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 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)				
These are inclusion criteria. Any box checked "No" disqualifies the person from enrollment.				
Demographic/Medical/Behavioral	Initials/ Date	Eligible	Not Eligible	
	_____	Yes ☐	No ☐	Assigned male at birth (includes MSM, TGW, and gender non-conforming people)
	_____	Yes ☐	No ☐	At enrollment, aged below 18 years
	_____	Yes ☐	No ☐	At enrollment, body weight ≥ 35 kg (77 lbs.)
	_____	Yes ☐	No ☐	Provided written informed consent
	_____	Yes ☐	No ☐	Self-reported sexual activity with a male in the past 12 months
	_____	Yes ☐	No ☐	In general, good health, as evidenced by the following laboratory values: • Non-reactive / negative HIV test results • Absolute neutrophil count > 799 cells/mm3, • Platelet count ≥ 100,000/mm3[+], • Hemoglobin ≥ 11g/dL[+], • Calculated creatinine clearance ≥ 60 mL/minute using modified Schwartz equation (≤ grade 2), • Alanine aminotransferase (ALT) < 2.0 times the upper limit of normal (ULN) and total bilirubin (Tbili) ≤ 2.5 x ULN, • Hepatitis B virus (HBV) surface antigen (HBsAg) negative and accepts vaccination[*]. • HCV Antibody negative[++]. [+] *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.* ** For participants who are negative for HBsAb at enrollment, HBsAb and HBcAb (total) will be checked at the end of the study.* [++] *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.*
	_____	Yes ☐	No ☐	Willing to undergo all required study procedures
	_____	Yes ☐	No ☐	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.			
Demographic/Medical/Behavioral	Initials	Not Eligible	Eligible	
	_____	Yes ☐	No ☐	Past or current participation in HIV vaccine trial with exception for participants who can provide documentation of receipt of placebo
	_____	Yes ☐	No ☐	Exclusively had sex with biological females in lifetime
	_____	Yes ☐	No ☐	In the last 6 months (at the time of screening): • 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 ☐	No ☐	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 ☐	No ☐	Inflammatory skin conditions that compromise the safety of intramuscular (IM) injections
	_____	Yes ☐	No ☐	Tattoo or other dermatological condition overlying the buttock region that may interfere with interpretation of injection site reactions;
	_____	Yes ☐	No ☐	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 ☐	No ☐	Known history of clinically significant bleeding
	_____	Yes ☐	No ☐	Surgically-placed or injected buttock implants or fillers, per self-report. (Contact the CMC for guidance regarding questions about individual cases.)
	_____	Yes ☐	No ☐	A history of seizure disorder, per self-report
	_____	Yes ☐	No ☐	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 ☐	No ☐	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 ☐	No ☐	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)

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 ☐☐☐ ☐☐☐☐ ☐☐

Visit Date ☐☐ ☐☐☐ ☐☐

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

Participant ID ☐☐☐ ☐☐☐☐ ☐☐

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**
_____	☐	Collect blood and perform testing for: ☐ HIV testing ☐ FDA-cleared HIV rapid test ☐ Laboratory based, instrument HIV Immunoassay (HIV antigen and antibody) ☐ HIV Viral Load (detection limit <50 copies/mL) ☐ 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. ☐ Hepatitis testing: HBsAg and HCVAb results are needed for the enrollment visit. HBcAb and HbSAb can be performed at screening or enrollment. ☐ CBC with differential ☐ Chemistry testing (creatinine only at Screening) ☐ Syphilis testing ☐ GC/CT testing (urine, rectal, and oral pharyngeal swabs ☐ LFTs (ALT and total bilirubin) ☐ Plasma for storage	
_____	☐	Provide HIV post-test counseling	
_____	☐	Offer condoms and lubricant; document whether participant took them	
*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.*			
_____	☐	Schedule enrollment visit, if eligible thus far	
_____	☐	Provide participant reimbursement and site contact information, if applicable	

Participant ID | **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: _____

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Participant ID ☐☐☐ ☐☐☐☐ ☐ ☐

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**
_____	☐	Confirm participant identity and PTID.	
_____	☐	Confirm participant eligibility to continue with Enrollment visit based on Screening test results. Provide participant with test results.	
_____	☐	Confirm last time participant ate. *Reminder: Participants should have fasted for at least 8 hours (preferably 12 hours) prior to blood collection.*	
_____	☐	Verify participant is within the screening window. ❒ Within 30 days of specimen collection ❒ Within 14 days of HIV RNA sample collection	
_____	☐	Administer PHQ-9.	
_____	☐	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.	
_____	☐	Confirm that informed consent was obtained and review elements of the consent as needed.	
_____	☐	Review/update locator information.	
_____	☐	Collect demographic information (if not collected at Screening).	
_____	☐	Collect complete medical history including concomitant medications.	
_____	☐	Perform full physical exam.	
_____	☐	Complete Enrollment CASI.	

Participant ID **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**
_____	☐	Collect urine and perform testing for: ☐ Urinalysis (protein and glucose)	
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 PRIOR to provision of study product.* *Results from the chemistry testing, LFTs, lipid profile, hematology testing, and urinalysis from this visit are NOT required to issue study product.*			
_____	☐	Provide HIV pre-test counseling	

Participant ID ☐☐☐ ☐☐☐☐ ☐☐

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**
_____	☐	Collect blood and perform testing for: ☐ HIV testing ☐ FDA-cleared HIV rapid test ☐ Laboratory based, instrument HIV Immunoassay (HIV antigen and antibody) ☐ HIV Viral Load (detection limit <50 copies/mL) ☐ 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) o HBsAg and HCVAb results are needed for the enrollment visit. HBcAb and HBsAb can be performed at screening or enrollment. ☐ CBC with differential ☐ Chemistry panel (BUN/Urea, creatinine, CPK, calcium, phosphorous, glucose, amylase, lipase) ☐ LFTs (AST, ALT, total bilirubin, alkaline phosphatase) ☐ Fasting lipid profile (total cholesterol, HDL, triglycerides, LDL) ☐ Urinalysis (protein and glucose- can be done locally or at the clinic) ☐ Plasma storage	
_____	☐	Provide HIV post-test counseling	
_____	☐	Provide adherence counseling	
_____	☐	Provide oral study drug and observe participant dose	
_____	☐	Offer condoms and lubricant; document whether participant took products	

Participant ID ☐☐☐ ☐☐☐☐ ☐ ☐

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**
_____	☐	Schedule next study visit. If possible, generate and review with participant the visit calendar for upcoming visits.	
_____	☐	Provide site contact information and instructions to report symptoms and/or clarify any questions.	
_____	☐	Remind participant to bring unused study product at next study visit.	
_____	☐	Provide participant reimbursement, if applicable.	

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

Comments: _____

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Participant ID ☐☐☐ ☐☐☐☐ ☐☐

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**
_____	☐	Confirm participant identity and PTID	
_____	☐	Review/update locator information	
_____	☐	Collect targeted medical history including concomitant medications	
_____	☐	**Week 4 only:** Remind participants that the use of anticoagulant and/or antiplatelet medications as outlined are prohibited within 7 days before injections	
_____	☐	**Week 4 only:** Participant completes Behavioral/Acceptability Assessment (CASI)	
_____	☐	Perform targeted physical exam	
_____	☐	Provide HIV pre-test counseling	
_____	☐	Collect blood for: ☐ HIV testing ☐ FDA-cleared HIV rapid test ☐ Laboratory based, instrument HIV Immunoassay (HIV antigen and antibody) ☐ HIV Viral Load (detection limit <50 copies/mL) ☐ CBC with differential ☐ Chemistry panel (BUN/Urea, creatinine, CPK, calcium, phosphorous, glucose, amylase, lipase) ☐ LFTs (AST, ALT, total bilirubin, alkaline phosphatase) (Week 4 only) ☐ Plasma storage	
_____	☐	Provide HIV post-test counseling	

Participant ID | **Visit Date**

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.

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

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

Comments: _____

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Participant ID ☐☐☐ ☐☐☐☐ ☐☐

Visit Date ☐☐ ☐☐☐ ☐☐

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: Week 5 Visit (First Injection Visit)			
Initials/date	**Completed**	**Procedures**	**Comments**
_____	☐	Confirm participant identity and PTID	
_____	☐	Review/update locator information	
_____	☐	Collect targeted medical history (including concomitant medications)	
_____	☐	Perform targeted physical exam	
_____	☐	Administer Step 2 Week 5 CASI	
_____	☐	Provide HIV pre-test counseling	
_____	☐	Collect blood and perform testing for: ☐ HIV testing ☐ FDA-cleared HIV rapid test ☐ Laboratory based, instrument HIV Immunoassay (HIV antigen and antibody) ☐ HIV Viral Load (detection limit <50 copies/mL) ☐ CBC with differential ☐ Chemistry testing (BUN/urea, creatinine, CPK, calcium, phosphorous, glucose, amylase, and lipase) ☐ Liver function (AST, ALT, TBili, and alkaline phosphatase) ☐ Urinalysis (protein, glucose; at the clinic or local lab) ☐ Plasma storage (must be drawn PRIOR to injection)	
_____	☐	Provide HIV post-test counseling	

Participant ID ☐☐☐ ☐☐☐☐ ☐ ☐

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.

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.*			
_____	☐	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)	
_____	☐	Provide adherence counseling	
_____	☐	Offer condoms and lubricant; document whether taken	
_____	☐	Schedule next study visit	
_____	☐	Provide site contact information and instructions to report symptoms and/or clarify any questions	
_____	☐	Provide participant reimbursement, if applicable	

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

Comments: _____

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Participant ID ☐☐☐ ☐☐☐☐ ☐ ☐

Visit Date ☐☐ ☐☐☐ ☐☐

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**
_____	☐	Confirm participant identity and PTID	
_____	☐	Review/update locator information	
_____	☐	Collect targeted medical history (including concomitant medications)	
_____	☐	Remind participants that the use of anticoagulant and/or antiplatelet medications are prohibited within 7 days before and after injections	
_____	☐	Perform targeted physical exam	
_____	☐	Conduct ISR evaluation	
_____	☐	Provide HIV prevention counseling	
_____	☐	Provide HIV pre-test counseling	
_____	☐	Collect blood for: ☐ HIV testing ☐ FDA-cleared HIV rapid test ☐ Laboratory based, instrument HIV Immunoassay (HIV antigen and antibody) ☐ HIV Viral Load (detection limit <50 copies/mL) ☐ CBC with differential ☐ Chemistry panel (BUN/Urea, creatinine, CPK, calcium, phosphorous, glucose, amylase, lipase) ☐ LFTs (AST, ALT, total bilirubin, alkaline phosphatase) ☐ Fasting lipid profile (total cholesterol, HDL, triglycerides, and LDL (either	

Participant ID | **Visit Date**

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

Participant ID | **Visit Date**

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: _____

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Participant ID ☐☐☐ ☐☐☐☐ ☐ ☐

Visit Date ☐☐ ☐☐☐ ☐☐

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

Participant ID ☐☐☐ ☐☐☐☐ ☐☐

Visit Date ☐☐ ☐☐☐ ☐☐

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**	
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.*			
_____	☐	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)	
_____	☐	Provide adherence counseling	
_____	☐	Step 3 product choice discussion (Week 33 only; can be extended to continue discussion at Week 34)	
_____	☐	Offer condoms and lubricant; document whether taken	
_____	☐	Provide site contact information and instructions to report symptoms and/or clarify any questions	
_____	☐	Schedule next study visit	
_____	☐	Provide participant reimbursement, if applicable	

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

Comments: _____

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Participant ID ☐☐☐ ☐☐☐☐ ☐ ☐

Visit Date ☐☐ ☐☐☐ ☐☐

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

Participant ID | **Visit Date**

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

Participant ID ☐☐☐ ☐☐☐☐ ☐ ☐

Visit Date ☐☐ ☐☐☐ ☐☐

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

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Step 3: (Step 3 – Injection) Weeks +8, +16,+24, +32, +40, and +48 (post-last injection) *Circle applicable visit week*			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	Confirm participant identity and PTID	

Participant ID ☐☐☐ ☐☐☐☐ ☐ ☐

Visit Date ☐☐ ☐☐☐ ☐☐

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) *Circle applicable visit week*			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	Review/update locator information	
_____	☐	Collect targeted medical history (including concomitant medications)	
_____	☐	Perform targeted physical exam	
_____	☐	Every visit except Week +8: Conduct ISR evaluation	
_____	☐	Every visit except Week +8: CASI	
_____	☐	Qualitative interviews continue (approximately Weeks +16 and +24)	
_____	☐	Weeks +24 and +48 ONLY: rectal and oral pharyngeal swabs	
_____	☐	Weeks +24 and +48 ONLY: collect urine	
_____	☐	Provide HIV pre-test counseling (**ALL visits**)	

Participant ID **Visit Date**

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

Participant ID ☐☐☐ ☐☐☐☐ ☐ ☐

Visit Date ☐☐ ☐☐☐ ☐☐

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) *Circle applicable visit week*			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	Provide injections **(All visits)**	
_____	☐	Provide adherence counseling **(All visits)**	
_____	☐	Offer condoms and lubricant; document whether taken	
_____	☐	Provide site contact information and instructions to report symptoms and/or clarify any questions	
_____	☐	Schedule next study visit, if applicable	
_____	☐	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: _____

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Participant ID ☐☐☐ ☐☐☐☐ ☐ ☐

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**
_____	☐	Confirm participant identity and PTID	
_____	☐	Review/update locator information	
_____	☐	Collect targeted medical history (including concomitant medications)	
_____	☐	Perform targeted physical exam	
_____	☐	Provide HIV pre-test counseling (**HIV confirmation visit only**)	

Participant ID ☐☐☐ ☐☐☐☐ ☐ ☐ **Visit Date** ☐☐ ☐☐☐ ☐☐

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.

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**
_____	☐	Collect blood for: ☐ HIV testing (FDA-cleared HIV rapid test Laboratory based, instrument HIV Immunoassay (HIV antigen and antibody) (**HIV confirmation visit only**) ☐ HIV resistance testing (**HIV confirmation visit only**) ☐ DBS storage (**HIV confirmation visit only**) ☐ CD4 cell count (**HIV confirmation visit, Weeks +24, +48 only)** ☐ HIV viral load testing (**HIV confirmation visit, Weeks +24, +48 only**) ☐ Chemistry (BUN/Urea, creatinine, CPK, calcium, phosphorous, glucose, amylase, lipase; **Weeks +24, +48 only**) ☐ LFTs (AST, ALT, total bilirubin, alkaline phosphatase; **Weeks +24, +48 only**) ☐ Plasma storage	
_____	☐	Provide HIV post-test counseling (**HIV confirmation visit only)**	
_____	☐	Offer condoms and lubricant; document whether taken	
_____	☐	Provide site contact information and instructions to report symptoms and/or clarify any questions	
_____	☐	Schedule next study visit, if applicable	
_____	☐	Provide participant reimbursement, if applicable	

Participant ID | **Visit Date**

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: _____

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