Note: Systematic assessment of participants' decision-making capacity is encouraged. This form is optional but recommended; PI may use another tool if desired—please append.

Prospect Name:________________________________ Date:________

Brief Protocol Title:____________________________________ IRB #________

There are four key elements of decision-making capacity to assess. Please ask prospect the questions following the element or make the requested observation or judgment.

1. Understanding.
   What is the purpose of the study—what are we trying to learn?
   What will happen to you—what will you be asked to do—in this study?

2. Appreciation
   What are the risks or dangers of this study?
   What are the possible benefits—good things—from this study?
   Are these benefits/good things for you or mainly for others?

3. Reasoning
   What alternative is there if you decide not to be in this study?
   (If you do not want to be in the study, can you choose something else to treat your problem?)

4. Expressing a Choice
   (Observe). Does the person voluntarily express a choice about whether to participate? YES NO
   IF YES, why do you think you want to be in this study?
   IF NO, do you think you want to be in this study?

5. Judgment: Based on the sample criteria and the person’s responses, do you believe s/he has the decision-making capacity to give informed consent for this study? YES NO
   Is a second opinion needed? YES NO

______________________________
Signature of Evaluator

Date