

# 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**

- |   |              |
|---|--------------|
| <p>1. Is the patient alert and able to communicate with the examiner?<br/>                 yes = 2 no = 0</p>   | <p>_____</p> |
| <p>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</p> <p>_____</p> <p>_____</p>  | <p>_____</p> |
| <p>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</p> <p>_____</p> <p>_____</p> | <p>_____</p> |
| <p>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</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p>_____</p>                 | <p>_____</p> |
| <p>0 = doesn't know, 1 = answers but not the most appropriate response, 2 = correct answer</p> <p>_____</p> <p>_____</p>  | <p>_____</p> |

**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