GUIDELINE FOR ASSESSING CAPACITY TO CONSENT IN CHILDREN

OHSP Policy 601 Research Involving Children, permits a minor (i.e., an individual under the age of 18) to provide consent for him or herself to participate in research under certain conditions, without permission of a parent or guardian. In addition, minors who are parents of children may consent for their children to participate in research under certain conditions.

Studies enrolling children in the categories that may consent to participate in research without the permission of a parent or guardians, as listed in Policy 601, or where a minor may be consenting to the participation of his or her child in research, must include appropriate measures to ensure subjects (or their minor parents) have the capacity to comprehend the nature, risks, benefits and alternatives of the research. Assessing capacity to consent should be appropriate to the nature, complexity and risks related to the study and may range from informal discussions with the study team to formal assessments that may involve asking subjects general open-ended questions about the study, or providing a study "quiz" to potential subjects. The greater the complexity or risk related to the study, the greater the need for a more rigorous method of assessing capacity. Documentation of all capacity assessments (whether verbal or otherwise) must be kept in the study records.

A child may be determined to lack capacity if the ability to understand and appreciate the nature and consequences of enrolling in the study, including potential benefits, risks, and alternatives, the meaning of personal participation in the study, or to reach and communicate an informed decision is found to be deficient. **In the event capacity is found to be deficient, the subject (or the minor's child, if applicable) cannot be enrolled in the study.**

Directions

The following templates are provided as examples of mechanisms for documenting a capacity assessment, should the investigator and/or Reviewing IRB require documentation of this assessment beyond that of a notation in the subject's study file. These templates should be modified as applicable to the needs of the study. The final version of the assessment must be submitted to the Reviewing IRB for review and approval.

SAMPLE 1:

DETERMINATION OF CAPACITY TO GIVE INFORMED CONSENT FOR MINORS

Study Title: X
RSRB #: XXXXX
Subject Name: _____

Instructions: All potential subjects should be recruited and informed of the study as outlined in the study protocol. To determine whether the subject has the capacity to provide consent, ask the following questions at the conclusion of the consent process.

- Why is this study is being done?
- What will happen to you/your child if you decide to participate in this study?
- What are the potential risks to you/your child of participating in this study?
- What are the benefits of participating in this study?
- Do you/your child have to be in this study?
- What will happen if you decide not to participate?
- What will happen if you decide to be in the study and then change your mind later?
- Who should you call if you have questions or experience a problem while participating in the study?
- Do you have any questions?

Individuals who achieve a demonstrated understanding of the study are determined to have capacity to provide informed consent.

If in answering these questions, the potential subject is unable to demonstrate an understanding or appreciation of the issues, the consent form should be reviewed further and the pertinent questions repeated. If, after a second review, the potential subject is still unable to demonstrate an understanding of the study, he/she cannot be enrolled in the study.

Capacity Assessment Checklist:

- ☐ Potential subject was able to convey the purpose of the study.
- ☐ Potential subject was able to convey the study procedures.
- ☐ Potential subject was able to convey the potential risks of the study.
- ☐ Potential subject was able to convey the potential benefits of the study.
- ☐ Potential subject was able to convey alternatives to participation.
- ☐ Potential subject recognized the voluntary nature of the study.
- ☐ Questions were answered to the subject's satisfaction.

Additional Comments:

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Printed Name of Investigator Signature of Investigator Date

SAMPLE 2:

DETERMINATION OF CAPACITY TO GIVE INFORMED CONSENT FOR MINORS

Study Title: X
RSRB #: XXXXX
Subject Name: _____

Instructions: All potential subjects should be recruited and informed of the study as outlined in the study protocol. To determine whether the subject has the capacity to provide consent, ask the following questions at the conclusion of the consent process. Use the corresponding 5-point scale to document the potential subject's level of understanding as below.

Level of Understanding 5-Point Scale

1	2	3	4	5
None	Poor	Unclear	Good	Excellent

Assessment Questions	**Level of Understanding**
Why is this study being done?	1 2 3 4 5
What will happen to you/your child if you decide to participate in this study?	1 2 3 4 5
What parts of the study are being done as part of your/your child's regular care and what parts of the study are being done only for the research?	1 2 3 4 5
How long will you/your child be in the study?	1 2 3 4 5
What are the potential risks to you/your child of participating in this study?	1 2 3 4 5
What are the benefits of participating in this study?	1 2 3 4 5
Who will be able to see your/your child's information during the study?	1 2 3 4 5
Will there be any costs to you for participating in this study?	1 2 3 4 5
What will happen if you decide not to be in the study?	1 2 3 4 5
What will happen if you decide to be in the study and then change your mind later?	1 2 3 4 5
Additional Comments:	

Potential subjects scoring a 4 or 5 on all questions have demonstrated an understanding of the study and are determined to have capacity to provide informed consent. Potential subjects scoring less than 4 on any question have not demonstrated an understanding of the study and therefore cannot be enrolled in the study.

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Printed Name of Investigator Signature of Investigator Date