GENERAL HEALTH SELF-ASSESSMENT FORM

NIAID 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 following questionnaire asks the patient about many aspects of his/her health and health care. It should be given to the patient prior to the clinical exam and preferably in a quiet secluded area (e.g., exam room or other office). The patient 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 participant:

"We would like you to answer some questions about how you are feeling and the kinds of things you are able to do. 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 participant 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 patient the questionnaire, please fill out the header(s) and DETACH THIS PAGE.

Each question is in the same general format. Note that the patient is always asked to circle a number or make an “X” or a “✓” next to the appropriate category. All questions refer to the PAST 4 WEEKS.

Collect the completed questionnaire before the clinical exam. Before going on, review the questionnaire for omissions. If the participant missed any of the questions, point this out and have him/her complete the omissions.

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

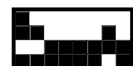
1. How was the questionnaire completed? .... ☐
   - 1 - Self administered by the study participant
   - 2 - Face-to-face interview that you conducted
   - 3 - Phone interview
   - 4 - Not completed
   - 5 - Other

   If Other, specify [30]: ______________________________

2. If you answered ‘4 - Not completed’, please indicate the reason(s) why: (1-Yes, 2-No)

   Patient refused initially: .... ☐
   Patient's reading level not adequate: .... ☐
   Patient could not complete it after trying: .... ☐
   There was not enough time: .... ☐
   Patient forgot reading glasses: .... ☐
   Other reason: .... ☐

   If Other, specify [30]: ______________________________



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INSTRUCTIONS TO PATIENT: **Please answer the following questions by circling the most appropriate response.**

A. On a scale from 1 to 10 (1 being the very worst, and 10 being the very best):

HOW HAVE YOU BEEN FEELING, ON THE AVERAGE, DURING THE PAST 4 WEEKS?

(Please circle a number between 1 and 10 in each question)

	The Very Worst I Ever Felt									The Very Best I Ever Felt	
1. Overall, in general?	1	2	3	4	5	6	7	8	9	10	☐
2. Physically?	1	2	3	4	5	6	7	8	9	10	☐
3. Emotionally?	1	2	3	4	5	6	7	8	9	10	☐
4. Personal Life?	1	2	3	4	5	6	7	8	9	10	☐
5. About your job, work*?	1	2	3	4	5	6	7	8	9	10	☐

* If you are a homemaker, student, retired, or unemployed, YOUR WORK means your daily duties, chores, routine, or school.

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B. HOW MUCH, if at all, has YOUR HEALTH interfered with your ability in each of the following activities during the PAST 4 WEEKS?

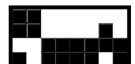
(Please circle one number for each question.)

HOW MUCH HAS YOUR HEALTH INTERFERED WITH…?	**Not at all**	**A little bit**	**Moderately**	**Quite a bit**	**Extremely**	
1. The kinds or amounts of vigorous activities you can do, like lifting heavy objects, running, or participating in strenuous sports?	1	2	3	4	5	☐
2. The kinds or amounts of moderate activities you can do, like moving a table, carrying groceries, or moderately active sports like bowling?	1	2	3	4	5	☐
3. Walking uphill or climbing a few flights of stairs?	1	2	3	4	5	☐
4. Walking one block?	1	2	3	4	5	☐
5. Bending, lifting or stooping?	1	2	3	4	5	☐
6. Eating, dressing, bathing or using the toilet?	1	2	3	4	5	☐

Please comment on any other problems if you wish [140]:

____

____



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C. These questions are about HOW YOU FEEL and HOW THINGS HAVE BEEN WITH YOU during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling DURING THE PAST 4 WEEKS.

(Please circle one number for each question.)

HOW MUCH OF THE TIME HAVE YOU…?	**None of the Time**	**A Little of the Time**	**Some of the Time**	**A Good Bit of the Time**	**Most of the Time**	**All of the Time**	
1. Been a very nervous person? ……	1	2	3	4	5	6	[ ]
2. Felt so down in the dumps nothing could cheer you up? ……..	1	2	3	4	5	6	[ ]
3. Felt full of pep and vitality? ……….	1	2	3	4	5	6	[ ]
4. Felt calm and peaceful? …………..	1	2	3	4	5	6	[ ]
5. Felt downhearted and blue? ………	1	2	3	4	5	6	[ ]
6. Felt worn out? ………………………	1	2	3	4	5	6	[ ]
7. Been a happy person? …………….	1	2	3	4	5	6	[ ]
8. Felt tired? ……………………………	1	2	3	4	5	6	[ ]
9. Had enough energy to do the things you wanted to do? …………	1	2	3	4	5	6	[ ]
10. Had trouble remembering things? ..	1	2	3	4	5	6	[ ]
11. Had difficulty doing activities involving concentration or thinking?	1	2	3	4	5	6	[ ]
12. Reacted slowly to things that were said or done? ………………………..	1	2	3	4	5	6	[ ]

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D. HOW MUCH OF THE TIME has YOUR HEALTH (physical or emotional problems) caused you to do any of the following things, DURING THE PAST 4 WEEKS?

(Please circle one number for each question.)

HOW MUCH OF THE TIME HAS YOUR HEALTH CAUSED YOU TO…?	**None of the Time**	**A Little of the Time**	**Some of the Time**	**A Good Bit of the Time**	**Most of the Time**	**All of the Time**	
1. Stay in bed because you were not feeling well? …………………………	1	2	3	4	5	6	☐
2. Cut down on your usual daily activities such as your job, housework, school? ………………	1	2	3	4	5	6	☐
3. Cut down on your social activities, like visiting with friends and relatives? ……………………………	1	2	3	4	5	6	☐

E. DURING THE PAST 4 WEEKS you might have received medical care or general assistance. AS WELL AS YOU CAN REMEMBER, **HOW MANY NIGHTS, VISITS, OR TIMES?**
(Place an "X" or a "✓" on the line next to your answer)

1. HOW MANY NIGHTS did you stay in a hospital?

0 ____ (1) **1-2** ____ (2) **3-5** ____ (3) **6-10** ____ (4) **11-15** ____ (5) **16-20** ____ (6) **>20** ____ (7) ☐

2. HOW MANY VISITS did you make to a clinic, office or emergency room to see a doctor, nurse or other specialist?

0 ____ (1) **1-2** ____ (2) **3-5** ____ (3) **6-10** ____ (4) **11-15** ____ (5) **16-20** ____ (6) **>20** ____ (7) ☐

3. HOW MANY TIMES have you been visited by a nurse or other health care provider at your home?

0 ____ (1) **1-2** ____ (2) **3-5** ____ (3) **6-10** ____ (4) **11-15** ____ (5) **16-20** ____ (6) **>20** ____ (7) ☐

4. HOW MANY TIMES have you received general assistance with your household chores, shopping or personal care (e.g., bathing or dressing)?

0 ____ (1) **1-2** ____ (2) **3-5** ____ (3) **6-10** ____ (4) **11-15** ____ (5) **16-20** ____ (6) **>20** ____ (7) ☐

5. HOW MANY TIMES have you called your clinic, physician, nurse or other health care provider for a medical consultation over the telephone?

0 ____ (1) **1-2** ____ (2) **3-5** ____ (3) **6-10** ____ (4) **11-15** ____ (5) **16-20** ____ (6) **>20** ____ (7) ☐

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F. The following questions ask about SYMPTOMS OR FEELINGS you might have had during the past 4 weeks. Please answer HOW DISTRESSING the following symptoms have been for you DURING THE PAST 4 WEEKS.

(Please circle one number for each question)

HOW MUCH WERE YOU DISTRESSED BY THIS SYMPTOM OR FEELING?	Not at All	Very Mildly	Mildly	Moderately	Very Much	Extremely
1. Physical or bodily pain	1	2	3	4	5	6
2. Coughing, wheezing	1	2	3	4	5	6
3 Nausea, vomiting, abdominal/stomach pain	1	2	3	4	5	6
4. Rash, itching, or other skin problems	1	2	3	4	5	6
5. Fatigue, weakness	1	2	3	4	5	6
6. Feeling dizzy or lightheaded	1	2	3	4	5	6
7. Fever, night sweats, shaking, chills	1	2	3	4	5	6
8. Loss of appetite	1	2	3	4	5	6
9. Trouble sleeping	1	2	3	4	5	6
10. Eye trouble, problems with vision	1	2	3	4	5	6
11. Headache	1	2	3	4	5	6
12. Dry or painful mouth, trouble swallowing	1	2	3	4	5	6
13. Chest pain or tightness	1	2	3	4	5	6
14. Difficulty breathing or catching breath	1	2	3	4	5	6
15. Runny nose, sinus trouble	1	2	3	4	5	6
16. Muscle aches, joint, bone pain	1	2	3	4	5	6
17. Pain, numbness, or tingling in hands or feet	1	2	3	4	5	6
18. Overall discomfort	1	2	3	4	5	6

THANK YOU VERY MUCH FOR YOUR TIME.

YOUR EFFORTS WILL BE VERY VALUABLE IN EVALUATING NEW THERAPIES.

Language: English [ ]

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