

ACTG ADHERENCE FOLLOW-UP QUESTIONNAIRE

NIAID ADULT AIDS CLINICAL TRIALS GROUP

Page 1 of 5

Patient Number	<input type="text"/>	<input type="text"/>	<input type="text"/>	Date of Patient Visit	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
					mmm	dd	yyyy		
Protocol Number	<input type="text"/>	<input type="text"/>	<input type="text"/>	Institution Code	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Form Week	<input type="text"/>	*Seq No.	<input type="text"/>	**Step No.	<input type="text"/>	Key Operator Code	<input type="text"/>	<input type="text"/>	<input type="text"/>

* 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 PERSONNEL:

The ACTG ADHERENCE FOLLOW-UP QUESTIONNAIRE 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.

For question "A," review with the subject what treatment they are receiving and complete the worksheet together. 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 5 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. Drug names and abbreviations of the most common anti-HIV drugs and of any other study drugs have been included on the worksheet for reference and use.

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]: _____



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mmm dd yyyy

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.

SUBJECT ONLY continue here.

The next section of the questionnaire asks about your study medications that you took over the last four days. Drug codes and abbreviations of the possible study medications have been included for your reference and use on page 2.



Most people with HIV have many pills to take at different times during the day. Many people find it hard to always remember their pills:

- Some people get busy and forget to carry their pills with them.
- Some people find it hard to take their pills according to all the instructions, such as “with meals” or “on an empty stomach,” “every 8 hours,” “with plenty of fluids.”
- Some people decide to skip pills to avoid side effects or to just not be taking pills that day.

We need to understand how people with HIV are really doing with their pills. Please tell us what you are **actually** doing. Don't worry about telling us that you don't take all your pills. We need to know what is really happening, not what you think we “want to hear.”

1. The next section of the questionnaire asks about the study medications that you may have **missed** taking over the last four days. Please complete the table below, using one line for each study medication you are taking, and using the abbreviations on the previous page. If you did not miss any doses, write a zero (0) in the box. Note that the table asks about **DOSES**, not **PILLS**.

IF YOU TOOK ONLY A PORTION OF A DOSE ON ONE OR MORE OF THESE DAYS, PLEASE REPORT THE DOSE(S) AS BEING MISSED.

Step 1 Abbreviations/Names of your study drugs	HOW MANY DOSES DID YOU <u>MISSE</u> ...			
	Step 2 Yesterday	Step 3 Day before yesterday (2 days ago)	Step 4 3 days ago	Step 5 4 days ago
<hr/>	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses
<hr/>	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses
<hr/>	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses
<hr/>	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses
<hr/>	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses
<hr/>	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses
<hr/>	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses



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The following questions pertain to the study regimen on page 2.

If you took only a **portion** of a dose on one or more of these days, please report the dose(s) as being **missed**.

B. During the past 4 days, on **how many days** have you missed taking **all your doses**?

(Check one box)

- None 0
- One day 1
- Two days 2
- Three days 3
- Four days 4

C. Most study medications need to be taken on a schedule, such as "2 times a day" or "3 times a day" or "every 8 hours." How closely did you follow your specific schedule over the last four days?

- | | | | | | |
|--|--|--|--|---|--------------------------|
| Never
<input type="checkbox"/>
0 | Some Of
The Time
<input type="checkbox"/>
1 | About Half
Of The Time
<input type="checkbox"/>
2 | Most Of
The Time
<input type="checkbox"/>
3 | All Of
The Time
<input type="checkbox"/>
4 | <input type="checkbox"/> |
|--|--|--|--|---|--------------------------|

D. Do any of your study medications have special instructions, such as "take with food" or "on an empty stomach" or "with plenty of fluids"?

- Yes No

If Yes, how often did you follow those special instructions over the last four days?

- | | | | | | |
|--|--|--|--|---|--------------------------|
| Never
<input type="checkbox"/>
0 | Some Of
The Time
<input type="checkbox"/>
1 | About Half
Of The Time
<input type="checkbox"/>
2 | Most Of
The Time
<input type="checkbox"/>
3 | All Of
The Time
<input type="checkbox"/>
4 | <input type="checkbox"/> |
|--|--|--|--|---|--------------------------|

E. Some people find that they forget to take their pills on the weekend days. Did you miss any of your study medications last weekend - last Saturday or Sunday?

- Yes No

F. When was the last time you missed 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 0

If you **Never** miss your study medications, please STOP.
 Otherwise, please continue by answering the next set of questions.



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G. People may miss taking their study medications for various reasons. Here is a list of possible reasons why you may miss taking your medications. How often have you missed taking your study medications because you: **(Check one)**

Please check one box for each question.

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

**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

