Procedures for Determination of Decisional Capacity in Persons Participating in Research Protocols

by
The UCSD Task Force on Decisional Capacity*
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Background

It is universally agreed that persons signing valid research consent forms must have adequate decision-making capacity to do so. Yet the procedures for ensuring such capacity have not been formally specified or mandated. Provided here are flexible guidelines with options for the wide variety protocols that exceed minimal risk. The guidelines presented here apply not only to primary conditions of cognitive impairment, such as dementia or psychosis, but also to conditions in which patients might reasonably be expected to have cognitive impairments as a consequence of severe pain or anxiety or confusion, such as cancer or trauma or life-threatening illness. Excluded from consideration here are pediatric subjects as well as emergency research since there are separate sets of guidelines for these areas. We have, at this stage, limited the application of the procedures for evaluating decisional capacity to those studies that, by design, would be expected to recruit a "significant" number of decisionally impaired individuals. This is a test of a prototype approach to this issue, and until it has been shown to be practical and robust in the protection of human research participants, we would not mandate this approach for all human subjects research.

Below we explain some basic underlying concepts and then briefly describe the flexible guidelines proposed.

A. What is Informed Consent?

Three essential components of informed consent are:

(1) The consent is given in the absence of coercion or duress;

(2) The potential participant is provided with all the information (in language understandable to him or her) relevant to making a meaningful decision whether or not to participate (or to continue participating), and;

(3) The potential participant has a level of decision-making capacity needed to make a meaningful choice about whether or not to participate in the study.

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B. What is Decision-Making Capacity, and how does it differ from Competence?

The phrase "decision-making capacity" refers to a potential participant's ability to make a meaningful decision about whether or not to participate. It is generally thought to include at least the following four elements:

(1) Understanding, i.e., the ability to comprehend the disclosed information about the nature and purpose of the study, the procedures involved, as well as the risks and benefits of participating versus not participating;
(2) Appreciation, i.e., the ability to appreciate the significance of the disclosed information and the potential risks and benefits for one's own situation and condition;
(3) Reasoning, i.e., the ability to engage in a reasoning process about the risks and benefits of participating versus alternatives, and;
(4) The ability to express a choice about whether or not to participate.

"Decision-making capacity" should not be confused with the legal concept of "competence." Incompetence is a legal determination made by a court of law. While the court may consider information about a patient's decision-making capacity in making a competency determination, the terms are not synonymous. For example, someone who is judged legally incompetent to handle their financial affairs may retain sufficient decision-making capacity to make meaningful decisions about participating in a particular research protocol. As well, persons who have normal cognitive functioning may be put into circumstances where their decision-making capacity is temporarily impaired by severe pain or overwhelming anxiety or confusion.

Decision-making capacity is protocol-specific and situation-specific. Thus a subject may have capacity to consent to a low-risk research protocol in usual circumstances, but not have the capacity to consent to a high-risk protocol or when he or she is confused or under duress.

C. When is Explicit Assessment of Decisional Capacity Required?

(a) Any study involving more than "minimal risk" (as defined by federal guidelines on research involving human subjects) and;
(b) The protocol is specifically intended for participants at least a proportion of whom can be reasonably expected to have diminished decision-making capacity. Such diminished capacity may be due to significantly impaired cognitive abilities (as in cases of dementia or psychosis), or due to conditions whereby participants may feel desperate for an experimental treatment and/or hopeless about their future (as in patients with severe chronic pain, cancer, etc.) or selected emergency and trauma studies.

In such cases, either all the research participants may be assessed for decisional capacity, or there may be a 2-step process. The first step may involve a quick determination of the need for a detailed assessment - for example, the subject may be asked: "Can you tell me

what this study is about?" An adequate answer to this question may eliminate the necessity for further evaluation of the decisional capacity.

Alternatively, a standardized cognitive test may be used for this purpose - an example is the Mini-Mental State Examination or MMSE (Folstein et al., 1975). Subjects with scores of 24 or higher on the MMSE may be exempted from having a further assessment of decisional capacity. (Acceptable scores may change in the future if additional data validates decisional capacity for lower MMSE scores.)

Repeat assessment of decisional capacity would be indicated when there is an Institutional Review Board (IRB)-mandated re-consent.

D. Procedures for Assessing Decision-Making Capacity

The assessment of decision-making will be protocol specific. Thus, subjects' capacity to understand, appreciate, reason with, and express a choice about the specific protocol to which they are being enrolled must be determined. This can be done with at least one of the following methods:

1. A standardized and validated instrument that can be tailored to the specific study protocol, such as the MacArthur Competence Assessment Tool – Clinical Research (MacCAT-CR) developed by Appelbaum and Grisso (1995).

2. A post-consent quiz documenting the subjects' knowledge of critical elements in the informed consent form - i.e., nature of the illness being studied, voluntary nature of participation, ability to withdraw at any time, consequences of withdrawing, possible risks and benefits of participation, procedures involved, time required, confidentiality, and whom to call with any questions. For subjects who score less than perfect on the initial presentation, educational procedures may be employed to raise their understanding to sufficient levels for them to make a meaningful choice about participating. Such procedures may include simple repetition of the relevant information in the consent form or more detailed explanations of items that the subject has difficulty understanding. For examples of educational procedures and the content of such 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.), or Wirshing et al. (Am J Psychiatry; 1998; 155: 1508-1511).

3. The study investigators may develop and suggest alternative procedures for evaluating the presence of decision-making capacity, - e.g., someone outside the research team making the evaluation as to the potential participant's decisional capacity. Such procedures must be reviewed and approved by the IRB prior to enrollment of subjects in the protocol.

E. Documentation Requirements

(1) Application for IRB Approval: Every protocol submitted to the IRB should explicitly address the issue of decision-making capacity within the "Decisional Capacity/Surrogate Consent" portion of the application. This may be done by documenting that the protocol involves minimal risk, and/or targets only populations wherein impaired decision-making capacity is unlikely, or by explicitly stating the procedures that will be implemented for evaluating the presence of decision-making capacity of each participant prior to enrollment, using one or more of the options listed above. If a standardized decision-making capacity instrument is to be used, a copy of the instrument, tailored to the specific protocol should be included with the application. If a post-test/questionnaire is employed, a copy of the questionnaire to be used should be included. If another method is developed, copies of the relevant materials to that method should be included with the application.

(2) For the studies covered by this requirement, the decision-making capacity determination should be documented in each participant's research file. This may be done by including a copy of the relevant materials in the research file, i.e., a copy of the record form from the standardized instrument (including the participant's responses to each item), a copy of the post-test with the participant's answers to each item, or

(3) relevant documents from any other procedure employed sufficient to permit a third-party reviewer to evaluate the participant's responses and judge presence of decision-making capacity.

F. What if a potential study participant fails to demonstrate adequate decisional capacity?

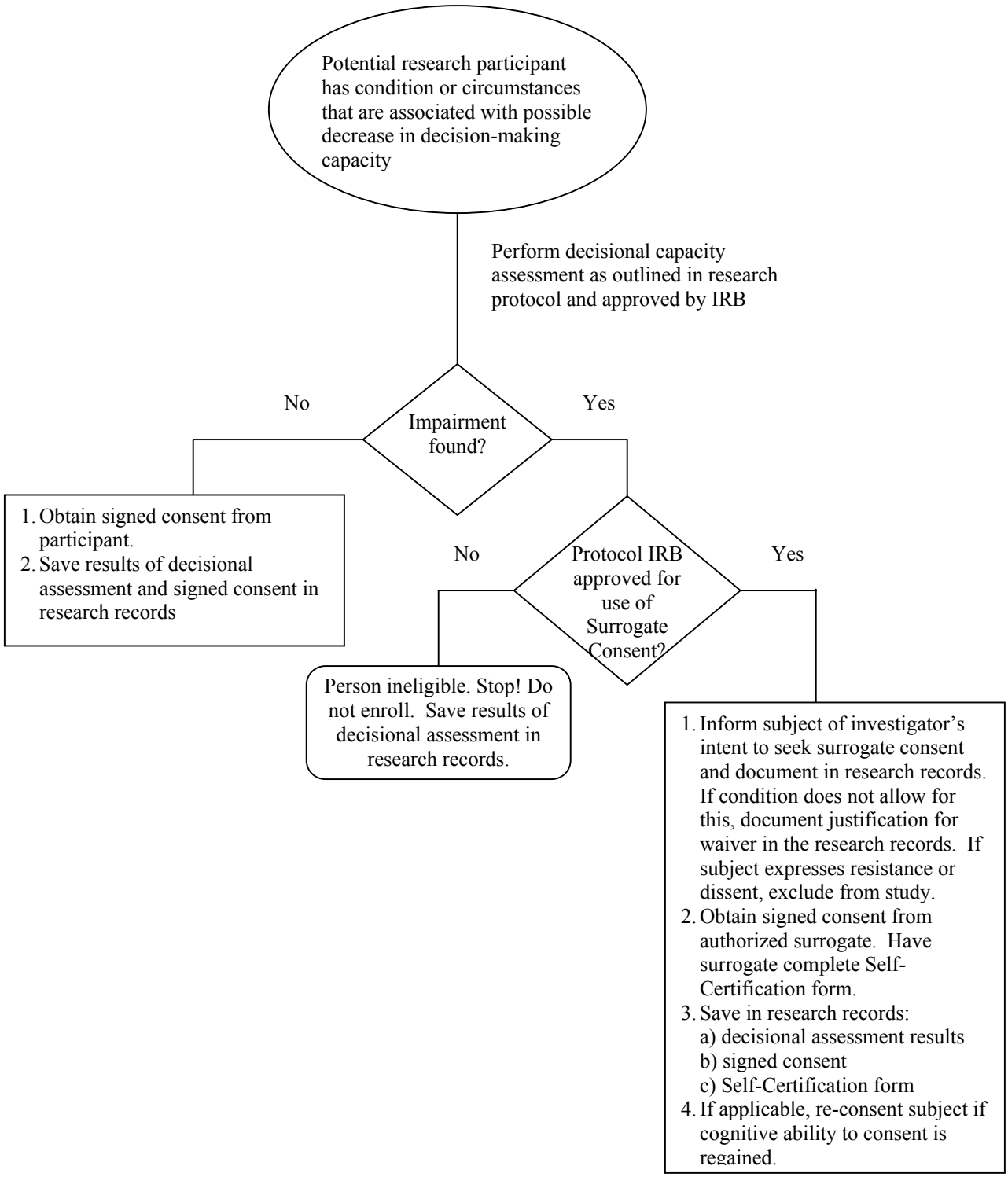
Effective January 1, 2003 the State of California Health and Safety Code Section 24178 was amended to provide for surrogate consent. Researchers who wish to have the option of consent by legally authorized representatives of the potential research participant must specifically request this option in their research application to the IRB, and require a Self-Certification to be filled out by the person giving the surrogate consent, in addition to the signing of a standard consent form. See the University of California Office of Research *Guidance on Surrogate Consent for Research*, available on the HRPP website at http://irb.ucsd.edu.

G. A Decisional Capacity Decision Tree

Stated simply, a researcher has two options in obtaining informed consent in the setting of questions about a potential participant's decisional capacity: either demonstrate by a documented assessment measure that the participant does have sufficient decisional capacity, and use a standard consent signed by them, complemented in the research record by the documented results of their assessment, or; demonstrate by a documented assessment measure that they do *not* have decisional capacity, inform participant of the researcher's intent to seek surrogate consent if possible, and then obtain signed consent

from a person authorized by California law to serve as a surrogate, along with that person's self-certification as the decision-maker, archived in the research record.

Presented here in graphical format is a decision tree (flow diagram) of the options and sequence of actions for research protocols that would reasonably be expected to recruit persons with diminished or questionable decision-making capacity.



When in Doubt

Whenever there is a question about the need for assessing decisional capacity or about the procedures to be employed, investigators are urged to contact the UCSD Human Research Protections Program office by phone (858-455-5050) or e-mail <hrpp@ucsd.edu>. Even without investigator-initiated queries, the Institutional Review Board may require, based on its analysis of risks and benefits of a research plan, that a decisional capacity assessment be performed as a component of the research.

References

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