

EVALUATION TO SIGN CONSENT FORM

Subject I.D. #: _____ Subject Initials: _____ Subject Source: _____
 Rater I.D. #: _____ Rater Initials: _____
 Date of Rating: _____ Date of Entry (Data Mgmt): _____
 Protocol (Optional): _____ Time Frame: _____
 Notes (Optional): _____

PROCEDURE:

Make a subjective judgement regarding item 1 below. Ask the patient questions 2-6. The evaluator may select the language to use in asking the questions in order to help the patient understand them.

ITEMS:

SCORE

- | | |
|---|-------|
| 1. Is the patient alert and able to communicate with the examiner?
yes = 2 no = 0 | _____ |
| 2. Ask the patient to name at least two (2) potential risks incurred as a result of participating in the study. 0 = unable to list potential risks, 1 = can list one risk, 2 = can list two risks | _____ |
| _____ | |
| 3. Ask the patient to name at least two (2) things that will be expected of him/her in terms of patient cooperation during the study. 0 = not able to list expectations, 1 = able to list one expectation, 2 = able to list two expectations | _____ |
| _____ | |
| 4. Ask the patient to explain what he/she would do if he/she decides that they no longer wish to participate in the study. 0 = doesn't know, 1 = answers but not the most appropriate response, 2 = talk to any staff member | _____ |
| _____ | |
| 5. Ask the patient to explain what he/she would do if he/she is experiencing distress or discomfort. 0 = doesn't know, 1 = answers but not the most appropriate response, 2 = talk to any staff member | _____ |
| _____ | |
| 6. Ask the patient to explain how medications (or treatments) are assigned during the study. 0 = doesn't know, 1 = answers but not the most appropriate response, 2 = correct answer | _____ |
| _____ | |

SIGNATURES:

I hereby certify that the above patient is alert, able to communicate and able to give acceptable answers to items 2,3,4,5, and 6 above.

Total Score _____

Evaluator Date

Witness Date