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# Yale University Institutional Review Boards Procedure

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## Procedure 340 PR.1

### Assessment of Capacity to Consent

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#### Overview

Some decisionally impaired individuals may be capable of providing consent to enroll into a research study. Although the decision-making capacities of such individuals may be in question, an investigator should not assume that they are unable to provide consent. Rather, investigators should seek to determine objectively whether or not individuals are capable of consent. The purpose of identifying individuals who may be decisionally impaired is not necessarily to exclude them from research, but rather, when appropriate, to seek ways to enable their participation in an ethically acceptable manner that is also compliant with regulatory requirements and guidance as well as institutional policies.

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#### Assessment Process

##### Investigator Responsibilities

Investigators must conduct an assessment of a potential participant's capacity to consent. The Principal Investigator or person obtaining consent should use professional judgment to determine if the potential participant is capable of providing consent. The individual who is responsible for determining whether a potential participant has the capacity to consent must have appropriate expertise necessary to make such a determination. This determination may rely on individual observation of and interaction with the potential participant as well as the opinion of the medical provider or caregiver, when available. The individual determining a participant's capacity to consent should also have the expertise to monitor the participant's ability to continue to participate in the research. The competence of the potential participant should be evaluated in relation to the proposed study in order for him or her to be judged capable of providing informed consent for that study.

In general, an assessment of an individual's capacity to consent should be based on her/his:

- Ability to communicate a reasoned choice regarding participation;
- Ability to understand relevant information about the study, including consequences of participation for the participant's own situation (such as health condition) and consequences of the alternatives to participation;
- Ability to comprehend the nature of the situation and its likely consequences; and
- Ability to manipulate information rationally.<sup>1</sup>

Investigators should consult the Points to Consider checklist (Checklist 340 CH. 1) for additional guidance related to the involvement of individuals with impaired consent capacity in human subjects research.

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<sup>1</sup>Appelbaum, PS, and Grisso, T: MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR), Professional Resource Press, Law and Psychiatry Program, University of Massachusetts Medical School, Worcester, MA, 2001.

## **Assessment Methods and Considerations**

The method(s) used to assess capacity to consent should be commensurate with the level of risk to the participant, the complexity of the research, and the anticipated duration of the participant's involvement. A relatively unsophisticated level of assessment may be acceptable for a minimal risk interview study in which the participant's involvement is rather short in duration. More sophisticated and rigorous method(s) of assessment would be required for participation in an investigational drug study. Likewise, additional monitoring at specified study time points may be required when the participant's involvement will continue over a period of time. Assessments in a minimal risk study could be as simple as a verbal interaction between the investigator and the potential participant. More complicated assessments could include administration of a formal assessment instrument or an independent clinical (interview-type) assessment, administered after the potential participant has been fully informed of the study, which documents that the potential participant demonstrated sufficient recall and comprehension. The assessment method should allow for a repeat assessment or monitoring if the potential participant's decisional impairment changes or is expected to change.

An individual's cognitive abilities can be assessed by discussing the proposed study with her/him and then asking specific questions. It is usually more useful to ask for descriptive answers from potential participants rather than to ask questions requiring a simple yes or no answer. Such questions may include:

Can you tell me what will happen if you agree to take part in this study?

How might this study help you?

How might this study not help you, or even hurt you?

Do you have to be in this study?

What would you do if you wanted to leave the study?

What will happen if you decide not to be in the study?

The consent process often may involve at least several meetings, with a review of consent information, and quizzes, for example, to establish whether or not the subject fully understands the research. Education of family members should be incorporated. Potential participants must be given the opportunity to assent, or to object, if possible. Other mechanisms, such as use of a consent monitor, subject advocate, or independent clinician may need to be built into the logistics of the consent process.

If adequate consent capacity is not found upon assessment, then the investigator usually needs to either exclude the prospective subject from the study or seek surrogate consent for his/her participation.

## **Independent Assessment of Capacity to Consent**

The independent assessment is conducted by an individual who has no interest in or affiliation with the study or the sponsors of the study. The methods for assessing an individual's capacity to consent range from informal investigator/peer evaluation to an independent health care professional using formal assessment instruments (e.g., dementia rating scales). The use of an independent assessor may be necessary when the clinician/researcher is not the appropriate person to determine when a person is not capable of providing consent.

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## **Consent/Assent Concerns**

### **Fluctuating Capacity**

For research involving individuals who are able to provide informed consent, but are expected to have fluctuating, limited, or diminishing decision-making capacity during the course of the research study, special processes or procedures should be implemented, in order to ensure that the rights and welfare of such individuals remain adequately protected. Investigators should establish and maintain ongoing communications with involved caregivers, consistent with the participants' autonomy and with medical confidentiality. The PI should plan for such change or fluctuations by considering specific measures such as advance consent or advance directives for participants with prospective incapacity to consent.

### **Prospective Consent with Affirmation**

Under certain circumstances, and with certain populations or individuals, an investigator may obtain consent in advance of an event expected to cause the participant to experience stress and/or pain. At the time of the occurrence of the event (during which the research will be conducted), an investigator may then use an affirmation form (summary of previous consent) or otherwise seek affirmation (e.g., verbal inquiry) to confirm that the participant recalls the circumstances of the study and still wishes to participate in the study. This is distinguished from the use of surrogate permission, below.

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### **Assent Procedures**

Individuals who are able to read and write should participate in the consent process by using an assent form written at a level especially suited to their cognitive abilities. Investigators must submit assent procedures to the IRB for approval. In all cases in which assent is sought from an individual with impaired consent capacity, the assent discussion between the researcher and the individual should include all of the required elements of informed consent [See Policy 200, Informed Consent for Human Research]:

- A simplified description of the purpose of the research, including the risks and benefits (may be presented in an Information Sheet);
- A description of the procedures and interventions to which the participant will be exposed;
- An explanation of any procedures that may hurt and for how long the pain will last;
- An explanation that the potential participant has the right to decide whether or not to participate in the research study;
- An explanation of the research alternatives;
- A question and answer period in which the potential participant should be encouraged to ask questions about her/his participation in the study; and
- An explanation that the potential participant may withdraw from the research at any time.