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**PrEP Stop Questionnaire Visit Month**

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

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|  | **PrEP Stop Questionnaire** | | | | | | | | | **Participant already had a PrEP Stop** | | | | | | | | | | | ***End of form.*** | | | | |
|  | Has the index participant been using ART for > 6 months? | | | | | | | | | | | **yes** | | | **No** | | **Don’t know** | | **If no, *End of form.*** | | | | | | |
| **2** | Is the participant discontinuing PrEP due to index ART use? | | | | | | | | | | |  | | |  | | **If yes, *Go to item 3.***  ***If no, Complete item 2a, then end of form.*** | | | | | | | | |
| **A** | Why not? *Mark all that apply.* | | | | | | | | | | | | | | | | | | | | | | | | |
| i | *index viral load not suppressed* | | | | | | |  | | v | *outside partner HIV infected with unknown or unsuppressed viral load* | | | | | | | | | | | | |  | | |
| ii | *waiting for longer ART use by index* | | | | | | |  | | vi | *index not adherent to ART* | | | | | | | | | | | | |  | | |
| iii | *consented to PrEP during pregnancy* | | | | | | |  | | vii | *has not taken PrEP since the last scheduled quarterly visit* | | | | | | | | | | | | |  | | |
| iv | *immediate fertility desire* | | | | | | |  | | viii | *Other:* | | | | | | | | | | | | | | | |
|  | ***Items 3-9 are interviewer-administered questions, and should be read aloud directly as written.*** | | | | | | | | | | | | | | | | | | | | | | | | |
| **3** | Why do you think you are stopping PrEP? | | | | | | | | | | | | | | | | | | | | | | | | |
|  | *my partner is on ARVs now* | | | | | | |  | | | *Other:* | | | | | | | | | | | | | | |
| **4** | Are you concerned about stopping PrEP? | | | | | | | | | | | | | | | | | | | **yes** | | *No* | | | |
| **5** | If you could choose, would you prefer to stop PrEP or stay on PrEP? | | | | | | | | | | | | | | | | | | |  | |  | | | |
| **6** | Now that you are stopping PrEP, do you have more concerns about getting HIV than you had while you were getting PrEP? | | | | | | | | | | | | | | | | | | | | | | | | |
|  | *more concern* | | |  | | *less concern* | | | | | | |  | | | *No change in concern* | | | | | | |  | | |
| **7** | Do you think you will have sex with your partner more or less often now that you are not using PrEP? | | | | | | | | | | | | | | | | | | | | | | | | |
|  | *more often* | | |  | | *less often* | | | | | | |  | | | *No change* | | | | | | |  | | |
| **8** | Do you think you will use condoms with your partner more or less often now that you are not using PrEP? | | | | | | | | | | | | | | | | | | | | | | | | |
|  | *more often* | | |  | | *less often* | | | | | | |  | | | *No change* | | | | | | |  | | |
| **9** | How well do you think your study partner has taken his / her ARVs? | | | | | | | | | | | | | | | | | | | | | | | | |
|  | *very poor* |  | *poor* | |  | | *fair* | |  | | *good* | | |  | | *Very good* | |  | | *excellent* | | | | |  |
|  | *Don’t know* | | | |  | |  | | | | | | | | | | | | | | | | | | |

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

**Forms Instruction**

The **PrEP Stop Questionnaire** CRF is completed at all follow up visits to assess whether the partner participant needs a PrEP stop due to the index participant using ARVs for at least 6 months. Contact the SMDC if there is any question about whether this CRF should be completed.

This form is not completed when study drug is withheld for other reasons (i.e., HIV seroconversion, renal toxicity, adverse event, refusal, pregnancy, breastfeeding, investigator decision, or other reasons).

**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. |
| **CRF not**  **administered** | If this form is not administered at a required visit, then it must still be faxed with the “CRF not administered” box marked. It is not necessary to line through the entire form and write “not administered.” |
| **PrEP Stop** | If the partner participant already had a PrEP Stop at a previous visit, mark this box and fax this form. |
| **Item 2a** | • If the partner participant already had a PrEP Stop at a previous visit, do not complete items 1 and 2. Instead, mark “Participant already had a PrEP Stop” at the top of the form.  • If the partner participant has a current study drug interruption (as recorded on a **PrEP Stop Questionnaire** due to HIV seroconversion, renal toxicity, adverse event, refusal, pregnancy, breastfeeding, investigator decision, or other reasons) or never initiated PrEP during the study, mark “has not taken PrEP since last quarterly visit.” Do not mark this box if the participant initiated but did not take study drug due to low adherence, missed visits, or another reason not previously recorded on a **PrEP Stop Questionnaire**.  • If the partner participant is continuing PrEP because the index participant has not been using ART for at least 6 months, mark “waiting for longer ART use by index.” |
| **Item 3** | Select “other” only if the participant gives other reasons for their PrEP stop and does not consider their partner's ART use to be a reason for stopping PrEP. |
| **Items 3-9** | These items are interviewer-administered and should be read aloud directly as written. |