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 protocol version 3.0 and higher 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**

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 4a- Procedures for participants initially randomized to TDF/FTC who elect to move to CAB LA with the optional oral lead-in			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	Confirm participant identity and PTID	
_____	☐	Informed Consent for OLE	
_____	☐	Offer CAB LA and counseling on direct to inject vs. oral lead in including adherence counseling	
_____	☐	Acceptability Assessment	
_____	☐	Behavioral Assessment	
_____	☐	Review/update locator information	
_____	☐	HIV prevention counseling	
_____	☐	Offer condoms	
_____	☐	Medical history, conmeds, targeted physical exam (pulse, BP, weight and BMI calculated)	
_____	☐	Collect blood	
_____	☐	Collect urine *(may not be necessary depending on site specific pregnancy testing sample- refer to protocol and site SOPs)*	
_____	☐	Dispense 4 weeks of oral CAB	

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 4a- Procedures for participants initially randomized to TDF/FTC who elect to move to CAB LA with the optional oral lead-in			
Initial/date	**Completed**	**Procedures**	**Comments**

_____	☐	Collect blood and 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)
		• Pregnancy testing (if not performed via urine sample)
		• CBC with differential
		• Chemistry panel (Albumin, BUN/Urea, creatinine)
		• Liver function tests (AST, ALT, total bilirubin)
		• Fasting lipid profile (total cholesterol, HDL, triglycerides, LDL calculated or measured)
		• Plasma storage
		• DBS storage	

_____	☐	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	

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.

Step 4b: Procedures for participants initiating or re-starting CAB LA without the optional oral lead-in; initial dose visit (Day 0)			
Initials/date	**Completed**	**Procedures**	**Comments**
_____	☐	Confirm participant identity and PTID	
_____	☐	Informed Consent	
_____	☐	Review/update locator information	
_____	☐	Offer CAB LA and adherence counseling as applicable	
_____	☐	Acceptability assessment	
_____	☐	Behavioral assessment	
_____	☐	HIV prevention counseling	
_____	☐	Offer condoms	
_____	☐	Medical history, conmeds, targeted physical exam (pulse, BP, weight and BMI calculated at each visit)	
_____	☐	Collect Blood	
_____	☐	Collect Urine (if pregnancy testing via urine)	

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.

_____	☐	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 testing (if not performed via urine sample)
		• CBC with differential
		• Chemistry panel (Albumin, BUN/Urea, creatinine)
		• LFTs (AST, ALT, total bilirubin)
		• Fasting Lipid profile (total cholesterol, HDL, triglycerides and LDL calculated or measured)
		• Plasma storage
		• DBS storage	

_____	☐	Provide site contact information and instructions to report symptoms and/or clarify any questions	
_____	☐	Schedule next study visit	
_____	☐	Provide participant reimbursement, if applicable	

Comments: _____

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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**

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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**

_____	☐	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)
		• Plasma storage
		• DBS storage
		• Other samples to be tested: Vaginal GC/CT (urine or vaginal swab) and TV testing (vaginal swab) (Weeks 0, 24 and 48- refer to protocol and SSP) Urinalysis (protein, glucose) Weeks 0, 24 and 48)	

_____	☐	Collect and test urine for: • Pregnancy testing (if site using urine for Pregnancy testing) • GC/CT testing (if site using urine for this)	
_____	☐	Provide HIV post-test counseling	

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

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Procedures listed in Appendix 4d: Schedule of Evaluations for Pregnant/Breastfeeding Participants on CAB LA **Note: only for participants who have had at least one injection of CAB LA** **Visits:** *Enter applicable visit week* _____			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	Confirm participant identity and PTID	
_____	☐	Informed Consent	
_____	☐	Review/update locator information	
_____	☐	HIV prevention counseling	
_____	☐	Contraceptive Counseling (Post-partum only Weeks 8, 16, 24, 32, 40 and 48)	
_____	☐	Acceptability Assessment (Weeks 0, 12, 32 and post-partum weeks 24 and 48)	
_____	☐	Conduct Behavioral Assessment (all visits except Weeks 0 (delivery), 2 and 4 post-partum)	
_____	☐	Offer condoms	
_____	☐	Dispense/ administer study product as appropriate (Weeks 0, 8, 16, 24, 32, 40 and post-partum weeks 8, 16, 24*, 32, 40 and 48) *CAB LA may no longer be offered via the study. Refer to local access program if available. Refer to protocol for additional information.	
_____	☐	ISR assessment at Weeks 4, 12, 20, 28, 36 and post-partum Week 8	
_____	☐	Breast milk collection post-partum weeks 2, 4, 8, 16, 24 (Breast milk collection does not need to be performed if the mother is not breastfeeding or producing milk)	

Participant ID **Visit Date**

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Procedures listed in Appendix 4d: Schedule of Evaluations for Pregnant/Breastfeeding Participants on CAB LA **Note: only for participants who have had at least one injection of CAB LA** **Visits:** *Enter applicable visit week* _____			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	Medical history, concomitant medications (including folate intake) (all visits except Weeks 0 (delivery), 2 and 4 post-partum)	
_____	☐	Targeted physical exam including antenatal assessment per SOC (all visits during pregnancy; only Weeks 8 and 48 post-partum)	
_____	☐	Ultrasound or refer for ultrasound (Ideally the ultrasound should be completed by Week12)	

_____	☐	Collect and test 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)
		• Pregnancy (blood or urine) post-partum weeks 8, 16, 24, 32, 40 and 48
		• CBC with differential (weeks 0, 24, 36 and post-partum weeks 8 and 48)
		• Chemistry testing (albumin, bun/urea, creatinine) (Weeks 0, 24, 36 and post-partum weeks 8 and 48)
		• LFT (AST, ALT, total bilirubin) (Weeks 0, 24, 36 and post-partum weeks 8 and 48)
		• Syphilis testing (Weeks 0, 24 and post-partum 8 and 48)
		• Breastmilk storage (post-partum weeks 2, 4, 8, 16 and 24)
		• Plasma storage (every visit)	

Participant ID | **Visit Date**

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Procedures listed in Appendix 4d: Schedule of Evaluations for Pregnant/Breastfeeding Participants on CAB LA **Note: only for participants who have had at least one injection of CAB LA** **Visits:** *Enter applicable visit week* _____			
Initial/date	**Completed**	**Procedures**	**Comments**
		• DBS for women on TDF/FTC only (all visits; delivery and post-partum except weeks 2, 32, 40, 48	
_____	☐	Pregnancy outcome assessment including abbreviated infant exam (post-partum weeks 8 and 48)	
_____	☐	Infant feeding history (post-partum weeks 8, 16 and 24)	
_____	☐	Infant HIV testing, if the mother has one or more reactive/positive HIV results (delivery and all post-partum visits)	
_____	☐	Infant AE assessment (post-partum visits 0 (delivery) and Weeks 2, 4, 8, 16, 24) (Only Grade 2 and above AEs need to be reported into the database up to and including 24 weeks post-partum. All SAEs, including deaths and congenital anomalies, must be reported throughout Step 4d.)	
_____	☐	Cord blood storage (delivery)	
_____	☐	Infant plasma storage (post partum visits 0 (delivery) and Weeks 2, 4, 8, 16, 24, 32, 40 and 48)	
_____	☐	Infant DBS storage (delivery and all visits)	
_____	☐	Provide site contact information and instructions to report symptoms and/or clarify any questions	

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.

Procedures listed in Appendix 4d: Schedule of Evaluations for Pregnant/Breastfeeding Participants on CAB LA **Note: only for participants who have had at least one injection of CAB LA** **Visits:** *Enter applicable visit week* _____			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	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.

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 and test 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)
		• 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**
		• GC/CT and TV testing weeks 0, 24 and 48 (GC/CT NAAT may use urine or vaginal swab. TV must be vaginal swab)	
_____	☐	Adherence counseling and pill dispensation (not at week 48)	
_____	☐	Plasma storage	
_____	☐	DBS storage	
_____	☐	Collect urine	
_____	☐	Collect vaginal swab (weeks 0, 24 and 48)	
_____	☐	Schedule next study visit, if applicable (not at week 48)	

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 6 **Visits:** **Weeks in Study Step 6** **Weeks 56, 64, 72, 80, 88, 96** *Circle applicable visit week*			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	Confirm participant identity and PTID	
_____	☐	Informed Consent Confirm participant identity and PTID	
_____	☐	Review/update locator information	
_____	☐	Acceptability Assessment (Weeks 72 & 96)	
_____	☐	Behavioral Assessment (Weeks 72 & 96)	
_____	☐	HIV 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 and test 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)
		• Pregnancy, if indicated
		• Chemistry (Week 96)
		• Liver function testing (Week 96)
		• Syphilis testing (Week 72 & 96)
		• GC/CT and TV testing (Week 72 & 96)	

_____	☐	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.

Step 6 **Visits:** **Weeks in Study Step 6** **Weeks 56, 64, 72, 80, 88, 96** *Circle applicable visit week*			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	Administer CAB LA	
_____	☐	Plasma storage	
_____	☐	DBS storage	
_____	☐	Collect urine (Only collect when needed for pregnancy testing or for GC/CT testing)	
_____	☐	Collect vaginal swab (Weeks 72 & 96)	
_____	☐	Schedule next study visit, 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.

Schedule of additional procedures for women with reactive/postitive HIV tests (HIV confirmation visit) *Study visit week* _____			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	Date of first HIV positive test/ 084HIV@hptn.org email alias list contacted: _____	
_____	☐	Confirm participant identity and PTID	
_____	☐	Confirm prior HIV results	
_____	☐	Offer condoms	
_____	☐	Review/update locator information	
_____	☐	Provide HIV counseling	
_____	☐	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 confirmation visit must be on a different day from the first reactive/positive HIV test. The 084 HIV alias committee may dictate which tests**) • CD4 cell count • HIV viral load testing (must be 50 copies/ml or lower) • HIV resistance (**if able to conduct for local mgmt.)** • Chemistry (Albumin, BUN/urea, creatinine) • LFTs (AST, ALT, total bilirubin) • Plasma storage • DBS storage	

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.

Schedule of additional procedures for women with reactive/postitive HIV tests (HIV confirmation visit) *Study visit week* _____			
Initial/date	**Completed**	**Procedures**	**Comments**
_____	☐	Provide site contact information and instructions to report symptoms and/or clarify any questions	
_____	☐	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.	
_____	☐	Provide participant reimbursement, if applicable	

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***. You may also contact the CMC.***

Comments: _____

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