

# PEDIATRIC ADHERENCE QUESTIONNAIRE MODULE 1- REVISED

## Behavior/Identification

NIAID PEDIATRIC AIDS CLINICAL TRIALS GROUP

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Patient Number	<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"/>
Protocol Number	<input type="text"/>	<input type="text"/>	<input type="text"/>	Institution Code	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Form Week	<input type="text"/>	* Seq No.	<input type="text"/>	** Step No.	<input type="text"/>	Key Operator Code	<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 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 subject, if the subject has assumed responsibility for his/her own drug regimen OR the subject'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 subject 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 subjects.

**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:.....   
 1-Subject refused  
 2-Primary caregiver refused  
 3-Subject 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-Subject  
 2-Biological mother  
 3-Biological father  
 4-Other relative, specify  
 5-Adoptive parent  
 6-Foster parent  
 9-Other, specify

If "4-Other relative" or "9-Other", specify [30]: \_\_\_\_\_





