ADOLESCENT ADHERENCE QUESTIONNAIRE MODULE 2 - REVISED
GENERAL REASONS FOR NON-ADHERENCE
NIAID PEDIATRIC AIDS CLINICAL TRIALS GROUP   **Page 1 of 4**

Patient Number [ ] [ ] [ ] [ ] [ ] [ ] [ ]   Date of Patient Visit [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]
                                                                              mmm   dd   yyyy

Protocol Number **0 0 0 0**   Institution Code [ ] [ ] [ ] [ ] [ ] [ ]

Form Week [ ] [ ]   * Seq. No. [ ]   ** Step No. [ ] [ ]   Key Operator Code [ ] [ ] [ ]

* 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.

This module captures 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 ADHERENCE QUESTIONNAIRE MODULE 2 - REVISED form (QL5004).
- 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.

QUESTIONS 1 - 5 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, specify [30]: _____

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

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

4. 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 "9-Other", specify [30]: _____

5. Who responded to the questions?……………………………………
   1-Primary caregiver
   2-Caregiver and study participant jointly
   3-Study participant alone
   9-Other, specify   [ ]

   If "9-Other", specify [30]: _____

11-22-04

GENERAL REASONS FOR NON-ADHERENCE

Pt. No. ☐☐☐☐☐☐☐   * Seq. No. ☐   ** Step No. ☐☐   Date ☐☐☐ ☐☐ ☐☐☐☐

mmm   dd   yyyy

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 bottom of this page for the list of most commonly used anti-HIV medications. Refer to Appendix 3 or the Drug Code Lookup Program at the DMC Web Site (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 drug (question 6 on pages 3 and 4):
"Have any of the following been problems for you with ＿(drug name or characteristics)＿＿＿?"

If "Yes," enter the frequency code for each reason (a-u).
If "No," go to the next drug.
For data entry, use the tab key after the last entry on the page.

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 for Protocol ＿＿＿＿＿.			
08180407	Abacavir/ABC/Ziagen/1592U89	08180415	FTC/Emtriva/emtricitabine
08180025	Alovudine/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	Atevirdine mesylate U-87201E	08180026	Lamivudine/3TC/Epivir
08180006	Azidouridine/AzdU/azido-2',3'-dideoxyuridine	08181208	Lopinavir/Ritonavir (LPV/RTV)/Kaletra/
08180021	AZT/ZDV/Zidovudine/Retrovir		ABT-378/r
08180032	CD4/RST4	08180048	Loviride/Lotrene
08180412	Combivir (3TC/ZDV)	08181204	Nelfinavir/NFV/Viracept
08180024	d4T/Stavudine/Zerit	08180013	Nevirapine/NVP/Viramune
08180052	d4T XR/Zerit XR	08181203	Ritonavir/RTV/Norvir
08180414	DAPD/Amdoxovir/trimeric	08181209	Saquinavir soft gel/FTV/Fortovase
08180020	ddC/Zalcitabine/HIVID	08180030	Saquinavir/SQV/Invirase/R031-8959
08180007	ddI/Didanosine/Videx	08188804	T-20/pentafuside/Enfuvirtide/ENF
08180051	ddI EC/Didanosine EC/Videx EC	08182002	TDF/Tenofovir/Tenofovir disoproxil
08180031	DLV/delavirdine mesylate/Rescriptor		fumarate/Viread
08180804	Efavirenz/EFV/Sustiva/DMP266/Stocrin®	08180418	Trizivir (3TC/ABC/ZDV)
08180420	Epzicom(Abacavir/lamivudine)	08180421	Truvada(tenofovir disoproxil/emtricitabine)
08180411	Fluorouridine/935U83		

11-22-04

Pt. No. ☐☐☐☐☐☐☐ * Seq. No. ☐ ** Step No. ☐☐ Date ☐☐☐ ☐☐ ☐☐☐☐

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　mmm　dd　yyyy

DRUG SPECIFIC ADHERENCE DIFFICULTIES:

Frequency Codes

Use these codes to 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.

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

Enter Drug Code and Name:	Drug Code [8]: Drug #1 Name [30]:	Drug Code [8]: Drug #2 Name [30]:	Drug Code [8]: Drug #3 Name [30]:	Drug Code [8]: Drug #4 Name [30]:	Drug Code [8]: Drug #5 Name [30]:
6. Problem identified? (1-Yes, 2-No)	☐	☐	☐	☐	☐
Reasons for Non-adherence:					
a. Can't get drug at drugstore	☐	☐	☐	☐	☐
b. Didn't get prescription refilled; ran out	☐	☐	☐	☐	☐
c. Made me sick to my stomach; threw up; it tasted bad	☐	☐	☐	☐	☐
d. Forgot	☐	☐	☐	☐	☐
e. It caused me to have other physical symptoms (e.g., rash, headache)	☐	☐	☐	☐	☐
f. Got in the way of daily schedule (school, work); too busy	☐	☐	☐	☐	☐
g. Couldn't deal with it; didn't feel like taking it; needed a break	☐	☐	☐	☐	☐
h. Change in living situation; moved	☐	☐	☐	☐	☐
i. Worried people would find out about HIV; didn't want friends asking questions; felt embarrassed	☐	☐	☐	☐	☐
j. Got sick with another illness; wasn't feeling well (e.g., cold, flu, stomach bug)	☐	☐	☐	☐	☐
k. Don't think I need it anymore; I can stay healthy without it	☐	☐	☐	☐	☐
l. Family and/or friends don't help me remember; tell me I shouldn't take it	☐	☐	☐	☐	☐
m. Nowhere to keep it at school or work	☐	☐	☐	☐	☐

11-22-04

Pt. No. ☐☐☐☐☐☐☐☐ * Seq. No. ☐ ** Step No. ☐☐ Date ☐☐☐ ☐☐ ☐☐☐☐
Mmm   dd   yyyy

Frequency Codes

Use these codes to 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.

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

	Drug #1	Drug #2	Drug #3	Drug #4	Drug #5
Reasons for Non-adherence (cont'd):					
n. Don't understand why I have to take it	☐	☐	☐	☐	☐
o. I keep getting sick even when I do take it	☐	☐	☐	☐	☐
p. Taking it reminds me of the HIV; just want to forget about the diagnosis	☐	☐	☐	☐	☐
q. I don't want to talk about it	☐	☐	☐	☐	☐
r Doesn't remember/not sure if dose was taken	☐	☐	☐	☐	☐
s. Fell asleep	☐	☐	☐	☐	☐
t. Away from home	☐	☐	☐	☐	☐
u. Other, specify	☐	☐	☐	☐	☐
Specify [30]:					

Language: ☐ **E**
English

11-22-04

Date Form Keyed (DO NOT KEY): _____ /_____ / _____