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**Study Drug Adherence Visit Month**

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| Screening ID:

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

 *Site Study Screening Number* | Participant ID:

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

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

|  |  |  |  |  |  |  |  |
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|  |  |  |  |  |  |  |  |

 *dd mm yy*  |

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| --- |
| **Study Drug Adherence** *These are interviewer-administered questions and should be read aloud directly as written.* |
| **1** | When was the last time you took study pills? |

|  |  |
| --- | --- |
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| --- | --- |
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 dd mm yyyy |
| **2** | During the last month, did you take the tablet every day? | **yes** | **no** | ***If yes, go to item 3.*** |
| **2a** | How many days did you miss to take a study tablet? |  |
| **2b** | What is the most number of days in a row that you did not take a study tablet? |  |
| **3** | Please tell me how well you have taken your study tablets as directed since the last visit. | **Very poor** | **poor** | **fair** | **good** | **Very good** | **Excellent** |
|  |  |  |  |  |  |
| **4** | In general, how often do you take your study tablets? | **None of the time** | **A little of the time** | **Some of the time** | **A good bit of the time** | **Most of the time** | **All of the time** |
|  |  |  |  |  |  |
| **5** | During the past month, what has helped you to remember to take your tablets? *Mark all that apply.* |
| *Nothing* | *Watch/clock* | *Alarm* | *Pill box* | *Study partner/family members* | *Radio* | *Associates it with daily activity* |
|  |  |  |  |  |  |  |
|  | *Other, specify* |
| **6** | During the past month, what caused you to not take your tablets? *Mark all that apply* ***OR*** | **NA** |
|  | *Forgot* |  | *alcohol use* |  | *Change in routine* |  | *prefer to take just before**or after sex* |  |
|  | *Illness* |  | *Not having sex* |  | *lost tablets* |  | *missed a visit and had no tablets* |  |
|  | *Do not have food* |  | *Traveled* |  | *Confidentiality/stigma* |  | *shared tablets with someone else* |  |
|  | *Tablet stolen* |  | *thought tablets caused side effects* |  | *Others*  |
| **7** | Did you decide ***not*** to have sex because you did ***not*** take your study tablets that day? | *Yes*  | *No*  | *Missed no tablet* |
| **8** | For a variety of reasons, other persons may want to use your study medication. Do you think that someone other than you has used any of your study tablets? | *Yes*  | *No*  | *Not sure* | *If no, end of form.* |
| **a** | Do you think your study partner has used any of your tablets? | *Yes*  | *No*  | *Not sure* |  |
| **b** | Do you think someone else has used any of your study tablets? | *Yes*  | *No*  | *Not sure* | *If no or not sure, go to item 8c* |
| **bi** | Who? |  | ***Don’t know*** |
| **c** | Estimate how many tablets were used by someone other than you: |  | ***Don’t know*** |

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

**Forms Instruction**

The **Study Drug Adherence** CRF should be completed at each follow-up visit to assess adherence to study drug for index and partner participants. These questions should be answered about the last month. If the participant is not on study drug, then this form must still be faxed with the “CRF not administered” box on the top right hand corner of the form marked.

This entire CRF is interviewer-administered. If a participant does not fully understand a question when it is first read, the interviewer may clarify with additional prompting statements. This form should be administered at a separate time from the pill count. To get the most honest answers, this form should be administered to the participant without his or her study partner 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. |
| **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.” |
| **Introduction** | Please read the following aloud before asking questions: *Many people find it difficult to always take all of their tablets. Some people become busy and forget to carry their tablets with them. It is important for the study that we understand how participants are really doing with taking their study tablets.* |
| **“In the past****month”****“In the last****month”** |  “In the past month” or “In the last month” refers to behavior occurring during the four week period immediately before the current visit. |
| **Item 1** | Prompt the participant to try to estimate the approximate time the last study medication was taken. If participant cannot recall the time (or date, or both), write “don't know” next to the boxes. |
| **Items 3 & 4** | Mark the appropriate box. We want the participant’s opinion, regardless of how it compares with any other adherence data. Read the answers aloud as written. |
| **Items 5 & 6** | Read the questions aloud as written. Do not read the categories aloud. Mark appropriate boxes based on discussion with participant.• Indexes may use pill boxes as reminder tools.• Partners should not take multiple pills out of the special medication bottle, so that the MEMS cap can record adherence.• The response “did not have food” refers to the perception that they could not take their pills because they did not have food. *Of note, there is no requirement that these pills be taken with food.*• Similarly, “alcohol use” refers to the perception that the participant could not take the pill because of alcohol use, or because use of alcohol impeded their ability to remember to take their medication. *Of note, alcohol use does not preclude the participant from taking their study drug.* |
| **Item 7** | Mark the appropriate box. We want to know if the decision ***not*** to have sex was influenced by ***not*** taking the study tablet. Other factors should not be considered. |
| **Items 8-8c** | These questions should be answered about the last month. |
| **Item 8bi** | Indicate the relationship to the study participant (e.g., sister) rather than a name of a specific person (e.g., Mary). |