HIV TEST RESULTS	<input type="text"/> <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>		
	1a. HIV Rapid Test 1 Kit Code	Not done <input type="checkbox"/>	Kit code <input type="text"/> <input type="text"/>	1a1. HIV Rapid 1	Non-reactive <input type="checkbox"/>	Reactive <input type="checkbox"/>
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"/>	
<b>2</b>	Not collected <input type="checkbox"/>	Specimen #2 Collection Date		Visit Code		
	HIV TEST RESULTS	<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>dd</i>	<i>MMM</i>	<i>yy</i>		
	2a. HIV Rapid Test 1 Kit Code	Not done <input type="checkbox"/>	Kit code <input type="text"/> <input type="text"/>	2a1. HIV Rapid 1	Non-reactive <input type="checkbox"/>	Reactive <input type="checkbox"/>
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"/>	
<b>3</b>	Final HIV Status:		<input type="checkbox"/> Negative	<input type="checkbox"/> Positive	<input type="checkbox"/> Indeterminate	

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. Fax this form to DataFax when the final test results are available and recorded.

**Item-specific Instructions:**

<b>Specimen Collection Date</b>	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.																
<b>Not collected</b>	If sample 1 and/or sample 2 were not collected at all, mark the “Not collected” box next to the Specimen Collection Date. 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, to be collected, record the reason(s) in the Comments.																
<b>Not done</b>	For each test, mark either the “Not done” box or enter a test result.																
<b>Items 1 and 2 Kit codes</b>	<p>Record the rapid and/or EIA test kit codes from the tables below. If a test kit being used at your site is not listed, contact the SCHARP Project Manager for a new code.</p> <table border="1" data-bbox="496 891 1353 1115"> <thead> <tr> <th data-bbox="496 891 1190 945">RAPID TEST KIT</th> <th data-bbox="1193 891 1353 945">Code</th> </tr> </thead> <tbody> <tr> <td data-bbox="496 949 1190 1003">OraQuick ADVANCE Rapid HIV-1/2</td> <td data-bbox="1193 949 1353 1003">02</td> </tr> <tr> <td data-bbox="496 1008 1190 1061">Uni-Gold™ Recombigen HIV-1/2</td> <td data-bbox="1193 1008 1353 1061">03</td> </tr> <tr> <td data-bbox="496 1066 1190 1115">Alere Determine™ HIV-1/2</td> <td data-bbox="1193 1066 1353 1115">16</td> </tr> </tbody> </table> <table border="1" data-bbox="496 1173 1353 1397"> <thead> <tr> <th data-bbox="496 1173 1190 1227">HIV EIA TEST KIT</th> <th data-bbox="1193 1173 1353 1227">Code</th> </tr> </thead> <tbody> <tr> <td data-bbox="496 1232 1190 1285">ARCHITECT HIV Ag/Ab Combo<sup>35</sup></td> <td data-bbox="1193 1232 1353 1285">50</td> </tr> <tr> <td data-bbox="496 1290 1190 1344">Vironostika Ag/Ab HIV-1/2</td> <td data-bbox="1193 1290 1353 1344">59</td> </tr> <tr> <td data-bbox="496 1348 1190 1397">Murex HIV Ag/Ab combination</td> <td data-bbox="1193 1348 1353 1397">60</td> </tr> </tbody> </table>	RAPID TEST KIT	Code	OraQuick ADVANCE Rapid HIV-1/2	02	Uni-Gold™ Recombigen HIV-1/2	03	Alere Determine™ HIV-1/2	16	HIV EIA TEST KIT	Code	ARCHITECT HIV Ag/Ab Combo <sup>35</sup>	50	Vironostika Ag/Ab HIV-1/2	59	Murex HIV Ag/Ab combination	60
RAPID TEST KIT	Code																
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ARCHITECT HIV Ag/Ab Combo <sup>35</sup>	50																
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Murex HIV Ag/Ab combination	60																



**Item-specific Instructions:**

<b>Initial Specimen Collection Date</b>	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.					
<b>Not done/Not collected</b>	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.					
<b>Alternate Collection Date</b>	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.					
<b>Item 2b</b>	<p>Record the kit code from the table below. If a test kit being used at your site is not listed, contact the SCHARP Project Manager for a new code.</p> <table border="1" data-bbox="429 667 1286 779"> <thead> <tr> <th data-bbox="432 667 1121 723"><b>RNA PCR KIT</b></th> <th data-bbox="1121 667 1283 723"><b>Code</b></th> </tr> </thead> <tbody> <tr> <td data-bbox="432 723 1121 779">Abbott m2000 Real-time</td> <td data-bbox="1121 723 1283 779"><b>0406</b></td> </tr> </tbody> </table>		<b>RNA PCR KIT</b>	<b>Code</b>	Abbott m2000 Real-time	<b>0406</b>
<b>RNA PCR KIT</b>	<b>Code</b>					
Abbott m2000 Real-time	<b>0406</b>					



Visit Code   .

Participant ID:

-      -   
*Site Number Participant Number Chk*

Initial Specimen Collection Date:

*dd MMM yy*

**Specimen Storage**

<b>1</b>	<p><b>Plasma</b></p> <p><i>Alternate Collection Date</i></p> <p><input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  <i>dd MMM yy</i></p> <p><i>Time Collected</i></p> <p><i>hr min</i></p> <p><input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>                  (24-hour clock)</p> <p><i>Reason not stored or not collected:</i> _____</p>	<p><i>stored</i></p> <p><input type="checkbox"/></p>	<p><i>not stored</i></p> <p><input type="checkbox"/></p>	<p><i>not collected</i></p> <p><input type="checkbox"/></p>	<p><i>not required</i></p> <p><input type="checkbox"/></p>
		<p>←</p>			
<b>2</b>	<p><b>Urine</b></p> <p><i>Alternate Collection Date</i></p> <p><input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  <i>dd MMM yy</i></p> <p><i>Time Collected</i></p> <p><i>hr min</i></p> <p><input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>                  (24-hour clock)</p> <p><i>Reason not stored or not collected:</i> _____</p>	<p><i>stored</i></p> <p><input type="checkbox"/></p>	<p><i>not stored</i></p> <p><input type="checkbox"/></p>	<p><i>not collected</i></p> <p><input type="checkbox"/></p>	<p><i>not required</i></p> <p><input type="checkbox"/></p>
		<p>←</p>			
<b>3</b>	<p><b>Rectal Swab-Storage</b></p> <p><i>Alternate Collection Date</i></p> <p><input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  <i>dd MMM yy</i></p> <p><i>Time Collected</i></p> <p><i>hr min</i></p> <p><input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>                  (24-hour clock)</p> <p><i>Reason not stored or not collected:</i> _____</p>	<p><i>stored</i></p> <p><input type="checkbox"/></p>	<p><i>not stored</i></p> <p><input type="checkbox"/></p>	<p><i>not collected</i></p> <p><input type="checkbox"/></p>	<p><i>not required</i></p> <p><input type="checkbox"/></p>
		<p>←</p>			
<b>4</b>	<p><b>Rectal Swab-GC/CT Testing</b></p> <p><i>Alternate Collection Date</i></p> <p><input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  <i>dd MMM yy</i></p> <p><i>Time Collected</i></p> <p><i>hr min</i></p> <p><input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>                  (24-hour clock)</p> <p><i>Reason not stored or not collected:</i> _____</p>	<p><i>stored</i></p> <p><input type="checkbox"/></p>	<p><i>not stored</i></p> <p><input type="checkbox"/></p>	<p><i>not collected</i></p> <p><input type="checkbox"/></p>	<p><i>not required</i></p> <p><input type="checkbox"/></p>
		<p>←</p>			
<b>5</b>	<p><b>Pharyngeal Swab-GC/CT Testing</b></p> <p><i>Alternate Collection Date</i></p> <p><input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>  <i>dd MMM yy</i></p> <p><i>Time Collected</i></p> <p><i>hr min</i></p> <p><input type="text"/> <input type="text"/> : <input type="text"/> <input type="text"/>                  (24-hour clock)</p> <p><i>Reason not stored or not collected:</i> _____</p>	<p><i>stored</i></p> <p><input type="checkbox"/></p>	<p><i>not stored</i></p> <p><input type="checkbox"/></p>	<p><i>not collected</i></p> <p><input type="checkbox"/></p>	<p><i>not required</i></p> <p><input type="checkbox"/></p>
		<p>←</p>			

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:**

<b>Initial Specimen Collection Date</b>	Record the date that the first specimen(s) was collected for this visit. A complete date is required.
<b>Alternate Collection Date</b>	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.
<b>Items 1–5</b>	<ul style="list-style-type: none"> <li>• If a specimen was collected and stored, mark “stored.”</li> <li>• If a specimen was collected but not stored, mark “not stored.”</li> <li>• If a specimen was required to be collected and stored at this visit but was not collected, mark “not collected.”</li> <li>• 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 (such as the 2nd rectal swab) because the participant did not consent to long-term specimen storage of that sample, mark “not required.”</li> </ul>



(HPTN 075) DF/Net 070

(PUL) 450

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

Page #

Participant ID:

<div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div>	<div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto;"></div>
Site Number	Participant Number						Chk				

**PrEP Use Log**

**1**

Truvada     FTC/TDF     Other, specify: \_\_\_\_\_

Is the participant participating in a PrEP demonstration project?     yes     no

By whom was the PrEP prescribed?

PrEP demonstration project  
 Healthcare provider  
 Other specify: \_\_\_\_\_

At what visit did the participant report he started taking PrEP?

.  Visit Code

Date Started:

/  /

*dd                  MMM                  yy*

Date Stopped:

/  /

*dd                  MMM                  yy*

OR  Continuing at end of study

Staff Initials/  
Log Entry Date:

**2**

Truvada     FTC/TDF     Other, specify: \_\_\_\_\_

Is the participant participating in a PrEP demonstration project?     yes     no

By whom was the PrEP prescribed?

PrEP demonstration project  
 Healthcare provider  
 Other specify: \_\_\_\_\_

At what visit did the participant report he started taking PrEP?

.  Visit Code

Date Started:

/  /

*dd                  MMM                  yy*

Date Stopped:

/  /

*dd                  MMM                  yy*

OR  Continuing at end of study

Staff Initials/  
Log Entry Date:

**3**

Truvada     FTC/TDF     Other, specify: \_\_\_\_\_

Is the participant participating in a PrEP demonstration project?     yes     no

By whom was the PrEP prescribed?

PrEP demonstration project  
 Healthcare provider  
 Other specify: \_\_\_\_\_

At what visit did the participant report he started taking PrEP?

.  Visit Code

Date Started:

/  /

*dd                  MMM                  yy*

Date Stopped:

/  /

*dd                  MMM                  yy*

OR  Continuing at end of study

Staff Initials/  
Log Entry Date:

**Purpose:** This log form is used to document a participant's use of PrEP throughout the course of the study.

**General Information and Instructions:** When to fax this form:

- The first time the participant reports using PrEP while in the study;
- When log pages have been updated or additional log pages have been completed (only fax updated or new pages);
- When the participant has completed the study; and/or
- When instructed by the data manager

**Item-specific Instructions:**

<b>Page #</b>	Number pages sequentially for each participant, starting with 01. Do not re-assign page numbers if a form is marked for deletion.
<b>Date Started</b>	If the participant is unable to recall the exact date, get the participant's best estimate. At minimum, the month and year are required.
<b>Date Stopped</b>	At the participant's termination, the "Date Stopped" must be recorded OR the "Continuing at end of study" box must be marked. At minimum, the month and year are required.



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 allowable 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.*
  - 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. Fax 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:**

<b>Item 1</b>	Record the target date of the visit. A complete date is required.
<b>Item 2</b>	Record the reason the participant missed the visit.



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(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"/>	-	<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:

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

**General Information/Instructions:**

- 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:**

<b>Item 4</b>	A complete date is required.
---------------	------------------------------



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(PRC) 466

Participant ID:

			-					-	
<i>Site Number</i>				<i>Participant Number</i>					<i>Chk</i>

Form Completion Date:

<i>dd</i>		<i>MMM</i>		<i>yy</i>	

**Participant Receipt**

*Instruction: Do not assign a new Participant ID. Record the Participant ID assigned by the original study site.*

**1** Name of receiving study site \_\_\_\_\_

**2** Name of transferring study site \_\_\_\_\_

**3** Date informed consent signed at receiving study site 

--	--

--	--	--	--

--	--

*dd*      *MMM*      *yy*

**4** Did participant provide informed consent for specimen storage at receiving study site?  *yes*  *no* —▶ *If no, end of form.*

4a. Date informed consent for specimen storage signed 

--	--

--	--	--	--

--	--

*dd*      *MMM*      *yy*

*Comments:*

**Purpose:** Complete this form when a transferred participant has provided informed consent at the receiving study clinic/site.

**General Information/Instructions:**

- 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:**

<b>Participant ID</b>	Do not assign a new Participant ID. Record the Participant ID assigned by the original study site.
<b>Item 3</b>	A complete date is required.



(HPTN 075) DF/Net 070

(TM) 490

Participant ID:

			-						-		
<i>Site Number</i>				<i>Participant Number</i>							<i>Chk</i>

**Termination**

<b>1</b>	Termination Date:	<table border="1" style="width: 100%;"><tr><td style="width: 15px; height: 15px;"></td><td style="width: 15px; height: 15px;"></td></tr></table>			<table border="1" style="width: 100%;"><tr><td style="width: 15px; height: 15px;"></td><td style="width: 15px; height: 15px;"></td><td style="width: 15px; height: 15px;"></td></tr></table>				<table border="1" style="width: 100%;"><tr><td style="width: 15px; height: 15px;"></td><td style="width: 15px; height: 15px;"></td></tr></table>			<i>Date the site determined that the participant was no longer in the study.</i>
		<i>dd</i>	<i>MMM</i>	<i>yy</i>								

<b>2</b>	Reason for termination. <i>Mark only one.</i>						
	<input type="checkbox"/> 2a. Scheduled exit visit/end of study <input type="checkbox"/> 2b. Death (Indicate date and cause if known.) <div style="margin-left: 40px;"> <table style="display: inline-table; border: none;"> <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> </tr> <tr> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> <td style="border: 1px solid black; width: 30px; height: 15px;"></td> <td style="border: 1px solid black; width: 20px; height: 15px;"></td> </tr> </table> </div> <div style="margin-left: 100px;"> <i>OR</i> <input type="checkbox"/> date unknown  <input type="checkbox"/> cause unknown             </div> <div style="margin-left: 40px;">                 2b1. Date of death: _____                  2b2. Cause of death: _____             </div> <input type="checkbox"/> 2c. Participant refused further participation, specify: _____ <input type="checkbox"/> 2d. Participant unable to adhere to visit schedule <input type="checkbox"/> 2e. Participant relocated, no follow-up planned <input type="checkbox"/> 2f. Investigator decision, specify _____ <input type="checkbox"/> 2g. Unable to contact participant 2h. NOT APPLICABLE FOR THIS PROTOCOL <input type="checkbox"/> 2i. Inappropriate enrollment <input type="checkbox"/> 2j. Invalid ID due to duplicate screening/enrollment <input type="checkbox"/> 2k. Other, specify _____ <input type="checkbox"/> 2l. Early study closure 2m. NOT APPLICABLE FOR THIS PROTOCOL 2n. NOT APPLICABLE FOR THIS PROTOCOL	<i>dd</i>	<i>MMM</i>	<i>yy</i>			
<i>dd</i>	<i>MMM</i>	<i>yy</i>					

<b>Comments:</b>	
------------------	--

Version 1.0, 11-MAY-15		Completed by: _____ <i>(initials/date)</i>
------------------------	--	--

**Item-specific Instructions:**

<b>Item 1</b>	Document the date that the participant declares that he/she does not want to continue in the study. If the termination is due to death, indicate the date that the site is notified that the participant is deceased. A complete date is required.
<b>Item 2</b>	Mark only the primary reason for termination.
<b>Item 2a</b>	<b>Scheduled exit visit/end of study:</b> Only mark 2a if the participant completes the protocol-defined final visit.
<b>Item 2b1</b>	If date is recorded, at a minimum, the month and year are required.
<b>Item 2I</b>	<b>Early study closure:</b> Only mark 2I when instructed by SCHARP.



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(PDL) 495

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

Page #

Participant ID:

- 
 




 -

*Site Number*      *Participant Number*      *Chk*

Form Completion Date:

*dd*      *MMM*      *yy*

**Protocol Deviation Log**

<b>1</b>	Site awareness date:	<span style="border: 1px solid black; display: inline-block; width: 20px; height: 20px;"></span> <span style="border: 1px solid black; display: inline-block; width: 20px; height: 20px;"></span> <span style="border: 1px solid black; display: inline-block; width: 20px; height: 20px;"></span>	<i>dd</i> <i>MMM</i> <i>yy</i>
<b>2</b>	Deviation date:	<span style="border: 1px solid black; display: inline-block; width: 20px; height: 20px;"></span> <span style="border: 1px solid black; display: inline-block; width: 20px; height: 20px;"></span> <span style="border: 1px solid black; display: inline-block; width: 20px; height: 20px;"></span>	<i>dd</i> <i>MMM</i> <i>yy</i>
<b>3</b>	Has or will this deviation be reported to local IRB/EC?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<b>4</b>	Has or will this deviation be reported to DAIDS as a critical event?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
<b>5</b>	Type of deviation:	<span style="border: 1px solid black; display: inline-block; width: 20px; height: 20px;"></span> <span style="border: 1px solid black; display: inline-block; width: 20px; height: 20px;"></span>	<i>deviation code</i> (See back of form for code listing.)
<b>6</b>	Description of deviation:		
<b>7</b>	Plans and/or action taken to address the deviation:		
<b>8</b>	Plans and/or action taken to prevent future occurrences of the deviation:		
<b>9</b>	Deviation reported by (staff name): _____		

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

**General Information and Instructions:**

- Consult HPTN 075 Management Group (075mgmt@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	<b>Inappropriate enrollment:</b> The participant enrolled and not all eligibility requirements were met.
02	CODES 02, 03, AND 04 ARE NOT APPLICABLE FOR THIS PROTOCOL
03	
04	
05	<b>Conduct of non-protocol procedure:</b> 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	<b>Breach of confidentiality:</b> 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	<b>Physical assessment deviation:</b> 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	<b>Lab assessment deviation:</b> 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	<b>Use of non-IRB/EC-approved materials:</b> Examples include use of ANY study-related material that has not received IRB or EC approval for use per site requirements.
10	<b>Informed assent/consent process deviation:</b> Examples include failure to accurately execute and/or document any part of the informed consent process.
99	<b>Other</b>