6. Visit Checklists

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.
- At the enrollment visit, randomization assignment must take place after final confirmation and verification of eligibility (for sites that do split enrollment visits

due to physical location constraints, randomization can take place prior to performing the rapid HIV test required at the Enrollment visit , which in most cases would be performed on the second day of the split visit), and collection of blood for plasma storage. If a participant is subsequently found to be ineligible and is not randomized, 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 ☐	MSM or TGW (male at birth), age 18 or older at screening
	_____	Yes ☐	No ☐	Provided written informed consent
	_____	Yes ☐	No ☐	At high risk for sexually acquiring HIV infection based on self-report of at least one of the following: ☐ Any condomless receptive anal intercourse with male-at birth sexual partners in the 6 months prior to enrollment (condomless anal intercourse within a monogamous HIV seronegative concordant relationship does not meet this criterion) ☐ More than five male-at-birth sexual partners in the 6 months prior to enrollment (regardless of condom use and HIV serostatus, as reported by the enrollee. Additionally, a partner with whom only oral sex occurs is not considered a sexual partner in this context). ☐ Any stimulant drug use in the 6 months prior to enrollment (e.g. cocaine, methamphetamine, or non-physician prescribed pharmaceutical grade stimulants). Any questions regarding stimulant drugs, consult the CMC. ☐ Rectal or urethral gonorrhea or chlamydia or incident syphilis in the 6 months prior to enrollment ☐ SexPro score of ≤16 (US sites only)
	_____	Yes ☐	No ☐	Willing to undergo all required study procedures
	_____	Yes ☐	No ☐	No medical condition that, in the opinion of the study investigator, would interfere with the conduct of the study (e.g., provided by self-report, or found upon medical history and examination or in available medical records)

Blood/Urine Samples	_____	Yes ☐	No ☐	Non-reactive / negative HIV test results. Based on HIV test results at Screening and just prior to provision of study product, including: ❒ FDA-cleared HIV rapid test performed at screening ❒ 4th or 5th generation HIV immunoassay ❒ HIV RNA performed within 14 days of Enrollment. NOTE: 14-day window starts on the day sample for HIV RNA is collected, which is considered Day 0 (e.g., if collected on January 1, that blood draw is valid through January 15).
	_____	Yes ☐	No ☐	Hemoglobin > 11 g/dL, absolute neutrophil count > 750 cells/mm^3, and platelet count ≥ 100,000/mm^3
	_____	Yes ☐	No ☐	Calculated creatinine clearance ≥ 60 mL/min using the Cockcroft-Gault equation (use sex at birth for calculation) • Although not protocol exclusionary, sites should carefully consider the advisability of enrolling participants with calculated creatinine clearance between 60-70 mL/min, as limited changes in creatinine clearance during study conduct will lead to protocol-mandated product holds and may alter the risk-benefit considerations of study participation
	_____	Yes ☐	No ☐	Alanine aminotransferase (ALT) < 2 times the upper limit of normal (ULN)
	_____	Yes ☐	No ☐	Total bilirubin ≤ 2.5 times ULN
	_____	Yes ☐	No ☐	Hepatitis B virus (HBV) surface antigen (HBsAg) negative
	_____	Yes ☐	No ☐	Hepatitis C (HCV) Ab negative
	_____	Yes ☐	No ☐	No Grade 3 or higher laboratory abnormalities on any laboratory tests obtained at screening, including tests obtained as part of a panel of tests ordered to obtain the protocol-required laboratory test results.
These are exclusion criteria. Any box checked "Yes" disqualifies the person from enrollment.				
Demographic/ Behavioral/	Initials	Eligible	Not Eligible	
	_____	No ☐	Yes ☐	**MUST BE SIGNED PRIOR TO RANDOMIZATION** One or more reactive or positive HIV test results at Screening _____ Signature Line A: Investigator of Record or designated Physician sub-investigator _____ Date

	N/A	No ☐	Yes ☐	**MUST BE SIGNED PRIOR TO PROVISION OF STUDY PRODUCT** A reactive/positive rapid HIV test at Enrollment _____ Signature Line B: Investigator of Record, Designated Physician sub-investigator, or designated staff member _____ Date (This date may be different for sites that conduct split enrollment visits due mainly to having off-site pharmacies)
	____	No ☐	Yes ☐	Active or recent use of any illicit intravenous drugs ("recent" defined as in the 90 days prior to enrollment)
	____	No ☐	Yes ☐	Co-enrollment in any other interventional research study or other concurrent studies that may interfere with this study
	____	No ☐	Yes ☐	Past or current participation in HIV vaccine trial (without documentation of assignment to placebo arm) Note: Past participation in a monoclonal antibody study is not exclusionary, effective as of Version 1.0 of HPTN 083.
	____	No ☐	Yes ☐	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
	____	No ☐	Yes ☐	QTc interval (B or F) > 500 msec
	____	No ☐	Yes ☐	Inflammatory skin conditions that compromise the safety of intramuscular (IM) injections
	____	No ☐	Yes ☐	Tattoo or dermatological condition overlying the buttock region which may interfere with interpretation of injection site reactions
	____	No ☐	Yes ☐	Current or chronic history of liver disease or known hepatic or biliary abnormalities
	____	No ☐	Yes ☐	Coagulopathy (primary or iatrogenic) which would contraindicate IM injection
	____	No ☐	Yes ☐	Active or planned use of prohibited medications (per IB and SSP)
	____	No ☐	Yes ☐	Known or suspected allergy to study product components (active or placebo), including egg or soy products (egg and soy products are contained in Intralipid)
	____	No ☐	Yes ☐	Surgically-placed or injected buttock implants or fillers, per self-report
	____	No ☐	Yes ☐	Alcohol or substance use that, in the opinion of the study investigator, would jeopardize the safety of the participant on study
	____	No ☐	Yes ☐	History of seizure disorder, per self-report (<u>any</u> seizure episode independent of frequency or timeframe)

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 prior to randomization. In addition, a second signature is required of a designated staff member also listed on the Form FDA 1572 prior to

randomization. Signature lines A, C and D must be signed prior to randomization (but can be signed on different dates, as long as it is prior to randomization). Signature line B can be signed after randomization but before provision of study product.

_____	_____
Signature Line C: Investigator of Record or designated Physician Sub-investigator	Date
_____	_____
Signature Line D: Second reviewer – designated staff member	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, please refer to SSP Appendix III, HPTN 083 Schedule of Forms

Screening Visit			
Initial/date	**Completed**	**Procedure**	**Comments**
_____	☐	Confirm participant identity and age per site SOPs.	
_____	☐	Determine screening attempt (Verify if HPTN 083 PTID has previously been assigned) ❒ First attempt ==>CONTINUE. ❒ Second attempt ==> Confirm reason for screen failure during the first screening attempt (see Section 4.7 of the SSP manual for further information.	
_____	☐	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	
_____	☐	Collect locator information per site SOP	
_____	☐	Administer SexPro assessment (US only for inclusion purposes; South American sites only for data collection purposes).	
_____	☐	Targeted medical history (including bleeding history and concomitant medications)	
_____	☐	Perform targeted physical exam for ascertainment of eligibility	
_____	☐	Perform ECG (baseline value)	
_____	☐	Assess medical eligibility (see Eligibility Checklist for details).	
_____	☐	Provide HIV pre-test counseling	

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

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NOTE: For a listing of forms required at each visit, please refer to SSP Appendix III, HPTN 083 Schedule of Forms

Screening Visit			
Initial/date	**Completed**	**Procedure**	**Comments**
_____	☐	Collect blood for: ☐ HIV testing ☐ FDA-cleared HIV rapid test ☐ 4th or 5th generation HIV immunoassay ☐ 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 ☐ CBC with differential ☐ Chemistry panel (creatinine) ☐ LFTs (ALT and bilirubin) ☐ Plasma for storage	
_____	☐	Provide HIV post-test counseling	
_____	☐	Offer condoms and lubricant	
*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	

Notes for Screening Visit: Please refer to Section 5.1 of the HPTN 083 Protocol

Comments: _____

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_____

Participant ID ☐☐☐ ☐☐☐☐ ☐ ☐

Visit Date ☐☐ ☐☐☐ ☐☐

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NOTE: For a listing of forms required at each visit, please refer to SSP Appendix III, HPTN 083 Schedule of Forms

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 45 days of specimen collection ❒ Within 14 days of HIV RNA sample collection	
_____	☐	Confirm HIV test results from screening visit (rapid HIV test, 4th or 5th generation immunoassay, HIV RNA) 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	
_____	☐	Collect complete medical history including concomitant medications	
_____	☐	Perform complete physical exam	
_____	☐	Enrollment CASI and Interviewer-administered: Baseline	
_____	☐	Collect rectal swab for GC/CT testing	
_____	☐	Collect urine for: □ Urinalysis (protein and glucose) □ GC/CT testing	

Participant ID ☐☐☐ ☐☐☐☐ ☐ ☐

Visit Date ☐☐ ☐☐☐ ☐☐

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NOTE: For a listing of forms required at each visit, please refer to SSP Appendix III, HPTN 083 Schedule of Forms

Step 1: Enrollment, Week 0/Day 0			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	DXA Scan (only if part of DXA subset; may be performed -30 days/+ 7 days of enrollment); dietary Vitamin D and Calcium Assessment	
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	
_____	☐	Collect blood for: ☐ HIV testing ☐ FDA-cleared HIV rapid test ☐ 4th or 5th generation HIV immunoassay ☐ Hepatitis B testing (HBsAb and HBcAb) ☐ 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) ☐ Syphilis serology ☐ DXA Scan Subset only: 25-OH-Vitamin D ☐ Plasma storage ☐ Sample storage for pharmacogenomics testing (at discretion of study site; participants must provide specific consent)	
_____	☐	Provide HIV post-test counseling	

Participant ID **Visit Date**

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NOTE: For a listing of forms required at each visit, please refer to SSP Appendix III, HPTN 083 Schedule of Forms

Step 1: Enrollment, Week 0/Day 0			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	Randomize participant and complete randomization CRF. **Note: For sites that do split enrollment visits due to physical location constraints, this procedure can be moved prior to collection of blood for HIV testing*	
_____	☐	Provide adherence counseling	
_____	☐	Complete Pill Count – Enrollment CRF	
_____	☐	Provide oral study drug	
_____	☐	Offer condoms and lubricant	
_____	☐	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 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, please refer to SSP Appendix III, HPTN 083 Schedule of Forms

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	
_____	☐	Perform targeted physical exam	
_____	☐	Provide HIV pre-test counseling	
_____	☐	Collect blood for: ☐ HIV testing ☐ FDA-cleared HIV rapid test ☐ 4th or 5th generation HIV immunoassay ☐ CBC with differential ☐ Chemistry panel (BUN/Urea, creatinine, CPK, calcium, phosphorous, glucose, amylase, lipase) ☐ LFTs (AST, ALT, total bilirubin, alkaline phosphatase) ☐ Plasma storage ☐ DBS storage (**Week 4 only**)	
_____	☐	Provide HIV post-test counseling	
_____	☐	Conduct pill count and complete pill count -follow up CRF	
_____	☐	Provide adherence counseling	
_____	☐	Offer condoms and lubricant	

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, please refer to SSP Appendix III, HPTN 083 Schedule of Forms

_____	☐	**Week 2 only**: 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 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, please refer to SSP Appendix III, HPTN 083 Schedule of Forms

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 and Interviewer-administered Follow-Up 1	
_____	☐	Provide HIV pre-test counseling	
_____	☐	Collect blood for: ☐ HIV testing ☐ FDA-cleared HIV rapid test ☐ 4th or 5th generation HIV immunoassay ☐ Plasma storage (must be drawn PRIOR to injection)	
_____	☐	Provide HIV post-test counseling	
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 oral study drug	
_____	☐	Provide adherence 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, please refer to SSP Appendix III, HPTN 083 Schedule of Forms

_____	☐	Offer condoms and lubricant	
_____	☐	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 5.4 of the HPTN 083 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, please refer to SSP Appendix III, HPTN 083 Schedule of Forms

Step 2: (Safety Visits) Weeks 6, 10, 19, 27, 35, 43, 51, 59, 67, 75, 83, 91, 99, 107, 115, 123, 131, 139, 147 *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 and Post-injection exercise assessment	
_____	☐	Provide HIV pre-test counseling	
_____	☐	Collect blood for: ☐ HIV testing ☐ FDA-cleared HIV rapid test ☐ 4th or 5th generation HIV immunoassay ☐ CBC with differential ☐ Chemistry panel (BUN/Urea, creatinine, CPK, calcium, phosphorous, glucose, amylase, lipase) ☐ LFTs (AST, ALT, total bilirubin, alkaline phosphatase) ☐ Plasma storage	
_____	☐	Conduct acceptability assessments: ☐ SMSQs (**All safety visits**) ☐ SMSQc (**Week 19**)	
_____	☐	Provide HIV post-test counseling	
_____	☐	Provide adherence 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, please refer to SSP Appendix III, HPTN 083 Schedule of Forms

_____	☐	Offer condoms and lubricant	
_____	☐	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 Safety Visits: Please refer to Section 5.5 and 5.7 of the HPTN 083 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, please refer to SSP Appendix III, HPTN 083 Schedule of Forms

Step 2: (Remaining Injection Visits) Weeks 9, 17, 25, 33, 41, 49, 57, 65, 73, 81, 89, 97, 105, 113, 121, 129, 137, and 145 *Circle applicable visit week*			
Initial/date	**Completed**	**Procedures**	
_____	☐	Confirm participant identity and PTID	
_____	☐	Review/update locator information	
_____	☐	Confirm last time participant ate. (**Weeks 57, 105 only**) *Reminder: Participants should have fasted for at least 8 hours (preferably 12 hours) prior to blood collection*	
_____	☐	Collect targeted medical history (including concomitant medications)	
_____	☐	Perform targeted physical exam	
_____	☐	Perform ECG (**Weeks 57 and 105 only**)	
_____	☐	Administer Step 2 CASI (Weeks 9, 17, 25, 33, 41, 49, 57, 65, 73, 81, 89, 97, 105, 121, and 137)	
_____	☐	Interviewer-Administered: Follow-up 1 (Weeks 17, 33, 49, 65, 81, 97, 105, 121 and 137)	
_____	☐	Interview-Administered: Follow-up 2 (Weeks 9, 25, 41, 57, 73, 89)	
_____	☐	Collect rectal swab for GC/CT testing (**Weeks 33, 57, 81, 105, 129**)	
_____	☐	Collect urine for: ☐ Urinalysis (**Weeks 57, 105**) ☐ GC/CT testing (**Weeks 33, 57, 81, 105, 129**)	
_____	☐	DXA Scan **subset only; Weeks 57, 105 only**)	
_____	☐	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, please refer to SSP Appendix III, HPTN 083 Schedule of Forms

Step 2: (Remaining Injection Visits) Weeks 9, 17, 25, 33, 41, 49, 57, 65, 73, 81, 89, 97, 105, 113, 121, 129, 137, and 145 *Circle applicable visit week*			
Initial/date	**Completed**	**Procedures**	
_____	☐	Collect blood for ☐ HIV testing ☐ FDA-cleared HIV rapid test ☐ 4th or 5th generation HIV immunoassay ☐ HCV testing (**Weeks 57, 105)** ☐ CBC with differential ☐ Chemistry panel (BUN/Urea, creatinine, CPK, calcium, phosphorous, glucose, amylase, lipase) ☐ LFTs (AST, ALT, total bilirubin, alkaline phosphatase) ☐ Fasting lipid profile (**Weeks 57, 105**) ☐ Syphilis serology (**Weeks 33, 57, 81, 105, 129**) ☐ Plasma storage ☐ DBS storage ☐ Plasma storage for pharmacology testing (must be drawn PRIOR to injection)	
_____	☐	Provide HIV post-test counseling	
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 oral study drug	

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, please refer to SSP Appendix III, HPTN 083 Schedule of Forms

Step 2: (Remaining Injection Visits) Weeks 9, 17, 25, 33, 41, 49, 57, 65, 73, 81, 89, 97, 105, 113, 121, 129, 137, and 145 *Circle applicable visit week*			
Initial/date	**Completed**	**Procedures**	
_____	☐	Provide adherence counseling	
_____	☐	Offer condoms and lubricant	
_____	☐	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 5.6 of the HPTN 083 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, please refer to SSP Appendix III, HPTN 083 Schedule of Forms

Week 153, Last Visit of Step 2/Day 0, First Visit of Step 3

NOTE: Participants who transition to Step 3 prematurely, the timeline for Day 0 begins 8 weeks after participant's last injection, even if the participant does not report to the Day 0 visit. See Appendix IB for further informaiton.

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	
_____	☐	Collect any remaining blinded oral study product.	
_____	☐	Dispense open-label TDF/FTC	
_____	☐	Administer Step 3 Day 0 CASI (If the behavioral assessment was done within the last month prior to prematurely transitioning to Step 3, skip Day 0 and administer on Week 12.)	
_____	☐	Interviewer-Administered: Follow-up 1	
_____	☐	SMSQs (this should be administered at this visit if it was not done in the last 6 months before entering Step 3)	
_____	☐	Collect urine and rectal swab for GC/CT testing (**do not collect/do not perform test if testing occurred within 3 months prior to entering Step 3**)	
_____	☐	Perform ECG	
_____	☐	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, please refer to SSP Appendix III, HPTN 083 Schedule of Forms

Week 153, Last Visit of Step 2/Day 0, First Visit of Step 3

NOTE: Participants who transition to Step 3 prematurely, the timeline for Day 0 begins 8 weeks after participant's last injection, even if the participant does not report to the Day 0 visit. See Appendix IB for further informaiton.

Initial/date	Completed	Procedures	Comments
_____	☐	Collect blood for: ☐ HIV testing ☐ FDA-cleared HIV rapid test ☐ 4th or 5th generation HIV immunoassay ☐ CBC with differential ☐ HCV testing ☐ Chemistry panel (BUN/Urea, creatinine, CPK, calcium, phosphorous, glucose, amylase, lipase) ☐ LFTs (AST, ALT, total bilirubin, alkaline phosphatase) ☐ Syphilis serology (**do not perform test if testing occurred within 3 months prior to entering Step 3**) ☐ Plasma storage ☐ DBS storage	
_____	☐	Provide HIV post-test counseling	
_____	☐	Provide adherence counseling	
_____	☐	Offer condoms and lubricant	
_____	☐	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	

Notes for Step 3: Please refer to Section 5.8 of the HPTN 083 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, please refer to SSP Appendix III, HPTN 083 Schedule of Forms

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, please refer to SSP Appendix III, HPTN 083 Schedule of Forms

Step 3: (Open-label daily oral TDF/FTC) 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	
_____	☐	Administer Step 3 CASI (**Week 24, and 48**) (If the behavioral assessment was not done at Day 0, administer at Week 12)	
_____	☐	Interviewer-Administered: Follow-up 1 (**Weeks 24, 48 only**)	
_____	☐	Collect urine for GC/CT testing (**Weeks 24, 48 only**)	
_____	☐	Collect rectal swab for GC/CT testing (**Weeks 24, 48 only**)	
_____	☐	Provide HIV pre-test counseling	
_____	☐	Collect blood for: ☐ HIV testing ☐ FDA-cleared HIV rapid test ☐ 4th or 5th generation HIV immunoassay ☐ Chemistry panel (BUN/Urea, creatinine, CPK, calcium, phosphorous, glucose, amylase, lipase; **Weeks 24 and 48**) ☐ LFTs (AST, ALT, total bilirubin, alkaline phosphatase; **Weeks 24 and 48**) ☐ Syphilis serology (**Week 24, 48**) ☐ 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, please refer to SSP Appendix III, HPTN 083 Schedule of Forms

Step 3: (Open-label daily oral TDF/FTC) Weeks 12, 24, 36, 48 *Circle applicable visit week*			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	Provide oral study drug (**Weeks 12, 24, 36**)	
_____	☐	Provide adherence counseling (**Weeks 12, 24, 36**)	
_____	☐	Offer condoms and lubricant	
_____	☐	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	

Notes for Step 3: Please refer to Section 5.9 of the HPTN 083 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, please refer to SSP Appendix III, HPTN 083 Schedule of Forms

Procedures for Enrolled Participants who Seroconvert (HIV confirmation visit, Week 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**)	
_____	☐	Collect blood for: ☐ HIV testing (**HIV confirmation visit only**) ☐ HIV resistance (**HIV confirmation visit only**) ☐ DBS storage (**HIV confirmation visit only**) ☐ CD4 cell count (**HIV confirmation visit, Weeks 24, 48 only)** ☐ HIV viral load (**HIV confirmation visit, Weeks 24, 48 only**) ☐ Chemistry (BUN/Urea, creatinine, CPK, calcium, phosphorous, glucose, amylase, lipase) ☐ LFTs (AST, ALT, total bilirubin, alkaline phosphatase) ☐ Plasma storage	
_____	☐	Provide HIV post-test counseling (**HIV confirmation visit only)**	
_____	☐	Offer condoms and lubricant	
_____	☐	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, please refer to SSP Appendix III, HPTN 083 Schedule of Forms

Notes for Procedures for Enrolled Participants who Seroconvert: Please refer to Appendix II of the HPTN 083 Protocol. DO NOT contact the CMC regarding questions about HIV seroconversions and management of participants with HIV infection. For any questions related to the requirements for suspected or confirmed HIV infection or clinical management questions, email 083HIV@hptn.org.

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, please refer to SSP Appendix III, HPTN 083 Schedule of Forms

Procedures for Annual HIV Testing Visits			
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	
_____	☐	Collect blood for ☐ HIV testing ☐ FDA-cleared HIV rapid test ☐ 4th or 5th generation HIV immunoassay ☐ Plasma storage ☐ DBS storage	
_____	☐	Provide HIV post-test counseling	
_____	☐	Offer condoms and lubricant	
_____	☐	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	