ASSESSMENT OF CAPACITY TO CONSENT TO PARTICIPATE IN RESEARCH

Date: _____

IRB #: _____

Title of Protocol: _____

Principal Investigator: _____

Subject Identifier: _____

Instructions: In order to obtain a subject's legally effective informed consent, he/she must have the capacity (i.e. cognitive ability) to decide whether or not to participate in the research. The following questions are designed to assist the investigator/designee in assessing a prospective subject's capacity to consent to participate in research when their ability is in question. The prospective subject should be asked each of these questions during the process of consent and the assessment recorded on this form along with any relevant comments.

Answers by the subject to questions from the examiner should be evaluated and a determination made that the subject's answer reflects adequate understanding or inadequate understanding. This determination should be indicated by checking the appropriate box. The examiner should be aware that the final check mark could reflect an iterative process (i.e. the person only partly understood the concept the first time but after some additional clarification and education they were able (or not) to grasp each concept.) A copy of the completed form must be maintained on file in the research record.

Assessment of Understanding		**Question**
Adequate	**Inadequate**	
☐	☐	What is the purpose of this research study?
☐	☐	What are the risks if you take part in this research study?
☐	☐	How might this research study help you?
☐	☐	Do you have to be in this research study?
☐	☐	What will happen if you decide not to be in this research study?
☐	☐	What would you do if you wanted to leave this research study?

Comments:

Assessment Outcome:

Based upon my assessment of the prospective subject's capacity to consent to participate in research, I have determined the following:

☐ The individual identified above has the capacity to consent to participate in this research study and can provide legally effective informed consent.

☐ The individual identified above does not have the capacity to consent to participate in this research study and, therefore, cannot provide legally effective informed consent. Enrollment requires consent by the subject's legally authorized representative (LAR).

_____

Printed Name of Examiner

_____ _____

Signature of Examiner **Date**