

Instructions: Assess the participant's baseline medical history using this guide. If the participant has any gradable conditions, or if determined relevant by the clinician, document on the **Baseline Medical History Log CRF** including the description, onset/outcome date(s), and severity grade. Relevant conditions include (but are not limited to): hospitalizations; surgeries; allergies; conditions requiring prescription or chronic medication (lasting for more than 2 weeks); and, any condition(s) currently experienced by the participant. Add any associated medications the participant is currently taking on the **Concomitant Medications Log CRF**.

General Medical History

- Does the participant have any health problems?
- Has the participant ever been hospitalized for any reason other than giving birth?
- Has the participant ever had surgery?
- In the past year, has the participant been to the emergency room?
- Has the participant had any medical or health problems in the past year?
- Does the participant have any symptoms suggestive of acute HIV, such as fevers, rash, or swollen lymph nodes?

Body System Medical History

Assess any significant medical problems involving the following organ/systems.

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| • Head, Eyes, Ears, Nose and Throat (HEENT) | • Skin |
| • Gastrointestinal (GI) | • Neurologic |
| • Lymphatic | • Endocrine/metabolic |
| • Cardiovascular | • Hematologic |
| • Liver | • Cancer |
| • Respiratory | • Allergies |
| • Renal | • Malnutrition |
| • Musculoskeletal | • Mental illness |
| • OB/GYN (e.g., postpartum hemorrhage, sepsis, pre-eclampsia/eclampsia) | • History of investigational drug exposure during recent pregnancy or during breastfeeding |
| • STI/RTI (e.g., HPV, HSV, NG/CT, syphilis, trichomoniasis, candidiasis, PID) | • Alcohol/recreational drug /tobacco use during recent pregnancy or during breastfeeding |
| • Breast (including surgery, breastfeeding issues) | • Any other health issues |

Genitourinary Symptoms

Assess any symptoms in the last 6 months

- Genital/vaginal burning
- Genital sores
- Genital/vaginal itching
- Genital/vaginal pain during sex
- Post-coital bleeding (bleeding after sex)
- Genital/vaginal pain not during sex
- Abnormal genital/vaginal discharge
- Unusual genital/vaginal odor
- Dysuria
- Urinary frequency
- Leaking urine

Obstetric History – Most Recent Pregnancy

Assess for the following conditions during **most recent** pregnancy

(Note information may come through medical record review and/or discussion with participant.)

- Multiple gestation
- Premature rupture of membranes (PROM)
- Placental abnormalities (e.g., persistent placenta previa, vasa previa)
- Cervical cerclage
- Abnormal fetal anatomy (in the opinion of the IoR or designee)
- Intrauterine growth restriction
- Pre-existing or gestational diabetes
- Hypertensive disorder of pregnancy
- Malaria
- Obstructed labor
- Shoulder dystocia
- Cesarean delivery
- Vaginal laceration or episiotomy
- Cervical laceration
- Vacuum-assisted delivery or forceps
- Retained placenta
- Postpartum hemorrhage
- Blood transfusion
- Chorioamnionitis
- Endometritis
- Sepsis
- Vesicovaginal or rectovaginal fistula, fistula repair
- Preterm birth
- Abnormal quantity of amniotic fluid (oligohydramnios or polyhydramnios)
- Bleeding or spotting during pregnancy (subchorionic hematoma, chronic placental abruption, or friable cervix)
- Report of any exposures to toxic chemicals, substances, or materials such as work pollutants, contaminated water, pesticides, fertilizers, environmental toxins, cleaning agents, etc.