

ADOLESCENT ADHERENCE QUESTIONNAIRE

NIAID AIDS CLINICAL TRIALS GROUP

Patient Number	<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"/>
					mmm	dd	yyyy		
Protocol Number	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	<input type="text" value="0"/>	Institution Code	<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"/>	<input type="text"/>	Key Operator Code	<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.

The **purpose** of this questionnaire is to collect data which will quantify the proportion of prescribed antiretroviral therapy actually taken within the last 3 days in order to examine drug effect during the analysis phase of a study protocol. In order to have confidence in the data that will be collected with this instrument, the **process** through which these data are collected has been **standardized**. Please read and observe the following directions.

QUESTIONS 1-7 INSTRUCTIONS:

Who administers? Any member of the professional clinical care or research team who has experience filling out other ACTG study forms.

Who is questioned? The research study participant, if the study participant has assumed responsibility for his/her own drug regimen OR the study participant's primary caregiver (the person responsible for administering the prescribed drugs at home). If the appropriate respondent is the primary caregiver and she/he is not present for a particular study visit when this form is scheduled, the form should be marked as such (below) and the assessment omitted.

How is the questionnaire administered? The questionnaire has very specific introductory comments (and prompts) which should be read as stated, item after item, until the assessment is completed. No interruptions for study participant education should occur; any necessary or additional education or counseling should take place **after** the questionnaire is completed.

The accuracy of self report is very good if the attitude of the interviewer is non-judgemental and supportive. The form has introductory statements to set this tone. However, since information about erratic adherence may be elicited by the survey, what interaction happens after the questionnaire is completed is critically important. The attitude of the clinical response, the manner in which information is subsequently corrected, and the nature of behavioral counseling will **absolutely** influence future validity. It is imperative that clinical teams review the characteristics of therapeutic relationships and strive to adopt these practices in promoting drug adherence in study participants.

QUESTIONS 8-10 INSTRUCTIONS:

These questions capture the general reasons for non-adherence linked to each drug taken. In this step, the interviewer will collect information on reasons why the study participant may be having difficulty taking each agent.

This form should be completed for study participants >13 years of age. For study participants < 13 years of age, complete the PEDIATRIC DOMESTIC ADHERENCE QUESTIONNAIRE form (QL5005).

If the study participant has assumed sole responsibility for his/her own drug regimen, the study participant should complete this form.

If the primary caregiver is solely responsible for distributing the medications to the study participant, the primary caregiver should complete this form.

If the responsibility is shared, the study participant and the caregiver should jointly complete this form.

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QUESTIONS 1 - 6 ARE TO BE COMPLETED BY THE STUDY NURSE:

1. Was the questionnaire completed at this visit?(1-Yes, 2-No)
If Yes, go to question 2.
If No, complete 'a' and STOP.
- a. Indicate the reason the questionnaire was not completed:
 1-Study participant refused
 2-Primary caregiver refused
 3-Study participant missed clinic visit
 4-There was not enough time
 5-Primary caregiver not available
 9-Other reason, specify

If Other reason, specify [30]: _____

2. Who responded to the questions?.....
 11-Primary caregiver
 12-Study participant
 13-Study participant and primary caregiver jointly
 14-Study participant and other individual
 15-Biological mother
 16-Biological father
 17-Other relative, specify
 18-Adoptive parent, specify
 19-Foster parent, specify
 99-Other, specify

If '17', '18', '19' or '99', specify [30]: _____

3. Does the study participant know his/her HIV status?
 1-Yes
 2-No
 3-Information not available/not known

4. Was the study participant perinatally infected?
 1-Yes
 2-No
 3-Information not available/not known

5. Who is responsible for administering the medications? ...
 1-Primary caregiver solely responsible
 2-Study participant solely responsible
 3-Study participant and primary caregiver jointly
 4-Study participant and other individual
 9-Other, specify

If Other, specify [30]: _____

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6. Since the last visit, did the study participant or primary caregiver utilize any of the following aids for improving adherence? (1-Yes, 2-No)

If No, go to question 7.
If Yes, answer 'Yes', 'No' or 'Not known' to each of the following and continue.

(1-Yes, 2-No, 3-Not known)

- a. Labels:
- b. Calendars:
- c. Pill boxes:
- d. Beepers:
- e. Monitoring caps (MEMS):
- f. Timers:
- g. Programmable wrist watches:
- h. Diary:
- i. "Buddy system":
- j. PEG/gastrostomy tube:.....
- k. Activity of daily living triggers, specify:
 Specify[30]: _____
- l. Other, specify:
 Specify[30]: _____

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INSTRUCTIONS FOR COMPLETION OF MEDICATION TABLE

- **Columns A-D:** Prior to the study visit, the study nurse should fill in the information in these columns **for which adherence information is being collected as specified by the protocol.**
- **Column A:** List the drug name (if known, or, if double-blinded study, record as marked on bottle).
- **Column B:** List the eight-digit drug code for the drug listed in Column A. Refer to the last page for the list of most commonly used anti-HIV medications. Refer to Appendix 3 or the Drug Code Lookup Program at the DMC Portal (<http://www.fstrf.org>) for any medications not listed.
- **Column C:** List the drug color, type (blue pill, pink liquid, etc.) and note any special identifying labels.
- **Column D:** List the expected number of **doses** per 24-hour period. This refers to the **schedule** (e.g. 3 times per day, 4 times per day) and **not** the number of pills. Particulars of the schedule will not be addressed (e.g. TID and q8 hr. would both be recorded as 3 times per day).
- **Columns E-I:** This information is to be obtained from the study participant or primary caregiver in the subsequent interview. Refer to “Scripts for Adolescent Adherence Questionnaire” for completing the Medication Table. This document is located in the Forms Instruction section of the CRF Notebook.

7. MEDICATION LIST TABLE: Do not key column C.

¹ Identification Codes

- 1-Volunteered without prompt
- 2-Volunteered with prompt
- 3-Acknowledged when reminded
- 4-Did not acknowledge

² Doses Missed

- Enter “-1” if study participant/primary caregiver isn’t sure if study participant missed any doses.
- Enter “0” if no doses were missed.

Complete Prior to Visit				Complete During Interview				
A	B	C	D	E	F	G	H	I
Drug Name(s) [30]	Drug Code [8]	(DO NOT KEY)	Expected # Doses	ID Code ¹	Reported # Doses	Doses Missed ²		
		Drug Color, Type and Labels				Yesterday	2 days ago	3 days ago
a.			<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
b.			<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
c.			<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
d.			<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
e.			<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
f.			<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
g.			<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
h.			<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

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8. Since the last visit, when was the last time you/your child missed a dose of any of these medications?
- At Entry: When was the last time you/your child missed a dose of any of these medications?**
- If '2'-'5', read instructions below and go to question 10.
 If '1', continue.
- 1-Never
 - 2-During the previous 2 weeks
 - 3-During the last month
 - 4-Over a month ago
 - 5-Don't remember

INSTRUCTIONS FOR COMPLETION OF DRUG SPECIFIC TABLE:

Enter the drug code name of each antiretroviral drug that the study participant is receiving in the space provided at the top of each column. Refer to the chart below for the list of most commonly used anti-HIV medications. Refer to Appendix 3 or the Drug Code Lookup Program at the DMC Portal (<http://www.fstrf.org>) for any medications not listed.

Identification of Reasons for Non-Adherence:

READ the following paragraph to the study participant or primary caregiver:

"Many people at one time or another have trouble with these medications. We would like to better understand the things that make giving medications hard for families. These are some of the reasons others have identified which have made it difficult to take [give] all of the HIV medicines."

Show and read the list of reasons to the study participant or primary caregiver.

After the list is read, ask the following question for each medication:

9. Since the last visit, have any of the reasons read to you been a problem or caused a situation that make it hard to take or to give your child every dose of _____ (medication name or characteristics) every day? (1-Yes, 2-No)
- (Refer to the chart in question 10 for a list of possible problems.)

At Entry: Are there any problems or situations that make it hard to take or to give your child every dose of medication every day?

If No, STOP.
 If Yes, continue.

If "Yes," enter the frequency code listed in question 10 for each reason.

If "No," go to the next drug.

For data entry, use the tab key after the last entry on the page.

DRUG CODE REFERENCE
Anti-HIV Drugs
Insert current drug list here.

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DRUG SPECIFIC ADHERENCE DIFFICULTIES:

Enter Drug Code and Name (Refer to page 5 for drug codes): DO NOT KEY DRUG NAME	Drug Code [8]:	Drug Code [8]:	Drug Code [8]:	Drug Code [8]:	Drug Code [8]:
	Drug #1 Name [30]:	Drug #2 Name [30]:	Drug #3 Name [30]:	Drug #4 Name [30]:	Drug #5 Name [30]:
10. Has there been a problem identified with this drug since the last visit? (1-Yes, 2-No)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

FOR QUESTIONS 10a - 10u: Indicate the frequency with which each listed reason for non-adherence occurs. This needs to be done for each antiretroviral drug the study participant is taking. Use the following codes:

Frequency Codes:

- | | |
|---|--|
| 0-Never a problem | 2-Frequent problem (1-2 times per week) |
| 1-Hardly ever a problem (1-2 times per month) | 3-Almost always a problem (≥ 3 times per week) |

a. Can't get drug at drugstore	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. Didn't get prescription refilled; ran out	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. Made me sick to my stomach; threw up; it tasted bad	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. Forgot	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. It caused me to have other physical symptoms (e.g., rash, headache)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Got in the way of daily schedule (school, work); too busy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g. Couldn't deal with it; didn't feel like taking it; needed a break	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. Change in living situation; moved	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. Worried people would find out about HIV; didn't want friends asking questions; felt embarrassed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j. Got sick with another illness; wasn't feeling well (e.g., cold, flu, stomach bug)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k. Don't think I need it any more; I can stay healthy without it	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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FOR QUESTIONS 10a - 10u: Indicate the frequency with which each listed reason for non-adherence occurs. This needs to be done for each antiretroviral drug the study participant is taking. Use the following codes:

Frequency Codes:

0-Never a problem 2-Frequent problem (1-2 times per week)
 1-Hardly ever a problem (1-2 times per month) 3-Almost always a problem (≥ 3 times per week)

Enter Drug Code and Name (Refer to page 5 for drug codes):	Drug Code [8]:	Drug Code [8]:	Drug Code [8]:	Drug Code [8]:	Drug Code [8]:
DO NOT KEY DRUG CODE OR DRUG NAME	Drug #1 Name [30]:	Drug #2 Name [30]:	Drug #3 Name [30]:	Drug #4 Name [30]:	Drug #5 Name [30]:
i. Family and/or friends don't help me remember; tell me I shouldn't take it	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
m. Nowhere to keep it at school or work	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
n. Don't understand why I have to take it	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
o. I keep getting sick even when I <u>do</u> take it	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
p. Taking it reminds me of the HIV; just want to forget about the diagnosis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
q. I don't want to talk about it	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
r. Doesn't remember/not sure if dose was taken ...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
s. Fell asleep	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
t. Away from home	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
u. Other, specify	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Specify [30]:	_____	_____	_____	_____	_____

Language: E
English