**Partner Study Drug Interruption**

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1** | Date study medication discontinued: | | | | | | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |   *dd mm yy* | | | |
| **2** | Reason for interrupting or discontinuing study medication: *Mark all that apply.* | | | | | | | | | |
| **3** | PrEP Stop: Index partner has been on ARVs for over six months | | Yes | | No | | | *If yes Complete PrEP Stop Questionnaire* | | |
| **4** | Participant is a possible HIV seroconverter | | | | | | *Yes* | | *No* | |
| **5** | Renal toxicity | | | | | | *Yes* | | *No* | |
| **6** | Serious AE, and / or AE felt related to PrEP | | | | | | *Complete Reportable Adverse Event* | | | |
| **7** | Adverse Event (other than renal toxicity or RAE), describe: | | | | | | | | | |
| **8** | Participant refused study medication  *(Specify reason in Comments.)* |  | | | | | | | | |
| **a** | Participant has had a positive pregnancy test *(women only)* | *Yes* | | *No* | | *Complete Pregnancy Report* | | | | |
| **b** | Participant is breastfeeding *(women only)* | *Yes* | | *No* | |  | | | | |
| **c** | Investigator decision, specify: |  | | | | | | | | |
|  | Other reasons, specify: |  | | | | | | | | |
| *Item 8 may be completed at a later time than items 1 & 2. Fax this form again when study medication is re-established, when study medication is permanently discontinued, or when participant completes study follow-up without re-establishing study medication.* | | | | | | | | | | |
| **9** | Date study medication re-established: | |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | |  |  |  |  |  |  |  |  |   *dd mm yy* | | | | | | | | |
| *study medication not re-established at end of study participation.* | | | | | | | |  |
| *study medication permanently discontinued* | | | | | | | |  |
|  | Comments : | | | | | | | | | |

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

**Forms Instruction**

The **Partner Study Drug Interruption (PSDI)** CRF is completed when study drug is interrupted, for reasons including pregnancy, HIV seroconversion (or possible seroconversion), adverse events thought potentially related to study drug, or at the PrEP Stop visit.

• This form should be completed for participants who refuse to take further study medication.

• This form should **not** be completed for the following: missed visits, lost to follow-up, study stop, or death.

**If the participant is pregnant and is also a seroconverter, notify the SDMC within 48 hours.**

Like other forms, some fields may be updated as the situation changes. If study drug is temporarily withheld, the form will be faxed twice: first to report study drug interruption and again to report that study drug was re-established.

**Item-specific Instructions:**

|  |  |
| --- | --- |
| **Item 1** | Record the date the medication was discontinued by the study site. This does **not** include dates that the participant did not take study drug of his/her own accord. |
| **Item 2 to 8** | The response selected in this item should be only for the **initial** reason(s) that a partner participant’s study drug is interrupted. |
| **Item 8a and b** | If a participant is pregnant, then starts breastfeeding, and study drug is not re-established between those two events, then the only response that should be marked in item 7b is “participant has had a positive pregnancy test.” And she should discontinue PrEP during pregnancy. |
| **Item 8** | If the participant does not want to accept PrEP for any reason (e.g., partner is upcountry, traveling, etc.), mark “participant refused study medication” and specify the reason in the comments section. |
| **Item 9** | Item 3 may be left blank the first time this form is completed. This item must be filled out when the study medication is re-established by the site and the form must then be refaxed. If the study drug is not re-established, then the date should be left blank and the appropriate box should be marked. If study medication is permanently discontinued, note the reason in the comments.  **Special considerations for seroconverters:**   * If seroconversion is confirmed, mark the box for “study medication permanently discontinued” and provide comments in item 4. * If seroconversion is not confirmed contact the study medical director.    ***Do not re-start study drug.*** |