

Appendix III to SSP Section 13

HPTN 083 Schedule of Forms and CASI Surveys

<b>Screening Visit: V1.0</b>
Participant Identifier
Specimen Storage
Inclusion / Exclusion

**Step 1**

	Day 0 V2.0	Week 2 V3.0	Week 4 V4.0
Enrollment (all screened participants)	x		
<i>If participant is enrolling:</i>			
Date of Visit		x	x
Demographics	x		
DXA Scan	x		
Hematology	x	x	x
Hepatitis Test Results	x		
HIV Test Results	x	x	x
Interviewer Administered: Baseline	x		
Lead Electrocardiogram (may have Screening date/result)	x		
Local Laboratory Results	x	x	x
Pill Count – Enrollment	x		
Pill Count – Follow Up		x	x
Pre-existing Conditions Y/N	x		
Randomization	x		
Sexually Transmitted Infections	x		
Specimen Storage	x	x	x
Vital Signs	x	x	x
Vitamin D and Calcium Assessment	x		
CASI Survey	x		

**Step 2 Oral and Injections weeks 5 - 43**

	<b>Week 5 V5.0</b>	<b>Week 6 V6.0</b>	<b>Week 9 V7.0</b>	<b>Week 10 V8.0</b>	<b>Week 17 V9.0</b>	<b>Week 19 V 10.0</b>	<b>Week 25 V 11.0</b>	<b>Week 27 V 12.0</b>	<b>Week 33 V 13.0</b>	<b>Week 35 V 14.0</b>	<b>Week 41 V 15.0</b>	<b>Week 43 V 16.0</b>
Date of Visit	x	x	x	x	x	x	x	x	x	X	x	x
DXA Scan												
Hematology	--	x	x	x	x	x	x	x	x	x	x	x
Hepatitis Test Results												
HIV Test Results	x	x	x	x	x	x	x	x	x	x	x	x
Injection Administration	x		x		x		x		x		x	
Interviewer Administered: Follow-up 1	x				x				x			
Interviewer Administered: Follow-up 2			x				x				x	
Local Laboratory Results	--	x	x	x	x	x	x	x	x	x	x	x
Post-Injection Exercise Assessment		x		x		x		x		x		x
Sexually Transmitted Infections									x			
SMSQc						x						
SMSQs		x		x		x		x		x		x
Specimen Storage	x	x	x	x	x	x	x	x	x	x	x	x
Vital Signs	x		x		x		x		x		x	
CASI Survey	x		x		x		x		x		x	

**Step 2 Oral and Injections weeks 49 - 91**

	<b>Week 49 V 17.0</b>	<b>Week 51 V 18.0</b>	<b>Week 57 V 19.0</b>	<b>Week 59 V 20.0</b>	<b>Week 65 V 21.0</b>	<b>Week 67 V 22.0</b>	<b>Week 73 V 23.0</b>	<b>Week 75 V 24.0</b>	<b>Week 81 V 25.0</b>	<b>Week 83 V 26.0</b>	<b>Week 89 V 27.0</b>	<b>Week 91 V 28.0</b>
Date of Visit	x	x	x	x	x	x	x	x	x	x	x	x
DXA Scan			x									
Hematology	x	x	x	x	x	x	x	x	x	x	x	x
Hepatitis Test Results			x									
HIV Test Results	x	x	x	x	x	x	x	x	x	x	x	x
Injection Administration	x		x		x		x		x		x	
Interviewer Administered: Follow-up 1	x				x				x			
Interviewer Administered: Follow-up 2			x				x				x	
Lead Electrocardiogram			x									
Local Laboratory Results	x	x	x	x	x	x	x	x	x	x	x	x
Post-Injection Exercise Assessment		x		x		x		x		x		x
Sexually Transmitted Infections			x						x			
SMSQs		x		x		x		x		x		x
Specimen Storage	x	x	x	x	x	x	x	x	x	x	x	x
Vital Signs	x		x		x		x		x		x	
CASI Survey	x		x		x		x		x		x	

**Step 2 Oral and Injections weeks 97 - 139**

	<b>Week 97 V 29.0</b>	<b>Week 99 V 30.0</b>	<b>Week 105 V 31.0</b>	<b>Week 107 V 32.0</b>	<b>Week 113 V 33.0</b>	<b>Week 115 V 34.0</b>	<b>Week 121 V 35.0</b>	<b>Week 123 V 36.0</b>	<b>Week 129 V 37.0</b>	<b>Week 131 V 38.0</b>	<b>Week 137 V 39.0</b>	<b>Week 139 V 40.0</b>
Date of Visit	x	x	x	x	x	x	x	x	x	x	x	x
DXA Scan			x									
Hepatitis Test Results			x									
HIV Test Results	x	x	x	x	x	x	x	x	x	x	x	x
Injection Administration	x		x		x		x		x		x	
Interviewer Administered: Follow-up 1	x		x				x				x	
Lead Electrocardiogram			x									
Local Laboratory Results	x	x	x	x	x	x	x	x	x	x	x	x
Post-Injection Exercise Assessment		x		x		x		x		x		x
Sexually Transmitted Infections			x						x			
SMSQs		x		x		x		x		x		x
Specimen Storage	x	x	x	x	x	x	x	x	x	x	x	x
Vital Signs	x		x		x		x		x		x	
CASI Survey	x		x				x				x	

	Week 145 V 41.0	Week 147 V 42.0	Week 153 V 43.0	These visits are only completed if Version 3.0 has not been approved at your site.								
				Week 155 V 44.0	Week 161 V 45.0	Week 163 V 46.0	Week 169 V 47.0	Week 171 V 48.0	Week 177 V 49.0	Week 179 V 50.0	Week 185 V 51.0	Week 187 V 52.0
Date of Visit	x	x	x	x	x	x	x	x	x	x	x	x
DXA Scan			x									
Hepatitis Test Results			x									
HIV Test Results	x	x	x	x	x	x	x	x	x	x	x	x
Injection Administration	x		X*		x		x		x		x	
Interviewer Administered: Follow-up 1			x				x				x	
Lead Electrocardiogram			x									
Local Laboratory Results	x	x	x	x	x	x	x	x	x	x	x	x
Post-Injection Exercise Assessment		x		x		x		x		x		x
Sexually Transmitted Infections			x						x			
SMSQs		x		x		x		x		x		x
Specimen Storage	x	x	x	x	x	x	x	x	x	x	x	x
Vital Signs	x		x		x		x			x		x
CASI Survey			x				x				x	

*\*If V3.0 of the protocol has been approved at your site do not complete the Injection Administration form. Visit 43.0 will act as the Step 3 Day 0 visit*

### Step 3 Open label Oral

*Step 3 Day 0 should occur within 8 weeks after last injection.*

	Day 0 V ###*	Week 12 V 54.0	Week 24 V 55.0	Week 36 V 56.0	Week 48 V 57.0
Date of Visit	X	x	x	x	x
HIV Test Results	x	x	x	x	x
Interviewer Administered: Follow-up 1**	x		x		x
Local Laboratory Results			x		x
Sexually Transmitted Infections	x		x		x
SMSQs <sup>1</sup>	x				
Specimen Storage	x	x	x	x	x
Vital Signs	x	x	x	x	x
CASI Survey	X***	x±	x		x
<p><i>*Day 0 is combined with a final step 2 visit and will receive that Step 2 visit code.</i>  <i>**If Interviewer Administered Follow-up 2 is already required at the final Step 2 visit, complete only Follow-Up 1</i>  <i>***The Day 0 CASI is not required if behavioral assessment was done in the last 4 weeks AND acceptability assessment was done in the previous 24 weeks.</i>  <i>± If the behavioral assessment was not done at Day 0, administer at Week 12</i>  <sup>1</sup> <i>SMSQs is not required if completed within the last 24 weeks.</i></p>					

## Step 2 participants with confirmed HIV Infection

Note that the confirmation visit in Step 2 serves as “Day 0” in this scenario; visit 54.0 should occur approximately 12 weeks after HIV infection is confirmed.

	<b>Week 12 V 54.0</b>	<b>Week 24 V 55.0</b>	<b>Week 36 V 56.0</b>	<b>Week 48 V 57.0</b>
Date of Visit	x	x	x	x
CD4/Viral Load		x		x
Local Laboratory Results		x	x	x
Specimen Storage	x	x	x	x
Vital Signs	x	x	x	x

### 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

#### Found in “Add Event” function

Interim Visit
Yearly Visit

#### Additional Forms

Termination
Participant Transfer
Participant Receipt

HPTN 083 Survey Information according to the protocol appendix labels

**Baseline Acceptability Assessment**

CASI pages 16 (starting with “Attitudes toward PrEP methods”) - 18

**Baseline Behavioral Assessment**

CASI pages 5-6

Interviewer Administered: Baseline

**Follow Up Acceptability Assessment**

CASI Pages 16 (starting with Overall satisfaction with study product”) - 18

Interviewer Administered: Follow Up 1 – Bottom of Page 65 of the PDF (“I would like to ask you about your preferences...”) – 66; Study Medication Satisfaction Questionnaire (SMSQ), SMSQ (Change).

**Follow Up Behavioral Assessment**

CASI pages 5-6, 8-15

Interviewer Administered: Follow Up 1 (all but bottom of page 65 -66)

Interviewer Administered: Follow Up 2