**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.

| **MOTHER (Visits 3, 5, 7, 9, 11, 13, 102)** |  |  |
| --- | --- | --- |
| **Procedure** | **Staff Initials** | **Comments:** |
|  | Confirm identity and PTID, explain the purpose of today’s call (or visit, if done at the clinic) |  |  |
|  | If participant has had a pregnancy outcome 🡪 PAUSE. Capture pregnancy outcome date and enter in Visit Scheduling Tool to generate Post-pregnancy visit schedule. Conduct 1-week PPO phone visit for mother (v 102) and infant (v 202—see separate checklist), if within window. Schedule participant for PPO visit. |  |  |
|  | Review elements of informed consent, as needed.  |  |  |
|  | Review/update locator information using site-specific form. |  |  |
|  | ***For calls prior to delivery (Visits 3, 5, 7, 9, 11, 13):*** Confirm plans to deliver at a hospital/ delivery facility. Update [site-specific form or chart notes] with any changes. |  |  |
|  | Provide available test results from previous visit. Schedule in clinic visit for treatment and/or provision of referrals for care, as required. |  |  |
|  | * ***For calls prior to delivery (Visits 3, 5, 7, 9, 11, 13):*** Complete the **Follow-Up Visit Y/N - Pre-PO CRF**
* ***For 1-week PPO call (Visit 102):*** Complete the **Follow-Up Visit Y/N CRF**
 |  |  |
|  | Collect follow-up medical history/antenatal/obstetric/medications (including medicated vaginal products) history and document any AE; as needed, review and update:* **Adverse Event Y/N and Adverse Event Log CRFs**
* **Concomitant Medications Y/N and Concomitant Medications Log CRFs**
* ***For 1-week PPO call (Visit 102) only:* Pregnancy Outcome CRF, Product Discontinuation CRF, Adverse Event Y/N – Non-Enrolled Infant and Adverse Event Log – Non-enrolled infant CRFs** *(if infant is not enrolled)*
 |  |  |
|  | Since her last visit, has the participant inserted anything in her vagina? Please include non-medicated gels, water, soap, dry materials (such as paper, ashes, or powders), and any other materials inserted vaginally. If yes, complete a **Vaginal Practices CRF**.*Note: all medicated vaginal products (including prescription medications, over-the-counter preparations, vitamins and nutritional supplements, and herbal preparations which are intended to function as medication) should be recorded on the* ***Concomitant Medications Log.*** |  |  |
|  | ***If indicated****,* schedule in clinic visit to further evaluate any reported medical conditions, AE, or to test/treat for STI/RTI/UTIs per local standard of care. |  |  |
|  | ***If indicated*,** provide HIV/STI risk reduction counseling and document on the **HIV Pre-/Post-Test and HIV/STI Risk Counseling Worksheet** |  |  |
|  | ***If indicated****,* provide protocol adherence counseling using the *MTN-042 Protocol Counseling Guide.* Document any questions or issues on this checklist or in chart notes. |  |  |
|  | **For calls prior to delivery (Visits 3, 5, 7, 9, 11, 13)** ask if the participant has any questions or concerns about the study product (ring/pill) she is currently taking. Document participant responses on this checklist or in chart notes.  |  |  |
|  | Complete the **Follow-up Visit Summary** **CRF.** |  |  |
|  | Perform QC1: while participant is still present (on the phone or at the clinic), review the following for complete and clear documentation:* **Follow-up Visit Y/N** **– Pre-PO** *(Visits 3, 5, 7, 9, 11, 13 only),* **Follow-up Visit Y/N** *(Visit 102 only) and* **Follow-up Visit Summary CRFs**
* **AE Log, Non-Enrolled Infant AE Log** and **Concomitant Medications Log CRFs** to ensure all conditions, medications, AEs are captured consistently and updated.
* **Pregnancy Outcome and Product Discontinuation CRFs**
* **Chart notes**
 |  |  |
|  | Schedule/confirm next visit. Provide contact information and instructions to report symptoms and/or request information, counseling, a new ring/pills, or condoms before next visit. Provide instruction to report delivery of infant, as applicable. |  |  |
|  | Provide reimbursement per site SOP |  |  |
|  | Perform QC2 review and ensure that data is entered in Medidata for the following CRFs/forms:Required CRFs* Follow-up Visit Y/N – Pre-PO *(Visit 3, 5, 7, 9, 11, 13 only)*
* Follow-up Visit Y/N *(Visit 102 only)*
* Follow-up Visit Summary

*As needed:** Adverse Events Summary/ Log
* Adverse Events Summary/ Log – Non-enrolled Infant
* Concomitant Medications Summary/ Log
* Pregnancy Outcome CRF
* Product Discontinuation CRF

Paper Forms:* HIV Pre/Post-Test and Risk Counseling Worksheet, *if indicated*
 |  |  |