|  |
| --- |
|  |

**Partner Visit Summary**

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

|  |
| --- |
|  |

**Sero-Converter:** VISIT MONTH:

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 | Did participant attend the visit? | | | | | | | yes | | | no | *If yes, Go to item 2.*  *If no, Complete item 1a, then end of form.* | | | | | | | | | | | | | | | | |
| 1a | Why did the participant miss the visit? | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| i. | *traveling or out of area* | | |  | | | | *ii.* | *family or personal issues* | | | | | | | | | | | | | | | | |  | | |
| iii. | *refused visit* | | |  | | | | *iv.* | *planned absence* | | | | | | | | | | | | | | | | |  | | |
| v. | *work or school issues* | | |  | | | | *vi.* | *transportation issues* | | | | | | | | | | | | | | | | |  | | |
| vii. | *illness or hospitalized* | | |  | | | | *viii.* | *incarcerated* | | | | | | | | | | | | | | | | |  | | |
| ix. | *relocated or moved* | | |  | | | | *x.* | *unknown / unable to contact* | | | | | | | | | | | | | | | | |  | | |
| xi. | *other, specify:* | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 2 | Location of study visit: | | | |  | | | | | | | | | *clinic* | | |  | | | *home* | | | | | |  | | |
|  | *other, specify:* | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| 3 | Since the last visit, has the participant taken HIV medication for post-exposure prophylaxis (PEP) against HIV? | | | | | | | | | | | | | | *Yes* | | | | | | *No* | | | | *If no, go to item 4.* | | | |
| 3a | For how many days was medication taken? | | | | | | | | | | | | | |  | | | | | | | | | | | | | |
| 3b | Is the participant currently on PEP? | | | | | | Yes | | | No | | | *If yes, stop study drug and complete Partner*  *Study Drug Interruption.* | | | | | | | | | | | | | | | |
| 4 | Type of visit: | *Scheduled* | | | | | | *monthly pregnancy* | | | | | *interim* | | | *stop visit* | | | | | | | *If interim, go to 5* | | | | | |
| 5 | Reason for interim visit: *Mark all that apply.* | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| i | *complete scheduled procedures* | |  | | | *ii.* | | *report social harm* | | | | | | | | | | |  | | | *iii.* | | *pill count* | | | |  |
| iv. | *blood draw for additional testing* | |  | | | *v.* | | *STI symptoms* | | | | | | | | | |  | | | | *If diagnosed with STI*  *Physical* e*xam.* | | | | | | |
| vi. | *return or pick up study drug* | |  | | | *vii.* | | *suspected or confirmed pregnancy* | | | | | | | | | |  | | | | *viii.* | | *Complete Pregnancy*  *Report* | | |  | |
| ix. | *other, specify:* | | | | | | | | | | | | | | | | | | | | | | | | | | | |

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

**Forms Instruction**

The **Partner Visit Summary** CRF is used to summarize general information about each follow-up or interim study visit. This is not an interviewer-administered form. Do not read items to the participant. This form is required for every follow-up study visit, including both attended visits (scheduled or interim) conducted at the clinic or off-site, and missed visits. Fax this form at each visit.

**Item-specific Instructions:**

|  |  |
| --- | --- |
| **Seroconverter** | Mark this box only for confirmed seroconverters. |
| **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. |
| **Codes/**  **Interim Visits** | For index participants, the visit windows are:   * **Enrollment window:** 1 to 27 days after the enrollment date (28 days total). * **Month 1:** 7 days before the target date up to 48 days after the target date (56 days total). * **Quarterly visits (months 3-24):** 7 days before the target date up to 76 days after the target date (84 days total).   The first visit within the visit window should be marked “scheduled.” “Interim” visits occur in the following scenarios:  The participant completes the regularly scheduled visit, and subsequently has additional visits within the same visit window.   * The participant does not complete all procedures for a scheduled visit on a single day, and subsequently completes scheduled visit procedures at a later date within the same visit window.   For pregnant partner participants on a monthly visit schedule, visit codes should continue sequentially from the last visit prior to the start of the pregnancy.  • **Pregnancy monthly visit windows are:** 7 days before the target date and up to 20 days after (28 days total). |
| **Visit Date** | If a scheduled visit was missed, please mark “yes” on item 1 and use the last date of that visit window as the visit date. |
| **Item 1a** | Only one box should be marked. If more than one reason can be given, choose the primary reason.  • **Illness**: If the participant cannot attend the visit because he/she is ill, mark the box for “illness or hospitalized.” If the participant cannot attend the visit because he/she is taking care of a sick relative, mark the box for “family or personal issues.” |
| **Item 3b** | If a participant is on PEP, a new or updated **Partner Study Drug Interruption** CRF must be filed. |
| **Item 4** | Mark “monthly pregnancy” if this is a pregnant participant on a monthly visit schedule and this is a non-quarterly visit (i.e., month 7, 8, 10 or 11, etc.). For pregnant participants attending quarterly visits, mark the box for “scheduled” visit and complete all procedures for quarterly visits. |
| **Item 4a** | In most cases, all procedures for a visit will be conducted on a single day. However, there may be times when procedures need to be completed on another day. Any incomplete scheduled visit procedures conducted at a later date within the same visit window must have a higher visit month denoted by having a higher number after the decimal point.  • If the incomplete scheduled visit has a visit month of XX.0, then the subsequent visit at which the scheduled visit procedures are completed (within the same visit window) must have a visit month of XX.1. |