**DECISION-MAKING CAPACITY ASSESSMENT TOOL**

Potential Subject: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Protocol Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Protocol IRB #: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

This form may be helpful in assessing the decision-making capacity of potential subjects. There are four primary elements of decision-making capacity to assess for a specific protocol. The use of this form is not required.

1. **Understanding:**

What is the purpose of the research study? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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What will happen to you in this research study? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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1. **Appreciation:**

What are the potential risks of this research study? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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What are the potential benefits of this research study? \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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1. **Reasoning:**

What alternative is there if you choose not to participate in this study? \_\_\_\_\_\_\_\_\_\_\_

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1. **Expressing a Choice:**

Does the individual express a choice about whether or not to participate? \_\_\_\_\_\_\_\_\_

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1. **Does the individual have the decision-making capacity to give informed consent for this study?**

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Printed Name of Evaluator Signature of Evaluator

**NOTE:** The person who evaluates/assesses capacity should be a member of the research team or a consultant who is qualified to assess and monitor capacity to consent.

Version: 6/12/16