

**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 and/or diagnosed during her current or any past pregnancies. 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.*

- |  |   |
|--|---|
| • Head, Eyes, Ears, Nose and Throat (HEENT)                  | • Skin  |
| • Gastrointestinal (GI)                                      | • Neurologic  |
| • Lymphatic  | • Endocrine/Metabolic   |
| • Cardiovascular   | • Hematologic   |
| • Liver  | • Cancer  |
| • Respiratory  | • Allergies   |
| • Renal  | • Mental Illness  |
| • Musculoskeletal  | • STI/RTI (HPV, HSV, GC/CT, Syphilis, Trichomoniasis, Candidiasis, PID) |
| • OB/GYN (uterine fibroids, abnormal PAP, genital infection) | • Any other health issues   |

### Genital Symptoms

*Assess any genital symptoms in the last 6 months*

- |   |                                       |
|---|---------------------------------------|
| • Genital/vaginal burning                   | • Genital/vaginal pain not during sex |
| • Genital sores                             | • Abnormal genital/vaginal discharge  |
| • Genital/vaginal itching                   | • Unusual genital/vaginal odor        |
| • Genital/vaginal pain during sex           | • Dysuria                             |
| • Post-coital bleeding (bleeding after sex) |                                       |

## Obstetric History – Current Pregnancy

Assess for the following conditions during **current** 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
- Treatment for preterm labor
- Abnormal quantity of amniotic fluid (oligohydramnios or polyhydramnios)
- Bleeding or spotting during pregnancy (subchorionic hematoma, chronic placental abruption, or friable cervix)
- Alcohol / Recreational Drug / Tobacco Use during current pregnancy
- Report of any exposures to toxic chemicals, substances, or materials such as work pollutants, contaminated water, pesticides, fertilizers, environmental toxins, cleaning agents, etc.

## Obstetric History – Past Pregnancies

Assess for the following conditions in any **past** pregnancies

- Intrauterine growth restriction
- Gestational diabetes
- Hypertensive disorder of pregnancy
- Intrauterine fetal demise (estimated gestational age  $\geq 20$  weeks)
- Delivery prior to 37 0/7 weeks

## Genetic Screening History

Assess if the participant, biological father of the baby, or members of their family (mother or father of baby), has ever been diagnosed with the following conditions:

- Cleft-Lip or Palate
- Heart Defects
- Spina Bifida (Open Spine)
- Muscle Disease/Muscular Dystrophy
- Mental Retardation
- Down Syndrome
- Cystic Fibrosis
- Kidney Disease
- Sickle Cell Anemia
- Hemophilia (Bleeder's Disease)
- Thalassemia (Mediterranean or Cooley's Anemia)
- Is the biological father a blood relative of the participant (woman)?