



**ASSESSING THE CAPACITY TO CONSENT FORM**

The following is a guideline that may be modified to fit your participants, though the basic concepts should remain. Remember that consent is an on-going process and it is important to gauge throughout the study if the participant understands what you are asking them to do.

<p><b>Step 1: Determine if the participant has a surrogate or not.</b> A surrogate is usually the individual with the legal responsibility for making choices on the participant’s behalf, usually a spouse or family member, though in some cases it may be a partner or friend. Sometimes the individual may not have the legal distinction and you will need to question whether the person acting as a surrogate has the ability to provide consent.</p>	
Please mark one of the following and follow the directions:	<b>YES</b>
<p><b>A. The participant already has a surrogate.</b> If the box is marked “yes” skip to Step 4.</p>	
<p><b>B. The participant DOES NOT have a surrogate.</b> If this box is marked “yes” go to the next step.</p>	
<p><b>Step 2: Assess capacity to consent.</b> Review the consent form with the participant and ask open ended questions about your study to determine comprehension. For example, “Can you tell me what will happen if you agree to take part in this study?”, “Do you have to be in this study?”, “Will this study help you?” etc. As you review the consent information, determine if the participant meets the criteria below:</p>	
Please mark any of the following that apply:	<b>YES</b>
<p><b>A. The participant has the ability to communicate a yes or no decision.</b> This standard is applicable to all risk/benefit levels.</p>	
<p><b>B. The participant has the ability to understand relevant information;</b> the person can tell you what the research procedures involve and what</p>	

<p>the consent information includes. This standard applies to all risk/benefit levels.</p>	
<p><b>C. The participant has the ability to appreciate the situation and its likely consequences.</b> This standard applies to all research involving more than minimal risk.</p>	
<p><b>D. The participant has the ability to manipulate information rationally.</b> This standard focuses on process, not outcome. For example, are decisions consistent with the religious, moral, and other beliefs of the person? This standard is critical for the most unfavorable risk/benefit levels.</p>	
<p><b>Step 3: Scoring the assessment.</b> For all studies, you should answer “yes” to <b>A</b> and <b>B</b> in order for the participant to consent. If your study is above minimal risk (the level for potential harm is above what the participant would normally experience), you should also answer “yes” to <b>C</b> and <b>D</b>.</p>	
<p><b>Step 4: Documenting the assessment.</b> Use the following form to document your assessment based on the score in Step 3. If you marked A in Step 1, mark d in the form below:</p> <p>I examined _____ (name) on _____ (date) for the purpose of determining whether he/she is capable of understanding the purpose, nature, risks, benefits, and alternatives (including nonparticipation) of the research, making a decision about participation, and understanding that the decision about participation in the research will involve no penalty or loss of benefits to which the patient is otherwise entitled for the research project: _____ (project title).</p> <p>On the basis of this examination I have arrived at the conclusion that:</p> <ul style="list-style-type: none"> <li>a. This participant has this capacity at this time ( )</li> <li>b. There is a doubt about this participant’s capacity at this time and further evaluation is necessary ( )</li> <li>c. This participant clearly lacks this capacity at this time and will need surrogate consent ( )</li> <li>d. This participant already has a designated surrogate ( )</li> </ul> <hr/> <p>Signature of the evaluator:</p>	
<p><b>Step 5: Include this form with the participant’s signed consent form (or signed surrogate form and participant’s assent form, where appropriate).</b></p>	

