ADHERENCE/QUALITY OF LIFE/PSYCHOSOCIAL INTERVIEW

NIAID AIDS CLINICAL TRIALS GROUP

Patient Number ☐☐☐ ☐☐☐☐ ☐

Date of Patient Visit/Contact ☐☐☐ 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 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

1. Was the questionnaire conducted as a face-to-face interview? ………… (1-Yes, 2-No) ☐
   If Yes, go to question 2.
   If No, continue.

   a. Indicate the reason why :………………………..……….. ☐
      - 1-Study participant refused
      - 2-Study participant missed clinic visit
      - 3-There was not enough time
      - 4-Self-administered by the study participant
      - 9-Other reason, specify

      If 1-3, STOP.
      If 4, go to question 2.
      If 9, complete 'a1' and STOP.

   a1. **If 9-Other reason,** specify [30]: ______________________________

2. Indicate the language used to conduct the interview or self-administer the form [30]: ______________________________

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Protocol Number A 0 0 0 0 ☐ Institution Code ☐☐☐☐☐☐

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

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**Enter the subject's current study step number. Enter '1' if the study does not have multiple steps.

INSTRUCTIONS TO SITE PERSONNEL:

- Please check one box for each question where there are check boxes.
- In question 2, enter the name or abbreviation for each drug that the study participant is taking from the list below. For each drug, enter the number of prescribed doses that the study participant is supposed to be taking each day. In the remaining columns enter the number of doses missed for each time period listed.

1. Have you been prescribed any anti-HIV medications today or since the last visit?... ☐ Yes (1) ☐ No (2) ☐

   If No, go to question 7.
   If Yes, continue.

The next section of the questionnaire asks about the study medications that you may have missed taking over the **past three days** and the **past two weeks**. Using the drug abbreviations provided, please complete the table on the next page using one line for each study medication you are taking.

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2. How many doses did you miss…?

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.

Abbreviation/ Name of Your Drugs [30]	Number of Prescribed Doses *Per Day*	Number of Prescribed Doses Missed *Yesterday*	Number of Prescribed Doses Missed *Day before yesterday (2 days ago)*	Number of Prescribed Doses Missed *(3 days ago)*	Number of Prescribed Doses Missed *(Past 2 weeks)**
	☐ 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

**** Past two weeks includes the doses missed yesterday, 2 days ago, and 3 days ago.***

Anti-HIV Drugs for Protocol A0000:
Insert current drug code list here.

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The following questions pertain to the medications on page 2.

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

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	☐

4. During the past 4 days, for **how many days** have you missed taking **all your doses?**

None	0	☐
One day	1	☐
Two days	2	☐
Three days	3	☐
Four days	4	☐

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

☐ Yes (1) ☐ No (2)

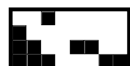
People may miss taking their medications for various reasons. Here is a list of possible reasons why you may have missed taking any medications within the **past month.**

6. If you have **NOT TAKEN ANY** medications within the **past month**, please check this box. ☐ 1

In the **past month**, how often have you **missed taking your medications** because you:

Please check one box for each question.

	Never	Rarely	Some-Times	Often
a. Wanted to avoid side effects? …………	☐ 0	☐ 1	☐ 2	☐ 3
b. Could not follow dietary instruction? …….	☐ 0	☐ 1	☐ 2	☐ 3
c. Sharing ART with other family members and friends? ……………………………….	☐ 0	☐ 1	☐ 2	☐ 3
d. Religious beliefs? …………………………	☐ 0	☐ 1	☐ 2	☐ 3
e. Not fully understanding the regimen and its requirements? …………………………	☐ 0	☐ 1	☐ 2	☐ 3
f. Traveling away from home? ……………..	☐ 0	☐ 1	☐ 2	☐ 3
g. Transportation problems getting to the clinic? ……………………………………….	☐ 0	☐ 1	☐ 2	☐ 3
h. Lost pills? …………………………………..	☐ 0	☐ 1	☐ 2	☐ 3
i. Had too many pills? ……………………….	☐ 0	☐ 1	☐ 2	☐ 3
j. Had a bad event happen that you felt was related to taking the pills? ………….	☐ 0	☐ 1	☐ 2	☐ 3



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6. Continued…
Please check one box for each question.

	Never	Rarely	Some-Times	Often
k. Forgot?	☐ 0	☐ 1	☐ 2	☐ 3
l. Ran out of pills?	☐ 0	☐ 1	☐ 2	☐ 3
m. Busy doing other things (e.g. working, trying to survive, getting food)?	☐ 0	☐ 1	☐ 2	☐ 3
n. Tired of taking too many pills?	☐ 0	☐ 1	☐ 2	☐ 3
o. Other illness or health problems got in the way?	☐ 0	☐ 1	☐ 2	☐ 3
p. Stigmatization (what others may say or discover about my disease) by people outside of one's family?	☐ 0	☐ 1	☐ 2	☐ 3
q. Fear of stigmatization within the home (e.g. not wanting the husband or wife to know)?	☐ 0	☐ 1	☐ 2	☐ 3
r. Pills got damaged from heat or getting wet?	☐ 0	☐ 1	☐ 2	☐ 3
s. Too ill to attend clinic to collect drugs?	☐ 0	☐ 1	☐ 2	☐ 3
t. Pills getting stolen (e.g. while in transit in a taxi/bus/train)?	☐ 0	☐ 1	☐ 2	☐ 3
u. Having to wake up very early to commute to work and no time to eat?	☐ 0	☐ 1	☐ 2	☐ 3
v. Didn't think they would really work?	☐ 0	☐ 1	☐ 2	☐ 3
w. Bothered by your dreams?	☐ 0	☐ 1	☐ 2	☐ 3
x. Other?	☐ 0	☐ 1	☐ 2	☐ 3

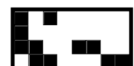
Specify [30]: ______________________

7. During the **past 4 weeks**, has your health kept you from working at a job, doing work around the house, or going to school?

- Yes, for all of the time .... 1 ☐
- Yes, for some of the time .... 2 ☐
- No .... 3 ☐

8. During the **past 4 weeks**, how much pain have you had (e.g., headache, muscle pain, back pain, stomach ache)?

- None .... 1 ☐
- Very Mild .... 2 ☐
- Mild .... 3 ☐
- Moderate .... 4 ☐
- Severe .... 5 ☐
- Very severe .... 6 ☐



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9. During the **past 4 weeks**, how much has your physical health or emotional problems interfered with your normal social activities (e.g., socializing with friends or family)?
   - Not at all .... 1 ☐
   - A little bit .... 2 ☐
   - Moderately .... 3 ☐
   - Quite a bit .... 4 ☐
   - Extremely.................................. 5 ☐

10. During the **past 4 weeks**, have you been unable to do certain kinds or amounts of work, housework, or schoolwork because of your health?
    - Yes, for all of the time .... 1 ☐
    - Yes, for some of the time .... 2 ☐
    - No .... 3 ☐

11. During the **past 4 weeks**, how much did pain interfere with your normal work (including housework)?
    - Not at all .... 1 ☐
    - A little bit .... 2 ☐
    - Moderately .... 3 ☐
    - Quite a bit .... 4 ☐
    - Extremely.................................. 5 ☐

12. How much, if at all, does your health now limit you in the following activities?

	YES Limited A Lot	**YES Limited A Little**	**NO Not Limited At All**
a. The kind or amounts of vigorous activities you can do, like lifting heavy objects or running.	☐ 1	☐ 2	☐ 3
b. The kind or amounts of moderate activities you can do, like going to the market.	☐ 1	☐ 2	☐ 3
c. Walking uphill or climbing a few flights of stairs.	☐ 1	☐ 2	☐ 3
d. Eating, dressing, bathing, or toileting.	☐ 1	☐ 2	☐ 3

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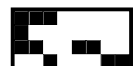
13. In general, would you say your health is:

(Mark One)

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

14. How much of the time during the **past 4 weeks**...

	All of the Time	Most of the Time	A Good Bit of Time	Some of the Time	A Little of the Time	None of the Time
a. Has your health limited your social activities, like visiting with family and friends?.........................	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
b. Did you have trouble keeping your attention on any activity for long?.........	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
c. Did you have difficulty reasoning and solving problems?.....................	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
d. Have you been nervous?...	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
e. Have you felt very sad or depressed?.....................	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
f. Did you feel tired or fatigued?......................	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
g. Did you have enough energy to do the things you wanted to do?...........	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
h. Have you been a happy person?........................	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
i. Have you had trouble remembering things?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6



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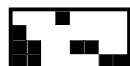
15. These are some questions about your general health, how you've been feeling and support from family and friends.

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False	
a. My health is excellent.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐
b. I have been feeling bad lately.	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐

	Very Dissatisfied	Somewhat Dissatisfied	Somewhat Satisfied	Very Satisfied	
16. In general, how satisfied are you with the overall support you get from your friends and family members?	☐ 0	☐ 1	☐ 2	☐ 3	☐

	Not At All	A Little	Somewhat	A lot	Not Applicable	
17. To what extent do your friends or family members help you remember to take your medication?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4	☐



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18. People have various health habits. The following questions ask about your alcohol and drug use, past and current.

a. During the **past 30 days**, how often have you had 5 or more drinks of alcohol (e.g., fermented beverages, beer, wine, or spirits) in a row within a couple of hours (e.g., 2 - 4 hours)?

Daily	Nearly Every Day	3 or 4 Times A Week	Once or Twice A Week	2 or 3 Times A Month	Once A Month	Never	
☐ 6	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1	☐ 0	☐

b. In the **past 30 days**, have you used any of the following substances? ☐ Yes 1 ☐ No 2 ☐
If No, go to question 19.
If Yes, continue.

b1. Marijuana?	☐ Yes 1	☐ No 2	☐
b2. Cocaine (powder, crack, freebase injections)?	☐ Yes 1	☐ No 2	☐
b3. Heroin?	☐ Yes 1	☐ No 2	☐
b4. Amphetamines (speed)?	☐ Yes 1	☐ No 2	☐
b5. Sniffing organic solvents, glues or thinners?	☐ Yes 1	☐ No 2	☐
b6. Other?	☐ Yes 1	☐ No 2	☐

Specify [30]: ______________________________

b7. For the substance used most, indicate how often it was used in the **past 30 days**:

Daily	Nearly Every Day	3 or 4 Times A Week	Once or Twice A Week	2 or 3 Times A Month	Once A Month	Never	
☐ 6	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1	☐ 0	☐

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These questions are about the different ways people have sex. Some of the questions ask you about vaginal sex, and some are about anal sex. By vaginal sex, we mean when a man puts his penis inside a woman's vagina. By anal sex, we mean a man puts his penis inside someone's anus.

19. In the **past 3 months**, how many sex partners have you had? By sex partner, I mean someone with whom you have had vaginal or anal sex:.......................... ☐☐☐☐
    If 0, STOP.
    If 1 or more, continue.

  a. In the **past 3 months**, did you have vaginal sex? .... ☐ Yes (1) ☐ No (2) ☐
     If No, skip to question 20.

  b. In the **past week**, how many times did you have vaginal sex with your primary partner? By primary partner, I mean a wife/husband, girlfriend/boyfriend, or steady partner with whom you have a primary relationship?.............................. ☐☐☐☐

  b1. Of those times, how often was a condom used? By condom, I mean a male or female condom: .... ☐☐☐☐

  c. In the **past week**, how many times did you have vaginal sex with someone other than your primary partner? .... ☐☐☐☐

  c1. Of those times, how often was a condom used? By condom, I mean a male or female condom: .... ☐☐☐☐

  d. The last time you had vaginal sex, was a condom used? ...... ☐ Yes (1) ☐ No (2) ☐

20. In the **past 3 months**, did you have anal sex? .... ☐ Yes (1) ☐ No (2) ☐
    If No, STOP.

  a. In the **past week**, how many times did you have anal sex with your primary partner? .... ☐☐☐☐

  a1. Of those times, how often was a condom used? By condom, I mean a male or female condom: .... ☐☐☐☐

  b. In the **past week**, how many times did you have anal sex with someone other than your primary partner? .... ☐☐☐☐

  b1. Of those times, how often was a condom used? By condom, I mean a male or female condom: .... ☐☐☐☐

  c. The last time you had anal sex, was a condom used? .... ☐ Yes (1) ☐ No (2) ☐

Thank you very much for completing these questions.

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