**Index Physical Examination**

**Visit Code 01.00**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| Screening ID:   |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |  |  |  |   *Site Study Screening Number* | Participant ID:   |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |  |  |  |  |  |   *Site Study Couple I/P Chk* | Visit Date:   |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |   *dd mm yy* |

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| 1 | **Height *(Enrollment only)*** | | | | | | \_\_\_\_\_\_\_\_\_\_ cm | | | | | | | | | | |
| 2 | **Weight** | | | | | | *\_\_\_\_\_ . \_\_\_\_ kg* | | | | | | | | | | |
| 3 | **Temperature** | | | | | | *\_\_\_\_\_.\_\_\_ Oc* | | | | | | | | | | |
| 4 | **Blood pressure** | | | | | | *\_\_\_\_\_\_/\_\_\_\_\_mgHg* | | | | | | | | | | |
| 5 | **Respiratory rate** | | | | | | *\_\_\_\_\_/min* | | | | | | | | | | |
| 6 | **Pulse rate** | | | | | | *\_\_\_\_\_\_/min* | | | | | | | | | | |
| **Syndromic Diagnoses** | | | | | | | | | | | | | | | | | |
| 7 | Genital ulcer disease (GUD) | | | | | | **Yes** | | | | | | **No** | | | **Not done** | |
| ***Items 8-10 are for women only.*** | | | | | | | | | | | | | | | | | |
| 8 | Vaginitis or vaginal discharge | | | | | | **Yes** | | | | | | **No** | | | **Not done** | |
| 9 | Cervicitis or cervical discharge | | | | | | **Yes** | | | | | | **No** | | | **Not done** | |
| 10 | Pelvic inflammatory disease (PID) | | | | | | **Yes** | | | | | | **No** | | | **Not done** | |
| ***Items 11-12 are for men only.*** | | | | | | | | | | | | | | | | | |
| 11 | Urethritis or urethral discharge | | | | | | **Yes** | | | | | | **No** | | | **Not done** | |
| 12 | Circumcision status | Fully circumcised | | | Partially circumcised | | | | | | Not circumcised | | | | | | |
| **STI Treatment** | | | | | | | | | | | | | | | | | |
| 13 | Treatment given for a genital tract infection? | | | | | | **Yes** | | **No** | | | | | | **If no, go to item 14.** | | |
| a | List medications: | | | | | | | | | | | | | | | | |
| 14 | **Physical Signs** | | | | | | | | | | | | | | | | |
| Oral abnormalities: *Mark all that apply* | | | | | | | | | | | | | | | | | |
|  | *gingivitis/periodontitis* | |  | *Thrush* | | | | | |  | | | | ***Not eligible*** | | | |
|  | *Ulcer* | |  | *oral hairy leukoplakia* | | | | | |  | | | | ***Not eligible*** | | | |
|  |  | |  | *Kaposi Sarcoma* | | | | | |  | | | | ***Not eligible*** | | | |
|  |  | |  | Others: | | | | | | | | | | | | | |
| 15 | Skin abnormalities: *Mark all that apply* | | | | | | | | | | | | | | | | |
|  | *generalized skin rash* | |  | Kaposi Sarcoma | | | | | |  | | | | ***Not eligible*** | | | |
|  | Zoster | |  | *Others:* | | | | | | | | | | | | | |
| 16 | Lymph node enlargement? | | | | | Yes | | *No* | | | | ***If no, end of form*** | | | | | |
| a | Site of lymph node(s) | | | | | | | | | | | | | | | | |
|  | *Cervical* | |  | *Inguinal* | | | | | | | | | | | | |  |
|  | *Axillary* | |  | *Others (specify):* | | | | | | | | | | | | | |
| b | Size of largest lymph node | | *\_\_\_\_.\_\_\_ cm* | | | | | | | | | | | | | | |

**Completed by:** *(initials/date) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

**Forms Instruction**

The **Index Physical Exam** CRF is completed by a study clinician following a complete physical examination at Enrollment, then as necessary during follow-up visits. If a complete physical is not necessary during a follow-up visit, record the parts that were completed. Line through unused portions and write “not done.” Questions do not need to be asked directly to the participant. If any findings from a follow-up physical exam would change the participant’s WHO stage, record the new WHO stage on the **Index Enrollment Medical History form.**

The same form is used for male and female partner participants.

**Item-specific Instructions:**

|  |  |
| --- | --- |
| **Screening ID** | Screening IDs will be assigned from the site list and are unique to the individual. They are numeric and should be assigned sequentially. The Index Screening ID is assigned to the HIV-positive participant, and the Partner Screening ID is assigned to the HIV-negative participant. |
| **Participant ID** | Participant IDs are assigned from a list provided by the PROJECT. They are assigned once eligibility has been determined and the subject has been enrolled. The Participant ID should be left blank until the eligibility status of the participant is known. If eligible, the Participant ID should be entered and initialed and dated (if being added on a different date). If the participant is not eligible, then the Participant ID should be left blank. |
| **Item 1** | This should be completed at Enrollment only. |
| **Items 7-11** | Note if any syndromic diagnoses were made during this visit. Mark all that apply. |
| **Item 12** | When otherwise doing a physical exam at follow-up, inquire about circumcision status as male participants may become circumcised during the course of the study. Mark “partially circumcised” if there is residual foreskin that partially covers the glans. |
| **Item 13** | Answer this question for all STIs that were diagnosed. |
| **Item 13a** | List medications given for genital tract infection, including syphilis and herpes. |
| **Items 14 & 15** | For each question, if no abnormalities, mark “none.” Otherwise mark “yes,” then mark all boxes that apply. For conditions not listed, mark the box for “other” and write the condition in the space provided. Evidence of previously healed zosters should not be included. This item only refers to active zosters.  If “thrush,” oral hairy leukoplakia”, or “Kaposi's Sarcoma” are marked at Enrollment, participant is ineligible. |
| **Item 16b** | Enter the size of the largest lymph node found anywhere on the body. |