# ADHERENCE / PSYCHOSOCIAL FACTORS QUESTIONNAIRE

NIAID AIDS CLINICAL TRIALS GROUP



Patient Number [ ][ ][ ] [ ][ ][ ][ ] [ ]

Protocol Number [ ][ ][ ][ ][ ][ ]

Date of Patient Visit/Contact [ ][ ][ ] mmm [ ][ ] dd [ ][ ][ ][ ] yyyy

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 PAGES 1 AND 2

**INSTRUCTIONS TO THE STUDY NURSE:**

The ADHERENCE / PSYCHOSOCIAL FACTORS QUESTIONNAIRE should be given to the study participant prior to the clinical exam and preferably in a quiet secluded area (for example, exam room or other office). This questionnaire is designed for study participants who can read at the sixth-grade level; participants who have difficulty reading may need 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 participant:

> "We are trying to understand better what factors make it easier or harder for you to take your anti-HIV medications. Please answer all questions honestly; you will not be 'judged' based on your responses. If you do not wish to answer a question, please draw a line through it. Please feel free to ask if you need any of the questions explained to you."

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 15-20 minutes to complete. Before giving the study participant the questionnaire, please fill out the header(s) and DETACH PAGES 1 AND 2 from the rest of the form.

Each question is in the same general format and contains several items. Note that the study participant is always asked to make a check (✓) in the box for each question where there are check boxes.

Instruct the study participant to place the completed questionnaire in the envelope, seal it, and return it to you. The completed form can either be faxed or mailed to the Data Management Center.

- When faxing, address the fax to the DMC study data manager. The fax number is 716-834-8432. Include the country code when faxing from an international site. The person faxing should be someone other than the study nurse.
- If sending by postal mail, send to:

ACTG DATA FSTRF
Attn.: ACTG [enter study number] Data Manager
4033 Maple Road
Amherst, New York 14226

**Questions 1 through 3 on page 2 are completed and keyed by the clinic personnel.**

## ADHERENCE / PSYCHOSOCIAL FACTORS QUESTIONNAIRE

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1. Was the questionnaire given to the participant?

☐ 1-Yes → a. How was the questionnaire completed?
☐ 1-Self administered by the participant
2-Face-to-face interview
3-Both self-administered and interview
9-Other, specify [70]:

_____

**Go to question 2.**

2-No → b. Indicate reason:
☐ 1-Participant declined
2-Not enough time to complete form in clinic
9-Other, specify [70]:

_____

**STOP.**

2. Was the sealed envelope returned to you to send to the Data Management Center? ..... (1-Yes, 2-No) ☐

3. 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:** ☐☐

# ADHERENCE / PSYCHOSOCIAL FACTORS QUESTIONNAIRE

NIAID AIDS CLINICAL TRIALS GROUP



Patient Number ☐☐☐ ☐☐☐☐ ☐ Date of Patient Visit/Contact ☐☐☐ mmm ☐☐ dd ☐☐☐☐ yyyy

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

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

**Please check one box for each question where there are check boxes. If you do not wish to answer a question, please draw a line through it.**

## SECTION A

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

| Not at all | Some of the time | All of the time |
|---|---|---|
| ☐ 0 | ☐ 1 | ☐ 2 |

2. During the **past 4 weeks**, how much pain have you had (for example, headache, muscle pain, back pain, stomach ache)? ***(Check one)***

| None | Very Mild | Mild | Moderate | Severe | Very severe |
|---|---|---|---|---|---|
| ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

3. During the **past 4 weeks**, how much has your physical health or emotional problems interfered with your normal social activities (for example, socializing with friends or family)? ***(Check one)***

| Not at all | A little bit | Moderately | Quite a bit | Extremely |
|---|---|---|---|---|
| ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 |

4. In general, how satisfied are you with the overall support you get from your friends and family members? ***(Check one)***

| Very dissatisfied | Somewhat dissatisfied | Somewhat satisfied | Very satisfied |
|---|---|---|---|
| ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |

5. To what extent do your friends or family members help you remember to take your medication? ***(Check one)***

| Not at all | A little | Somewhat | A lot | Not applicable |
|---|---|---|---|---|
| ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 |

6. How sure are you that:

| ***Please check one box for each question.*** | Not at all sure | Somewhat sure | Very sure | Extremely sure |
|---|---|---|---|---|
| a. You will be able to take all or most of your anti-HIV medication as directed? ..... | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| b. The anti-HIV medication will have a positive effect on your health? ..... | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| c. If you do not take your anti-HIV medication exactly as directed, the HIV in your body will become resistant to this medication? .. | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |

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People may miss taking their anti-HIV medications for various reasons. Here is a list of possible reasons why you may have missed taking your anti-HIV medications.
If you have <u>never</u> taken anti-HIV medications, go to question 8.

7. During the last month, have you been prescribed any anti-HIV medications? ☐ Yes (1) ☐ No (2) → **Go to question 8.**

↓

**Continue with questions.**

***Please check one box for each question.***

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

| | Never | Rarely | Sometimes | Often |
|---|---|---|---|---|
| a. You wanted to avoid side effects? ..... | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| b. Of sharing anti-HIV medications with other family members and friends? ..... | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| c. Of religious beliefs? ..... | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| d. Of not fully understanding the anti-HIV medications and their requirements? ..... | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| e. Of traveling away from home (for example to work, family, friends)? ..... | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| f. Of transportation problems getting to the clinic? ..... | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| g. Of lost or stolen pills (for example, while in transit in a taxi/bus/train/car)? ..... | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| h. You had too many pills? ..... | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| i. You had a bad event happen that you felt was related to taking the pills? ..... | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| j. You forgot? ..... | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| k. You ran out of pills? ..... | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| l. You were busy doing other things (for example, working, trying to survive, getting food)? ..... | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| m. Of not having enough food to eat (for example, to take with your pills)? ..... | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| n. Of concern that anti-HIV medications would work so well that you would lose public financial support? ..... | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| o. Of fear of stigmatization or being discriminated against outside the home (for example, what others may say)? | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |

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7. Continued.

***Please check one box for each question.***

| | Never | Rarely | Sometimes | Often |
|---|---|---|---|---|
| p. Of fear of stigmatization or being discriminated against within the home (for example, not wanting husband, wife, partner to know)? ..... | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| q. You felt the anti-HIV medications were toxic or harmful? ..... | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| r. Your pills got damaged by heat or getting wet? ..... | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| s. You were too ill to attend clinic visits to collect medications? ..... | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| t. You felt depressed or overwhelmed? ..... | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| u. You didn't think they would really work? ..... | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| v. You were bothered by your dreams? ..... | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| w. Other reason? Please specify below. ..... | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |

Specify [70]: _____

## SECTION B

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

**Definition of a drink:** Although the types of drink differ in size, each has about the same amount of alcohol and counts as a single drink.

| | |
|---|---|
| Beer (about 5% alcohol by volume)..... | 12-ounce (355 mL) can, bottle, glass |
| Cooler (about 5% alcohol by volume)..... | 12-ounce (355 mL) bottle, glass |
| Malt Liquor (about 7% alcohol by volume)..... | 8-ounce (237 mL) glass |
| Wine (about 12% alcohol by volume)..... | 5-ounce (148 mL) glass |
| 80-proof distilled spirits or liquor (for example, gin, vodka, tequila, rum, or whiskey; about 40% alcohol by volume).... | 1.5-ounce (44 mL) shot or a mixed drink |

8. **During the past 30 days**, how often have you had a drink containing alcohol - beer, wine, a mixed drink, or any kind of alcoholic beverage? ***(Check one)***

| Never | Once a month | 2 or 3 times a month | Once or twice a week | 3 or 4 times a week | 5-6 times a week | Daily |
|---|---|---|---|---|---|---|
| ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | ☐ 6 |

**If Never,** go to question 11.

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9. **During the past 30 days**, on a typical day when you drank any alcoholic beverages, how many drinks did you usually have altogether? ***(Check one)***

| 1 drink per day | 2 drinks per day | 3 drinks per day | 4 drinks per day | 5 or more drinks per day |
|---|---|---|---|---|
| ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

10. **During the past 30 days**:
**For males**, how often have you had 5 or more drinks of alcohol in a row, that is, within 2 hours?
**For females**, how often have you had 4 or more drinks of alcohol in a row, that is, within 2 hours?
***(Check one)***

| Never | Once a month | 2 or 3 times a month | Once or twice a week | 3 or 4 times a week | 5-6 times a week | Daily |
|---|---|---|---|---|---|---|
| ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 | ☐ 6 |

***Please check one box for each question.***

| 11. How often have you: | Never | Rarely | Sometimes | Often |
|---|---|---|---|---|
| a. Felt that using alcohol has resulted in your not getting things done in your life or not doing something you should have done like go to work or school?..... | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| b. Had any emotional or psychological problems from using alcohol such as feeling uninterested in things, feeling depressed or suspicious of people or having strange ideas? | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |

***Please check one box for each question.***

| 12. When was the last time you used….. | Never Used | More than one year ago | Within the past year up until 1 month ago | Within the past month |
|---|---|---|---|---|
| a. tobacco (such as cigarettes, cigars, chew)?. | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| b. marijuana (pot, hashish)?…… | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| c. cocaine (crack, powder)?…… | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| d. heroin (smack, horse)?..... | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| e. amphetamines (speed, crystal meth)? ……. | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| f. other non-prescribed drugs including sedatives (downers, sleeping pills), street drugs (ecstasy, LSD), pain pills (morphine, Oxycontin) or inhalants (amylnitrate, glue)?.. | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |

Please list the other drug(s) that you took on your own without a prescription:

[70] _____

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13. Have you used any of the substances listed above in question 12? ☐ Yes (1) ☐ No (2) → **Go to question 15.**
**Continue with questions.**

| 14. Please check one box for each question: | Never | Rarely | Sometimes | Often |
|---|---|---|---|---|
| a. How often have you felt that using the substances listed above has resulted in your not getting things done in your life or not doing something you should have done like go to work or school? …….. | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |
| b. How often have you had any emotional or psychological problems from using these substances such as feeling uninterested in things, feeling depressed or suspicious of people or having strange ideas? …… | ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 |

**Section C**

15. How many children have you had (for example, babies born alive)? ***(Check one)***

| None | One | Two | Three | Four | More than four |
|---|---|---|---|---|---|
| ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

If more than four, also indicate the number of children: _____

16. How many children less than 18 years of age currently live with you (your own and/or others')? ***(Check one)***

| None | One | Two | Three | Four | More than four |
|---|---|---|---|---|---|
| ☐ 0 | ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

If more than four, also indicate the number of children: _____

17. Do you want to have more children (for example, make a baby or adopt/foster a baby/child) in the future? ***(Check one)***

| Yes | No | Not sure |
|---|---|---|
| ☐ 1 | ☐ 2 | ☐ 3 |

If **Yes** or **Not sure**, when? ***(Check one)***

| Within the next year | 1 to 2 years from now | 3 to 4 years from now | More than 4 years from now | I don't know |
|---|---|---|---|---|
| ☐ 1 | ☐ 2 | ☐ 3 | ☐ 4 | ☐ 5 |

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**Birth Control Methods**

18. Some forms of birth control could have occurred years ago, such as an intrauterine device (IUD) that is currently in place or a surgery that prevents pregnancy. Indicate if you or your partner(s) had any of the following procedures that prevent pregnancy done:

***(Check ALL that apply)***

a. Tied tubes, tubal ligation, hysterectomy (surgery of women to prevent pregnancy)..... 1☐
b. Vasectomy (surgery of men to prevent pregnancy)..... 1☐
c. An intrauterine device (IUD)..... 1☐

19. In the last 3 months, indicate if you and your partner(s) used any of the following birth control methods:

***(Check ALL that apply)***

a. Male condoms..... 1☐
b. Female condoms..... 1☐
c. Birth control Pills..... 1☐
d. Withdrawal, pulling out..... 1☐
e. 3-month shot, Depo-Provera..... 1☐
f. A diaphragm..... 1☐
g. Emergency contraception (Morning-after pill, Plan B)..... 1☐
h. Monthly injection..... 1☐
i. Weekly hormonal patch (Ortho-Evra)..... 1☐
j. Spermicide..... 1☐
k. Abstinence (not having sex with someone of the other sex)..... 1☐
l. None..... 1☐
m. Other, please list [70]: _____ 1☐

**Thank you very much for completing this questionnaire.**



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