ACTG BASELINE ADHERENCE QUESTIONNAIRE II

NIAID ADULT AIDS CLINICAL TRIALS GROUP

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

Protocol Number [ ][ ][ ][ ][ ][ ] 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 BASELINE ADHERENCE QUESTIONNAIRE II SHOULD BE GIVEN TO THE SUBJECT PRIOR TO THE CLINICAL EXAM. The subject must be able to read at the sixth-grade level at a minimum to complete the questionnaire without 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:

- The purpose of this form is to learn about potential influences of treatment adherence.
- 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.
- When completed, the form will be quickly reviewed to make sure you didn't mistakenly skip questions (without crossing them out); your specific responses to questions will not be reviewed.
- 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. The questionnaire is very brief and should take no more than 10 minutes to complete. Before giving the subject the questionnaire, please fill out the header(s) and DETACH THIS PAGE.

Each question is in the same general format and contains several items. Note that the subject is always asked to make a "✓" next to the appropriate category.

Collect the completed questionnaire before the clinical exam. Before going on, review the questionnaire for omissions. If the participant missed any of the questions, point this out and encourage him/her to complete the omissions.

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

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

1. How was the questionnaire completed? ..... [ ]
   1-Self administered by the study participant
   2-Face-to-face interview that you conducted
   3-Both self-administered and interview
   4-Not completed
   9-Other, specify

   If Other, specify [30]: _____

   a. If you answered "4-Not completed," please indicate the reason why : [ ]
      1-Subject refused
      2-Subject missed clinic visit
      3-There was not enough time
      9-Other reason, specify

   If Other, specify [30]: _____

ACTG BASELINE ADHERENCE QUESTIONNAIRE II

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The answers you give on this form will be used to plan ways to help other people who must take pills on a difficult schedule. Please do the best you can to answer all the questions. If you do not wish to answer a question, please draw a line through it. If you do not know how to answer a question, ask your study nurse to help. Thank you for helping in this important study.

INSTRUCTIONS: Please answer the following questions by placing a "✓" in the appropriate box.

A. How sure are you that:

(Check one)

Please check one box for each question.

	Not At All Sure	Somewhat Sure	Very Sure	Extremely Sure
1. You will be able to take all or most of the study medication as directed?	☐ 0	☐ 1	☐ 2	☐ 3
2. The medication will have a positive effect on your health?	☐ 0	☐ 1	☐ 2	☐ 3
3. If you do not take this study medication exactly as instructed, the HIV in your body will become resistant to HIV medications?	☐ 0	☐ 1	☐ 2	☐ 3

B. The following questions ask about your social support.

(Check one)

Please check one box for each question.

	Very Dissatisfied	Somewhat Dissatisfied	Somewhat Satisfied	Very Satisfied
1. In general, how satisfied are you with the overall support you get from your friends and family members?	☐ 0	☐ 1	☐ 2	☐ 3

	Not At All	A Little	Somewhat	A lot	Not Applicable
2. To what extent do your friends or family members help you remember to take your medication?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

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C. People may miss taking their medications for various reasons. Here is a list of possible reasons why you may have missed taking any medications within the **past month.**

If you have **NOT** taken **any** medications within the **past month**, please check this box and skip to Section D: ..... ☐ 1

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

(Check one)

Please check one box for each question.	**Never**	**Rarely**	**Some-Times**	**Often**
1. Were away from home?	☐ 0	☐ 1	☐ 2	☐ 3
2. Were busy with other things?	☐ 0	☐ 1	☐ 2	☐ 3
3. Simply forgot?	☐ 0	☐ 1	☐ 2	☐ 3
4. Had too many pills to take?	☐ 0	☐ 1	☐ 2	☐ 3
5. Wanted to avoid side effects?	☐ 0	☐ 1	☐ 2	☐ 3
6. Did not want others to notice you taking medication?	☐ 0	☐ 1	☐ 2	☐ 3
7. Had a change in daily routine?	☐ 0	☐ 1	☐ 2	☐ 3
8. Felt like the drug was toxic/harmful?	☐ 0	☐ 1	☐ 2	☐ 3
9. Fell asleep/slept through dose time?	☐ 0	☐ 1	☐ 2	☐ 3
10. Felt sick or ill?	☐ 0	☐ 1	☐ 2	☐ 3
11. Felt depressed/overwhelmed?	☐ 0	☐ 1	☐ 2	☐ 3
12. Had problem taking pills at specified times (with meals, on empty stomach, etc.)?	☐ 0	☐ 1	☐ 2	☐ 3
13. Ran out of pills?	☐ 0	☐ 1	☐ 2	☐ 3
14. Felt good?	☐ 0	☐ 1	☐ 2	☐ 3

D. When was the last time you missed taking any of your medications?

(Check one box)

Within the past week	5 ☐
1-2 weeks ago	4 ☐
2-4 weeks ago	3 ☐
1-3 months ago	2 ☐
More than 3 months ago	1 ☐
Never skip medications or not applicable	0 ☐

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E. In the **past week** how often did you:
Please check one box for each question.

	Never/ Rarely	Sometimes	Often	*(Check one)* Mostly or Always
1. Feel like you couldn't shake off the blues even with help from your family or friends?	☐ 0	☐ 1	☐ 2	☐ 3
2. Have trouble keeping your mind on what you were doing?	☐ 0	☐ 1	☐ 2	☐ 3
3. Feel that everything you did was an effort?	☐ 0	☐ 1	☐ 2	☐ 3
4. Have trouble sleeping?	☐ 0	☐ 1	☐ 2	☐ 3
5. Feel lonely?	☐ 0	☐ 1	☐ 2	☐ 3
6. Feel sad?	☐ 0	☐ 1	☐ 2	☐ 3
7. Feel like you just couldn't "get going"?	☐ 0	☐ 1	☐ 2	☐ 3

F. In the **past month**, how often have you:
Please check one box for each question.

	Never	Almost Never	Some-times	Fairly Often	*(Check one)* Very Often
1. Been upset because of something that happened unexpectedly?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
2. Felt unable to control the important things in your life?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
3. Felt nervous and "stressed"?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
4. Felt confident in your ability to handle your personal problems?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
5. Felt that things were going your way?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
6. Found that you could not cope with all the things that you had to do?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
7. Been able to control irritations in your life?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
8. Felt that you were on top of things?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
9. Been angered because of things that happened that were outside of your control?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
10. Felt problems were piling up so high that you could not overcome them?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

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G. People have various health habits. The following questions ask about your alcohol and drug use, past and current.

1. How often have you had a drink containing alcohol - a glass of beer, wine, a mixed drink, or any kind of alcoholic beverage - in the last 30 days? ***(Check one)***

Daily	Nearly Every Day	3 or 4 Times A Week	Once or Twice A Week	2 or 3 Times A Month	Once A Month	Never
☐ 6	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1	☐ 0

If Never, skip ahead to question 4.

2. On days when you drank any alcoholic beverages, in the last 30 days, how many drinks did you usually have altogether? By a drink, we mean a can or glass of beer, a 4-ounce glass of wine, a 1½ ounce shot of liquor, or a mixed drink with 1½ ounces of liquor. ***(Check one)***

1 or 2 Drinks Per Day	3 or 4 Drinks Per Day	5 or 6 Drinks Per Day	7 or 8 Drinks Per Day	9 - 11 Drinks Per Day	12 or More Drinks Per Day
☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

3. During the past 30 days, how often have you had 5 or more drinks of alcohol in a row, that is, within a couple of hours (e.g., 2-4 hours)? ***(Check one)***

Daily	Nearly Every Day	3 or 4 Times A Week	Once or Twice A Week	2 or 3 Times A Month	Once A Month	Never
☐ 6	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1	☐ 0

4. Please check "Yes" or "No" for each question:

a. ☐ Yes (1) ☐ No (2) Have you ever used marijuana?
If you used this drug, have you used it within the past 6 months?
☐ Yes (1) ☐ No (2)

b. ☐ Yes (1) ☐ No (2) Have you ever used cocaine (powder, crack, freebase)?
If you used this drug, have you used it within the past 6 months?
☐ Yes (1) ☐ No (2)

c. ☐ Yes (1) ☐ No (2) Have you ever used heroin?
If you used this drug, have you used it within the past 6 months?
☐ Yes (1) ☐ No (2)

d. ☐ Yes (1) ☐ No (2) Have you ever used amphetamines (speed)?
If you used this drug, have you used it within the past 6 months?
☐ Yes (1) ☐ No (2)

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5. Are you **currently** in methadone treatment? ..... ☐ Yes 1 ☐ No 2
   If Yes, skip to Question H.
   If No, have you **ever** been in methadone treatment? ..... ☐ Yes 1 ☐ No 2

H. These last questions ask about your background.

1. What is the highest level of education you have completed? ***(Check one box)***

11th grade or less	0 ☐
High school graduate or GED	1 ☐
2 years of college/AA degree/Technical school training	2 ☐
College graduate (BA or BS)	3 ☐
Master's degree	4 ☐
Doctorate/medical degree/law degree	5 ☐

2. What is (are) the most likely way(s) that you became infected with HIV?
   (Check "Yes" or "No" for each question.)

	Yes	No
a. Sex with a man who was HIV+	1 ☐	2 ☐
b. Sex with a woman who was HIV+	1 ☐	2 ☐
c. Shared needles with a person who was HIV+	1 ☐	2 ☐
d. Blood transfusion or other medical procedure	1 ☐	2 ☐
e. Don't know	1 ☐	2 ☐
f. Other (needle stick at work, etc.)	1 ☐	2 ☐

   If Other, please specify: _____

3. Do you work for pay outside the home? ☐ Yes 1 ☐ No 2

4. Do you have any children? ☐ Yes 1 ☐ No 2
   If Yes, how many live with you? ..... ☐

Thank you very much for completing these questions.
The information that you provided will help with the development of better drug regimens for all subjects with HIV.

Language: English E

01-19-98/04-16-99/01-19-01

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