

PEDIATRIC INTERNATIONAL ADHERENCE QUESTIONNAIRE

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/Contact	<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="P"/> <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"/> <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 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 study medication 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 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-judgmental 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 - 3 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:

- 11-Study participant refused
- 12-Primary caregiver refused
- 13-Study participant missed clinic visit
- 14-There was not enough time
- 15-Primary caregiver not available
- 99-Other reason, specify

If Other, specify [30]: _____

2. Who responded to the questions?.....

- | | |
|----------------------|-------------------|
| 11-Study participant | 16-Foster mother |
| 12-Biological mother | 17-Foster father |
| 13-Biological father | 18-Stepmother |
| 14-Grandmother | 19-Stepfather |
| 15-Grandfather | 99-Other, specify |

If Other, specify [30]: _____

3. Who is responsible for administering the medications?

- 11-Primary caregiver solely responsible
- 12-Study participant solely responsible
- 13-Study participant and caregiver jointly
- 14-Study participant and other individual
- 99-Other, specify

If Other, 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 medication 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 Appendix 3 or by using the Drug Code Lookup Program at the DMC Web Site (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 International Adherence Questionnaire" for completing the Medication Table. This document is located in the Forms Instruction section of the CRF Notebook.

4. MEDICATION LIST TABLE: **Do not key Column C.**

¹ Identification Codes	² Doses Missed
1-Volunteered without prompt	Enter "-1" if study participant isn't sure if he/she missed any doses. Enter "0" if no doses were missed.
2-Volunteered with prompt	
3-Acknowledged when reminded	
4-Did not acknowledge	

Complete Prior to Visit				Complete During Interview				
A	B	C	D	E	F	Doses Missed ²		
Drug Name(s) [30]:	Drug Code [8]:	Drug Color, Type and Labels	Expected # Doses	ID Code ¹	Reported # Doses	Yesterday	2 days ago	3 days ago
a.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. When was the last time you/your baby/your child 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

6. Are there any problems or situations that make it difficult for you to take or give your baby/your child every dose of medication every day? (1-Yes, 2-No)
 If No, STOP.
 If Yes, go to question 7.

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INSTRUCTIONS FOR COMPLETION OF MEDICATION SPECIFIC TABLE:

- Enter the drug code of each medication that the study participant is receiving in the space provided at the top of each column.

Problems Giving/Taking Medications:

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 medications."

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:

"Have any of the following been problems with giving/taking _____ ?"
(medication name or characteristics)

If "Yes," enter the frequency code for each reason.

If "No," go to the next drug.

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

Frequency Codes

Use these codes to indicate how often the listed reason makes it harder to take (give) each of the medications the study participant is taking.

- 0-Never
- 1-(1-2) times per month
- 2-(1-2) times per week
- 3-(≥ 3) times per week

	Enter Drug Code and Name: (Refer to last page for Drug Codes) [8]: _____	Drug Code [8]: _____	Drug Code [8]: _____	Drug Code [8]: _____	Drug Code [8]: _____
	DO NOT KEY	Drug #1 Name [30]: _____	Drug #2 Name [30]: _____	Drug #3 Name [30]: _____	Drug #4 Name [30]: _____
		Drug #5 Name [30]: _____			
7. Problem identified? (1-Yes, 2-No)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
a. I ran out of medicine; didn't come for medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b. The medicine tastes bad	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c. I just forgot	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d. I was worried about the side effects	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e. There was a change in daily routine ...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f. Too busy with the baby/child	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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	Enter Drug Code and Name: <i>(Refer to last page for Drug Codes)</i>	Drug Code [8]: _____	Drug Code [8]: _____	Drug Code [8]: _____	Drug Code [8]: _____	Drug Code [8]: _____
	DO NOT KEY	Drug #1 Name [30]: _____	Drug #2 Name [30]: _____	Drug #3 Name [30]: _____	Drug #4 Name [30]: _____	Drug #5 Name [30]: _____
g. My baby/child refused to take medicine or spat it out	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h. There are lots of people looking after the baby/child and I am not always with him/her at the right time	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i. I did not want others to notice me giving the medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j. My baby/child was ill	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k. Don't think baby/child needs it anymore	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
l. Family said someone told them not to give/take the medicine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
m. I was ill	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
n. I felt the medicine might be harmful to my baby/child.....	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
o. The baby/child was not staying in the house where the medicine was kept	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
p. I felt depressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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	Drug Code [8]: _____	Drug Code [8]: _____	Drug Code [8]: _____	Drug Code [8]: _____	Drug Code [8]: _____
Enter Drug Code and Name: <i>(Refer to last page for Drug Codes)</i>					
DO NOT KEY	Drug #1 Name [30]: _____	Drug #2 Name [30]: _____	Drug #3 Name [30]: _____	Drug #4 Name [30]: _____	Drug #5 Name [30]: _____
q. My baby/child was well	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
r. There was too much medicine to give	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
s. I was away from home	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
t. I was busy with other things	<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"/>
[30]: _____					

Country: Enter 'SA' in the country box for South Africa.
 Enter 'T' in the country box for Thailand.

Language: Enter 'E' if the scripts were read to the study participant in English.
 Enter 'A' if the scripts were read to the study participant in Afrikaans.
 Enter 'X' if the scripts were read to the study participant in Xhosa.
 Enter 'Z' if the scripts were read to the study participant in Zulu.
 Enter 'So' if the scripts were read to the study participant in Sotho.
 Enter 'T' if the scripts were read to the study participant in Thai.

Country:

Language:

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	08180043	Indinavir/IDV/Crixivan
08180025	Alovudine/CL-184824	10920013	Interleukin-2/IL-2
08181205	Amprenavir/APV/Agenerase/141W94/VX-479	08180026	Lamivudine/3TC/Epivir
08181214	Atazanavir/ATV/BMS-232632	08181218	Lexiva/Fosamprenavir/GW433908
08180018	Ateviridine mesylate U-87201E	08181208	Lopinavir/Ritonavir (LPV/RTV)/Kaletra/ ABT-378/r
08180006	Azidouridine/AzdU/azido-2',3'-dideoxyuridine	08180048	Loviride/Lotrene
08180021	AZT/ZDV/Zidovudine/Retrovir	08181204	Nelfinavir/NFV/Viracept
08180032	CD4/RST4	08180013	Nevirapine/NVP/Viramune
08180412	Combivir (3TC/ZDV)	08181203	Ritonavir/RTV/Norvir
08180024	d4T/Stavudine/Zerit	08181209	Saquinavir soft gel/FTV/Fortovase
08180052	d4T XR/Zerit XR	08180030	Saquinavir (HGC)/SQV/Invirase/R031-8959
08180414	DAPD/Amdoxovir/trimeric	08188804	T-20/pentafuside/Enfuvirtide/ENF
08180020	ddC/Zalcitabine/HIVID	08182002	TDF/Tenofovir/Tenofovir disoproxil fumarate/Viread
08180007	ddl/Didanosine/Videx	08180418	Trizivir (3TC/ABC/ZDV)
08180051	ddl EC/Didanosine/Videx EC	99999998	Blinded Study Drug
08180031	DLV/delavirdine mesylate/Rescriptor	99999999	Drug Code Pending
08180804	Efavirenz/EFV/Sustiva/DMP266/Stocrin		
08180411	Fluorouridine/935U83		
08180415	FTC/Emtriva/emtricitabine		