

# ACTG ADHERENCE SELF REPORT

NIAID AIDS CLINICAL TRIALS GROUP

Patient Number	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <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"/>	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
			mmm	dd	yyyy
Protocol Number	<input type="text" value="A"/> <input type="text" value="0"/> <input type="text" value="0"/> <input type="text" value="0"/> <input type="text" value="0"/> <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"/> <input type="text"/> <input type="text"/> <input type="text"/>	* Seq. No.	<input type="text"/> <input type="text"/>	** Step No.	<input type="text"/> <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 NURSE:

The ACTG ADHERENCE SELF REPORT should be given to the study participant prior to the clinical exam and preferably in a quiet secluded area (e.g., exam room or other office). The study participant 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 study participant:

“We would like you to answer some questions about your medication. Your answers will help us understand the effects of the medication you are taking. We appreciate your filling out this questionnaire.”

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 10 minutes to complete. Before giving the study participant the questionnaire, please fill out the header(s) and DETACH THIS PAGE.

Each question is in the same general format and contains several items. Drug names and abbreviations of the **anti-HIV medications for Protocol A0000** have been included on page 3 for reference and use.

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 STUDY 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 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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**INSTRUCTIONS:** Please answer the following questions about the study medication(s) you are taking.

- Are you currently expected to be taking any medications?  
**For Protocol A0000: Medication refers to [study medication].**

**(Check One)**

Yes     No  
 1                      2

**If No, STOP.**  
**If Yes, continue.**

- When people have many pills to take at different times during the day, it may be hard to always remember to take 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 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.”

Please complete the table on page 3 to tell us about the **[study medication]** medications that you may have **missed** taking over the last four days. Use one line for each study medication you are prescribed to be taking. The drug names are provided in the chart on the bottom of the page.

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mmm dd yyyy

**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.**

Abbreviation/Name Of Your Drugs [70]	Number of Prescribed Doses Per Day	HOW MANY DOSES DID YOU MISS...			
		Yesterday	Day before yesterday (2 days ago)	3 days ago	4 days ago
a. _____	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses
b. _____	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses
c. _____	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses
d. _____	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses
e. _____	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses
f. _____	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses
g. _____	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses
h. _____	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses
i. _____	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses
j. _____	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses

**Anti-HIV Drugs**

**Insert latest template here.**

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Pt. No.        \*Seq. No.   \*\*Step No.   Date        
mmm dd yyyy

**INSTRUCTIONS:** Place a “✓” in the appropriate box. Please check one box for each question.

**For Protocol A000: Medication refers to [study medication].**

3. Most 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?

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

4. Do any of your medications have special instructions, such as “take with food” or “on an empty stomach” or “with plenty of fluids”?

**Yes**       **No**  
1      2

**If No,** go to question 5.

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

a. 

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

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

**(Check one box)**

Within the past week	5	<input type="checkbox"/>
1-2 weeks ago	4	<input type="checkbox"/>
3-4 weeks ago	3	<input type="checkbox"/>
About 1-3 months ago	2	<input type="checkbox"/>
More than 3 months ago	1	<input type="checkbox"/>
Never skip medications	0	<input type="checkbox"/>