PEDIATRIC ADHERENCE QUESTIONNAIRE MODULE 1- REVISED

Behavior/Identification

	NIAID PEDIATRIC	AIDS CLINICAL TR	RIALS GROUP	Page 1 of 3
Patient Number Protocol Number		Date of Patient	mmm do	d yyyy
Form Week	* Seq No.	Ins	stitution Code Key Operator C	ode
	first of this form for this date. De	esignate subsequent for	ms on same date with a 2,	
The purpose of the antiretroviral therap analysis phase of a	rent study step number. Enter '1' s questionnaire is to collect y actually taken within the I study protocol. In order to cess through which these clowing directions.	data which will qua ast 3 days in order have confidence in	ntify the proportion of to examine drug effec the data that will be o	t during the collected with this
Who administers filling out other AC	Any member of the profe G study forms.	essional clinical care	e or research team wh	o has experience
Who is questione drug regimen OR t prescribed drugs a present for a partic (below) and the as	1? The research subject, if ne subject's primary caregiv home). If the appropriate it ular study visit when this for sessment omitted.	the subject has ass er (the person resp espondent is the pr m is scheduled, the	umed responsibility fo onsible for administer imary caregiver and s form should be mark	r his/her own ing the .he/he is not ed as such
(and prompts) which interruptions for su	onnaire administered? The should be read as stated, bject education should occupter the questionnaire is co	item after item, unt ir; any necessary or	il the assessment is c	ompleted. No
erratic adherence is completed is critical subsequently correlated it is imperative that	f report is very good if the a m has introductory statement hay be elicited by the surve lly important. The attitude o cted, and the nature of beha- clinical teams review the ch es in promoting drug adher-	y, what interaction h f the clinical respon avioral counseling v naracteristics of the	nappens after the quesse, the manner in whi vill absolutely influend rapeutic relationships	stionnaire is ch information is ce future validity.
QUESTIONS 1 - 3	ARE TO BE COMPLETED	BY THE STUDY N	URSE:	
If Yes , go to	onnaire completed at this v question 2. lete 'a' and STOP.	isit?	(1-Yes, 2-	·No)
a. Indicate the	reason the questionnaire v	vas not completed:.	1-Subject refused 2-Primary caregiver ref 3-Subject missed clinic 4-There was not enoug 5-Primary caregiver no 9-Other reason, specify	: visit jh time t available
If Other	reason, specify [30]:			
2. Who responded	to the questions?			her e, specify ent t
If "4-Other	relative" or "9-Other", spe	ecify [30]:		



QL5002(000)/00-00-00 PEDIATRIC ADHERENCE QUESTIONNAIRE MODULE 1 - REVISED Page 2 of 3 Patient Number Seq.# Step # Date mmm dd VVV 3. Since the last visit, did the subject 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: (1-Yes, 2-No, 3-Not known) a. Labels: Calendars: Pill boxes: d. Beepers: Monitoring caps (MEMS): Timers: Programmable wrist watches: Diary: "Buddy system": PEG/gastrostomy tube: Activity of daily living triggers, specify: Specify[30]: Other, specify: Specify[30]:

1	PEDIATRIC ADI	HERENCE OF	IESTION	VAIRE	MODIII E 1	QL - REVISEI	.5002(00	0)/00-00-00 Page 3 of 3
Patient Number			Seq. #			ate	Ĭ	
			ου ς . <i>π</i>		,p #0	mmm	dd d	
						111111111	uu	уууу
 INSTRUCTIONS Columns A 	S FOR COMPLE	<u>ETION OF ME</u> e study visit,	the study r	N TABL	<u>.E</u>	the informa	ation in th	1000
• Columns A	columns f	or which adh	nerence in	format	ion is bein	a collecte	d as spe	cified
	by the pro	otocol.				•	•	
• Column A:	List the dr	ug name (if k	nown or, it	f double	e-blinded st	udy, record	l as mark	ced on
Column B:	bottle).	ght digit drug	code for t	he drug	listed in C	olumn A E	Pafar to /	Annendiy 3
Column b.	or by usin	g the Drug Co	ode Looku	p Progr	am at the [DMC Webs	ite (www	fstrf.org).
• Column C:	List the dr	ug color, type	e (blue pill,	pink lic	ιuid, etc.) a	nd note any	y special	identifying
Column D:	labels.	mosted numb	or of doo	an nor (1 hour nor	iad Thiara	oforo to t	ho
• 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.							ne of pills
	Particulars of the schedule will not be addressed (e.g. TID and q8 hr. would both							ould both
0.1 5	be record	ed as 3 times	per day).					
Columns E-	I NIS INTORI	mation is to be	e obtained view Refe	i irom ti ≘r to "S	ie study su crints for Pa	bject or prir ediatric Adh	mary car	egiver
	Questionr	sequent inter naire Module	1 – Revise	d" for c	ompleting t	he Medicat	ion Table	e. This
	document	is located in	the Forms	Instruc	tion section	n of the CR	F Notebo	ook.
MEDICATION L	<u> IST TABLE:</u> Do	not key Col	umn C.					
	1 ldei	ntification Cod	des		² Dose	s Missed		
	ompt	Enter "-1" if subject isn't sure if he/she						
		red with promp			issed any do			
		edged when re acknowledge	minded	Enter	"U" if no dos	es were mis	sed.	
					0	(D 1	4	
	Complete Prior to	Visit				te During In		
Α			D	E	Comple F	G	Н	
	Complete Prior to	Visit	D	E		G		l d ²
	Complete Prior to	Visit	D	E		G	Н	l d ²
A	Complete Prior to B	Visit C Drug Color, Type and	Expected	ID	F Reported	G Dos	H ses Misse 2 days	3 days
	Complete Prior to	Visit C Drug Color,			F	G	H ses Misse 2 days	
A	Complete Prior to B	Visit C Drug Color, Type and	Expected	ID	F Reported	G Dos	H ses Misse 2 days	3 days
A	Complete Prior to B	Visit C Drug Color, Type and	Expected	ID	F Reported	G Dos	H ses Misse 2 days	3 days
A	Complete Prior to B	Visit C Drug Color, Type and	Expected	ID	F Reported	G Dos	H ses Misse 2 days	3 days
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A	Complete Prior to B	Visit C Drug Color, Type and	Expected	ID	F Reported	G Dos	H ses Misse 2 days	3 days
A	Complete Prior to B	Visit C Drug Color, Type and	Expected	ID	F Reported	G Dos	H ses Misse 2 days	3 days
A	Complete Prior to B	Visit C Drug Color, Type and	Expected	ID	F Reported	Yesterday United States of the Control of the Cont	2 days ago	3 days
A rug Name(s) [30]	Complete Prior to B	Visit C Drug Color, Type and Labels	Expected # Doses	ID Code¹	Reported # Doses	Yesterday Lan	es Misse 2 days ago	3 days

12-13-99/03-27-00/07-05-01



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