SYMPTOMS DISTRESS MODULE

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 SYMPTOMS DISTRESS MODULE 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 the kinds of symptoms and feelings you have been having. 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 5 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 a "✓" in the box that comes the closest to how he/she has been feeling.

For data keying, if the subject did not answer a question, enter "-1."

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

Protocol Number ☐☐☐☐☐☐ Institution Code ☐☐☐☐☐☐

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

INSTRUCTIONS: Please answer the following questions by placing a "✓" in the appropriate box.

A. The following questions ask about symptoms you might have had during the **past four weeks.** Please check the box that describes how much you have been bothered by **each** symptom.

(Check one.)	I DO NOT HAVE THIS SYMPTOM	I HAVE THIS SYMPTOM AND…			
		It doesn't bother me	It bothers me a little	It bothers me	It bothers me alot
1. Fatigue or loss of energy?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
2. Fevers, chills or sweats?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
3. Feeling dizzy or lightheaded?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
4. Pain, numbness or tingling in the hands or feet?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
5. Trouble remembering?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
6. Nausea or vomiting?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
7. Diarrhea or loose bowel movements?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
8. Felt sad, down or depressed?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
9. Felt nervous or anxious?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
10. Difficulty falling or staying asleep?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
11. Skin problems, such as rash, dryness or itching?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

SYMPTOMS DISTRESS MODULE

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

(Check one.)	I DO NOT HAVE THIS SYMPTOM	I HAVE THIS SYMPTOM AND…			
		It doesn't bother me	It bothers me a little	It bothers me	It bothers me alot
12. Cough or trouble catching your breath?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
13. Headache?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
14. Loss of appetite or a change in the taste of food?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
15. Bloating, pain or gas in your stomach?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
16. Muscle aches or joint pain?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
17. Problems with having sex, such as loss of interest or lack of satisfaction?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
18. Changes in the way your body looks such as fat deposits or weight gain?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
19. Problems with weight loss or wasting?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4
20. Hair loss or changes in the way your hair looks?	☐ 0	☐ 1	☐ 2	☐ 3	☐ 4

Thank you very much for completing this questionnaire.

Language: English ☐ E

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