

ACTG SELF REPORT - REVISED
NIAID AIDS CLINICAL TRIALS GROUP

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"/>
					mmm	dd	yyyy	
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 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.

FOR OFFICE USE ONLY - TEAR OFF SHEET

INSTRUCTIONS TO THE STUDY NURSE:

The ACTG SELF REPORT - REVISED should be given to the study participant prior to the clinical exam and preferably in a quiet secluded area (e.g., exam room or other office). The study participant must be able to read at the sixth-grade level at a minimum to complete the questionnaire without additional assistance.

It is important to be familiar with the content and format of the questionnaire before giving it to study participants. At the first visit, please begin by telling the subject:

"We would like you to answer some questions about your medical care, health and medication. Your answers will help us understand the effects of the medication you are taking. We appreciate your filling out this questionnaire."

You should then briefly go over the format of the questions and how to complete them. Have the study participant complete the questionnaire before vital signs, history, and physical are completed. The questionnaire is very brief and should take no more than 10 minutes to complete. Before giving the study participant the questionnaire, please fill out the header(s) and DETACH THIS PAGE.

Each question is in the same general format and contains several items. Note that the study participant is always asked to make an "X" or a "✓" in the box that comes closest to how he/she has been feeling. Drug names and abbreviations of the most common anti-HIV drugs have been included on the worksheet for reference and use.

For data keying, if the subject did not answer a question, enter "-1." Do not leave any fields blank.

PLEASE COMPLETE THE FOLLOWING ITEMS AFTER STUDY PARTICIPANT COMPLETES THE QUESTIONNAIRE OR AFTER YOU ASCERTAIN THAT THIS IS NOT POSSIBLE:

1. How was the questionnaire completed?
- 1-Self administered by the study participant
 - 2-Face-to-face interview that you conducted
 - 3-Both self-administered and interview
 - 4-Not completed
 - 9-Other, specify

If Other, specify [30]: _____

- a. If you answered "4-Not completed," please indicate the reason why:
- 1-Study participant refused
 - 2-Study participant missed clinic visit
 - 3-There was not enough time
 - 9-Other reason, specify

If Other, specify [30]: _____

ACTG SELF REPORT - REVISED
 NIAID AIDS CLINICAL TRIALS GROUP

QL0744(000)/00-00-00

Patient Number Date of Patient Visit
mmm dd yyyy

Protocol Number Institution Code

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

INSTRUCTIONS: Please answer the following questions about your health and health care over the last four months.

A. DURING THE PAST 4 MONTHS, you might have received medical care. AS WELL AS YOU CAN REMEMBER, PLEASE ANSWER THE FOLLOWING QUESTIONS.

	NONE	1-2	3-5	6-10	11-16	>16	If >16, Indicate Number	
	0							
1. HOW MANY DAYS did you stay in bed because you were not feeling well?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="text"/> _____	<input type="text"/> <input type="text"/> <input type="text"/>
2. HOW MANY DAYS did you cut down on your usual daily activities, such as your job, housework, school?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="text"/> _____	<input type="text"/> <input type="text"/> <input type="text"/>
3. HOW MANY NIGHTS did you stay in a hospital ward (not the emergency room)?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="text"/> _____	<input type="text"/> <input type="text"/> <input type="text"/>
4. HOW MANY VISITS did you make to an emergency room?	<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	<input type="text"/> _____	<input type="text"/> <input type="text"/> <input type="text"/>

	Not Working, Not Looking for Work	Not Working, Looking for Work	Working Part-Time	Working Full-Time	
	0	1	2	3	
5. How would you describe your <u>work</u> over the past 4 months? (check one)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B. In general, would you say your health is:
 Place a "✓" in one box.

(Check One)

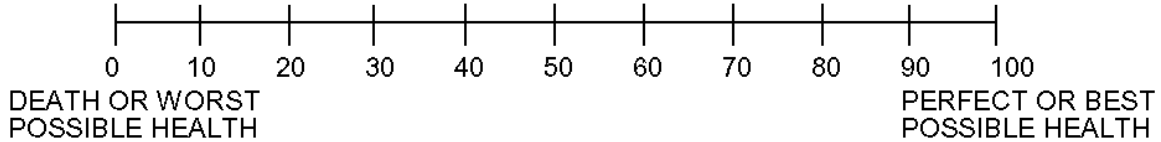
Excellent.....	1	<input type="checkbox"/>	<input type="checkbox"/>
Very Good	2	<input type="checkbox"/>	
Good	3	<input type="checkbox"/>	
Fair	4	<input type="checkbox"/>	
Poor.....	5	<input type="checkbox"/>	



ACTG SELF REPORT - REVISED

Pt. No. *Seq. No. **Step No. Date
mmm dd yyyy

C. On the line below, 0 is death and 100 is perfect health:



a. Using the above line as a guide, how would you rate your current state of health from '0' to '100'?

Write down any number between '0' and '100': _____

D. 1. Are you currently taking any anti-HIV medications? Yes No
1 2
If No, STOP.
If Yes, continue.

2. The next section of the questionnaire asks about the medications that you took over the last four days.

Most people with HIV have many pills to take at different times during the day. Many people find it hard to always remember their pills:

- Some people get busy and forget to carry their pills with them.
- Some people find it hard to take their pills according to all the instructions, such as "with meals" or "on an empty stomach," "every 8 hours," "with plenty of fluids."
- Some people decide to skip pills to avoid side effects or to just not be taking pills that day.

We need to understand how people with HIV are really doing with their pills. Please tell us what you are **actually** doing. Don't worry about telling us that you don't take all your pills. We need to know what is really happening, not what you think we "want to hear."

The next page of the questionnaire asks about the anti-HIV medications that you may have **missed** taking over the last four days. Please complete the table on page 4, using one line for each study medication you are prescribed to be taking, and using the drug codes and names in the chart on the bottom of the page.



ACTG SELF REPORT - REVISED

Pt. No. *Seq. No. **Step No. Date
mmm dd yyyy

If you did not miss any doses, write a zero (0) in the box. Note that the table asks about DOSES, not PILLS.

IF YOU TOOK ONLY A PORTION OF A DOSE ON ONE OR MORE OF THESE DAYS, PLEASE REPORT THE DOSE(S) AS BEING MISSED.

Drug Code	Abbreviation/Name Of Your Drugs [30]	Number of Prescribed Doses Per Day	HOW MANY DOSES DID YOU MISS...			
			Yesterday	Day before yesterday (2 days ago)	3 days ago	4 days ago
<input type="text"/>	<input type="text"/>	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses
<input type="text"/>	<input type="text"/>	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses
<input type="text"/>	<input type="text"/>	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses
<input type="text"/>	<input type="text"/>	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses
<input type="text"/>	<input type="text"/>	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses
<input type="text"/>	<input type="text"/>	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses
<input type="text"/>	<input type="text"/>	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses
<input type="text"/>	<input type="text"/>	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses
<input type="text"/>	<input type="text"/>	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses	<input type="text"/> doses

Anti-HIV Drugs for Protocol _____

Insert latest template here.



ACTG SELF REPORT - REVISED

Pt. No. *Seq. No. **Step No. Date
mmm dd yyyy

INSTRUCTIONS: Place a "✓" in the appropriate box. Please check one box for each question.

E. Most medications need to be taken on a schedule, such as "2 times a day" or "3 times a day" or "every 8 hours." How closely did you follow your specific schedule over the last four days?

Never	Some Of The Time	About Half Of The Time	Most Of The Time	All Of The Time	<input type="checkbox"/>
<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>

F. Do any of your medications have special instructions, such as "take with food" or "on an empty stomach" or "with plenty of fluids"?

<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/>
<small>1</small>	<small>2</small>	<input type="checkbox"/>

If No, go to G.

If Yes, how often did you follow those special instructions over the last four days?

Never	Some Of The Time	About Half Of The Time	Most Of The Time	All Of The Time	<input type="checkbox"/>
<input type="checkbox"/> 0	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/>

G. When was the last time you missed any of your medications?

(Check one box)

Within the past week	5 <input type="checkbox"/>	<input type="checkbox"/>
1-2 weeks ago	4 <input type="checkbox"/>	
2-4 weeks ago	3 <input type="checkbox"/>	
1-3 months ago	2 <input type="checkbox"/>	
More than 3 months ago	1 <input type="checkbox"/>	
Never skip medications	0 <input type="checkbox"/>	

Language:
English

