**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) | |  |  |