**Checklist Instructions:** Enter your initials next to the procedure(s) you completed. Do not initial for other staff members. 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 procedure is not conducted on the visit date recorded above, ensure the date the procedure was conducted is included.

RED TEXT = REDCap Instrument (direct data entry unless otherwise specified in site SOURCE DOCUMENT SOP)

GREEN TEXT = MATRIX-002 (Sample) Paper Document [HIGHLIGHTS = sites to include or delete text/row as applicable]

| **PROCEDURE** | **Initials** |
| --- | --- |
| Confirm participant identity and PTID, *per site SOP* |  |
| If selected for IDI, confirm IDI was completed prior to V10 procedures |  |
| Confirm visit is within window period, *per SSP* |  |
| Type of contact:   * Telephone contact * SMS * Email * In-person |  |
| Review/update medical and menstrual history and wellness by completing the UPDATED medical and menstrual history |  |
| Review/update concomitant medications |  |
| Assess for AEs/concerns. Document on ADVERSE EVENTS LOG as needed. Arrange additional discussion/interim visit as required |  |
| Ensure all open AEs and conmeds are reviewed and marked with appropriate end date or continuing. Make arrangements to follow up with participant regarding any ongoing AEs at this visit per protocol. Document in chart note as applicable. |  |
| Provide available test results if applicable |  |
| Review/update locator information |  |
| Provide reimbursement [sites may add details] |  |
| Document visit in a detailed chart note |  |
| Provide any other information or referrals if needed |  |
| Complete PARTICIPANT DISPOSITION |  |
| Perform QC1 review, including:   * Review of visit checklist items to ensure all relevant procedures were completed during the visit |  |
| Perform QC2 review, including accuracy and completeness of REDCap and paper forms |  |

Comments: