**Index Enrollment checklist Visit Code 01.0**

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Screening ID:

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |

 *Site Study Screening Number* | Participant ID:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |  |  |  |  |  |

*Site Study Couple I/P Chk* | Visit Date:

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |  |  |

 *dd mm yy*  |

|  |  |  |  |
| --- | --- | --- | --- |
| 1 | **Did the participant meet all eligibility criteria according to the Index Screening Eligibility Criteria** | Yes  | No  |
| a | Investigator / Designee signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |  |  |  |  |  |  |  |  |  |  |  |  |
|  **dd mm yyyy** |
| 2 | **Did the participant provide independent, written, informed consent for enrollment?** | Yes  | No  |
| a | When was the informed consent for enrollment marked or signed? |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
|  **dd mm yyyy** |
| b | Consented under protocol version #: |  |
| 3 | **Did the participant provide independent, written, informed consent for specimen storage?** | Yes  | No  | If no go to 4 |
| a | When was the informed consent for specimen storage marked or signed? |  |  |  |  |  |  |  |  |  |  |  |  |
|  **dd mm yyyy** |
| 4 | **Date Participant ID assigned:** |  |  |  |  |  |  |  |  |  |  |  |  |
|  **dd mm yyyy** |
| 5 | ***Female only:* Is the participant currently pregnant?** | Yes  | no | ***Complete Pregnancy Report*** |
| 6 | Is the participant eligible for ARVs today under current national guidelines? | Yes  | no | ***Go to 7*** |
| a123 | Is the participant being offered ARVs at Enrollment? |
| *ARVs offered on site**Participant referred to off site**not offered or referred, explain:* ***Please provide explanation and go to 7*** | Yes  |  | no |  |  |
| Yes  |  | no |  |
| Yes  |  | no |  |
|  |
| b123 | Did the participant accept ARVs at Enrollment? *Mark all that apply.* |
| *accepted on site**declined on site* |  |  4. *accepted referral* *5. declined referral* |  |  |
|  |  |
| *Others*  |  |  |
| 7 | Comments: |

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

**Forms Instruction**

The **Index Enrollment** CRF serves as final documentation for participants who are enrolling and have been determined eligible. Since this form is found in the participant binder and is completed only for participants who are enrolling, participants should be determined eligible prior to the completion of this form. All of these questions are completed by a study staff member, and do not need to be directly asked of the participant. For ineligible subjects who are HIV discordant, complete the **Couple Eligibility Summary** and the **Screening Demographics** CRFs. Once the participant is enrolled, fax this form.

**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** | Please refer to the **Index Screening Eligibility Criteria** CRF to answer this question. The participant must meet all criteria to be eligible. The investigator or designee’s signature indicates that the participant is eligible and should be signed and dated before the participant is enrolled. |
| **Item 2** | Please provide the date the participant signed or marked the enrollment consent form. A thumbprint in front of a witness who will sign the consent form is considered “written informed consent” for illiterate participants. |
| **Items 2a & 2b** | If a participant is re-consented under a later version of the protocol, do not update item 2a or 2b. In item 7 (Comments), write in a comment to detail this, such as “Reconsented to version 3.0 on dd/mm/yy.” |
| **Item 3** | Please provide the date the participant signed or marked the consent form for specimen storage. Participants who do not give consent to have their specimens stored can still participate in the study. |
| **Item 5** | Current pregnancy among index participants is not a study exclusion criterion. Index participants who are pregnant may enroll. Complete the **Pregnancy Report** CRFs. |
| **Item 6** | Select “no” if the participant is or has been eligible for ART in the past but has chosen not touse it. |