**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:** |
| --- | --- | --- |
|  | Confirm maternal identity and PID |  |  |
|  | Confirm if participant had a pregnancy outcome* No pregnancy outcome 🡪 STOP. Complete this visit as the next Antenatal Visit (using that Visit Checklist and Visit Code)
* Yes, pregnancy outcome.
* Live birth 🡪 CONTINUE. Considered enrolled if consent on file at time of birth
* Non-living (pregnancy loss/stillbirth) 🡪 infant not considered enrolled. Provide supportive grief counseling and/or referrals to mother.
	+ Complete procedures for maternal participant, including documenting fetal outcomes on the Infant Outcome CRF and Medical Event/Conditions CRF within the maternal record.

Indicate the number of enrolled infants or non-enrolled infants/fetus resulting from the pregnancy:

|  |  |
| --- | --- |
| # Enrolled | * Present
* Not present
 |
| # Not enrolled |  |

 |  |  |
|  | * *N/A – no enrolled infant(s)*

*If enrolled infant*, assign infant PID(s).* Select the next maternal PID from the listing under the record status dashboard on REDCap.
* Complete **Assign PID CRF** (INFANT).
* Add the PID(s) next to the mother’s PID on the **PID Name Linkage Log**.
 |  |  |
|  | Review elements of informed consent as needed. Explain procedures to be performed at today’s visit. |  |  |
|  | Confirm Mother’s consent for infant to continue in study today:* Consent for infant confirmed 🡪CONTINUE.
* Consent for infant withdrawn🡪 INFANT NOT ELIGIBLE TO CONTINUE. Complete the infant’s **Study Exit CRF**. Complete procedures for maternal participant only
 |  |  |
|  | Review/update **Participant Locator Form,** adding any enrolled infant information. |  |  |
|  | *If indicated,* obtain maternal vitals (BP only) and document on **Vitals CRF** (MATERNAL). |  |  |
|  | Administer maternal depression screener on **EPDS CRF** (MATERNAL)**.** If needed, refer per SOP. |  |  |
|  | Assess/review ANC, delivery, postnatal, and any other available medical records for maternal care, infant care, medical events/conditions, and medications. |  |  |
|  | Complete **Pregnancy Outcome CRF** (MATERNAL) to capture maternal outcome data, including procedures 11-15 below. Refer to the ***Medical and Medications Guide.*** |  |  |
|  | Update/review **Health Care Provider Form** with any changes, including confirming ANC, delivery location, and postnatal care for the mother or infant |  |  |
|  | *If applicable:* Review **Ultrasound Results CRF** (paper version). * *If not done previously,* complete the **GA Dating Tool** (Excel) to generate the final EDD. Print and file the completed tool.
* *If not done previously,* complete Final EDD field on paper form (refer to the ***Medical and Medications Guide*).**
* Create certified copy of paper Ultrasound Results CRF (by PID only) and provide original to participant.
* Transcribe results on **Ultrasound Results CRF** in REDCap.
 |  |  |
|  | Review **EDD CRF** (MATERNAL). Update with Final EDD, if applicable**.**  |  |  |
|  | Record new/update existing maternal medical events on MATERNAL **Medical Event/Conditions CRF.** Refer to ***Medical and Medications Guide.*** |  |  |
|  | Record new/update exiting 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.*  |  |  |
|  | Complete **Infant Outcome CRF** for each infant/fetus (MATERNAL)of the pregnancy. Refer to the ***Medical and Medications Guide.****Note: For enrolled infants, record infant PID in CRF Notes of the Infant Outcome CRF* |  |  |
|  | Record new infant medical events on INFANT **Medical Event/Conditions CRF.** Refer to ***Medical and Medications Guide.****Note:* * *For enrolled infants, record under the* INFANT *record.*
* *For non-enrolled infants/fetus, complete the CRF(s) in the MATERNAL record in REDCap using the Fetus ID assigned from the Ultrasound Results CRF.*
 |  |  |
|  | Record new infant medications on INFANT **Medications CRF.** Refer to ***Medical and Medications Guide.****Note: omit if non-live birth.* |  |  |
|  | Complete **Infant Feeding Assessment CRF** (INFANT)*Note: omit if non-live birth.* |  |  |
|  | 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 (from 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 treatment 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 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.Follow reporting procedures to notify the Safety Sub-committee. |  |  |
|  | *If indicated,* refer for clinical care based on clinical assessments. |  |  |
|  | *If indicated (not exited),* update the **Participant Scheduling CRF** (MATERNAL)**,** with the actual pregnancy outcome dateto produce the Postnatal Visit schedule. Schedule next visit document on [**Participant Tracker** or site-specific document]. |  |  |
|  | *If indicated,* exit maternal and/or infant participants by completing the **Study Exit CRF** for each exited participant.*Note: reasons for exit could be no further follow-up needed for maternal participant with a pregnancy loss, maternal death, infant death, withdraw of consent.* |  |  |
|  | Provide IRB-approved reimbursement. |  |  |
|  | Complete **Study Visit CRF** (MATERNAL) and update **Participant Tracker** |  |  |
|  | Check that visit checklist is complete, QC the 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* Pregnancy Outcome (Maternal)
* Infant Outcome (Maternal)
* PrEP Use (Maternal) (one per month since last visit)
* Testing Results Maternal)
* Infant Feeding assessment (Infant(s))
* Infant Physical Exam (Infant(s))
* Study Visit (Maternal)

*As needed* * Ultrasound results (Maternal)
* EDD (Maternal)
* Medical Events/Conditions (Maternal and Infant(s))\*
* Medications (Maternal and Infant(s))
* Vitals (Maternal)
* Social Harms
* Participant Scheduling (Maternal)

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

\*Complete CRF for each fetus/infant resulting from pregnancy. If non-enrolled infant, record CRF in Maternal record using the Fetus ID assigned on the Ultrasound CRF.  |  |  |