SUBSTANCE USE SELF REPORT

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 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 SUBSTANCE USE SELF REPORT 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 would like you to answer some questions about your health habits. 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."

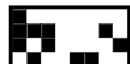
You should then briefly go over the format of the questions and how to complete them. Have the study participant complete the questionnaire before vital signs, history, and physical are completed. The questionnaire is very brief and should take no more than 5 minutes to complete. Before giving the study participant the questionnaire, please fill out the header(s) and DETACH THIS PAGE 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



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

Questions 1 through 3 are completed and keyed by the clinic personnel.

1. Was the questionnaire given to the participant?

☐ 1-Yes → 2-No

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.

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:** ☐☐

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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.

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

1. **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 5.

2. **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

☐

3. **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

☐

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mmm dd yyyy

Please check one box for each question.

4. 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.

5. 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] ____

6. Have you used any of the substances listed above in question 5? ☐ Yes (1) ☐ No (2) → **STOP.**

↓ **Continue with questions.**

Please check one box for each question.

7. How often have you:	Never	Rarely	Sometimes	Often
a. 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. 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

Thank you very much for completing this questionnaire.

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