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**Participant Initiated Periodic PrEP Use** **Visit Month**

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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 | At the last study visit attended, was the participant given PrEP? | | | | | | | | | | | | | **yes** | | | | **no** | | ***If no, end of form.*** | | | | |
| 2 | Since the last study visit, was there any period of time when the participant deliberately decided to take a break from taking PrEP? | | | | | | | | | | | | |  | | | |  | |  | | | | |
| 3 | How many deliberate breaks were there since the last attended study visit? | | | | | | | | | | | | |  | | | | | | | | | | |
| 4 | What was the length of the longest deliberate break? | | | | | | | | | | | | |  | | | | | | | | | | |
| 5 | During the longest break, why did the participant stop taking PrEP? *Mark all that apply* | | | | | | | | | | | | | | | | | | | | | | | |
| i | *participant was not at home* | |  | | iii | | *partner was not at home* | | | | |  | v | | | *ran out of pills* | | | | | |  | | |
| ii | *tired of taking the pills* | |  | | iv | | *Broke up with partner* | | | | |  | vi | | | *Others:* | | | | | | | | |
| 5a | If the participant reported more than 1 deliberate break in question 3, what are the reasons for the other breaks? *Mark all that apply* ***OR*** *N/A (only 1 break reported)* | | | | | | | | | | | | | | | | | | | | | | | |
| I | *participant was not at home* | |  | | | iii | *partner was not at home* | | | | |  | v | | | *ran out of pills* | | | | |  | | | |
| ii | *tired of taking the pills* | |  | | | iv | *Broke up with partner* | | | | |  | vi | | | *Others:* | | | | | | | | |
| 6 | During the longest break, how high did the participant think his / her risk for getting HIV was? | | | | | | | | | | | | | | | | | | | | | | | |
|  | *High* |  | | *moderate* | | | | |  | | *low* | |  | | | *none* | | | | | | | |  |
| 7 | During the longest break, did the participant’s partner know that the participant stopped taking PrEP? | | | | | | | | | | | | | | **yes** | | **no** | | **Don’t know** | | | | | |
| 8 | Did the participant start taking PrEP again after this break? | | | | | | | | | | | | | | **yes** | | **no** | | ***If no, go to item 9.*** | | | | | |
| 8a | Why did the participant decide to re-start PrEP? *Mark all that apply* | | | | | | | | | | | | | | | | | | | | | | | |
| I | *the reason mentioned in item 5 no longer applied* | | | | | |  | iii | | *new partner of unknown or positive HIV status* | | | | | | | | | | | | |  | |
| ii | *the participant wants to have a baby* | | | | | |  | iv | | *the participant thought his/her risk of getting HIV changed* | | | | | | | | | | | | |  | |
| v | *other, specify:* | | | | | | | | | | | | | | | | | | | | | | | |
| 9 | Comments *(Provide additional details about the time when the participant did not take PrEP, and whether the participant is currently using PrEP or plans to use PrEP in the future):* | | | | | | | | | | | | | | | | | | | | | | | |

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

**Forms Instruction**

The **Participant Initiated Periodic PrEP Use** formshould be completed at each follow up visit to assess whether participant driven periodic PrEP breaks are taking place. If the participant has had any periodic PrEP breaks, the counselor should have a discussion with the participant to fully understand the circumstances and then complete the CRF questions. To get the most honest answers, the participant should be administered this CRF when the study partner is not present.

**Item-specific Instructions:**

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| **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 2** | On this CRF, we want to capture periodic breaks from PrEP use that participants decide to take themselves. Site-driven PrEP holds due to pregnancy, seroconversion or other reasons should be recorded on the **Partner Study Drug Interruption Form** and not on this CRF. A periodic break could occur when a participant was given PrEP at the last study visit and decided to discontinue PrEP use for any number of days between study visits.  Forgetting to take PrEP is not considered to be a deliberate decision to not take PrEP. If a participant reports instances of forgetting to take PrEP, probe further to understand if there is another reason. Provide comments in item 9. |
| **Items 3 & 4** | We know that it may be difficult for participants to remember exactly the number of days they missed doses. You can help the participant to remember by talking about missed doses in reference to events that may have happened. We want to collect the best information we can. If the participant has difficulty recalling the exact numbers, (s)he can provide an estimated number of breaks and days. |
| **Item 4** | Enter the ***longest*** number of days when the participant deliberately did not take PrEP since the last study visit. |
| **Item 5** | Complete this item based on the episode described by item 4. If a participant reports instances of forgetting to take PrEP, probe further to understand if there is another reason. Provide comments in the “other, specify” option or in item 9. |
| **Item 5a** | Complete this item based on other episodes that are not described by item 4. |
| **Item 8** | If the participant answers that they did not re-start PrEP after their break, confirm that he/she wants to continue PrEP or discontinue it. If the participant wishes to discontinue PrEP and not receive any more bottles at this visit, complete a **Partner Study Drug Interuption form**. |