

OVERALL HEALTH STATUS ASSESSMENT

NIAID AIDS CLINICAL TRIALS GROUP

Patient Number	<input type="text"/>	<input type="text"/>	<input type="text"/>	Date of Patient Visit	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
					mmm	dd	yyyy		
Protocol Number	<input type="text"/>	<input type="text"/>	<input type="text"/>	Institution Code	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Form Week	<input type="text"/>	<input type="text"/>	<input type="text"/>	* Seq No.	<input type="text"/>	** Step No.	<input type="text"/>	Key Operator Code	<input type="text"/>

* 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
MODULE A**

INSTRUCTIONS TO THE STUDY NURSE:

Have the patient answer each question at each visit. If the patient does not answer a question at this visit, use "-1" to indicate "Not Done." OVERALL HEALTH STATUS ASSESSMENT - MODULE A 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. Your answers will help us understand the effects of the study medication. 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 clinical evaluations.

The questionnaire is very brief and should take no more than 5 minutes to complete. Before giving the patient the questionnaire, please fill out the header(s) and DETACH THIS PAGE.

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
 - 9-Other, specify

If Other, specify [30]: _____

- a. If you answered "4-Not completed," please indicate the reason why :
- 1-Patient refused initially
 - 2-Patient missed clinic visit
 - 3-There was not enough time
 - 9-Other reason, specify

If Other, specify [30]: _____



