**Instructions:** Complete staff initials next to procedures completed. 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. If any procedures are not conducted on the date recorded above, ensure the date procedure conducted is included in the comments section.

| **Procedure** | **Staff Initials** | **Comments:** |
| --- | --- | --- |
|  | Indicate which participants are present for visit. * Maternal
* Infant(s)

Confirm identity and PIDs for present participants |  |  |
|  | Has pregnancy outcome visit been completed?* Yes🡪 CONTINUE.
* No 🡪 STOP. Complete this visit using the Pregnancy Outcome Checklist but enter all CRFs under the Post-Natal Visit that is open in REDCap.
 |  |  |
|  | Review elements of informed consent as needed. Explain procedures to be performed at today’s visit. |  |  |
|  | Review/update **Participant Locator Form,** adding any enrolled infant information |  |  |
|  | *If indicated,* obtain maternal blood pressure and document on **Vitals CRF** (MATERNAL) |  |  |
|  | *Required at V202 and if indicated at V203,* Administer maternal depression screener using the **EPDS CRF.** If needed, refer per SOP. |  |  |
|  | Complete **Post-natal Care CRF** (MATERNAL) to capture maternal outcome data, including procedures 9-14 below. |  |  |
|  | Assess/review new delivery, postnatal records for maternal care, infant care, medical events/condition, and medications. |  |  |
|  | Update/review **Health Care Provider Form** with any changes, including for postnatal care for the mother or infant |  |  |
|  | Record new/update existing maternal medical events on MATERNAL **Medical Event/Conditions CRF.** Refer to ***Medical and Medications Guide.*** |  |  |
|  | Record new/update existing maternal medications on MATERNAL **Medications CRF.** Refer to ***Medical and Medications Guide.****Note: DO NOT include PrEP method use. DO include PEP use, if relevant* |  |  |
|  | Complete one **PrEP Use CRF** (MATERNAL)foreach month since lastvisit. For the current month, assess the month based on PrEP use through today’s date.*Note: Review the CRF for the last month recorded at the previous visit to reassess PrEP use for the full month.* . |  |  |
|  | Record new/update infant existing medical events on INFANT **Medical Event/Conditions CRF.** Refer to ***Medical and Medications Guide.*** |  |  |
|  | Review new/update infant medications on INFANT **Medications CRF.** Refer to ***Medical and Medications Guide.*** |  |  |
|  | Complete **Infant Feeding Assessment CRF** (INFANT) |  |  |
|  | Perform infant physical exam, including surface exam and growth measurements, and document on the **Infant Physical Exam CRF** (INFANT).*Note: omit if non-live birth.*  |  |  |
|  | ***If indicated,*** confirm photo/video consent (on Enrollment consent) and take photos/video of the infant to document any congenital abnormalities if mother agrees. Upload to the GBD App and document on **Infant Physical Exam CRF** (INFANT) and in chart notes. Notify the MATRIX-007 Safety Sub-Committee of the congenital anomaly |  |  |
|  | Complete *HIV Testing* section of **Test Results CRF** (Maternal) toassess availability of recent HIV test result/ART documentation or if testing is needed for maternal participant. * Documentation available; no testing needed at visit. Make certified copy of results and file in participant chart.
	+ *If a seroconversion,* document condition on the **Medical Events/Conditions CRF** and submit query to Safety Sub-committee.
* HIV rapid testing needed at visit
 |  |  |
|  | Complete *Syphilis Testing* section of **Test Results CRF** (Maternal)toassess availability of recent syphilis testing documentation or if testing is needed for maternal participant *(only if clinically indicated).* * New test documentation available.
	+ Make certified copy of results and file in participant chart
* No testing needed at visit

**OR*** *If indicated,* syphilis rapid testing needed at visit.

*Note: document any new syphilis diagnosis on the Medical Events/Conditions CRF and submit query to Safety Sub-Committee.* |  |  |
|  | Identify HIV and/or syphilis rapid testing needed:* HIV only
* Syphilis/HIV combo
* Neither

*Note: If only syphilis testing is needed, the syphilis/HIV combo test will be used, which will also provide a HIV test outcome.* |  |  |
|  | * N/A - no testing needed

*If HIV testing,* provide HIV pre-testing and HIV/STI risk reduction counseling using the ***HIV Testing and Counseling Guide****.*Perform fingerpick and process needed rapid test.  |  |  |
|  | * N/A - no testing
* HIV test results:
* If test negative 🡪 uninfected.
* If positive 🡪 Refer for confirmation testing per site SOP
* N/A - Syphilis test results:
* N/A (combo test not done).
* If test negative 🡪 uninfected, continue.
* If positive 🡪 infected, continue. Refer for Tx and clinical mgmt. per site SOP. *Note: document any new syphilis diagnosis on the Medical Events/Conditions CRF and submit query to Safety Sub-committee.*

*If HIV testing,* provide HIV post-test counseling using the ***HIV Testing and Counseling Guide****.*If syphilis/HIV combo rapid, document on the **Syphilis/HIV Testing Log**. If HIV rapid only, document on the **HIV Testing Log**. Document all results on the **Test Results CRF** (Maternal)**.** |  |  |
|  | *If indicated,* collect urine, perform hCG testing and document on the **Pregnancy Testing Log** and **Testing Results CRF** (MATERNAL)* Negative
* Positive 🡪 assess if participant is interested to enroll for the subsequent pregnancy.
 |  |  |
|  | *If reported,* document any SAE or Social Harm for either maternal or infant participants on the respective **Medical Event/Condition CRF** and **Social Harms CRF,** respectively.Following reporting procedures to notify the Safety Sub-committee. |  |  |
|  | *If indicated,* refer for clinical care based on clinical assessments. |  |  |
|  | *If indicated (not exited),* schedule next visit and document on [**Participant Tracker** or site-specific document]. Refer to the **Participant Scheduling CRF.** |  |  |
|  | *Visit 203 or if indicated,* exit maternal and/or infant participants by completing the **Study Exit CRF** for each exited participant.*Note: reasons for exit could be end of scheduled follow-up, maternal death, infant death, withdraw of consent.* |  |  |
|  | Provide IRB-approved reimbursement. |  |  |
|  | Complete **Study Visit CRF** (MATERNAL) and update **Participant Tracker.** |  |  |
|  | Check visit checklist is complete, QC data, and record chart note with any salient information, including types/sources of any medical records or test results reviewed. |  |  |
|  | Perform QC review and ensure that data is entered in REDCap for the following CRFs/forms:Required CRFs* Post-natal care (Maternal)
* Testing Results Maternal)
* Infant Feeding assessment (Infant(s))
* Infant Physical Exam (Infant(s))
* Study Visit (Maternal)

*As needed* * Medical Events/Conditions (Maternal and Infant(s))
* Medications (Maternal and Infant(s))
* Vitals (Maternal)
* Social Harms

Paper Forms:* Participant Locator Form
* Healthcare Provider Form
* HIV, Syphilis, and/or hCG Testing Logs *(if indicated)*
* Participant Tracker
 |  |  |