

## Guidance and Procedure: Research Involving Persons with Cognitive Impairments (last updated June 28, 2010)

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## Introduction

Conducting research that involves people with cognitive disorders or physical traumas is essential to further the understanding of these conditions and to develop new treatment approaches. Thus, it is critical to both acknowledge the ethical harm that may result by including or excluding people who might lack the capacity to consent to participate in research and to recognize that these groups require special research protections. The presence of a cognitive impairment, however, should not lead to a presumption that a person is not capable of making a decision to participate in research.

The following guidance provides investigators with an overview of the guiding principles and ethical considerations for involving research participants who have intellectual or cognitive impairments, as well as the requirements of [California law](#) and [UC guidance](#). Methods for accessing decisional capacity are also discussed.

This guidance will also assist UCLA investigators with enrolling research participants who have cognitive impairments that are acute or chronic in nature and that may worsen or improve over time, such as medical incapacities, intellectual disabilities, dementia, or psychosis.

## Definitions

**Capacity to Consent (to Research)/Decision Making Capacity:** The ability of an individual to understand the choices presented, to appreciate the implications of choosing one alternative or another, and to make and communicate a decision (e.g., whether or not to participate in a study).

### **Important Notes:**

- The capacity to consent is protocol and situation specific. A subject may have the ability to consent to a low-risk protocol in usual circumstances, but not have the capacity to consent to a high-risk protocol in a stressful situation.
- “Competence” is a legal term that should not be confused with “decision making capacity.” Someone who was judged legally incompetent to handle their finances may still be able to make a meaningful choice about taking part in a research study. Also, a person who has normal cognitive functioning may be in a circumstance where his/her decision making capacity to consent is temporarily impaired by physical (e.g., unconsciousness) or emotional trauma (e.g., pain, fear or anxiety).

**Surrogate Decision-Maker:** A legally authorized representative with reasonable knowledge of a potential research participant who lacks decision-making capacity, as defined under California law ([Health & Safety Code 24178](#)).

## Guiding Principles and Ethical Considerations

**Guiding Principles:** The following principles are important to consider when planning research which will or may include those with cognitive impairments:

- Investigators who plan to conduct studies involving subjects with cognitive impairment will need to provide a scientific and/or scholarly justification of the inclusion of this population and assure that appropriate additional safeguards are in place to protect this population from coercion or undue influence.
- Studies should not arbitrarily exclude cognitively impaired subjects if they might be able to give informed, voluntary consent and there is a chance they could benefit from participation.
- Higher risk studies need a higher level of safeguards.
- The primary additional safeguard for this vulnerable subject population is assessment of [capacity to consent](#).
- If adequate decisional capacity is not found upon assessment, the investigator usually needs to either exclude the prospective subject from the study or seek [surrogate consent](#) for their participation.

### Ethical Considerations: Exclusion from Study or Use of Surrogate Consent

A key choice in study design is whether to exclude people who cannot consent for themselves or include them with surrogate consent from a legally authorized representative.

- **Exclusion from the study:** Excluding those who do not show adequate capacity to consent is the first option, since it is generally considered preferable to do studies with those who can consent for themselves, if possible.
- **Surrogate consent:** Many studies cannot be done without including subjects who are unable to consent for themselves. In some studies, there is potential direct benefit to individuals or groups of subjects. Thus, it may be unethical to deny this possible benefit to those with impaired decisional capacity. In other studies, even with no direct benefits for subjects, the only practical way to answer scientific questions may be to enroll subjects without the capacity to consent for themselves. In such cases, surrogate consent may be sought, but *only if this is justified in the protocol and conforms to state law and UCOP guidance on surrogate consent in research*.
- **Other possible options:** In limited circumstances, studies may be approved for waiver of consent (see the following Guidances: [Obtaining and Documenting Informed Consent](#), and [Planned Research in Emergency Settings with Waiver of Consent](#)).

## Assessing Capacity to Consent for Research

### No Single Set of Standards

When assessing capacity to consent, it is important to know that ***no single set of standards for defining and implementing assessment of capacity to consent*** has received universal acceptance by experts in the field. This section will provide investigators with guidelines about when an assessment of capacity is needed, who should conduct the assessment and which methods of assessment are appropriate.

A number of sources propose differing lists of standard elements to consider in making this type of assessment. There are also differing opinions as to who is most appropriate to administer such assessments, what instruments should be used, and how formal the assessment procedure should be.

The above being said, the Investigator should consider, and the IRB application should describe:

- Who will conduct the assessment,

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- The method by which prospective subjects' capacity to consent will be evaluated, and
- The criteria for identifying subjects.
- Less formal procedures to assess potential subjects' capacity—including, for example, the ways professionals often make judgments about capacity in routine interactions—may be permitted if a formal assessment is not feasible or necessary.

### When Explicit Assessment of Decisional Capacity Is Necessary

- **Studies intended to include cognitively impaired subjects**
  - **More than minimal risk:** If a study involves more than “minimal risk” (as defined in [45 CFR 46.102\(i\)](#)), and target subjects can reasonably be expected to have diminished decision-making capacity, the investigator will need to consider, and the IRB will generally require assessment of decisional capacity for all prospective subjects.
  - **No more than minimal risk:** Even in research involving only minimal risk, the investigator will still need to consider and the IRB may still require such assessment if it believes that it is appropriate to safeguard the subjects' welfare.
- **Studies not intended to include cognitively impaired subjects**
  - **Presumption of capacity:** All persons who have reached the age of majority (in California, 18 years old) are presumed to have capacity to give informed consent to research. In the absence of any indication to the contrary, such capacity can be assumed without further evaluation or documentation.
  - **Indications of potentially diminished capacity:** On the other hand, if there are indications of potentially diminished capacity in an individual subject, assessment of decisional ability may need to occur.

**Important Note:** Potential subjects who are found to have diminished capacity must be excluded unless the IRB has approved the use of surrogate consent from legally authorized representatives for the study in question.

### Who Should Assess Capacity

In general, the consent assessor should be a researcher or consultant familiar with cognitive impairment and qualified to assess and monitor capacity and consent in such subjects on an ongoing basis. The IRB will consider the qualifications of the proposed individual(s).

### Methods of Assessment

Various methods of assessment may be acceptable for differing studies. In general, a greater capacity to consent and more rigorous methods of assessing capacity are needed in studies that have higher risks for subjects.

**Important Note:** If a study anticipates using surrogate consent from legally authorized representatives, the method of assessment must be specified in the IRB application.

- **UCOP Guidance:** In its Guidance on Surrogate Consent for Research, the University of California Office of the President offers the following advice: “While there are no standardized measures for determining capacity to consent, investigators may assess subjects on their abilities to understand and to express a reasoned choice concerning the:
  - Nature of the research and the information relevant to his/her participation;
  - Consequences of participation for the subject's own situation, especially concerning the subject's health condition; and
  - Consequences of the alternatives to participation.

[Applebaum, PS and T. Grisso. “[MacCAT-CR: MacArthur Competence Assessment Tool for Clinical Research.](#)” Professional Resource Press, 2001]

- **Other Instruments and Procedures:**

- The [UCLA Decision-making Capacity Assessment Tool](#) posted on the UCLA OHRPP website.
- A **standardized, validated instrument that can be tailored** to the specific study may be used, such as The MacArthur Competence Assessment Tool – Clinical Research (MacCAT-CR) (see reference in section directly above).
- Study **investigators may develop alternative procedures** for evaluating decision-making capacity, such as: Asking the prospective subject to explain the main elements of this study and indicating a decision about taking part or not. The prospective subject may use a simplified study summary to answer the questions. Based on these responses, and whether the decision to participate or not appears to be a rational choice reflecting an appreciation of the facts, the assessor can then make a final determination about capacity for consent.
- **Sample questions** to assess ability to consent:
  - Are we offering you your usual medical care, or asking you to be in a research study?
  - Do you have to take part in this study, or is it OK to say “no”?
  - What is the purpose of this study?
  - Tell me the main things that would happen to you in this study. ? Tell me the main risks to you of being in this study.
  - Will this study mainly help you or others?
  - If you want to drop out of the study, when can you do this?
  - Considering the risks and benefits we’ve discussed, what have you decided about taking part in this study?

### Educational Procedures:

For subjects scoring less than perfect on the initial presentation, educational procedures may be employed to raise understanding to sufficient levels for them to make a meaningful choice about participating. Potential measures include repetitive teaching, group sessions, and audiovisual presentations.

For examples of educational procedures and quizzes, see [Carpenter et al. \(Arch Gen Psychiatry, 2000; 57:533-538\)](#), [Dunn and Jeste \(Neuropsychopharmacology, 2001; 24:595-607\)](#), [Dunn et al. \(Am J Psychiatry, 2001; 18: 1911-1913\)](#), [Dunn et al. \(Am J Geriatric Psychiatry, 2002 Mar-Apr: 10\(2\):207-11\)](#), [Wirshing et al. \(Am J Psychiatry, 1998; 155:1508-1511\)](#).

### Reassessment of Decision Making Capacity:

Consenting is an ongoing process. Participants’ decision-making abilities may fluctuate, requiring on-going assessment during the course of the research. This may be particularly true in acute medical or psychiatric situations. If a study participant is determined to have regained decision making capacity, s/he must be re-consented using standard consent procedures.

## Safeguards for Research Subjects

Depending on the study and the level of risk involved, the IRB may require safeguards in addition to the assessment of the potential subjects to consent. These could include:

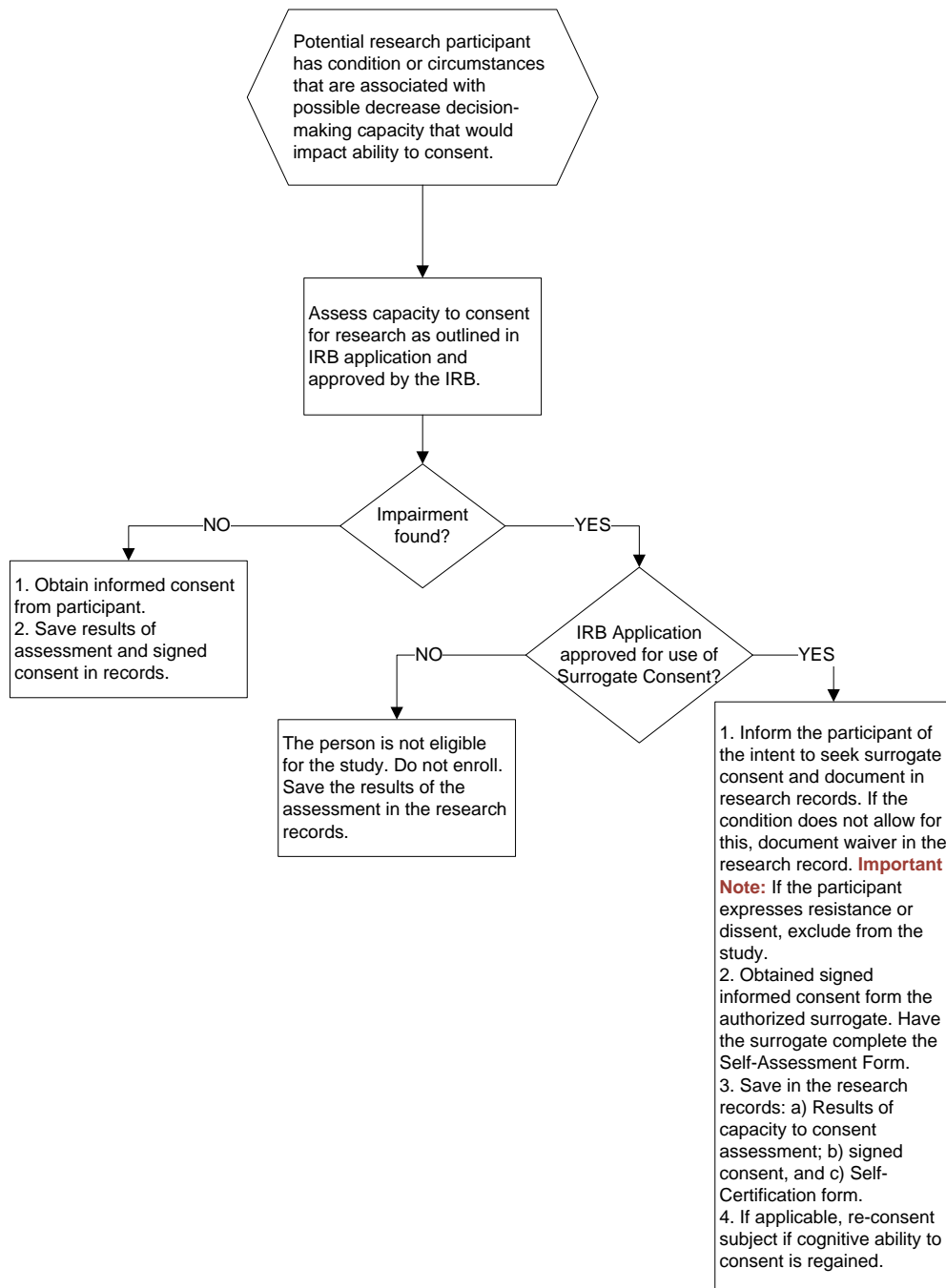
- The use of an independent monitor for the consent process;
- Special informational or educational techniques;
- Waiting periods for subjects to decide about participation; and/or
- Assent in addition to surrogate consent for subjects who do not have the cognitive ability to consent form themselves.

**Important Note:** The prospective subject’s objection or resistance to participation in any way, at any time, must be taken as a refusal or withdrawal and be immediately honored. Adult subjects may refuse to enter a study and may withdraw at any time, even if a surrogate consentor or study doctor disagrees with the decision.

## Research Outside of California

The determination of capacity to consent depends on the laws and regulations of the local jurisdiction. When investigators plan on enrolling research participants outside California, they should check with UCLA Legal Counsel and/or their collaborators out of state regarding the local consent laws and include Information on the local laws/regulations regarding capacity to consent for research and relevant citations.

## Flowchart: Assessment of Capacity to Consent



(Adapted from "Decision-Making Capacity Guidelines," University of California, San Diego Human Research Protection Program)



## References

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