HPTN 052 (096) ISC-1 (449)

Visit Code ___.___

Index ID

___ - ___ - 0 0 - ___

Site Number | Index Number | Partner | Chk

Index Specimen Collection

Initial Collection Date

dd MMM yy

Instructions: *Complete form for Enrollment, Quarterly, and Yearly visits, at partner seroconversion, at index virologic failure, and as clinically indicated.*

For each of the following, indicate if the specimen was collected.

		yes	no	Alternate Collection Date dd	MMM	yy
1.	Whole blood for plasma HIV genotyping:	☐	☐			
2.	Blood for storage:	☐	☐			
3.	Cervical sample for HIV-1 RNA:	☐	☐			
4.	Semen sample for HIV-1 RNA:	☐	☐			
5.	Genital secretions for storage:	☐	☐			

2a. Mark each component to be stored for this visit.

	Alternate Collection Date dd	MMM	yy
☐ whole blood			
☐ plasma			
☐ serum			
☐ PBMCs			

Index Specimen Collection (ISC-1)

- This form is used to track all specimens collected and used for data analysis. It is not used to track specimens collected and analyzed in your local lab.

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. Complete date required.
- **Alternate Collection Date**: This date is to be completed ONLY if the specimen was collected on a different day than the rest of the specimens. 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. Complete date required.
- **Results Reporting**
    - If a specimen was collected but results are not available because the specimen was lost or damaged, line through the results and write an explanation on the comments line.
    - 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 SCHARP. Refer to Study Specific Procedures (SSP) for conversion instructions.
    - 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.
- **Item 1**: Plasma for HIV genotyping is sent to a regional lab for processing. The U.S. site will conduct its own HIV genotyping.
- **Item 2:** Whole blood, plasma, serum, and PBMCs will be collected and stored at each site for future analysis. For participants who do not consent for long-term specimen storage, archived samples must be destroyed after all protocol-required and quality assurance testing has been completed.
- **Items 3–4:** Cervical and seminal samples are sent to the HPTN Central Lab.
- **Item 5:** Mark “yes” if an additional aliquot of cervical or semen sample is collected and stored locally as a back up for future analysis.