

**GUIDELINES FOR ASSESSING CONSENT CAPACITY IN ADULTS WITH DECISIONAL IMPAIRMENT**

Background

An adult participant is generally assumed to have the capacity to make an informed decision regarding participation in research. However, a participant may be determined to lack capacity if the individual is unable to understand the nature of enrolling in research, including understanding the benefits and risks, the meaning of personal participation in the study, and communicating an informed decision. The fact that a person has been determined to lack the capacity to make other decisions (e.g., a conservator of the person’s assets has been appointed) might not establish a lack of capacity for a decision about research participation, and neither does a determination of a lack of capacity to make a research enrollment decision mean that the person lacks the capacity to make other decisions.

IRB Application Requirements

The inability to provide initial or continued consent may result from a variety of causes that may be associated with memory, understanding, or reasoning. Also, the impairment may be stable, temporary, or progress over time. Studies involving a participant 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 IRB application:

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 participants 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 participants in the presence of the representative.
4. Appropriate procedures for the continuing/periodic capacity assessment of decisionally impaired participants, when appropriate.

Instruction for Consent Capacity Assessment

The following template is provided as an example of a mechanism for documenting a consent capacity assessment, should the investigator and/or IRB require documentation of this assessment beyond that of a notation in the participant’s study record. ***This template 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 participant. The final version of the assessment to be used in the study must be submitted with the IRB application for review and approval.

This document was adapted with permission from The University of Rochester Office of Human Subject Protection/Research Subjects Review Board.

**DETERMINATION OF CONSENT CAPACITY FOR ADULTS WITH DECISIONAL IMPAIRMENT**

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| --- |
| Study Title:  |
| IRB Protocol #:  |
| Participant Name:  |

Instructions: All potential participants should be recruited and informed of the study as outlined in the study protocol. To determine whether the participant 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 participant’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 participation, will you still be able to receive regular care?  | 1 | 2 | 3 | 4 | 5 |
| 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 |
| Whom should you contact if you have questions or experience a problem while in the study? | 1 | 2 | 3 | 4 | 5 |
| Additional Comments: |

Potential participants scoring a 4 or 5 on all questions have demonstrated an understanding of the study and are determined to have the capacity to provide informed consent. Potential participants 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 and the assent of the participant must be obtained.

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Printed Name of Investigator Signature of Investigator Date