Section 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 optional but is strongly recommended.***

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. Checklists are commonly used for following the participant through a study 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 add steps/activities/reminders to improve protocol adherence/implementation. Sites may also modify the order of procedures to maximize the efficiency with the following exceptions/considerations:

- Informed consent for the currently IRB-approved protocol at a given site must be obtained before any OLE study procedures are performed.
- Behavioral assessment and acceptability assessments must be administered prior to the delivery of HIV and adherence counseling.
- It is recommended that procedures for determining eligibility for continued product use (for example, HIV testing) be conducted early in the visit to ensure sufficient time is allowed for product to be prepared for dispensing.

When using the checklists, it is important to confirm 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.

Source documentation for procedures will need to be identified for some items that are in the protocol, but not on captured on the Case Report Forms (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

Participant ID **Visit Date**

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

Step 4c: Procedures for participants on maintentance doses of CAB LA or TDF/FTC (Weeks 0, 8, 16, 24, 32, 40 and 48) *Circle applicable visit week*			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	Confirm participant identity and PTID	
_____	☐	Review/update locator information	
_____	☐	Informed consent for those not part of Steps 4a or 4b	
_____	☐	Conduct Acceptability Assessment (Weeks 0, 24 and 48)	
_____	☐	Conduct Behavioral Assessment	
_____	☐	Provide HIV pre-test / prevention counseling	
_____	☐	Offer condoms	
_____	☐	Medical history (including concomitant medications, targeted physical exam (including pulse, temperature, BP, weight and BMI calculated at each visit)	

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.

Step 4c: Procedures for participants on maintentance doses of CAB LA or TDF/FTC (Weeks 0, 8, 16, 24, 32, 40 and 48) *Circle applicable visit week*			
Initial/date	**Completed**	**Procedures**	**Comments**

____	☐	Collect blood and test for:
		• HIV testing
		  • FDA-cleared HIV rapid test
		  • Laboratory based, instrument HIV Immunoassay (HIV antigen and antibody)
		  • HIV Viral Load (detection limit <50copies/mL)
		• Pregnancy testing (if not done via urine)
		• CBC with differential at Week 0 if not done in Steps 4a or b; otherwise, only at Weeks 24 and 48)
		• Chemistry panel (Albumin, BUN/urea, creatinine) at Week 0 if not done in Steps 4a or b; otherwise, only at Weeks 24 and 48)
		• LFTs (AST, ALT, total bilirubin) (Weeks 0, 24 and 48)
		• Fasting lipid profile (Week 48 only) total cholesterol, HDL, triglycerides, and LDL either calculated or measured
		• Syphilis testing (Weeks 0, 24 and 48)	

____	☐	Collect vaginal swab (Weeks 0, 24 and 48) and test for: • GC/CT (this may be done using urine instead) • TV testing	
____	☐	Collect urine and test for: • Pregnancy testing (if site using urine for Pregnancy testing) • GC/CT testing (if site using urine for this) (Weeks 0, 24 and 48) for urinalysis (protein, glucose) Weeks 0, 24 and 48)	

Participant ID **Visit Date**

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Step 4c: Procedures for participants on maintentance doses of CAB LA or TDF/FTC (Weeks 0, 8, 16, 24, 32, 40 and 48) *Circle applicable visit week*			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	Plasma storage	
_____	☐	DBS storage	
_____	☐	Provide HIV post-test counseling	
_____	☐	Provide Adherence counseling	
_____	☐	Dispense/provide study product	
_____	☐	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	

Comments: _____

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Visit Date ☐☐ ☐☐☐ ☐☐

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Procedures listed in Appendix 4d: Schedule of Evaluations for Pregnant/Breastfeeding Participants on CAB LA **Visits:** *Enter applicable visit week* _____			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	Confirm participant identity and PTID	
_____	☐	Review/update locator information, except at delivery and post-partum Weeks 2pp and 4pp	
_____	☐	Informed Consent, as is appropriate	
_____	☐	Acceptability Assessment (Weeks 0, 12, 32 and Post-partum Weeks 24pp and 48pp)	
_____	☐	Conduct Behavioral Assessment (all visits except Delivery and Post-partum Week 2pp and Week 4pp)	
_____	☐	HIV pre-test/ prevention counseling (all visits except Delivery and Post-partum Week 2pp and Week 4pp)	
_____	☐	Offer condoms (all visits except Delivery, Post-partum Week 2pp and Week 4pp)	
_____	☐	Medical history, concomitant medications (including folate intake) (all visits except Delivery, Post-partum Week 2pp and Week 4pp)	
_____	☐	Targeted physical exam including antenatal assessment per SOC (all visits during pregnancy; only Post-partum Weeks 8pp and 48pp)	
_____	☐	ISR assessment for PPTs taking CAB LA at Weeks 4, 12, 20, 28, 36 and beginning at Post-partum Week 8pp and all visits up to and including Week 48pp	

Participant ID | **Visit Date**

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Procedures listed in Appendix 4d: Schedule of Evaluations for Pregnant/Breastfeeding Participants on CAB LA **Visits:** *Enter applicable visit week* _____			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	Ultrasound or refer for ultrasound (Ideally the ultrasound should be completed by Week12)	

_____	☐	Collect blood and test for:
		• HIV testing
		  • FDA-cleared HIV rapid test
		  • Laboratory based, instrument HIV Immunoassay (HIV antigen and antibody)
		  • HIV Viral Load (detection limit <50copies/mL)
		• Pregnancy testing (if not done via urine; beginning at Post-partum Week 8pp and all visits up to and including Week 48pp)
		• CBC with differential at Week 0, 24 and 36 during pregnancy; then at Post-partum Week 8pp and 48pp
		• Chemistry panel (Albumin, BUN/urea, creatinine) at Week 0, 24 and 36 during pregnancy; then at Post-partum Week 8pp and 48pp
		• LFTs (AST, ALT, total bilirubin) at Week 0, 24 and 36 during pregnancy; then at Post-partum Week 8pp and 48pp
		• Syphilis testing at Week 0 and 24 during pregnancy; then at Post-partum Week 8pp and 48pp	

Participant ID | **Visit Date**

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Procedures listed in Appendix 4d: Schedule of Evaluations for Pregnant/Breastfeeding Participants on CAB LA **Visits:** *Enter applicable visit week* _____			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	Collect urine and conduct: • Pregnancy testing (if not done via blood; beginning at Post-partum Week 8pp and all visits up to and including Week 48pp) • GC/CT testing (if site using urine for this at Week 0 and 24 during pregnancy; then at Post-partum Week 8pp and 48pp • Urinalysis at Week 0, 24 and 36 during pregnancy; then at Post-partum Week 8pp and 48pp	
_____	☐	Collect vaginal swab at Week 0 and 24 during pregnancy; then at Post-partum Week 8pp and 48pp and conduct: • GC/CT (this may be done using urine instead) • TV testing	
_____	☐	Plasma storage	
_____	☐	DBS Storage only for TDF/FCT PPTs (all antenatal visits; at Delivery and Post-partum Weeks 4pp, 8pp, 16pp, 24pp	
_____	☐	Adherence counseling every visit except Delivery, Post-partum Week 2 pp and Week 4pp	
_____	☐	Contraceptive counseling beginning at Post-partum Week 8pp and all visits up to and including Week 48pp	
_____	☐	Dispense/ administer study product as appropriate (Weeks 0, 8, 16, 24, 32, 40 and Post-partum Weeks 8pp, 16pp, 24pp, 32pp, 40pp and 48pp)	

Participant ID **Visit Date**

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Procedures listed in Appendix 4d: Schedule of Evaluations for Pregnant/Breastfeeding Participants on CAB LA **Visits:** *Enter applicable visit week* _____			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	Breast milk collection Post-partum Weeks 2pp, 4pp, 8pp, 16pp, 24pp (Breast milk collection does not need to be performed if the mother is not breastfeeding or producing milk)	
_____	☐	Breast milk storage at Post-partum Weeks 2pp, 4pp, 8pp, 16pp, 24pp	
_____	☐	Pregnancy outcome assessment including abbreviated infant exam (Post-partum weeks 8 and 48)	
_____	☐	Infant feeding history (Post-partum weeks 8, 16 and 24)	
_____	☐	Infant AE assessment (Delivery and all Post-partum visits)	
_____	☐	Cord blood collection at Delivery	
_____	☐	Infant blood collection at Delivery and all subsequent visits	
_____	☐	Infant HIV testing, if the mother has one or more reactive/positive HIV results (Delivery and all subsequent visits)	
_____	☐	Cord blood storage (Delivery)	
_____	☐	Infant DBS storage (Delivery and all subsequent visits)	
_____	☐	Infant plasma storage (Delivery and all subsequent visits)	

Participant ID **Visit Date**

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Procedures listed in Appendix 4d: Schedule of Evaluations for Pregnant/Breastfeeding Participants on CAB LA **Visits:** *Enter applicable visit week* _____			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	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	

Comments: _____

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Visit Date ☐☐ ☐☐☐ ☐☐

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Step 5 Visits: **Weeks in Study Step 5 Day 0 (no later than 8 weeks after last injection), Weeks 12, 24, 36 and 48** *Circle applicable visit week*			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	Confirm participant identity and PTID	
_____	☐	Review/update locator information	
_____	☐	Acceptability Assessment (weeks 0 and 48)	
_____	☐	Behavioral Assessment (if done in last 4 weeks skip day 0 and start at week 12; otherwise weeks 0, 24 and 48)	
_____	☐	HIV prevention counseling	
_____	☐	Offer condoms	
_____	☐	Medical history, conmeds, targeted physical exam with pulse, BP, weight and BMI calculated at each visit	

_____	☐	Collect blood and test 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)
		• Pregnancy (can be urine, plasma or serum)
		• Chemistry (Albumin, BUN/Urea, creatinine- skip day 0 if testing was in last 3 months; only perform at weeks 0, 24 and 48)
		• Liver function testing at weeks 0 and 48 only (AST, ALT, total bilirubin)
		• Syphilis testing weeks 0, 24, and 48	

Participant ID **Visit Date**

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Step 5 Visits: **Weeks in Study Step 5 Day 0 (no later than 8 weeks after last injection), Weeks 12, 24, 36 and 48** *Circle applicable visit week*			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	Collect urine and conduct: • Pregnancy testing (if site using urine for Pregnancy testing) • GC/CT testing (if site using urine for this) (Weeks 0, 24 and 48)	
_____	☐	Collect vaginal swab (weeks 0, 24 and 48) and conduct: • GC/CT (this may be done using urine instead) • TV testing	
_____	☐	Plasma storage	
_____	☐	DBS storage	
_____	☐	Provide HIV post-test counseling	
_____	☐	Adherence counseling	
_____	☐	Pill dispensation (not at week 48)	
_____	☐	Provide site contact information and instructions to report symptoms and/or clarify any questions	
_____	☐	Schedule next study visit, if applicable (not at week 48)	
_____	☐	Provide participant reimbursement, if applicable	

Comments: _____

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Participant ID | **Visit Date**

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Step 6
Visits:
Weeks in Study Step 6
Weeks 56, 64, 72, 80, 88, 96, 104*, 112*)

***PPTs who do not have local access to CAB LA the PPT will be offered up to two additional injections on the study (Weeks 104 and 112).**

Circle applicable visit week

Initial/date	Completed	Procedures	Comments
_____	☐	Confirm participant identity and PTID	
_____	☐	Review/update locator information	
_____	☐	Informed Consent (Weeks 0 and 104)	
_____	☐	Acceptability Assessment (Weeks 72, 96, 112)	
_____	☐	Behavioral Assessment (Weeks 72, 96, 104, 112)	
_____	☐	Provide HIV pre-test/prevention counseling	
_____	☐	Offer condoms per local SOC	
_____	☐	Medical history, concomitant medications, targeted physical exam (with pulse, BP, weight and BMI calculated at each visit)	

_____	☐	Collect blood and test 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)
		• Pregnancy, if not done via urine
		• Chemistry (Weeks 96, 112)
		• Liver function testing (Weeks 96, 112)
		• Syphilis testing (Weeks 72, 96, 112)	

Participant ID **Visit Date**

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Step 6
Visits:
Weeks in Study Step 6
Weeks 56, 64, 72, 80, 88, 96, 104*, 112*)

***PPTs who do not have local access to CAB LA the PPT will be offered up to two additional injections on the study (Weeks 104 and 112).**

Circle applicable visit week

Initial/date	Completed	Procedures	Comments
_____	☐	Collect vaginal swab (Weeks 72, 96, 112) and test for: • GC/CT (this may be done using urine instead) • TV testing	
_____	☐	Collect urine and test for: • Pregnancy testing (if site using urine for Pregnancy testing) • GC/CT testing (if site using urine for this) (Weeks 72, 96, 112)	
_____	☐	Plasma storage	
_____	☐	DBS storage	
_____	☐	Provide HIV post-test counseling	
_____	☐	Adherence counseling	
_____	☐	Administer CAB LA	
_____	☐	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	

Comments: _____

Participant ID | **Visit Date**

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Schedule of additional procedures for women with reactive/postitive HIV tests (HIV confirmation visit) *Study visit week* _____			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	Confirm participant identity and PTID	
_____	☐	Review/update locator information	
_____	☐	Date of first HIV positive test/ 084HIV@hptn.org email alias list contacted: _____	
_____	☐	Confirm prior HIV results	
_____	☐	Provide HIV pre-test counseling	
_____	☐	Offer condoms	
_____	☐	Medical history, conmeds, physical exam (with pulse, BP, weight and BMI calculated)	

_____	☐	Collect blood and test for:
		• HIV testing
		  ○ FDA-cleared HIV rapid test,
		  ○ Laboratory based, instrument HIV Immunoassay (HIV antigen and antibody)
		  ○ HIV viral load testing (must be 50 copies/ml or lower)
		• CD4 cell count
		• ART resistance (**if able to conduct for local mgmt.)**
		• Chemistry (Albumin, BUN/urea, creatinine)
		• LFTs (AST, ALT, total bilirubin)	

Participant ID | **Visit Date**

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Schedule of additional procedures for women with reactive/postitive HIV tests (HIV confirmation visit)

Study visit week _____

Initial/date	Completed	Procedures	Comments
_____	☐	Plasma storage	
_____	☐	DBS storage	
_____	☐	Provide HIV post-test counseling, as is appropriate	
_____	☐	Provide site contact information and instructions to report symptoms and/or clarify any questions	
_____	☐	Provide participant reimbursement, if applicable	
_____	☐	Link to care and confirm when the participant has achieved viral suppression on ART. Document the ART regimen in the conmeds form. Terminate from the study once suppression is achieved.	

Notes for Procedures for Enrolled Participants who Seroconvert: Please refer to Appendix II of the HPTN 084 Protocol. For any questions related to the requirements for suspected or confirmed HIV infection or clinical management questions, email 084HIV@hptn.org ***and CMC at*** 084cmc@hptn.org

Comments: _____

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