

PEDIATRIC ADHERENCE QUESTIONNAIRE MODULE 1- III

Behavior/Identification

NIAID PEDIATRIC 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="0"/> <input type="text" value="0"/> <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"/> <input type="text"/> <input type="text"/>		
Form Week	<input type="text"/> <input type="text"/> <input type="text"/>	* Seq. No.	<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.

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.

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 1 - 4 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?.....

- 1-Study participant
- 2-Biological mother
- 3-Biological father
- 4-Other relative, specify
- 5-Adoptive parent, specify
- 6-Foster parent, specify
- 9-Other, specify

If "4, 5, 6 or 9", specify [30]: _____

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

If Other, specify [30]: _____

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

If No, go to the Medication Table.

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 Page 4 for a list of the most common Anti-HIV Drugs or Appendix 3 or by using the Drug Code Lookup Program at the DMC Website (www.fstrf.org).
- **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 Pediatric Adherence Questionnaire Module 1 - Revised” for completing the Medication Table. This document is located in the Forms Instruction section of the CRF Notebook.

5. 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 isn’t sure if he/she 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	Drug Color, Type and Labels	Expected # Doses	ID Code ¹	Reported # Doses	Doses Missed ²		
						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"/> <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"/> <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"/> <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"/> <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"/> <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"/> <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"/> <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"/> <input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>

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6. When was the last time your child/you missed a dose of any of these medications?..... 1-Never
 2-During the previous 2 weeks
 3-During the last month
 4-Over a month ago
 5-Don't remember

If Never, go to question 7.
If 2, 3, 4 or 5, STOP and complete the appropriate Module 2.

7. Are there any problems or situations that make it hard to give your child/take every dose of medication every day?.....(1-Yes, 2-No)

If No, STOP.
If Yes, complete the appropriate Module 2 Adherence Questionnaire.

Language:

**Enter an 'E' in the language box if the scripts were read to the study participant in English.
 Enter an 'S' in the language box if the scripts were read to the study participant in Spanish.**

DRUG CODE REFERENCE

Drug Codes and Names for Commonly Used Drugs. Refer to Appendix 3 or the Drug Code Lookup Program at the DMC Web Site (<http://www.fstrf.org>) for drugs not listed below.

Anti-HIV Drugs			
08180407	Abacavir/ABC/Ziagen/1592U89	08180415	FTC/Emtriva/emtricitabine
08180025	Alovedine/CL-184824	08180043	Indinavir/IDV/Crixivan
08181205	Amprenavir/APV/Agenerase/141W94/VX-479	10920013	Interleukin-2/IL-2
08181214	Atazanavir/ATV/BMS-232632	08181218	Lexiva/Fosamprenavir/GW433908
08180018	Ateviridine mesylate U-87201E	08180026	Lamivudine/3TC/Epivir
08180006	Azidouridine/AzdU/azido-2',3'-dideoxyuridine	08181208	Lopinavir/Ritonavir (LPV/RTV)/Kaletra/ABT-378/r
08180021	AZT/ZDV/Zidovudine/Retrovir	08180048	Loviride/Lotrene
08180032	CD4/RST4	08181204	Nelfinavir/NFV/Viracept
08180412	Combivir (3TC/ZDV)	08180013	Nevirapine/NVP/Viramune
08180024	d4T/Stavudine/Zerit	08181203	Ritonavir/RTV/Norvir
08180052	d4T XR/Zerit XR	08181209	Saquinavir soft gel/FTV/Fortovase
08180414	DAPD/Amdoxovir/trimeric	08180030	Saquinavir/SQV/Invirase/R031-8959
08180020	ddC/Zalcitabine/HIVID	08188804	T-20/pentafuside/Enfuvirtide/ENF
08180007	ddl/Didanosine/Videx	08182002	TDF/Tenofovir/Tenofovir disoproxil fumarate/Viread
08180051	ddl EC/Didanosine EC/Videx EC	08180418	Trizivir (3TC/ABC/ZDV)
08180031	DLV/delavirdine mesylate/Rescriptor	08180421	Truvada(tenofovir disoproxil/emtricitabine)
08180804	Efavirenz/EFV/Sustiva/DMP266/Stocrin®		
08180420	Epzicom(Abacavir/lamivudine)		
08180411	Fluorouridine/935U83		