

6. Visit Checklists

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6.1 Overview of Section 6

This section provides a template checklist for each of the required study visits. The use of visit checklists is strongly recommended but is optional; sites may modify them as needed.

6.2 Visit Checklists as Source Documentation

Checklists are convenient tools, which may serve as source documentation if designed and completed appropriately. These checklists alone may not be sufficient for documenting all procedures but can be used to indicate that the procedure was completed and by whom. Additional information could be documented on the checklist comment sections and/or chart notes. It is up to each site to determine whether and how to use the visit checklists as source documentation.

It also should be noted that the visit checklists outlined below depict the visit schedule for a participant completing all protocol-specified study visits. In what is hoped to be a rare occurrence, there may be cases where a participant may have a modified study visit; in which case, any modifications to the procedures could be noted in the comment section of the checklists.

6.3 Use of the Checklists

One checklist should be used for each participant. A common way that checklists are used is for the checklist to follow the participant through the visit; as activities are completed they are checked off the list. The checklists are designed so that there is one for each visit. Sites may modify order of procedures to maximize the efficiency of site-specific study operations, with the following exceptions/considerations:

- Informed consent must be obtained before any study procedures are performed.
- Once informed consent is obtained, the first procedure to be performed should be assignment of PTID.
- Enrollment must take place after final confirmation and verification of eligibility and collection of blood for plasma storage. If a participant is subsequently found to be ineligible, the plasma archive sample should be destroyed.

- During follow-up visits, behavioral assessment and acceptability assessments should be administered prior to the delivery of HIV and adherence counseling.
- It is recommended that procedures for determining eligibility for continued product use be conducted early in the visit to ensure sufficient time is allowed for product to be available for administration.
- For visits where collection of blood for lipid profile is required, inquire early in the visit about last time the participant ate or drank. As a reminder, for lipid profile participants should have fasted for at least 8 hours (preferably 12 hours) prior to blood collection. Also, collect blood early in the visit so participants can have something to eat or drink immediately after blood collection.

When using the checklists, it is important that every item is completed - this is done by initialing and dating each step of the checklist (to show that the step was completed), or by entering ND (not done), or NA (not applicable) if a procedure is not performed. See checklist instructions for further information.

The source documentation for the procedure will need to be identified for some items that are in the protocol, but not on captured on the CRFs.

A good example of this is locator information. At each visit, the protocol requires that locator information is confirmed and, if necessary, updated. Some of the ways that the “act” of confirming or updating can be documented at each visit include writing a note in the participant's chart, creating a locator information log, or having a review/revision log attached to the locator information itself. The checklist cannot serve as the source for the confirmation of locator information unless it is revised to show who confirmed the information, if changes were made to the form.

6.4 Visit Checklist Templates

Eligibility Checklist (Template)				
<i>These are inclusion criteria. Any box checked "No" disqualifies the person from enrollment.</i>				
Demographic/Medical/Behavioral	Initials/ Date	Eligible	Not Eligible	
	_____	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Assigned male at birth (includes MSM, TGW, and gender non-conforming people)
	_____	Yes <input type="checkbox"/>	No <input type="checkbox"/>	At enrollment, aged below 18 years
	_____	Yes <input type="checkbox"/>	No <input type="checkbox"/>	At enrollment, body weight \geq 35 kg (77 lbs.)
	_____	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Provided written informed consent
	_____	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Self-reported sexual activity with a male in the past 12 months
	_____	Yes <input type="checkbox"/>	No <input type="checkbox"/>	<p>In general, good health, as evidenced by the following laboratory values:</p> <ul style="list-style-type: none"> • Non-reactive / negative HIV test results • Absolute neutrophil count > 799 cells/mm³, • Platelet count $\geq 100,000$/mm³+, • Hemoglobin ≥ 11g/dL⁺, • Calculated creatinine clearance ≥ 60 mL/minute using modified Schwartz equation (\leq grade 2), • Alanine aminotransferase (ALT) < 2.0 times the upper limit of normal (ULN) and total bilirubin (Tbili) $\leq 2.5 \times$ ULN, • Hepatitis B virus (HBV) surface antigen (HBsAg) negative and accepts vaccination*. • HCV Antibody negative⁺⁺. <p>⁺ Participants below the cutoff may be considered for enrollment at the discretion of the PI and in consultation with the CMC if the PI can demonstrate that participant is in general good health despite being below the cutoff.</p> <p>[*] For participants who are negative for HBsAb at enrollment, HBsAb and HBcAb (total) will be checked at the end of the study.</p> <p>⁺⁺ HCV antibody testing should be repeated at the discretion of the IoR or designee during the study if clinically indicated, if the participant has elevated AST/ALT results (elevated level at discretion of IoR or designee), or if the participant expresses a concern about having acquired HCV infection after enrollment. HCV antibody testing will be repeated in all participants at the end of the study.</p>
	_____	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Willing to undergo all required study procedures
	_____	Yes <input type="checkbox"/>	No <input type="checkbox"/>	If receiving PrEP from a non-study source, agrees to discontinue oral PrEP and receive CAB LA injections instead

These are exclusion criteria. Any box checked "Yes" disqualifies the person from enrollment.			
Initials	Not Eligible	Eligible	
_____	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Past or current participation in HIV vaccine trial with exception for participants who can provide documentation of receipt of placebo
_____	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Exclusively had sex with biological females in lifetime
_____	Yes <input type="checkbox"/>	No <input type="checkbox"/>	In the last 6 months (at the time of screening): <ul style="list-style-type: none"> active or planned use of any substance use which would, in the opinion of the site investigator, would hinder study participation (including herbal remedies), as described in the IB or listed in the SSP, and/ or Protocol Section 4.4
_____	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Known history of clinically significant cardiovascular disease, as defined by history/evidence of symptomatic arrhythmia, angina/ischemia, coronary artery bypass grafting (CABG) surgery or percutaneous transluminal coronary angioplasty (PTCA) or any clinically significant cardiac disease
_____	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Inflammatory skin conditions that compromise the safety of intramuscular (IM) injections
_____	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Tattoo or other dermatological condition overlying the buttock region that may interfere with interpretation of injection site reactions;
_____	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Current or chronic history of liver disease (e.g., non-alcoholic or alcoholic steatohepatitis) or known hepatic or biliary abnormalities (with the exception of Gilbert's syndrome, asymptomatic gallstones, or cholecystectomy)
_____	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Known history of clinically significant bleeding
_____	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Surgically-placed or injected buttock implants or fillers, per self-report. (Contact the CMC for guidance regarding questions about individual cases.)
_____	Yes <input type="checkbox"/>	No <input type="checkbox"/>	A history of seizure disorder, per self-report
_____	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Medical, social, or other condition that, in the opinion of the site investigator, would interfere with the conduct of the study or the safety of the participant (e.g., provided by self-report, or found upon medical history and examination or in available medical records)
_____	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Plans to move out of the geographic area within the next 18 months or otherwise unable to participate in study visits, according to the site investigator

	_____	Yes <input type="checkbox"/>	No <input type="checkbox"/>	Co-enrollment in any other HIV interventional research study or other concurrent studies which may interfere with this study (as provided by self-report or other available documentation)
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The Investigator of Record or a Physician Sub-investigator listed on the Form FDA 1572, must review the eligibility checklist, as well as reports of information pertinent to the study, and sign and date the checklist to document his/her review and confirmation of eligibility.

 Signature Line: Investigator of Record
 or designated Physician Sub-investigator

 Date

Participant ID

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Visit Date

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INSTRUCTIONS: Enter staff initials next to each procedure completed. Do not initial procedures another staff member completed. If other staff members are not available to initial next to the procedure they completed, add a note on the checklist documenting who completed the procedure. If all procedures listed on a checklist are performed on the date entered in the top section of the checklist, it is not necessary to enter the date beside each item. If procedures listed on a checklist are performed on multiple dates, enter the date upon which each procedure is performed beside each item. Bracketing procedures which are consecutive and all done on the same date is also acceptable. If a procedure listed on the checklist is not performed, enter "ND" for "not done" or "NA" for "not applicable" beside the item and record the reason why (if not self-explanatory); initial and date this entry.

NOTE: For a listing of forms required at each visit, otherwise known as the HPTN 083-01 Schedule of Forms, please refer to Section 13.13 of the Data Management Section of this SSP.

Screening Visit			
Initial/date	Completed	Procedure	Comments
_____	<input type="checkbox"/>	Confirm participant identity and age per site SOPs.	
_____	<input type="checkbox"/>	Determine screening attempt (Verify if HPTN 083-01 PTID has previously been assigned); see Protocol Section 5.1 <input type="checkbox"/> First attempt ==> CONTINUE. <input type="checkbox"/> Second attempt ==> Was CMC contacted? Attach communication to the checklist.	
_____	<input type="checkbox"/>	Obtain written consent for screening/enrollment <i>If the individual does not consent to screening, STOP screening procedures.</i>	
_____	<input type="checkbox"/>	Assign Participant ID and record on the screening log	
_____	<input type="checkbox"/>	Demographic information may be collected at either Screening or Enrollment.	
_____	<input type="checkbox"/>	Collect locator information per site SOP	
_____	<input type="checkbox"/>	Targeted medical history (including bleeding history and concomitant medications)	
_____	<input type="checkbox"/>	Perform targeted physical exam for ascertainment of eligibility	
_____	<input type="checkbox"/>	Provide HIV pre-test counseling	

Participant ID

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Visit Date

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NOTE: For a listing of forms required at each visit, otherwise known as the HPTN 083-01 Schedule of Forms, please refer to Section 13.13 of the Data Management Section of this SSP.

Screening Visit			
Initial/date	Completed	Procedure	Comments
_____	<input type="checkbox"/>	Collect blood and perform testing for: <ul style="list-style-type: none"> <input type="checkbox"/> HIV testing <input type="checkbox"/> FDA-cleared HIV rapid test <input type="checkbox"/> Laboratory based, instrument HIV Immunoassay (HIV antigen and antibody) <input type="checkbox"/> HIV Viral Load (detection limit <50 copies/mL) <input type="checkbox"/> HIV RNA performed within 14 days of Enrollment. NOTE: 14-day window starts on the day the sample for HIV RNA is collected, which is considered Day 0. <input type="checkbox"/> Hepatitis testing: HBsAg and HCVAb results are needed for the enrollment visit. HBcAb and HbSAb can be performed at screening or enrollment. <input type="checkbox"/> CBC with differential <input type="checkbox"/> Chemistry testing (creatinine only at Screening) <input type="checkbox"/> Syphilis testing <input type="checkbox"/> GC/CT testing (urine, rectal, and oral pharyngeal swabs) <input type="checkbox"/> LFTs (ALT and total bilirubin) <input type="checkbox"/> Plasma for storage 	
_____	<input type="checkbox"/>	Provide HIV post-test counseling	
_____	<input type="checkbox"/>	Offer condoms and lubricant; document whether participant took them	
<i>If after evaluating the criteria listed above, the participant is not eligible, STOP screening procedures. Inform the participant of his/her ineligibility. Document the reason for ineligibility in the Screening Log. Retain documentation completed thus far, and fax only the Screening Outcomes CRF to the HPTN SDMC.</i>			
_____	<input type="checkbox"/>	Schedule enrollment visit, if eligible thus far	
_____	<input type="checkbox"/>	Provide participant reimbursement and site contact information, if applicable	

Participant ID

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Visit Date

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NOTE: For a listing of forms required at each visit, otherwise known as the HPTN 083-01 Schedule of Forms, please refer to Section 13.13 of the Data Management Section of this SSP.

Additional information for Screening Visit: Please refer to Section 5.1 and Appendix I of the HPTN 083-01 Protocol.

Comments: _____

Participant ID

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NOTE: For a listing of forms required at each visit, otherwise known as the HPTN 083-01 Schedule of Forms, please refer to Section 13.13 of the Data Management Section of this SSP.

Step 1: Enrollment, Week 0/Day 0			
Initial/date	Completed	Procedures	Comments
_____	<input type="checkbox"/>	Confirm participant identity and PTID.	
_____	<input type="checkbox"/>	Confirm participant eligibility to continue with Enrollment visit based on Screening test results. Provide participant with test results.	
_____	<input type="checkbox"/>	Confirm last time participant ate. <i>Reminder: Participants should have fasted for at least 8 hours (preferably 12 hours) prior to blood collection.</i>	
_____	<input type="checkbox"/>	Verify participant is within the screening window. <input type="checkbox"/> Within 30 days of specimen collection <input type="checkbox"/> Within 14 days of HIV RNA sample collection	
_____	<input type="checkbox"/>	Administer PHQ-9.	
_____	<input type="checkbox"/>	Confirm HIV test results from screening visit. FDA-cleared HIV rapid test, laboratory based, instrument HIV Immunoassay (HIV antigen and antibody), HIV Viral Load (detection limit <50 copies/mL) have been reviewed and are negative/non-reactive.	
_____	<input type="checkbox"/>	Confirm that informed consent was obtained and review elements of the consent as needed.	
_____	<input type="checkbox"/>	Review/update locator information.	
_____	<input type="checkbox"/>	Collect demographic information (if not collected at Screening).	
_____	<input type="checkbox"/>	Collect complete medical history including concomitant medications.	
_____	<input type="checkbox"/>	Perform full physical exam.	
_____	<input type="checkbox"/>	Complete Enrollment CASI.	

Participant ID

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Visit Date

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NOTE: For a listing of forms required at each visit, otherwise known as the HPTN 083-01 Schedule of Forms, please refer to Section 13.13 of the Data Management Section of this SSP.

Step 1: Enrollment, Week 0/Day 0			
Initial/date	Completed	Procedures	Comments
_____	<input type="checkbox"/>	Collect urine and perform testing for: <input type="checkbox"/> Urinalysis (protein and glucose)	
<p>NOTE: All HIV test results from Screening and at least one HIV test result from Enrollment must be available and confirmed to be negative/non-reactive <i>PRIOR</i> to provision of study product.</p> <p>Results from the chemistry testing, LFTs, lipid profile, hematology testing, and urinalysis from this visit are <i>NOT</i> required to issue study product.</p>			
_____	<input type="checkbox"/>	Provide HIV pre-test counseling	

Participant ID

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Visit Date

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NOTE: For a listing of forms required at each visit, otherwise known as the HPTN 083-01 Schedule of Forms, please refer to Section 13.13 of the Data Management Section of this SSP.

Step 1: Enrollment, Week 0/Day 0			
Initial/date	Completed	Procedures	Comments
_____	<input type="checkbox"/>	Collect blood and perform testing for: <ul style="list-style-type: none"> <input type="checkbox"/> HIV testing <ul style="list-style-type: none"> <input type="checkbox"/> FDA-cleared HIV rapid test <input type="checkbox"/> Laboratory based, instrument HIV Immunoassay (HIV antigen and antibody) <input type="checkbox"/> HIV Viral Load (detection limit <50 copies/mL) <input type="checkbox"/> Hepatitis B and C testing (HBsAb and HBcAb and HCVAb if not performed at Screening; results must be available and discussed with participant prior to enrollment) <ul style="list-style-type: none"> <input type="checkbox"/> HBsAg and HCVAb results are needed for the enrollment visit. HBcAb and HBsAb can be performed at screening or enrollment. <input type="checkbox"/> CBC with differential <input type="checkbox"/> Chemistry panel (BUN/Urea, creatinine, CPK, calcium, phosphorous, glucose, amylase, lipase) <input type="checkbox"/> LFTs (AST, ALT, total bilirubin, alkaline phosphatase) <input type="checkbox"/> Fasting lipid profile (total cholesterol, HDL, triglycerides, LDL) <input type="checkbox"/> Urinalysis (protein and glucose- can be done locally or at the clinic) <input type="checkbox"/> Plasma storage 	
_____	<input type="checkbox"/>	Provide HIV post-test counseling	
_____	<input type="checkbox"/>	Provide adherence counseling	
_____	<input type="checkbox"/>	Provide oral study drug and observe participant dose	
_____	<input type="checkbox"/>	Offer condoms and lubricant; document whether participant took products	

Participant ID

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NOTE: For a listing of forms required at each visit, otherwise known as the HPTN 083-01 Schedule of Forms, please refer to Section 13.13 of the Data Management Section of this SSP.

Step 1: Enrollment, Week 0/Day 0			
Initial/date	Completed	Procedures	Comments
_____	<input type="checkbox"/>	Schedule next study visit. If possible, generate and review with participant the visit calendar for upcoming visits.	
_____	<input type="checkbox"/>	Provide site contact information and instructions to report symptoms and/or clarify any questions.	
_____	<input type="checkbox"/>	Remind participant to bring unused study product at next study visit.	
_____	<input type="checkbox"/>	Provide participant reimbursement, if applicable.	

Notes for Enrollment and Weeks 0: Please refer to Section 5.2 of the HPTN 083-01 Protocol

Comments: _____

Participant ID

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Visit Date

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NOTE: For a listing of forms required at each visit, otherwise known as the HPTN 083-01 Schedule of Forms, please refer to Section 13.13 of the Data Management Section of this SSP.

Step 1: Weeks 2 and 4 (Oral Safety Visits)			
Circle applicable visit week			
Initials/date	Completed	Procedures	Comments
_____	<input type="checkbox"/>	Confirm participant identity and PTID	
_____	<input type="checkbox"/>	Review/update locator information	
_____	<input type="checkbox"/>	Collect targeted medical history including concomitant medications	
_____	<input type="checkbox"/>	Week 4 only: Remind participants that the use of anticoagulant and/or antiplatelet medications as outlined are prohibited within 7 days before injections	
_____	<input type="checkbox"/>	Week 4 only: Participant completes Behavioral/Acceptability Assessment (CASI)	
_____	<input type="checkbox"/>	Perform targeted physical exam	
_____	<input type="checkbox"/>	Provide HIV pre-test counseling	
_____	<input type="checkbox"/>	Collect blood for: <ul style="list-style-type: none"> <input type="checkbox"/> HIV testing <input type="checkbox"/> FDA-cleared HIV rapid test <input type="checkbox"/> Laboratory based, instrument HIV Immunoassay (HIV antigen and antibody) <input type="checkbox"/> HIV Viral Load (detection limit <50 copies/mL) <input type="checkbox"/> CBC with differential <input type="checkbox"/> Chemistry panel (BUN/Urea, creatinine, CPK, calcium, phosphorous, glucose, amylase, lipase) <input type="checkbox"/> LFTs (AST, ALT, total bilirubin, alkaline phosphatase) (Week 4 only) <input type="checkbox"/> Plasma storage 	
_____	<input type="checkbox"/>	Provide HIV post-test counseling	

Participant ID

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NOTE: For a listing of forms required at each visit, otherwise known as the HPTN 083-01 Schedule of Forms, please refer to Section 13.13 of the Data Management Section of this SSP.

_____	<input type="checkbox"/>	Conduct pill count (if the participant brought his pills) and complete pill count follow-up CRF	
_____	<input type="checkbox"/>	If participant brought their pills and has not dosed today, observe dosing (comment either way for the source)	
_____	<input type="checkbox"/>	Provide adherence counseling	
_____	<input type="checkbox"/>	Offer condoms and lubricant	
_____	<input type="checkbox"/>	Remind participant to bring unused study product at next study visit.	
_____	<input type="checkbox"/>	Schedule next study visit	
_____	<input type="checkbox"/>	Provide site contact information and instructions to report symptoms and/or clarify any questions	
_____	<input type="checkbox"/>	Provide participant reimbursement, if applicable	

Notes for Weeks 2 and 4: Please refer to Section 5.3 of the HPTN 083-01 Protocol

Comments: _____

Participant ID

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NOTE: For a listing of forms required at each visit, otherwise known as the HPTN 083-01 Schedule of Forms, please refer to Section 13.13 of the Data Management Section of this SSP.

Step 2: Week 5 Visit (First Injection Visit)			
Initials/date	Completed	Procedures	Comments
_____	<input type="checkbox"/>	Confirm participant identity and PTID	
_____	<input type="checkbox"/>	Review/update locator information	
_____	<input type="checkbox"/>	Collect targeted medical history (including concomitant medications)	
_____	<input type="checkbox"/>	Perform targeted physical exam	
_____	<input type="checkbox"/>	Administer Step 2 Week 5 CASI	
_____	<input type="checkbox"/>	Provide HIV pre-test counseling	
_____	<input type="checkbox"/>	Collect blood and perform testing for: <ul style="list-style-type: none"> <input type="checkbox"/> HIV testing <ul style="list-style-type: none"> <input type="checkbox"/> FDA-cleared HIV rapid test <input type="checkbox"/> Laboratory based, instrument HIV Immunoassay (HIV antigen and antibody) <input type="checkbox"/> HIV Viral Load (detection limit <50 copies/mL) <input type="checkbox"/> CBC with differential <input type="checkbox"/> Chemistry testing (BUN/urea, creatinine, CPK, calcium, phosphorous, glucose, amylase, and lipase) <input type="checkbox"/> Liver function (AST, ALT, TBili, and alkaline phosphatase) <input type="checkbox"/> Urinalysis (protein, glucose; at the clinic or local lab) <input type="checkbox"/> Plasma storage (must be drawn PRIOR to injection) 	
_____	<input type="checkbox"/>	Provide HIV post-test counseling	

Participant ID

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INSTRUCTIONS: Enter staff initials next to each procedure completed. Do not initial procedures another staff member completed. If other staff members are not available to initial next to the procedure they completed, add a note on the checklist documenting who completed the procedure. If all procedures listed on a checklist are performed on the date entered in the top section of the checklist, it is not necessary to enter the date beside each item. If procedures listed on a checklist are performed on multiple dates, enter the date upon which each procedure is performed beside each item. Bracketing procedures which are consecutive and all done on the same date is also acceptable. If a procedure listed on the checklist is not performed, enter "ND" for "not done" or "NA" for "not applicable" beside the item and record the reason why (if not self-explanatory); initial and date this entry.

NOTE: For a listing of forms required at each visit, otherwise known as the HPTN 083-01 Schedule of Forms, please refer to Section 13.13 of the Data Management Section of this SSP.

NOTE BEFORE INJECTION: All HIV test results from previous visits and at least one HIV test result from the Week 5 visit must be available and confirmed to be negative/non-reactive PRIOR to injection of study product. The injection must not be given if any HIV test is reactive/positive.

Results from all Week 4 clinical and laboratory evaluations (e.g., chemistry, LFTs, hematology) must be available and be reviewed by the IoR or their designee prior to injection.

_____	<input type="checkbox"/>	Administer injection (with counseling about possible side effects and remind participants that the use of anticoagulant and/or antiplatelet medications are prohibited within 7 days after injections)	
_____	<input type="checkbox"/>	Provide adherence counseling	
_____	<input type="checkbox"/>	Offer condoms and lubricant; document whether taken	
_____	<input type="checkbox"/>	Schedule next study visit	
_____	<input type="checkbox"/>	Provide site contact information and instructions to report symptoms and/or clarify any questions	
_____	<input type="checkbox"/>	Provide participant reimbursement, if applicable	

Notes for Week 5: Please refer to Section 5.5 of the HPTN 083-01 Protocol

Comments: _____

Participant ID

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Visit Date

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INSTRUCTIONS: Enter staff initials next to each procedure completed. Do not initial procedures another staff member completed. If other staff members are not available to initial next to the procedure they completed, add a note on the checklist documenting who completed the procedure. If all procedures listed on a checklist are performed on the date entered in the top section of the checklist, it is not necessary to enter the date beside each item. If procedures listed on a checklist are performed on multiple dates, enter the date upon which each procedure is performed beside each item. Bracketing procedures which are consecutive and all done on the same date is also acceptable. If a procedure listed on the checklist is not performed, enter "ND" for "not done" or "NA" for "not applicable" beside the item and record the reason why (if not self-explanatory); initial and date this entry.

NOTE: For a listing of forms required at each visit, otherwise known as the HPTN 083-01 Schedule of Forms, please refer to Section 13.13 of the Data Management Section of this SSP.

Step 2: (Safety Visits) Weeks 6, 10, 18, 26, 34			
Circle applicable visit week			
Initials/date	Completed	Procedures	Comments
_____	<input type="checkbox"/>	Confirm participant identity and PTID	
_____	<input type="checkbox"/>	Review/update locator information	
_____	<input type="checkbox"/>	Collect targeted medical history (including concomitant medications)	
_____	<input type="checkbox"/>	Remind participants that the use of anticoagulant and/or antiplatelet medications are prohibited within 7 days before and after injections	
_____	<input type="checkbox"/>	Perform targeted physical exam	
_____	<input type="checkbox"/>	Conduct ISR evaluation	
_____	<input type="checkbox"/>	Provide HIV prevention counseling	
_____	<input type="checkbox"/>	Provide HIV pre-test counseling	
_____	<input type="checkbox"/>	Collect blood for: <ul style="list-style-type: none"> <input type="checkbox"/> HIV testing <ul style="list-style-type: none"> <input type="checkbox"/> FDA-cleared HIV rapid test <input type="checkbox"/> Laboratory based, instrument HIV Immunoassay (HIV antigen and antibody) <input type="checkbox"/> HIV Viral Load (detection limit <50 copies/mL) <input type="checkbox"/> CBC with differential <input type="checkbox"/> Chemistry panel (BUN/Urea, creatinine, CPK, calcium, phosphorous, glucose, amylase, lipase) <input type="checkbox"/> LFTs (AST, ALT, total bilirubin, alkaline phosphatase) <input type="checkbox"/> Fasting lipid profile (total cholesterol, HDL, triglycerides, and LDL (either 	

Participant ID

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Visit Date

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INSTRUCTIONS: Enter staff initials next to each procedure completed. Do not initial procedures another staff member completed. If other staff members are not available to initial next to the procedure they completed, add a note on the checklist documenting who completed the procedure. If all procedures listed on a checklist are performed on the date entered in the top section of the checklist, it is not necessary to enter the date beside each item. If procedures listed on a checklist are performed on multiple dates, enter the date upon which each procedure is performed beside each item. Bracketing procedures which are consecutive and all done on the same date is also acceptable. If a procedure listed on the checklist is not performed, enter "ND" for "not done" or "NA" for "not applicable" beside the item and record the reason why (if not self-explanatory); initial and date this entry.

NOTE: For a listing of forms required at each visit, otherwise known as the HPTN 083-01 Schedule of Forms, please refer to Section 13.13 of the Data Management Section of this SSP.

		calculated or measured) – Week 34 ONLY <input type="checkbox"/> Plasma storage	
_____	<input type="checkbox"/>	Provide HIV post-test counseling	
_____	<input type="checkbox"/>	Collect urine for: <input type="checkbox"/> Urinalysis (protein, glucose; at the clinic or local lab)	
_____	<input type="checkbox"/>	Hep B vaccination (if needed) – Weeks 6 and 33 only*	
_____	<input type="checkbox"/>	Offer condoms and lubricant; document whether taken	
_____	<input type="checkbox"/>	Provide site contact information and instructions to report symptoms and/or clarify any questions	
	<input type="checkbox"/>	Provide adherence counseling	
	<input type="checkbox"/>	Step 3 product choice discussion – Week 34 only (and only if discussion not held at or finished at Week 33 injection visit)	
_____	<input type="checkbox"/>	Interviewer administered product choice assessment – Week 34 only	
_____	<input type="checkbox"/>	Provide TDF/FTC at Week 34 (3 months' worth) – only if participant chooses Step 3 – Oral PrEP	
_____	<input type="checkbox"/>	Schedule next study visit	
_____	<input type="checkbox"/>	REMINDER: Qualitative interviews begin around/after Week 34	
_____	<input type="checkbox"/>	Provide participant reimbursement, if applicable	

Participant ID

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Visit Date

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INSTRUCTIONS: Enter staff initials next to each procedure completed. Do not initial procedures another staff member completed. If other staff members are not available to initial next to the procedure they completed, add a note on the checklist documenting who completed the procedure. If all procedures listed on a checklist are performed on the date entered in the top section of the checklist, it is not necessary to enter the date beside each item. If procedures listed on a checklist are performed on multiple dates, enter the date upon which each procedure is performed beside each item. Bracketing procedures which are consecutive and all done on the same date is also acceptable. If a procedure listed on the checklist is not performed, enter "ND" for "not done" or "NA" for "not applicable" beside the item and record the reason why (if not self-explanatory); initial and date this entry.

NOTE: For a listing of forms required at each visit, otherwise known as the HPTN 083-01 Schedule of Forms, please refer to Section 13.13 of the Data Management Section of this SSP.

***NOTE FOR HEP B VACCINATION, IF NEEDED:** HBV vaccine schedules differ according to the product. Sites should create the schedule that fits the product they have access to. (For more information, see: <https://immunisationhandbook.health.gov.au/resources/handbook-tables/table-monovalent-hepatitis-b-vaccines-for-adolescents-and-adults>.)

Notes for Safety Visits: Please refer to Section 5.6 of the HPTN 083-01 Protocol

Comments: _____

Participant ID

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Visit Date

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INSTRUCTIONS: Enter staff initials next to each procedure completed. Do not initial procedures another staff member completed. If other staff members are not available to initial next to the procedure they completed, add a note on the checklist documenting who completed the procedure. If all procedures listed on a checklist are performed on the date entered in the top section of the checklist, it is not necessary to enter the date beside each item. If procedures listed on a checklist are performed on multiple dates, enter the date upon which each procedure is performed beside each item. Bracketing procedures which are consecutive and all done on the same date is also acceptable. If a procedure listed on the checklist is not performed, enter "ND" for "not done" or "NA" for "not applicable" beside the item and record the reason why (if not self-explanatory); initial and date this entry.

NOTE: For a listing of forms required at each visit, otherwise known as the HPTN 083-01 Schedule of Forms, please refer to Section 13.13 of the Data Management Section of this SSP.

Step 2: (Remaining Injection Visits) Weeks 9, 17, 25, 33			
Circle applicable visit week			
Initial/date	Completed	Procedures	
_____	<input type="checkbox"/>	Confirm participant identity and PTID	
_____	<input type="checkbox"/>	Review/update locator information	
_____	<input type="checkbox"/>	Collect targeted medical history (including concomitant medications)	
_____	<input type="checkbox"/>	Perform targeted physical exam	
_____	<input type="checkbox"/>	Administer CASI	
_____	<input type="checkbox"/>	<input type="checkbox"/> Urinalysis (protein, glucose; at the clinic or local lab) <input type="checkbox"/> GC/CT testing (urine, rectal, and pharyngeal swabs) (Weeks 17, 33 only)	
_____	<input type="checkbox"/>	Provide HIV pre-test counseling	
_____	<input type="checkbox"/>	Collect blood for <input type="checkbox"/> HIV testing <input type="checkbox"/> FDA-cleared HIV rapid test <input type="checkbox"/> Laboratory based, instrument HIV Immunoassay (HIV antigen and antibody) <input type="checkbox"/> HIV Viral Load (detection limit <50 copies/mL) <input type="checkbox"/> CBC with differential <input type="checkbox"/> Chemistry panel (BUN/Urea, creatinine, CPK, calcium, phosphorous, glucose, amylase, lipase) <input type="checkbox"/> LFTs (AST, ALT, total bilirubin, alkaline phosphatase) <input type="checkbox"/> Syphilis serology (Week 33 only) <input type="checkbox"/> Plasma storage for pharmacology testing (must be drawn PRIOR to injection)	
_____	<input type="checkbox"/>	Provide HIV post-test counseling	

Participant ID

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Visit Date

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NOTE: For a listing of forms required at each visit, otherwise known as the HPTN 083-01 Schedule of Forms, please refer to Section 13.13 of the Data Management Section of this SSP.

Step 2: (Remaining Injection Visits) Weeks 9, 17, 25, 33			
<i>Circle applicable visit week</i>			
Initial/date	Completed	Procedures	
NOTE BEFORE INJECTION: All HIV test results from previous visits and at least one HIV test result from the current visit must be available and confirmed to be negative/non-reactive PRIOR to injection of study product. The injection must not be given if any HIV test is reactive/positive.			
Results from the other laboratory evaluations (e.g., chemistry, LFTs, hematology) from the current visit are NOT required prior to injection.			
Results from all the previous safety visit clinical and laboratory evaluations (e.g., chemistry, LFTs, hematology) must be available and be reviewed by the IoR or their designee prior to injection.			
_____	<input type="checkbox"/>	Administer injection (with counseling about possible side effects and reminder that the use of anticoagulant and/or antiplatelet medications are prohibited within 7 days before and after injections)	
_____	<input type="checkbox"/>	Provide adherence counseling	
_____	<input type="checkbox"/>	Step 3 product choice discussion (Week 33 only; can be extended to continue discussion at Week 34)	
_____	<input type="checkbox"/>	Offer condoms and lubricant; document whether taken	
_____	<input type="checkbox"/>	Provide site contact information and instructions to report symptoms and/or clarify any questions	
_____	<input type="checkbox"/>	Schedule next study visit	
_____	<input type="checkbox"/>	Provide participant reimbursement, if applicable	

Notes for remaining injection visits: Please refer to Section 5.5 of the HPTN 083-01 Protocol

Comments: _____

Participant ID

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Visit Date

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NOTE: For a listing of forms required at each visit, otherwise known as the HPTN 083-01 Schedule of Forms, please refer to Section 13.13 of the Data Management Section of this SSP.

Step 3: (Step 3 – Oral PrEP) Weeks +8, +12, +24, +36 and +48 (post-last injection)			
Circle applicable visit week			
Initial/date	Completed	Procedures	Comments
_____	<input type="checkbox"/>	Confirm participant identity and PTID	
_____	<input type="checkbox"/>	Review/update locator information	
_____	<input type="checkbox"/>	: Collect targeted medical history (including concomitant medications)	
_____	<input type="checkbox"/>	: Perform targeted physical exam	
_____	<input type="checkbox"/>	Every visit except Week +8: CASI	
_____	<input type="checkbox"/>	Qualitative interviews continue (approximately Weeks +12 and +24)	
_____	<input type="checkbox"/>	Weeks +24 and +48 ONLY: rectal and oral pharyngeal swabs	
_____	<input type="checkbox"/>	Weeks +24 and +48 ONLY: collect urine	
_____	<input type="checkbox"/>	Provide HIV pre-test counseling	

Participant ID

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Visit Date

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NOTE: For a listing of forms required at each visit, otherwise known as the HPTN 083-01 Schedule of Forms, please refer to Section 13.13 of the Data Management Section of this SSP.

Step 3: (Step 3 – Oral PrEP) Weeks +8, +12, +24, +36 and +48 (post-last injection)			
Circle applicable visit week			
Initial/date	Completed	Procedures	Comments
_____	<input type="checkbox"/>	<input type="checkbox"/> HIV testing (ALL visits) <input type="checkbox"/> FDA-cleared HIV rapid test <input type="checkbox"/> Laboratory based, instrument HIV Immunoassay (HIV antigen and antibody) <input type="checkbox"/> HIV Viral Load (detection limit <50 copies/mL) <input type="checkbox"/> CBC with differential (Weeks +24 and +48 only) <input type="checkbox"/> Chemistry panel (Creatinine ONLY) – Weeks , +24, and +48 only <input type="checkbox"/> LFTs (AST, ALT, total bilirubin, alkaline phosphatase) – Weeks +24, and +48 only <input type="checkbox"/> Syphilis serology (Week +24) <input type="checkbox"/> GC/CT testing (urine, rectal and oral pharyngeal swabs) – Weeks +24 and +48 only <input type="checkbox"/> Urinalysis (protein, glucose; at the clinic or local lab) – Weeks +24 and +48 only <input type="checkbox"/> Plasma storage (ALL visits including Week +8) <input type="checkbox"/> DBS storage (Weeks +12, +24 and +48 only) <input type="checkbox"/> HBsAb and HBcAb (Week +48 only) ⁺⁺ <input type="checkbox"/> HCVAb (Week +48 only)	
_____	<input type="checkbox"/>	Provide HIV post-test counseling (ALL visits)	

Participant ID

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Visit Date

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NOTE: For a listing of forms required at each visit, otherwise known as the HPTN 083-01 Schedule of Forms, please refer to Section 13.13 of the Data Management Section of this SSP.

Step 3: (Step 3 – Oral PrEP) Weeks +8, +12, +24, +36 and +48 (post-last injection) <i>Circle applicable visit week</i>			
Initial/date	Completed	Procedures	Comments
_____	<input type="checkbox"/>	Provide oral study drug (Weeks +12, +24, +36)	
_____	<input type="checkbox"/>	Provide adherence counseling (ALL visits, except Week +8)	
_____	<input type="checkbox"/>	Offer condoms and lubricant; document whether taken	
_____	<input type="checkbox"/>	Provide site contact information and instructions to report symptoms and/or clarify any questions	
_____	<input type="checkbox"/>	Schedule next study visit, if applicable	
_____	<input type="checkbox"/>	Provide participant reimbursement, if applicable	

++ HBsAb and HBcAb will be tested in participants who received the HBV vaccine.

Notes for Step 3: Please refer to Section 5.7 of the HPTN 083-01 Protocol

Comments: _____

Step 3: (Step 3 – Injection) Weeks +8, +16, +24, +32, +40, and +48 (post-last injection) <i>Circle applicable visit week</i>			
Initial/date	Completed	Procedures	Comments
_____	<input type="checkbox"/>	Confirm participant identity and PTID	

Participant ID

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Visit Date

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NOTE: For a listing of forms required at each visit, otherwise known as the HPTN 083-01 Schedule of Forms, please refer to Section 13.13 of the Data Management Section of this SSP.

Step 3: (Step 3 – Injection) Weeks +8, +16,+24, +32, +40, and +48 (post-last injection) <i>Circle applicable visit week</i>			
Initial/date	Completed	Procedures	Comments
_____	<input type="checkbox"/>	Review/update locator information	
_____	<input type="checkbox"/>	Collect targeted medical history (including concomitant medications)	
_____	<input type="checkbox"/>	Perform targeted physical exam	
_____	<input type="checkbox"/>	Every visit except Week +8: Conduct ISR evaluation	
_____	<input type="checkbox"/>	Every visit except Week +8: CASI	
_____	<input type="checkbox"/>	Qualitative interviews continue (approximately Weeks +16 and +24)	
_____	<input type="checkbox"/>	Weeks +24 and +48 ONLY: rectal and oral pharyngeal swabs	
_____	<input type="checkbox"/>	Weeks +24 and +48 ONLY: collect urine	
_____	<input type="checkbox"/>	Provide HIV pre-test counseling (ALL visits)	

Participant ID

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Visit Date

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INSTRUCTIONS: Enter staff initials next to each procedure completed. Do not initial procedures another staff member completed. If other staff members are not available to initial next to the procedure they completed, add a note on the checklist documenting who completed the procedure. If all procedures listed on a checklist are performed on the date entered in the top section of the checklist, it is not necessary to enter the date beside each item. If procedures listed on a checklist are performed on multiple dates, enter the date upon which each procedure is performed beside each item. Bracketing procedures which are consecutive and all done on the same date is also acceptable. If a procedure listed on the checklist is not performed, enter "ND" for "not done" or "NA" for "not applicable" beside the item and record the reason why (if not self-explanatory); initial and date this entry.

NOTE: For a listing of forms required at each visit, otherwise known as the HPTN 083-01 Schedule of Forms, please refer to Section 13.13 of the Data Management Section of this SSP.

Step 3: (Step 3 – Injection) Weeks +8, +16, +24, +32, +40, and +48 (post-last injection) <i>Circle applicable visit week</i>			
Initial/date	Completed	Procedures	Comments
_____	<input type="checkbox"/>	<input type="checkbox"/> HIV testing (ALL visits) <input type="checkbox"/> FDA-cleared HIV rapid test <input type="checkbox"/> Laboratory based, instrument HIV Immunoassay (HIV antigen and antibody) <input type="checkbox"/> HIV Viral Load (detection limit <50 copies/mL) <input type="checkbox"/> CBC with differential (Weeks +24 and +48 only) <input type="checkbox"/> Chemistry panel (BUN/Urea, creatinine, CPK, calcium, phosphorous, glucose, amylase, lipase) – Weeks +24 and +48 only <input type="checkbox"/> LFTs (AST, ALT, total bilirubin, alkaline phosphatase) – Weeks, +24 and +48 only <input type="checkbox"/> Syphilis serology (Week +24) <input type="checkbox"/> GC/CT testing (urine, rectal and oral pharyngeal swabs) – Weeks +24 and +48 only <input type="checkbox"/> Urinalysis (protein, glucose; at the clinic or local lab) – Weeks +24 and +48 only <input type="checkbox"/> Plasma storage (ALL visits including Week +8) <input type="checkbox"/> DBS storage (Weeks +16, +24, +40, +48 only) <input type="checkbox"/> HBsAb and HBcAb (Week +48 only) ⁺⁺ <input type="checkbox"/> HCVAb (Week +48 only)	
_____	<input type="checkbox"/>	Provide HIV post-test counseling (All visits)	

Participant ID

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Visit Date

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NOTE: For a listing of forms required at each visit, otherwise known as the HPTN 083-01 Schedule of Forms, please refer to Section 13.13 of the Data Management Section of this SSP.

Step 3: (Step 3 – Injection) Weeks +8, +16, +24, +32, +40, and +48 (post-last injection) <i>Circle applicable visit week</i>			
Initial/date	Completed	Procedures	Comments
_____	<input type="checkbox"/>	Provide injections (All visits)	
_____	<input type="checkbox"/>	Provide adherence counseling (All visits)	
_____	<input type="checkbox"/>	Offer condoms and lubricant; document whether taken	
_____	<input type="checkbox"/>	Provide site contact information and instructions to report symptoms and/or clarify any questions	
_____	<input type="checkbox"/>	Schedule next study visit, if applicable	
_____	<input type="checkbox"/>	Provide participant reimbursement, if applicable	

++ HBsAb and HBcAb will be tested in participants who received the HBV vaccine.

Notes for Step 3: Please refer to Section 5.7 of the HPTN 083-01 Protocol

Comments: _____

Participant ID

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Visit Date

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NOTE: For a listing of forms required at each visit, otherwise known as the HPTN 083-01 Schedule of Forms, please refer to Section 13.13 of the Data Management Section of this SSP.

Procedures for Enrolled Participants who Seroconvert (See Protocol Section 5.11 and Appendix V)			
HIV Confirmation Visit, Weeks +12, +24, +36, +48			
<i>Circle applicable visit week</i>			
Initial/date	Completed	Procedures	Comments
_____	<input type="checkbox"/>	Confirm participant identity and PTID	
_____	<input type="checkbox"/>	Review/update locator information	
_____	<input type="checkbox"/>	Collect targeted medical history (including concomitant medications)	
_____	<input type="checkbox"/>	Perform targeted physical exam	
_____	<input type="checkbox"/>	Provide HIV pre-test counseling (HIV confirmation visit only)	

Participant ID

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Visit Date

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NOTE: For a listing of forms required at each visit, otherwise known as the HPTN 083-01 Schedule of Forms, please refer to Section 13.13 of the Data Management Section of this SSP.

Procedures for Enrolled Participants who Seroconvert (See Protocol Section 5.11 and Appendix V)			
HIV Confirmation Visit, Weeks +12, +24, +36, +48			
Circle applicable visit week			
Initial/date	Completed	Procedures	Comments
_____	<input type="checkbox"/>	Collect blood for: <ul style="list-style-type: none"> <input type="checkbox"/> HIV testing (FDA-cleared HIV rapid test Laboratory based, instrument HIV Immunoassay (HIV antigen and antibody) (HIV confirmation visit only)) <input type="checkbox"/> HIV resistance testing (HIV confirmation visit only) <input type="checkbox"/> DBS storage (HIV confirmation visit only) <input type="checkbox"/> CD4 cell count (HIV confirmation visit, Weeks +24, +48 only) <input type="checkbox"/> HIV viral load testing (HIV confirmation visit, Weeks +24, +48 only) <input type="checkbox"/> Chemistry (BUN/Urea, creatinine, CPK, calcium, phosphorous, glucose, amylase, lipase; Weeks +24, +48 only) <input type="checkbox"/> LFTs (AST, ALT, total bilirubin, alkaline phosphatase; Weeks +24, +48 only) <input type="checkbox"/> Plasma storage 	
_____	<input type="checkbox"/>	Provide HIV post-test counseling (HIV confirmation visit only)	
_____	<input type="checkbox"/>	Offer condoms and lubricant; document whether taken	
_____	<input type="checkbox"/>	Provide site contact information and instructions to report symptoms and/or clarify any questions	
_____	<input type="checkbox"/>	Schedule next study visit, if applicable	
_____	<input type="checkbox"/>	Provide participant reimbursement, if applicable	

Participant ID

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Visit Date

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INSTRUCTIONS: Enter staff initials next to each procedure completed. Do not initial procedures another staff member completed. If other staff members are not available to initial next to the procedure they completed, add a note on the checklist documenting who completed the procedure. If all procedures listed on a checklist are performed on the date entered in the top section of the checklist, it is not necessary to enter the date beside each item. If procedures listed on a checklist are performed on multiple dates, enter the date upon which each procedure is performed beside each item. Bracketing procedures which are consecutive and all done on the same date is also acceptable. If a procedure listed on the checklist is not performed, enter "ND" for "not done" or "NA" for "not applicable" beside the item and record the reason why (if not self-explanatory); initial and date this entry.

NOTE: For a listing of forms required at each visit, otherwise known as the HPTN 083-01 Schedule of Forms, please refer to Section 13.13 of the Data Management Section of this SSP.

Notes for Procedures for Enrolled Participants who Seroconvert: Please refer to Appendix V of the HPTN 083-01 Protocol.

Comments: _____

