



GUIDELINE FOR ASSESSING CONSENT CAPACITY IN ADULTS WITH DECISIONAL IMPAIRMENT

Policy 604 Research Involving Adults with Decisional Impairment requires that the research plan/protocol describe appropriate procedures for the initial and continuing/periodic assessment of consent capacity for persons with decisional impairment. Another individual should only provide consent for the subject to participate if an adult subject has been assessed as lacking consent capacity for the study.

Background

An adult subject is generally assumed to have the capacity to make an informed decision regarding participation in research. In accordance with standard clinical procedures, a subject may be determined to lack capacity if the individual is unable to understand and appreciate the nature and consequences of enrolling in research, including the benefits and risks, the meaning of personal participation in the study, and cannot reach or communicate an informed decision. The fact that a person has been determined to lack capacity to make other decisions (e.g., a conservator of the person's assets has been appointed) might not establish lack of capacity for a decision about research participation, nor does a determination of a lack of capacity to make a research enrollment decision mean that the person may also lack capacity to make other decisions.

Protocol Requirements

The inability to provide initial or continued consent may result from a variety of reasons that may be associated with memory, understanding, or reasoning. Also, the impairment may be stable, temporary, or progress over time. As such, studies involving a subject population whose capacity is known to be impaired, or is likely to be impaired either at the time of enrollment or during study participation, must address the following in the protocol:

- 1) Description of adequate procedures for making and documenting the determination of consent capacity.
- 2) Procedures for informing persons who are determined to have decisional impairment of that determination prior to (or at the earliest appropriate time after) enrollment in a study and procedures to document that this notice occurred.
- 3) Procedures for informing subjects that they are to be enrolled in research with permission of an authorized representative or research proxy (as applicable). Such information should be given to subjects in the presence of the representative.
- 4) Appropriate procedures for the continuing/periodic capacity assessment of decisionally impaired subjects, when appropriate.

Instruction for Consent Capacity Assessment

The following templates are provided as examples of mechanisms for documenting a consent capacity assessment, should the Investigator and/or RSRB 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* and the assessment should be completed by the Investigator (or other study team member authorized and trained to perform a capacity assessment) at the time the consent is reviewed with the prospective subject. The final version of the assessment to be used in the study must be submitted with the RSRB application for review and approval.

SAMPLE 1:

DETERMINATION OF CONSENT CAPACITY FOR ADULTS WITH DECISIONAL IMPAIRMENT

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 being done?
- If you decide to participate in the study, what are some of the things you will be asked to do?
- What parts of the study are being done as part of your regular care and what parts of the study are being done only for the research?
- Describe some of the risks or discomforts that people may experience if they participate in this study.
- Will this study help you?
- Do you have to be in this study?
- What will happen if you decide not to be in the study?
- If you are in the study and stop your participation, will you still be able to receive regular care?
- Who will pay for your medical care if you are injured while in this study?
- Who should you contact if you have questions or experience a problem while in the study?

Individuals who achieve a demonstrated understanding of the study are determined to have capacity to provide consent. However, if in answering these questions, the potential subject is unable to demonstrate understanding, reasoning, or appreciation of the study, and the Investigator still wishes to enroll the subject, the consent should be reviewed further and the above questions repeated. If, after a second review, the potential subject is still unable to demonstrate consent capacity, he/she must not be enrolled or may designate a representative (research proxy) to provide permission on his/her behalf to be enrolled. The assent of the subject should be obtained.

Consent 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.

OR

- Potential subject does not have capacity to consent.

Additional Comments:

Printed Name of Investigator

Signature of Investigator

Date

SAMPLE 2:

DETERMINATION OF CONSENT CAPACITY FOR ADULTS WITH DECISIONAL IMPAIRMENT

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
If you decide to participate in the study, what are some of the things you will be asked to do?	1	2	3	4	5
What parts of the study are being done as part of your regular care and what parts of the study are being done only for the research?	1	2	3	4	5
Describe some of the risks or discomforts that people may experience if they participate in this study.	1	2	3	4	5
What are the benefits of participating in this study?	1	2	3	4	5
Do you have to be in this study?	1	2	3	4	5
If you are in the study and stop your participation, will you still be able to receive regular care?					
Who will pay for your medical care if you are injured while 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
Who should you contact if you have questions or experience a problem while in the study?	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 a full understanding of the study and therefore must designate a representative (research proxy) to provide permission on his/her behalf to be enrolled. The assent of the subject should be obtained.

Printed Name of Investigator	Signature of Investigator	Date
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