**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 * Consent for infant withdrawn🡪 INFANT NOT ELIGIBLE TO CONTINUE.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. |  |  |