**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 identity and PID. |  |  |
|  | Confirm if participant had a pregnancy outcome.   * No pregnancy outcome🡪 CONTINUE. * Yes, pregnancy outcome 🡪 STOP. Complete this visit instead as a PO Visit with the PO V201 Visit checklist. |  |  |
|  | Review elements of informed consent as needed. Explain procedures to be performed at today’s visit. |  |  |
|  | Review/update **Participant Locator Form.** |  |  |
|  | Assess/review ANC records for obstetric care, medical events/condition, and medications. |  |  |
|  | Update/review **Health Care Provider Form** with any changes, including confirming ANC and delivery location(s). |  |  |
|  | *1st quarterly visit or if available at another visit:* Review **Ultrasound Results CRF** (paper version). Refer to the ***Pregnancy Dating Guide.***   * Complete the **GA Dating Tool** (excel) to generate the final EDD. Print and file the completed tool.  |  |  | | --- | --- | | ***Final EDD*** | \_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ |  * Complete ‘Final EDD’ field on paper **Ultrasound CRF.** * Create certified copy of paper Ultrasound Results CRF (by PID only) and provide original to participant/and another copy to ANC. * Transcribe results on **Ultrasound Results CRF** in REDCap. |  |  |
|  | Review/update **EDD CRF.**  *Note: Final EDD should be recorded if the MATRIX-007 Ultrasound Results CRF is assessed at this visit.* |  |  |
|  | Complete **Antenatal** **Care CRF**   |  |  | | --- | --- | | ***GA at study Visit*** | | | ***Date*** | \_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ | | ***GA*** | Wks:\_\_\_\_\_\_ Days:\_\_\_\_\_\_ | |  |  |
|  | Obtain vitals (weight, BP, fetal heart tones) and document on **Vitals CRF.**  *Note: Fetal heart tones via doppler only if gestational age estimated at >16 weeks.* |  |  |
|  | Record new/update existing medical events on **Medical Event/Conditions CRF.** Refer to ***Medical and Medications Guide.*** |  |  |
|  | Record new/update exiting medications on **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** 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 *HIV Testing* section of **Test Results CRF** toassess availability of recent HIV test result/ART documentation or if testing is needed.   * 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** toassess availability of recent syphilis testing documentation or if testing is needed *(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.** |  |  |
|  | *If reported,* document any SAE or Social Harm 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. |  |  |
|  | Schedule next visit and document on [**Participant Tracker** or site-specific document]. Refer to the **Participant Scheduling CRF.** |  |  |
|  | Provide IRB-approved reimbursement. |  |  |
|  | Complete **Study Visit CRF** 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   * Antenatal obstetric care * Testing Results * Vitals * Ultrasound results *(required for at least 1 AN Visit)* * EDD *(required if ultrasound results available)* * PrEP Use *(one per month since last visit)* * Study Visit   *As needed*   * Medical Events/Conditions * Medications * Social Harms * Participant Scheduling   Paper Forms and Trackers:   * Participant Locator Form * Healthcare Provider Form * HIV and/or Syphilis Testing Logs *(if indicated)* * Participant Tracker (Excel) |  |  |