

General Instructions

The PROMIS fatigue questionnaire is designed to measure fatigue and the impact fatigue has had on daily activities over the past 7 days. The PROMIS questionnaire will be administered at the Baseline (week 0) visit and at week 96 in both the treated and control patients.

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 is available in English and Spanish. If the patient cannot complete the questionnaire in English or Spanish then the questionnaire should not be administered.

The questionnaire is designed to be completed on-line via the HBRN web-based system. If completed on-line, the coordinator will initialize the session for the patient. The patient will complete the questionnaires and then turn the session over to the coordinator. The coordinator will have the opportunity to review incomplete items with the patient before exiting the session. If the questionnaire is completed on paper, the coordinator should review the questionnaire for completeness while the patient is still present.

The HBRN obtained permission to use the questionnaire - © 2009 PROMIS Health Organization and PROMIS Cooperative Group.

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). |
| PROMIS | Each statement refers to how often the patient has felt that way during the <i>past</i> 7 <i>days</i> . A response should be recorded for each question. |