

Section 6. Visit Checklists

6.1	Overview of Section 6.....	6-1
6.2	Visit Checklists as Source Documentation	6-1
6.3	Use of the Checklists.....	6-1
6.4	Visit Checklist Templates	6-2

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 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
_____	<input type="checkbox"/>	Confirm participant identity and PTID	
_____	<input type="checkbox"/>	Informed Consent for OLE	
_____	<input type="checkbox"/>	Offer CAB LA and counseling on direct to inject vs. oral lead in including adherence counseling	
_____	<input type="checkbox"/>	Acceptability Assessment	
_____	<input type="checkbox"/>	Behavioral Assessment	
_____	<input type="checkbox"/>	Review/update locator information	
_____	<input type="checkbox"/>	HIV prevention counseling	
_____	<input type="checkbox"/>	Offer condoms	
_____	<input type="checkbox"/>	Medical history, conmeds, targeted physical exam (pulse, BP, weight and BMI calculated)	
_____	<input type="checkbox"/>	Collect blood	
_____	<input type="checkbox"/>	Collect urine (<i>may not be necessary depending on site specific pregnancy testing sample- refer to protocol and site SOPs</i>)	
_____	<input type="checkbox"/>	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
_____	<input type="checkbox"/>	Collect blood and testing for: <ul style="list-style-type: none"> • HIV testing <ul style="list-style-type: none"> • 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 	
_____	<input type="checkbox"/>	Schedule next study visit. If possible, generate and review with participant the visit calendar for upcoming visits.	
_____	<input type="checkbox"/>	Provide site contact information and instructions to report symptoms and/or clarify any questions	
_____	<input type="checkbox"/>	Remind participant to bring unused study product at next study visit.	
_____	<input type="checkbox"/>	Provide participant reimbursement, if applicable	

Comments: _____

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
_____	<input type="checkbox"/>	Confirm participant identity and PTID	
_____	<input type="checkbox"/>	Informed Consent	
_____	<input type="checkbox"/>	Review/update locator information	
_____	<input type="checkbox"/>	Offer CAB LA and adherence counseling as applicable	
_____	<input type="checkbox"/>	Acceptability assessment	
_____	<input type="checkbox"/>	Behavioral assessment	
_____	<input type="checkbox"/>	HIV prevention counseling	
_____	<input type="checkbox"/>	Offer condoms	
_____	<input type="checkbox"/>	Medical history, conmeds, targeted physical exam (pulse, BP, weight and BMI calculated at each visit)	
_____	<input type="checkbox"/>	Collect Blood	
_____	<input type="checkbox"/>	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.

_____	<input type="checkbox"/>	Collect blood and test for: <ul style="list-style-type: none">• HIV testing<ul style="list-style-type: none">• 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	
_____	<input type="checkbox"/>	Provide site contact information and instructions to report symptoms and/or clarify any questions	
_____	<input type="checkbox"/>	Schedule next study visit	
_____	<input type="checkbox"/>	Provide participant reimbursement, if applicable	

Comments: _____

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 maintenance 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
_____	<input type="checkbox"/>	Confirm participant identity and PTID	
_____	<input type="checkbox"/>	Review/update locator information	
_____	<input type="checkbox"/>	Informed consent for those not part of Steps 4a or 4b	
_____	<input type="checkbox"/>	Conduct Acceptability Assessment (Weeks 0, 24 and 48)	
_____	<input type="checkbox"/>	Conduct Behavioral Assessment	
_____	<input type="checkbox"/>	Provide HIV pre-test / prevention counseling	
_____	<input type="checkbox"/>	Offer condoms	
_____	<input type="checkbox"/>	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 maintenance 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
_____	<input type="checkbox"/>	Collect blood and test for: <ul style="list-style-type: none"> • HIV testing <ul style="list-style-type: none"> • 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) 	
_____	<input type="checkbox"/>	Collect and test urine for: <ul style="list-style-type: none"> • Pregnancy testing (if site using urine for Pregnancy testing) • GC/CT testing (if site using urine for this) 	
_____	<input type="checkbox"/>	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.

Step 4c: Procedures for participants on maintenance 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
_____	<input type="checkbox"/>	Provide site contact information and instructions to report symptoms and/or clarify any questions	
_____	<input type="checkbox"/>	Schedule next study visit, if applicable	
_____	<input type="checkbox"/>	Provide participant reimbursement, if applicable	

Comments: _____

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.

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
_____	<input type="checkbox"/>	Confirm participant identity and PTID	
_____	<input type="checkbox"/>	Informed Consent	
_____	<input type="checkbox"/>	Review/update locator information	
_____	<input type="checkbox"/>	HIV prevention counseling	
_____	<input type="checkbox"/>	Contraceptive Counseling (Post-partum only Weeks 8, 16, 24, 32, 40 and 48)	
_____	<input type="checkbox"/>	Acceptability Assessment (Weeks 0, 12, 32 and post-partum weeks 24 and 48)	
_____	<input type="checkbox"/>	Conduct Behavioral Assessment (all visits except Weeks 0 (delivery), 2 and 4 post-partum)	
_____	<input type="checkbox"/>	Offer condoms	
_____	<input type="checkbox"/>	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.	
_____	<input type="checkbox"/>	ISR assessment at Weeks 4, 12, 20, 28, 36 and post-partum Week 8	
_____	<input type="checkbox"/>	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

--	--	--	--	--	--	--	--

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
_____	<input type="checkbox"/>	Medical history, concomitant medications (including folate intake) (all visits except Weeks 0 (delivery), 2 and 4 post-partum)	
_____	<input type="checkbox"/>	Targeted physical exam including antenatal assessment per SOC (all visits during pregnancy; only Weeks 8 and 48 post-partum)	
_____	<input type="checkbox"/>	Ultrasound or refer for ultrasound (Ideally the ultrasound should be completed by Week12)	
_____	<input type="checkbox"/>	Collect and test blood for: <ul style="list-style-type: none"> • HIV testing <ul style="list-style-type: none"> • 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

--	--	--	--	--	--	--	--

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
		<ul style="list-style-type: none"> DBS for women on TDF/FTC only (all visits; delivery and post-partum except weeks 2, 32, 40, 48) 	
_____	<input type="checkbox"/>	Pregnancy outcome assessment including abbreviated infant exam (post-partum weeks 8 and 48)	
_____	<input type="checkbox"/>	Infant feeding history (post-partum weeks 8, 16 and 24)	
_____	<input type="checkbox"/>	Infant HIV testing, if the mother has one or more reactive/positive HIV results (delivery and all post-partum visits)	
_____	<input type="checkbox"/>	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.)	
_____	<input type="checkbox"/>	Cord blood storage (delivery)	
_____	<input type="checkbox"/>	Infant plasma storage (post partum visits 0 (delivery) and Weeks 2, 4, 8, 16, 24, 32, 40 and 48)	
_____	<input type="checkbox"/>	Infant DBS storage (delivery and all visits)	
_____	<input type="checkbox"/>	Provide site contact information and instructions to report symptoms and/or clarify any questions	

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.

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
_____	<input type="checkbox"/>	Schedule next study visit, if applicable	
_____	<input type="checkbox"/>	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 <i>Circle applicable visit week</i>			
Initial/date	Completed	Procedures	Comments
_____	<input type="checkbox"/>	Confirm participant identity and PTID	
_____	<input type="checkbox"/>	Review/update locator information	
_____	<input type="checkbox"/>	Acceptability Assessment (weeks 0 and 48)	
_____	<input type="checkbox"/>	Behavioral Assessment (if done in last 4 weeks skip day 0 and start at week 12; otherwise weeks 0, 24 and 48)	
_____	<input type="checkbox"/>	HIV prevention counseling	
_____	<input type="checkbox"/>	Offer condoms	
_____	<input type="checkbox"/>	Medical history, conmeds, targeted physical exam with pulse, BP, weight and BMI calculated at each visit	
_____	<input type="checkbox"/>	Collect and test blood for: <ul style="list-style-type: none"> • HIV testing <ul style="list-style-type: none"> • 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

--	--	--	--	--	--	--	--

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 <i>Circle applicable visit week</i>			
Initial/date	Completed	Procedures	Comments
		<ul style="list-style-type: none"> GC/CT and TV testing weeks 0, 24 and 48 (GC/CT NAAT may use urine or vaginal swab. TV must be vaginal swab) 	
_____	<input type="checkbox"/>	Adherence counseling and pill dispensation (not at week 48)	
_____	<input type="checkbox"/>	Plasma storage	
_____	<input type="checkbox"/>	DBS storage	
_____	<input type="checkbox"/>	Collect urine	
_____	<input type="checkbox"/>	Collect vaginal swab (weeks 0, 24 and 48)	
_____	<input type="checkbox"/>	Review/update locator information	
_____	<input type="checkbox"/>	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.

Schedule of additional procedures for women with reactive/postitive HIV tests (HIV confirmation visit)			
Study visit week _____			
Initial/date	Completed	Procedures	Comments
_____	<input type="checkbox"/>	Date of first HIV positive test/ 084HIV@hptn.org email alias list contacted: _____	
_____	<input type="checkbox"/>	Confirm participant identity and PTID	
_____	<input type="checkbox"/>	Confirm prior HIV results	
_____	<input type="checkbox"/>	Offer condoms	
_____	<input type="checkbox"/>	Review/update locator information	
_____	<input type="checkbox"/>	Provide HIV counseling	
_____	<input type="checkbox"/>	Medical history, conmeds, physical exam (with pulse, BP, weight and BMI calculated)	
_____	<input type="checkbox"/>	Collect blood and test for: <ul style="list-style-type: none"> • 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)			
<i>Study visit week</i> _____			
Initial/date	Completed	Procedures	Comments
_____	<input type="checkbox"/>	Provide site contact information and instructions to report symptoms and/or clarify any questions	
_____	<input type="checkbox"/>	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.	
_____	<input type="checkbox"/>	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: _____
