**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)
 |  |  |