ADHERENCE BARRIERS QUESTIONNAIRE

NIAID AIDS CLINICAL TRIALS GROUP

Patient Number [ ][ ][ ][ ][ ][ ][ ][ ] Date of Patient Visit/Contact [ ][ ][ ] mmm [ ][ ] dd [ ][ ][ ][ ] yyyy

Protocol Number A 0 0 0 0 [ ] Institution Code [ ][ ][ ][ ][ ][ ]

Form Week [ ][ ][ ][ ] * Seq. No. [ ][ ] ** Step No. [ ][ ] Key Operator Code [ ][ ][ ]

* Enter a '1' if this is the first of this form for this date. Designate subsequent forms on the same date with a 2, 3, etc.
** Enter the subject's current study step number. Enter '1' if the study does not have multiple steps.

FOR OFFICE USE ONLY - TEAR OFF SHEET

INSTRUCTIONS TO THE STUDY NURSE:

The ADHERENCE BARRIERS QUESTIONNAIRE should be given to the study participant prior to the clinical exam and preferably in a quiet secluded area (for example, exam room or other office). This questionnaire is designed for study participants who can read at the sixth-grade level; participants who have difficulty reading may need additional assistance.

It is important to be familiar with the content and format of the questionnaire before giving it to study participants. At the first visit, please begin by telling the participant:

> "We are trying to understand better what factors make it easier or harder for you to take your anti-HIV medications. Please answer all questions honestly; you will not be 'judged' based on your responses. If you do not wish to answer a question, please draw a line through it. Please feel free to ask if you need any of the questions explained to you."

You should then briefly go over the format of the questions and how to complete them. Have the study participant complete the questionnaire before vital signs, history, and physical are completed. The questionnaire is very brief and should take no more than 5 minutes to complete. Before giving the study participant the questionnaire, please fill out the header(s) and DETACH THIS PAGE from the rest of the form.

Each question is in the same general format and contains several items. Note that the study participant is always asked to make a check (✓) in the box for each question where there are check boxes.

For data keying, if the study participant did not answer a question, enter "-1." Do not leave any fields blank.

PLEASE COMPLETE THE FOLLOWING ITEMS AFTER THE PARTICIPANT COMPLETES THE QUESTIONNAIRE OR AFTER YOU ASCERTAIN THAT THIS IS NOT POSSIBLE:

1. How was the questionnaire completed? …… [ ]
   If "4- Not completed", complete 'a' and Stop.
   1-Self administered by the study participant
   2-Face-to-face interview
   3-Both self-administered and interview
   4-Not completed
   9-Other, specify

   If Other, specify [70]: _____

   a. If **"4-Not completed"**, indicate the reason and stop: [ ]
      1-Participant declined
      2-There was not enough time
      9-Other reason, specify

      If Other, specify [70]: _____

2. Enter the country code for the location of the clinic and the language used to complete the form. Refer to Appendix 80 for Country and Language Codes.

   Country: [ ][ ] **Language:** [ ][ ]

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Patient Number ☐☐☐ ☐☐☐☐ ☐ Date of Patient Visit/Contact ☐☐☐ mmm ☐☐ dd ☐☐☐☐ yyyy

Protocol Number **A 0 0 0 0** ☐ Institution Code ☐☐☐☐☐☐

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Please check one box for each question where there are check boxes. If you do not wish to answer a question, please draw a line through it.

1. How sure are you that:

Please check one box for each question.	**Not at all sure**	**Somewhat sure**	**Very sure**	**Extremely sure**
a. You will be able to take all or most of your anti-HIV medication as directed? ……..	☐ 0	☐ 1	☐ 2	☐ 3
b. The anti-HIV medication will have a positive effect on your health? ……	☐ 0	☐ 1	☐ 2	☐ 3
c. If you do not take your anti-HIV medication exactly as directed, the HIV in your body will become resistant to this medication? ..	☐ 0	☐ 1	☐ 2	☐ 3

People may miss taking their anti-HIV medications for various reasons. Here is a list of possible reasons why you may have missed taking your anti-HIV medications.
If you have <u>never</u> taken anti-HIV medications, STOP.

2. During the last month, have you been prescribed any anti-HIV medications? …… ☐ Yes (1) ☐ No (2) → **STOP.**

↓

Continue with questions.

Please check one box for each question.

In the past month, how often have you **missed taking your medications** because:

	Never	**Rarely**	**Sometimes**	**Often**
a. You wanted to avoid side effects? ……	☐ 0	☐ 1	☐ 2	☐ 3
b. Of sharing anti-HIV medications with other family members and friends? ……	☐ 0	☐ 1	☐ 2	☐ 3
c. Of religious beliefs? ……	☐ 0	☐ 1	☐ 2	☐ 3
d. Of not fully understanding the anti-HIV medications and their requirements? ……	☐ 0	☐ 1	☐ 2	☐ 3
e. Of traveling away from home (for example to work, family, friends)? ……	☐ 0	☐ 1	☐ 2	☐ 3
f. Of transportation problems getting to the clinic? ……	☐ 0	☐ 1	☐ 2	☐ 3

Pt. No.[ ][ ][ ][ ][ ][ ][ ][ ] *Seq. No.[ ][ ] **Step No.[ ][ ] Date[ ][ ][ ] [ ][ ] [ ][ ][ ][ ]
mmm dd yyyy

2. Continued

	Never	Rarely	Sometimes	Often
g. Of lost or stolen pills (for example, while in transit in a taxi/bus/train/car)? ……..	☐ 0	☐ 1	☐ 2	☐ 3
h. You had too many pills? ……	☐ 0	☐ 1	☐ 2	☐ 3
i. You had a bad event happen that you felt was related to taking the pills? ……	☐ 0	☐ 1	☐ 2	☐ 3
j. You forgot? ……..	☐ 0	☐ 1	☐ 2	☐ 3
k. You ran out of pills? ……	☐ 0	☐ 1	☐ 2	☐ 3
l. You were busy doing other things (for example, working, trying to survive, getting food)? ……	☐ 0	☐ 1	☐ 2	☐ 3
m. Of not having enough food to eat (for example, to take with your pills)? ……	☐ 0	☐ 1	☐ 2	☐ 3
n. Of concern that anti-HIV medications would work so well that you would lose public financial support? ……	☐ 0	☐ 1	☐ 2	☐ 3
o. Of fear of stigmatization or being discriminated against outside the home (for example, what others may say)?	☐ 0	☐ 1	☐ 2	☐ 3
p. Of fear of stigmatization or being discriminated against within the home (for example, not wanting husband, wife, partner to know)? ……..	☐ 0	☐ 1	☐ 2	☐ 3
q. You felt the anti-HIV medications were toxic or harmful? ……	☐ 0	☐ 1	☐ 2	☐ 3
r. Your pills got damaged by heat or getting wet? ……	☐ 0	☐ 1	☐ 2	☐ 3
s. You were too ill to attend clinic visits to collect medications? ……	☐ 0	☐ 1	☐ 2	☐ 3
t. You felt depressed or overwhelmed? ……..	☐ 0	☐ 1	☐ 2	☐ 3
u. You didn't think they would really work? …….	☐ 0	☐ 1	☐ 2	☐ 3
v. You were bothered by your dreams? ……..	☐ 0	☐ 1	☐ 2	☐ 3
w. Other reason? Please specify below. ……..	☐ 0	☐ 1	☐ 2	☐ 3

Specify [70]: _____

Thank you very much for completing this questionnaire.

Date Form Keyed (DO NOT KEY): _____ / _____ / _____