INTERNATIONAL ADHERENCE QUESTIONNAIRE
Behavior/Identification
NIAID AIDS CLINICAL TRIALS GROUP   **Page 1 of 5**

Patient Number ☐☐☐☐☐☐☐   Date of Patient Visit ☐☐☐ ☐☐ ☐☐☐☐
                                                         mmm   dd   yyyy

Protocol Number **P 1 0 9 3** ☐   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.

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
       If Other, specify [30]: _____   99-Other reason, specify

2. Who responded to the questions? …………………………………………   11-Study participant   ☐☐
       12-Biological mother
       13-Biological father
       14-Grandmother
       15-Grandfather
       16-Foster mother
       17-Foster father
       18-Stepmother
       19-Stepfather
       If Other, specify [30]: _____   99-Other, specify

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
       If Other, specify [30]: _____   99-Other, specify

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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 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 (https://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.

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

[1] **Identification Codes**	[2] **Doses Missed**
1-Volunteered without prompt 2-Volunteered with prompt 3-Acknowledged when reminded 4-Did not acknowledge	• 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**
		(DO NOT KEY)				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.			☐☐	☐	☐☐	☐☐	☐☐	☐☐
b.			☐☐	☐	☐☐	☐☐	☐☐	☐☐
c.			☐☐	☐	☐☐	☐☐	☐☐	☐☐
d.			☐☐	☐	☐☐	☐☐	☐☐	☐☐
e.			☐☐	☐	☐☐	☐☐	☐☐	☐☐
f.			☐☐	☐	☐☐	☐☐	☐☐	☐☐
g.			☐☐	☐	☐☐	☐☐	☐☐	☐☐
h.			☐☐	☐	☐☐	☐☐	☐☐	☐☐

5. Toka hudhurio la mwisho,lini mara ya mwisho wewe/mtoto wako mchanga/mtoto
    Kukosa kumeza dawa hizi?…………………………………………………… 1-Kamwe   ☐
    At Entry: When was the last time you/your baby/your child missed   2-Wiki 2 zilizopita
    a dose of any of these medications?   3-Katika mwezi uliopita
    If Never, go to question 6.   4-Zaidi ya mwezi uliopita
    If '2', '3', '4' or '5', go to question 7.   5-Sikumbuki

6. Toka hudhurio la mwisho, kumekuwa na matatizo yeyote au hali
    Inayofanya kuwa vigumu kwako au kuumpa mtoto kila dozi ya dawa kila siku?
    (Rejea swali la 7 kwa orodha ya matatizo yawezekanayo.) …………………… (1-Yes, 2-No)   ☐
    At Entry: Have there been any problems or situations that made it difficult
    for you to take or give your baby/child every dose of medication every day?
    If No, go to Country and Language boxes on page 5.
    If Yes, go to question 7.

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                                                                  mmm   dd   yyyy

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:
"Watu wengi kwa wakati mmoja au mwengine huwa na shida na dawa hizi. Tunapenda kuuelwa mambo ambayo hufanya vigumu kutoa dawa dawa kwa bidii kwa familia. Hizi ni baadhi ya sababu zilizotambuliwa na wengine ambayo yalifanya kuwa vigumu kuchukua[kutoa] dawa zote"

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:
"Kuna yeyote ya fafuatayo yamekuwa matatizo au kuyanya vigumu kutoa/kutumia dawa_____ ?"
                                                        (jina la dawa au sifa)

If "Yes," enter the frequency code listed in question 7 for each reason.
If "No," go to the next drug.
For data entry, use the tab key after the last entry on the page.

Enter Drug Code and Name: *Refer to last page for Drug Code* **DO NOT KEY DRUG 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]:
7. Kumekuwa na tatizo lililojitokeza toka hudhurio la mwisho? (1-Ndio, 2-Hapana)	⬚	⬚	⬚	⬚	⬚

FOR QUESTIONS 7a - 7u: Indicate how often the listed reason makes it harder to take (give) each of the medications the study participant is taking. Use the following codes: **Frequency Codes:** 0-Never   2-(1-2) times per week 1-(1-2) times per month   3-($\geq$ 3) times per week

a. Niliishiwa dawa; sikuja chukua dawa	⬚	⬚	⬚	⬚	⬚
b. Dawa ina ladha mbaya	⬚	⬚	⬚	⬚	⬚
c. Nilisahau tu ……………..	⬚	⬚	⬚	⬚	⬚
d. Nilikuwa na wasiwasi juu ya madhara ………..	⬚	⬚	⬚	⬚	⬚
e. Kulikuwa na mabadiliko kwa taratibu za siku…	⬚	⬚	⬚	⬚	⬚
f. Nilikuwa na kazi nyingi za kulea mtoto……	⬚	⬚	⬚	⬚	⬚
g. Mtoto wangu alikataa kuchukua dawa au alitema dawa………...	⬚	⬚	⬚	⬚	⬚
h. Kuna watu wengi wa kuangalia mtoto wangu mchanga na mimi siko nae wakati muafaka…..	⬚	⬚	⬚	⬚	⬚

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mmm   dd   yyyy

FOR QUESTIONS 7a - 7u: Indicate how often the listed reason makes it harder to take (give) each of the medications the study participant is taking. Use the following codes:

Frequency Codes:
0-Never	2-(1-2) times per week
1-(1-2) times per month	3-($\geq$ 3) times per week

Enter Drug Code and Name: Refer to last page for Drug Code **DO NOT KEY DRUG 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]:
i. Sikutaka wengine kujua natoa/ natumia dawa ….	☐	☐	☐	☐	☐
j. Mimi/mtoto kuumwa …	☐	☐	☐	☐	☐
k. Sidhani kama mimi/ mtoto nahitaji tena, naweza kuwa na afya bila iyo ………………	☐	☐	☐	☐	☐
l. Familia ilisema fulani aliwaambia nisitoe/ nisitumie dawa ……..	☐	☐	☐	☐	☐
m. Mlezi alumwa…...	☐	☐	☐	☐	☐
n. Nilihisi dawa inaweza kuwa na madharia kwangu/mtoto …….	☐	☐	☐	☐	☐
o. Mtoto wangu hakuwa akiishi kwenye ambapo dawa zilikuwa zimeifadhiwa …..	☐	☐	☐	☐	☐
p. Nilihishi uzuni ………	☐	☐	☐	☐	☐
q. Mimi/mtoto kuwa vizuri	☐	☐	☐	☐	☐
r. Kulikuwa na dawa nyingi za kutumia…..	☐	☐	☐	☐	☐
s. Kuwa mbali na nyumbani	☐	☐	☐	☐	☐
t. Nilikuwa na mambo mengi …………………	☐	☐	☐	☐	☐
u. Nyingine, ainisha [140]:	☐	☐	☐	☐	☐

PEDIATRIC INTERNATIONAL ADHERENCE QUESTIONNAIRE

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mmm   dd   yyyy

NOTE: Refer to Appendix 80 for Country and Language Codes.

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 Portal (https://www.fstrf.org) for drugs not listed below.

Anti-HIV Drugs

Code	Drug	Code	Drug
08180407	Abacavir/ABC/Ziagen/1592U89	08180819	Lamivudine/Stavudine
08181214	Atazanavir/ATV/BMS-232632/Reyataz®/Zrivada	08180823	GSK1349572/GSK572
08180422	Atripla (Efavirenz/emtricitabine/Tenofovir)	08180026	Lamivudine/3TC/Epivir
08180021	AZT/ZDV/Zidovudine/Retrovir	08181208	Lopinavir/Ritonavir (LPV/RTV)/Kaletra®/ Aluvia®
08180412	Combivir (3TC/ZDV)		
08180024	d4T/Stavudine/Zerit	08182403	Maraviroc/MVC/Celsentri™/Selzentry™
08180052	d4T XR/Zerit XR	08180013	Nevirapine/NVP/Viramune
08181220	Darunavir/Prezista	08180814	Raltegravir/MK-0518/RGV/Isentress™/RAL
08180007	ddI/Didanosine/Videx	08181203	Ritonavir/RTV/Norvir
08180051	ddI EC/Didanosine EC/Videx EC	08180030	Saquinavir/SQV/Invirase/R031-8959
08180815	Duovir-N (ZDV/3TC/NVP)	08188804	T-20/pentafuside/Enfuvirtide/ENF/Fuzeon
08180804	Efavirenz/EFV/Sustiva/DMP266/Stocrin®	08182002	TDF/Tenofovir/Tenofovir disoproxil fumarate/Viread
08180420	Epzicom(Abacavir/lamivudine)/Kivexa		
08180809	Etravirine/TMC125/Intelence	08181210	Tipranavir/TPV/Aptivus
08180415	FTC/Emtriva/emtricitabine	08180810	Triomune (3TC/d4T/NVP)
08180043	Indinavir/IDV/Crixivan	08180418	Trizivir (3TC/ABC/ZDV)
08181218	Lexiva/Fosamprenavir/GW433908	08180421	Truvada® (tenofovir disoproxil/emtricitabine)
08180819	Lamivir-S (d4T/3TC)	08182402	Vicriviroc (SCH-417690)
08180815	Lamivudine/Zidovudine/Nevirapine		

10-15-04/04-10-06/11-06-07

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