ACTG SELF REPORT

NIAID ADULT 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 should be given to the subject prior to the clinical exam and preferably in a quiet secluded area (e.g., exam room or other office). The subject 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 subject 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 subject 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 subject 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.

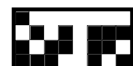
PLEASE COMPLETE THE FOLLOWING ITEMS AFTER SUBJECT COMPLETES THE QUESTIONNAIRE OR AFTER YOU ASCERTAIN THAT THIS IS NOT POSSIBLE:

1. How was the questionnaire completed? .... ☐
   - 1-Self administered by the study subject
   - 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-Subject refused
      - 2-Subject missed clinic visit
      - 3-There was not enough time
      - 9-Other reason, specify

   If Other, specify [30]: ____________________



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INSTRUCTIONS: Please answer the following questions about your health and health care over the last four months by placing a "✓" in the appropriate box.

A. DURING THE PAST 4 MONTHS, you might have received medical care. AS WELL AS YOU CAN REMEMBER, HOW MANY DAYS, NIGHTS, VISITS, OR TIMES DID YOU...
(Place a "✓" in the appropriate box. Please check one box for each question.)

	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	☐ ________	☐

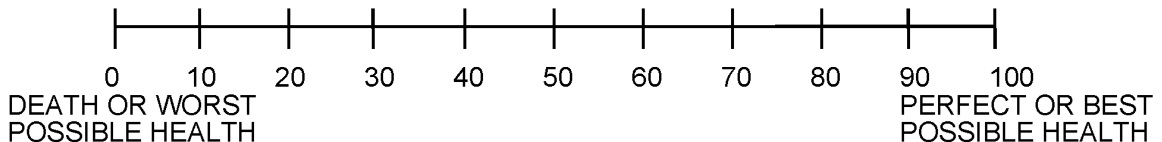
	Not Working, Not Looking for Work	Not Working, Looking for Work	Working Part-Time	Working Full-Time	
5. How would you describe your work over the **past 4 months?**	☐ 0	☐ 1	☐ 2	☐ 3	☐

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	☐	

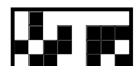
C. On the line below, 0 is death and 100 is perfect health:



0 10 20 30 40 50 60 70 80 90 100

DEATH OR WORST POSSIBLE HEALTH — PERFECT OR BEST POSSIBLE 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': ____________________ ☐☐☐



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

D. 1. Are you currently taking any anti-HIV medications? ☐ Yes (1) ☐ No (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. Please complete the following table by filling in the boxes below. Drug codes and abbreviations of the most common anti-HIV drugs have been included for your reference and use on the bottom of the page.

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."

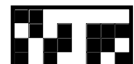
The next section of the questionnaire asks about the study medications that you may have **missed** taking over the last four days. Please complete the table below, using one line for each study medication you are taking, and using the abbreviations on this page. **If you did not miss any doses, write 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.

		HOW MANY DOSES DID YOU MISS…			
Step 1 Abbreviation/ Name of Your Drugs	**Number of Prescribed Doses Per Day**	**Step 2** Yesterday	**Step 3** Day before yesterday (2 days ago)	**Step 4** 3 days ago	**Step 5** 4 days ago
________	☐ doses	☐ doses	☐ doses	☐ doses	☐ doses
________	☐ doses	☐ doses	☐ doses	☐ doses	☐ doses
________	☐ doses	☐ doses	☐ doses	☐ doses	☐ doses
________	☐ doses	☐ doses	☐ doses	☐ doses	☐ doses
________	☐ doses	☐ doses	☐ doses	☐ doses	☐ doses
________	☐ doses	☐ doses	☐ doses	☐ doses	☐ doses
________	☐ doses	☐ doses	☐ doses	☐ doses	☐ doses

Anti-HIV Drugs for Protocol ____________.

Abacavir/ABC/Ziagen/1592U89
Alovudine/CL-184824
Amprenavir/APV/Agenerase/141W94/VX-479
Atazanavir/ATV/BMS-232632
Atevirdine mesylate U-87201E
Azidouridine/AzdU/azido-2',3'-dideoxyuridine
AZT/ZDV/Zidovudine/Retrovir
CD4/RST4
Combivir (3TC/ZDV)
d4T/Stavudine/Zerit
ddC/Zalcitabine/HIVID
ddI/Didanosine/Videx
DLV/delavirdine mesylate/Rescriptor
Efavirenz/EFV/Sustiva/DMP266
Fluorouridine/935U83
FTC/coviracil/emtricitabine
GW433908
Indinavir/IDV/Crixivan
Interleukin-2/IL-2
Lamivudine/3TC/Epivir
Lopinavir/Ritonavir (LPV/RTV)/Kaletra ABT-378/r
Loviride/Lotrene
Nelfinavir/NFV/Viracept
Nevirapine/NVP/Viramune
Ritonavir/RTV/Norvir
Saquinavir soft gel/FTV/Fortovase
Saquinavir (HGC)/SQV/Invirase/R031-8959
T-20/pentafuside
TDF/Tenofovir/Tenofovir disoproxil fumarate/Viread
Trizivir (3TC/ABC/ZDV)



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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. Some people find that they forget to take their pills on the weekend days. Did you miss any of your medications last weekend - last Saturday **or** Sunday?

☐ **Yes** (1) ☐ **No** (2)

☐

H. 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	☐

Language: English ☐

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