**Partner Enrollment Checklist Visit Code 01.00**

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

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
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 *Site Study Screening Number* | Participant ID:

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

|  |  |  |  |  |  |  |  |
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  *dd mm yy*  |

|  |  |
| --- | --- |
|  | **HIV Test Results** |
| 1 | Specimen collection date: |  |  |  |  |  |  |  |  |  |  |  |  |
|  dd mm yyyy |
| 2 | HIV status by national algorithm: |
|  | Negative  |  |  |
|  | Positive |  | ***Participant is ineligible.*** |
|  | Indeterminate |  | ***Participant is ineligible.*** |
| 3 | **Pregnancy Testing** *Complete this section for female participants only.* |
| A | Date of last menstrual period: |

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

 dd mm yyyy | Don’t know |
| 4 | Pregnancy specimen (urine) collection date: |

|  |  |  |  |  |  |  |  |  |  |  |
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 dd mm yyyy |  |
| 5 | Pregnancy test result: | Negative  |  | Positive  |  | ***Participant is ineligible.*** |
| **Enrollment** |
| 6 | Did the participant provide independent, written, informed consent for specimen storage? | Yes | No  |
| A | Investigator / Designee signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |

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 dd mm yyyy |
| 7 | Did the participant provide independent, written, informed consent for enrollment? | Yes  | No  |
|  | When was the informed consent for enrollment marked or signed? |

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

 dd mm yyyy |
| B | Consented under protocol version #: |  |
| 8 | Did the participant provide independent, written, informed consent for specimen storage? | Yes  | no | Go to 9 |
| A | When was the informed consent for specimen storage marked or signed? |

|  |  |  |  |  |  |  |  |  |  |  |
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 dd mm yyyy |
| 9 | Date Participant ID assigned: |

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

 dd mm yyyy |
| 10 | Did the participant accept PrEP at Enrollment? | Yes  | no |
| 11 | Comments: |

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

**Forms Instruction**

The **Partner 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.** 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. |
| **Items 1 & 4** | Please note that HIV and pregnancy testing (pregnancy testing only for female participants) are performed at Screening and then repeated at Enrollment. Do not enter the date the lab result was obtained, but the date the sample was obtained. |
| **Item 2** | If the HIV test result is positive or indeterminate, the participant is ineligible. Terminate Enrollment procedures. Do not assign a Participant ID. Do not fax this form. |
| **Item 3** | The date of her last menstrual period should be the first day of her last ***normal*** menstrual period. If she does not know, prompt her with a calendar and record the best estimate. |
| **Item 5** | If the pregnancy test is positive, the participant is ineligible. Terminate Enrollment procedures. Do not assign a Participant ID. Do not fax this form. |
| **Item 6** | Please refer to the **Partner Screening Eligibility Criteria** CRFs to answer this question. 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 7** | 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 7a & 7b** | If a participant is re-consented under a later version of the protocol, do not update item 7a or 7b. In item 11 (Comments), write in a comment to detail this, such as “Reconsented to version 3.0 on dd/mm/yy.” |
| **Item 8** | 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. |