**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 age per site SOPs. * Age 15 or under 🡪 STOP. NOT ELIGIBLE.
* Age 15-17 🡪 CONTINUE. Assess emancipated/mature minor status.
* Age 18+ 🡪CONTINUE.
 |  |  |
|  | Explain, conduct, and document the informed consent process for potential participant and infant(s). Refer to ***IC Job aid***. Complete **Informed Consent Coversheet.** * Willing and able to provide written informed consent for self and infant 🡪 CONTINUE. File completed consent and IC Coversheet in participant name file.
* NOT willing and able to provide written informed consent for self and infant 🡪 STOP. NOT ELIGIBLE. File started consent and/or IC Coversheet in study screening file.

*NOTE: Wait until live birth is confirmed to consider infant ‘enrolled’*  |  |  |
|  | Determine screening attempt (Verify if MATRIX-007 PID has previously been assigned for this participant and pregnancy)* First attempt 🡪 CONTINUE.
* Re-screen attempt (note: only 1 rescreen is allowed) 🡪 CONTINUE.

*Note: use the same PID if participant is re-screening; skip next step.* |  |  |
|  | Assign maternal PID. * Select the next maternal PID from the listing under the record status dashboard on REDCap.
* Complete **Assign PID CRF.**
* Complete new entry on **PID Name Linkage Log (paper-based)**.
 |  |  |
|  | Explain procedures to be performed at today’s visit. |  |  |
|  | Administer **Demographics CRF**. |  |  |
|  | Assess study eligibility using the **Eligibility CRF** and complete the following procedures (items 8-15). |  |  |
|  | *Pregnancy status* | Complete *Pregnancy Status* section of **Eligibility CRF** toassess if previous pregnancy test result or ultrasound result is available or testing is needed.* Documentation available; no testing needed at visit.
* Make certified copy of results and file in participant chart.
* hCG rapid testing needed at visit.
 |  |  |
|  | *HIV and Syphilis Status Assessment* | Complete *HIV Status* section of **Eligibility CRF** toassess availability of recent HIV test result/ART documentation or testing needed. * Documentation available; no testing needed at visit.
	+ Make certified copy of results and file in participant chart.
* HIV rapid testing needed at visit.
 |  |  |
|  | Complete *Syphilis Status* section of **Eligibility CRF** toassess availability of recent syphilis testing documentation. * Documentation available; no testing needed at visit.
	+ Make certified copy of results and file in participant chart.
	+ If syphilis diagnosis, submit query to PSRT.
* Syphilis testing needed at visit.

*Note: the only way to omit a test is if the participant has 1) a SD biosensor Standard Q combo rapid test, 2)performed within the pregnancy and in the past 3 months and 3) with a negative result* |  |  |
|  | 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 provide a HIV test outcome.*  |  |  |
|  | * N/A - no syphilis or HIV 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.  |  |  |
|  | Complete *Pregnancy dating, PrEP exposure*, and *Behavioral Assessment* sections of the **Eligibility CRF.**

|  |  |  |  |
| --- | --- | --- | --- |
| ***EDD*** | \_\_\_\_/\_\_\_\_\_/\_\_\_\_\_ | **LMP**  | * certain
* uncertain
 |

* Review any available records for pregnancy dating. Refer to ***Pregnancy Dating Guide***
* Complete **Participant Locator Form** to assess adequate locator information.
 |  |  |
|  | *HCG, HIV, Syphilis Test Results* | [ ]  N/A - no hCG testing Perform and document hCG test per site SOPs and complete test results and post-testing actions (including referrals if needed/requested per site SOPs):* If positive 🡪 continue
* If negative 🡪 STOP. Not eligible

Document test results onto the **Pregnancy Testing Log** and *HCG, HIV, Syphilis Test Results* section of the **Eligibility CRF.** |  |  |
|  | [ ]  N/A - no testing * HIV test results:
* If negative 🡪 uninfected. continue
* If positive 🡪 STOP. Not eligible
* Syphilis test results:
* N/A (combo test not done)
* If negative 🡪 uninfected. continue
* If positive 🡪 infected, continue. Submit query to PSRT. Refer for treatment and clinical mgmt. per site SOP

*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 in the *HCG, HIV, Syphilis Test Results* section of the **Eligibility CRF** |  |  |
|  | Confirm eligibility status by review/completion/submission of **Eligibility CRF.** * ELIGIBLE🡪 CONTINUE. Participant is officially ENROLLED when the CRF is submitted with the Enrollment status as ‘Enrolled”.
* NOT ELIGIBLE🡪 STOP. DO NOT enroll. Pause and evaluate whether participant is:
* NOT ELIGIBLE but likely to meet eligibility criteria within this screening attempt (35 days)🡪 PAUSE. Provide information to participant and clinical management as needed. Confirm locator information. Schedule another Enrollment Visit within the 35-day window when participant is likely to be eligible.
* NOT ELIGIBLE and NOT likely to meet eligibility criteria within this screening attempt 🡪 STOP. Provide clinical management as needed. One re-screen attempt is permitted.
 |  |  |
|  | Create entry on the ***Participant Tracker*** *(only for those with a PID and consent)* |  |  |
| FOR ENROLLED PARTICIPANTS ONLY |
|  | Obtain vitals (height, weight, BP, fetal heart tones) and document on **Vitals CRF** |  |  |
|  | Complete **Obstetric Care and History CRF,** including procedures 19-24 below.Refer to ***Medical and Medications Guide.*** |  |  |
|  | Complete **Health Care Provider Form** with any ANC providers and intended delivery location.  |  |  |
|  | *If available:* Review ultrasound results. Create certified copy of report (by PID only) and file in participant chart.Enter results on **Ultrasound Results CRF** in REDCap. |  |  |
|  | Complete the**Estimated Due Date (EDD CRF)** with EDD and LMP certainty**.***Note: Enter the working EDD unless an study-provided ultrasound scan has been completed and a final EDD is known.* |  |  |
|  | Record relevant past or current medical events and/or conditions on **Medical Event/Conditions CRF.** Refer to ***Medical and Medications Guide.*** |  |  |
|  | Record medications using during this pregnancy (past or current) on the **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 of the pregnancy to date including the current month. *Note: probe PrEP use recall using a calendar or talking through milestones in the participant’s life during the reporting month.* |  |  |
|  | *If indicated,* refer for clinical care based on clinical assessments. |  |  |
|  | Provide IRB-approved reimbursement. |  |  |
|  | Create the remaining study visit calendar using the **Participant Scheduling CRF.**  * Schedule Ultrasound appointment prior to 1st Antenatal Quarterly Visit.
* Schedule next Antenatal Quarterly Visit.
* Provide appointment card and PIC card, if applicable
* Document on [the ***Participant Tracker*** or site-specific document].
 |  |  |
|  | 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 are entered in REDCap for the following CRFs/forms:Required CRFs* Assigned PID
* Demographics
* Eligibility
* Obstretric History and Care
* Vitals
* EDD
* PrEP Use (one per month of pregnancy to date)
* Study Visit
* Participant Scheduling

*As needed* * Ultrasound results
* Medical Events/Conditions
* Medications

Paper Forms/Trackers:* Informed Consent and IC Coversheet
* Name Linkage Log
* Participant Locator Form
* Healthcare Provider Form
* Pregnancy, HIV and/or Syphilis Testing Logs *(if indicated)*
* Participant Tracker (Excel)
 |  |  |