

Appendix III to SSP Section 13
HPTN 083 Schedule of Forms and CASI Surveys

Step 4a

CRF Name	Day 0 V61.0	Week 4 V62.0
Date of Visit - OLE	x	x
Specimen Storage	x	x
HIV Test Results	x	x
Local Laboratory Results	x	x
Vital Signs	x	x
SMSQ-OLE	x	
Interviewer Administered - OLE	x	
CASI Survey	x	

Step 4b

CRF Name	Day 0 V63.0
Date of Visit - OLE	x
Specimen Storage	x
HIV Test Results	x
Injection Administration	x
Vital Signs	x
SMSQ-OLE	x
Interviewer Administered - OLE	x
Local Laboratory Results	x
CASI Survey	x

Step 4c

CRF Name	Day 0 V64.0	Week 8 V65.0	Week 16 V66.0	Week 24 V67.0	Week 32 V68.0	Week 40 V69.0	Week 48 V70.0
Date of Visit - OLE	x	x	x	x	x	x	x
Vital Signs	x	x	x	x	x	x	x
Injection Administration	x	x	x	x	x	x	x
HIV Test Results	x	x	x	x	x	x	x
Local Laboratory Results	x			x			x
Specimen Storage	x	x	x	x	x	x	x
SMSQ-OLE	x		x				x
Interviewer Administered - OLE	x		x				x
Sexually Transmitted Infections				x			x
Hepatitis Test Results							x
CASI Survey	x		x				x

Step 5

CRF Name	Day 0 V101.0	Week 12 V102.0	Week 24 V103.0	Week 36 V104.0	Week 48 V105.0	Week 60 V106.0	Week 72 V107.0	Week 84 V108.0	Week 96 V109.0
Date of Visit - OLE	x	x	x	x	x	x	x	x	x
Vital Signs	x	x	x	x	x	x	x	x	x
Sexually Transmitted Infections	x		x		x		x		x
HIV Test Results	x	x	x	x	x	x	x	x	x
Local Laboratory Results	x		x		x		x		x
Specimen Storage	x	x	x	x	x	x	x	x	x
SMSQ-OLE	x		x		x		x		x
Interviewer Administered - OLE	x		x		x		x		x
Hepatitis Test Results			x		x		x		x
CASI Survey	x		x		x		x		x

Step 5b

CRF Name	Day 0 V121.0	Week 12 V122.0	Week 24 V123.0	Week 36 V124.0	Week 48 V125.0	Week 60 V126.0	Week 72 V127.0	Week 84 V128.0	Week 96 V129.0
Date of Visit - OLE	x	x	x	x	x	x	x	x	x
Vital Signs	x	x	x	x	x	x	x	x	x
Sexually Transmitted Infections	x		x		x		x		x
HIV Test Results	x	x	x	x	x	x	x	x	x
Local Laboratory Results	x		x		x		x		x
Specimen Storage	x	x	x	x	x	x	x	x	x
SMSQ-OLE	x		x		x		x		x
Interviewer Administered - OLE	x		x		x		x		x
Hepatitis Test Results			x		x		x		x
CASI Survey	x		x		x		x		x

Seroconverter Schedule

CRF Name	Week 12 V91.0	Week 24 V92.0	Week 36 V93.0	Week 48 V94.0
Date of Visit - HIV	x	x	x	x
Vital Signs	x	x	x	x
Specimen Storage	x	x	x	x
Local lab Test Results		x		x
CD4		x		x
CASI Survey				

Additional / As Needed CRFs:

Found in Ongoing Logs Folder

Concomitant Medications Y/N
Adverse Event Y/N
ART Medication Y/N
Protocol Deviation Y/N
Social Impact Y/N
Product Hold Y/N
Injection Site Reaction Y/N
Log Revisions
Product Hold - OLE Y/N

Found in Participant Unblinding Folder

Participant Unblinding

Found in Product Choice Folder

Product Choice - OLE

Found in “Add Event” function

Yearly Visit
Interim Visit - OLE
V91.0 – Week 12

Additional Forms

Participant Transfer
Participant Receipt
Supplemental HIV Results