ACTG SELF REPORT - III

NIAID AIDS CLINICAL TRIALS GROUP

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

Protocol Number ☐☐☐☐☐☐ 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.

FOR OFFICE USE ONLY - TEAR OFF SHEET

INSTRUCTIONS TO THE STUDY NURSE:

The ACTG SELF REPORT - III 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 ***<insert study medications> for Protocol 0000*** 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? ..... ☐
   If '4', complete 'a' and STOP.
   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 [70]: _____

   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 [70]: _____

2. Enter the country code for the location of the clinic and the language used to complete the form. Refer to Appendix 80 for Country and Language Codes.

   Country: ☐☐ **Language:** ☐☐

12-17-09

ACTG SELF REPORT - III

NIAID AIDS CLINICAL TRIALS GROUP

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

Protocol Number A 0 0 0 0 ☐ 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 0	1-2	3-5	6-10	11-16	>16	If >16, Indicate Number
1. HOW MANY DAYS did you stay in bed because you were not feeling well?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ _____ ☐☐☐
2. HOW MANY DAYS did you cut down on your usual daily activities, such as your job, housework, school?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ _____ ☐☐☐
3. HOW MANY NIGHTS did you stay in a hospital ward (not the emergency room)?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ _____ ☐☐☐
4. HOW MANY VISITS did you make to an emergency room?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ _____ ☐☐☐

	Not Working, Not Looking for Work	Not Working, Looking for Work	Working Part-Time	Working Full-Time	
5. How would you describe your work over the **past 4 months?** (check one)	☐ 0	☐ 1	☐ 2	☐ 3	☐

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

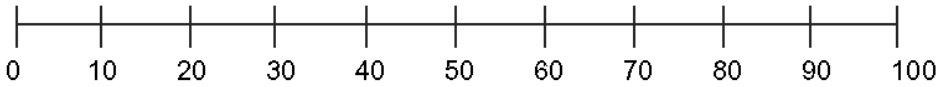
(Check One) ☐

Excellent.....	1	☐
Very Good	2	☐
Good	3	☐
Fair	4	☐
Poor.....	5	☐

12-17-09

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. ***For Protocol A0000:*** Are you currently taking any ***<insert study medication>*** 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 ***<insert study medication>*** 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.

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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 [1]	Abbreviation/Name Of Your Drugs [70]	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
a. [ ][ ][ ][ ][ ][ ][ ][ ]	_____	[ ] doses	[ ] doses	[ ] doses	[ ] doses	[ ] doses
b. [ ][ ][ ][ ][ ][ ][ ][ ]	_____	[ ] doses	[ ] doses	[ ] doses	[ ] doses	[ ] doses
c. [ ][ ][ ][ ][ ][ ][ ][ ]	_____	[ ] doses	[ ] doses	[ ] doses	[ ] doses	[ ] doses
d. [ ][ ][ ][ ][ ][ ][ ][ ]	_____	[ ] doses	[ ] doses	[ ] doses	[ ] doses	[ ] doses
e. [ ][ ][ ][ ][ ][ ][ ][ ]	_____	[ ] doses	[ ] doses	[ ] doses	[ ] doses	[ ] doses
f. [ ][ ][ ][ ][ ][ ][ ][ ]	_____	[ ] doses	[ ] doses	[ ] doses	[ ] doses	[ ] doses
g. [ ][ ][ ][ ][ ][ ][ ][ ]	_____	[ ] doses	[ ] doses	[ ] doses	[ ] doses	[ ] doses
h. [ ][ ][ ][ ][ ][ ][ ][ ]	_____	[ ] doses	[ ] doses	[ ] doses	[ ] doses	[ ] doses
i. [ ][ ][ ][ ][ ][ ][ ][ ]	_____	[ ] doses	[ ] doses	[ ] doses	[ ] doses	[ ] doses
j. [ ][ ][ ][ ][ ][ ][ ][ ]	_____	[ ] doses	[ ] doses	[ ] doses	[ ] doses	[ ] doses

Drugs for Protocol _____

Insert latest template here.

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	
☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐

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

☐ **Yes** 1 ☐ **No** 2 ☐

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	
☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐

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

(Check one box)

Within the past week	5 ☐	☐
1-2 weeks ago	4 ☐	
2-4 weeks ago	3 ☐	
1-3 months ago	2 ☐	
More than 3 months ago	1 ☐	
Never skip medications	0 ☐	

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