

General Instructions

The Quality of Life (SF-36) questionnaire is designed to measure the patient's quality of life through questions related to physical activities and emotional health. This Quality of Life questionnaire is completed at the Baseline (week 0) visit and at weeks 8, 48, and 96. At the Baseline, week 48, and week 96 visits, the Quality of Life questionnaire will include the Health Behavior questionnaire which captures tobacco, marijuana, coffee, tea and alcohol use during the past year. If the questionnaire is completed on-line, the system will allow the patient to enter "Unknown" or "Refused" responses for the health behavior questions.

The questionnaire is self-explanatory and the patient should be asked to complete it without additional instructions or assistance. The clinical coordinator should not attempt to interpret, elaborate upon, or rephrase questions. If the patient asks for assistance from the clinical coordinator, the coordinator should encourage the patient to do his/her best to complete the form on his/her own, stating that "there are no right or wrong answers".

The questionnaire will be available in multiple languages. For patients not fluent in English, a translated version of the questionnaire should be used if available or the information may be obtained via interview by a certified translator. If the patient is unable to understand the questions because of educational, cultural or language difficulties, and a trained translator is not available, help may be provided by the patient's next of kin or friend. In these situations the person helping the patient can read the questions to the patient and record the answers, or supply the answers to the best of his/her knowledge.

The English version of the questionnaire is designed to be completed via the HBRN web-based data management system. If completed on-line, the system will follow the skip pattern indicated on the form. If the questionnaire is completed on paper, be sure to review the questionnaire for completeness while the patient is still present.

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Specific Instructions

Patient ID:	Record the Patient ID in the top right hand corner.
Date of Evaluation:	Record the date (month/day/year) that the patient completed the questionnaire.
Protocol visit:	Record the protocol timepoint that corresponds to the visit.
Form completed by:	If the patient is unable to understand the questions because of educational, cultural or language difficulties help may be provided by a trained translator or the patient's next of kin or friend. In these situations the person helping the patient can read the questions to the patient and record the answers, or supply the answers to the best of his/her knowledge. Check each box to indicate who completed the form (patient, coordinator, interpreter, family member/friend or other).

Section I: Quality of Life

This section asks the patient about his/her view of his/her health. The questions ask how the patient feels and their ability to perform usual activities. A response should be recorded for each question.



Section II: Health Behaviors

	The questions in this section capture information regarding tobacco, marijuana, coffee, tea, and alcohol use during the past year.
Tobacco use:	(a) Check the status of the patient's tobacco use. Tobacco products include but are not limited to cigarettes, cigars, and smokeless tobacco products such as chewing/dipping tobacco or snuff.
	(b) If the patient formerly used tobacco, record the four digit year the patient stopped using tobacco products.
Marijuana use:	Check the appropriate category to indicate how often the patient used marijuana during the past year. Other terms used for marijuana include but are not limited to hash, THC, grass, or pot.
Coffee use:	Check the appropriate category for the number of cups of coffee the patient typically drinks per day over the past year. One cup of coffee equals 8 ounces and includes hot or cold. Espresso and other types of coffee beverages should be counted, even though a cup may not be a full 8 ounces.
Tea use:	Check the corresponding group for the number of cups of tea the patient typically drinks per day over the past year. One cup of tea equals 8 ounces and includes black or green tea and includes hot or cold.
Alcohol use	
Past 12 months:	(1) Check "Yes" or "No' to indicate if the patient had 12 or more drinks of any alcoholic beverages in the past 12 months. If "No", skip questions 6 through 9.
	(2) Check "Yes" or "No" to indicate if the patient had an alcoholic beverage at least once a week in the past 12 months. If "No", skip questions 7 through 9.
	(3) Record the number of days a week the patient had an alcoholic beverage during the past 12 months.
	(4) Record the number of alcoholic drinks per day the patient had on the days the patient drank alcohol.
	(5) Record the number of days a month the patient had 5 or more alcoholic drinks on one day in the past 12 months.