|  |
| --- |
| **Part I: General Medical History** |
| Ask participant the following questions. If response is **YES**, indicate the associated body system number from Part II where the description can be found and describe in Part II. If response is **NO,** the remainder of this form should still be completed. |
|  | **No** | **Yes 🡪** (associated body system)  | **Comments** |
| 1 | Does the participant have any health problems? |[ ]  [ ]  **🡪** ­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |  |
| 2 | Has the participant ever been hospitalized for any reason other than giving birth?  |[ ]  [ ]  **🡪** ­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |  |
| 3 | Has the participant ever had surgery, including a hysterectomy? |[ ]  [ ]  **🡪** ­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |  |
| 4 | In the past year, has the participant been to the emergency room? |[ ]  [ ]  **🡪** ­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |  |
| 5 | Has the participant had any medical or health problems in the past year? |[ ]  [ ]  **🡪** ­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  |  |

|  |
| --- |
| **Part II: Body System Medical History** |
| Ask if the participant ever experienced any significant medical problems involving the following organ/systems. If response is **YES**, include onset and outcome dates (if not resolved at baseline, mark “ongoing”), severity grade, medications taken, and any comments relevant to the diagnosis/description, and document on the **Medical History** **Log CRF.** |
| **#** | **Body System** | **No** | **Yes** | **Onset Date** | **Outcome Date** | **Severity Grade** | **Med. Taken?** | **Description/Comments** |
| 1 | Head, Eyes, Ears, Nose and Throat (HEENT) |[ ]  [ ]  |  | [ ]  ongoing |  |  |  |
| 2 | Gastrointestinal (GI) |[ ]  [ ]  |  | [ ]  ongoing |  |  |  |
| 3 | Lymphatic |[ ]  [ ]  |  | [ ]  ongoing |  |  |  |
| 4 | Cardiovascular  |[ ]  [ ]  |  | [ ]  ongoing |  |  |  |
| **#** | **Body System** | **No** | **Yes** | **Onset Date** | **Outcome Date** | **Severity Grade** | **Med. Taken?** | **Description/Comments** |
| 4 | Liver |[ ]  [ ]  |  | [ ]  ongoing |  |  |  |
| 5 | respiratory |[ ]  [ ]  |  | [ ]  ongoing |  |  |  |
| 6 | Renal  |[ ]  [ ]  |  | [ ]  ongoing |  |  |  |
| 7 | Musculoskeletal |[ ]  [ ]  |  | [ ]  ongoing |  |  |  |
| 8 | Breast |[ ]  [ ]  |  | [ ]  ongoing |  |  |  |
| 8 | Neurologic |[ ]  [ ]  |  | [ ]  ongoing |  |  |  |
| 9 | Skin |[ ]  [ ]  |  | [ ]  ongoing |  |  |  |
| 10 | Endocrine/Metabolic |[ ]  [ ]  |  | [ ]  ongoing |  |  |  |
| 11 | Hematologic |[ ]  [ ]  |  | [ ]  ongoing |  |  |  |
| **#** | **Body System** | **No** | **Yes** | **Onset Date** | **Outcome Date** | **Severity Grade** | **Med. Taken?** | **Description/Comments** |
| 12 | Cancer |[ ]  [ ]  |  | [ ]  ongoing |  |  |  |
| 13 | Allergies |[ ]  [ ]  |  | [ ]  ongoing |  |  |  |
| 14 | Mental Illness |[ ]  [ ]  |  | [ ]  ongoing |  |  |  |
| 15 | Alcohol / Recreational Drug Use |[ ]  [ ]  |  | [ ]  ongoing |  |  |  |
| 16 | STI/RTI (HPV, HSV, GC/CT, Syphilis, Trichomoniasis, Candidiasis, PID) |[ ]  [ ]  |  | [ ]  ongoing |  |  |  |
| 17 | OB/GYN (genital bleeding not associated with menses or childbirth, uterine fibroids, abnormal PAP, genital infection, hysterectomy e.g. uterus, at least one ovary) |[ ]  [ ]  |  | [ ]  ongoing |  |  |  |
| 18 | Are there any other health issues? |[ ]  [ ]  |  | [ ]  ongoing |  |  |  |

|  |  |
| --- | --- |
|  | **Part III: Genital Symptoms** |
|  | Ask if participant has experienced any of the following genital symptoms in the last 6 months? |
| **#** | **Body System** | **No** | **Yes** | **Onset Date** | **Outcome Date** | **Severity Grade** | **Med. Taken?** | **Description/Comments** |
| 1 | Genital/vaginal burning | [ ]  |[ ]   | [ ]  ongoing |  |  |  |
| 2 | Genital sores |[ ]  [ ]  |  | [ ]  ongoing |  |  |  |
| 3 | Genital/vaginal itching | [ ]  |[ ]   | [ ]  ongoing |  |  |  |
| 4 | Genital/vaginal pain during sex | [ ]  |[ ]   | [ ]  ongoing |  |  |  |
| 5 | Post-coital bleeding (bleeding after sex) | [ ]  |[ ]   | [ ]  ongoing |  |  |  |
| 6 | Genital/vaginal pain not during sex | [ ]  |[ ]   | [ ]  ongoing |  |  |  |
| 7 | Abnormal genital/vaginal discharge | [ ]  |[ ]   | [ ]  ongoing |  |  |  |
| 8 | Unusual genital/vaginal odor | [ ]  |[ ]   | [ ]  ongoing |  |  |  |
| 9 | Dysuria | [ ]  |[ ]   | [ ]  ongoing |  |  |  |

|  |
| --- |
| **Part IV: Menstrual History** |
| Ask participant the following about pregnancy and menstrual history. |
|  | **Since Screening Visit** | **Since Enrollment Visit** |
| 1 | What was the first and last day of your last menstrual period?*NOTE: For purposes of scheduling the Enrollment Visit (if otherwise eligible), discuss when the participant anticipates her next menses to start/end, as applicable. Ideally, no bleeding should occur within the first 7 days of product use, e.g., Study Visits 2-6 (Days 0, 1, 2, 3, 7).* | **First day:** | **First day:** |
| **Last Day:** | **Last Day:** |
| 2 | Provide additional details as needed to describe the participant's baseline menstrual bleeding pattern: |