Enrolling Individuals With Cognitive Impairments and Assessing Decisional Capacity

Background

Some studies propose to involve subjects whose capacity to make meaningful decisions is in question because they are "cognitively impaired.? Such subjects may include mentally disabled persons, and those with diagnosed psychoses, Alzheimer's disease or other cognitive disorders ? permanent or temporary. Other subjects may have cognitive impairments as a consequence of severe pain, anxiety or confusion, such as individuals with trauma, cancer or life-threatening illness.

Since many people with these conditions retain the capacity to consent to research, not allowing them to consent for themselves when able could compromise their rights.

Federal regulations [1], California state code [2], and UC policy [3] indicate that research studies may involve subjects who have cognitive impairments if adequate safeguards are in place. Individuals signing valid research consent forms for themselves must have adequate *decisional capacity*, but the relevant regulatory documents do not say how capacity should be determined.

The IRB will consider the following principles:

1. Studies should not arbitrarily exclude cognitively impaired subjects if they might be able to give informed consent and there is a chance they could benefit from participation.
2. Studies involving subjects with cognitive impairment can only be approved if justified and appropriate additional safeguards are in place. Higher risk studies need a higher level of safeguards.
3. The primary additional safeguard for this vulnerable subject population is assessment of decisional capacity.
4. 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 [3] for their participation.

Relevant regulations and policies

- Federal regulations (45 CFR 46.111 [1]) direct the IRB to approve a study only if it determines that informed consent will be sought from each prospective subject (unless specific exceptions are justified), and that for ?subjects?vulnerable to coercion or undue influence, such as ?mentally disabled persons?[the study includes] additional safeguards.?
- California law (Health & Safety Code §24178 [2]) allows surrogate consent [3] for certain research subjects with cognitive impairment ?if (the) person is unable to consent.?
- The University of California provides related UCOP Guidance on Surrogate Consent for Research [4].

These IRB guidelines also are based on other sources, such as the UC San Diego's Decision-Making Capacity Guidelines [5] and the UCSF Memory and Aging Center?s "Capacity to Consent" policies.

This guidance does not apply to pediatric subjects [6] and emergency research [7]. These guidelines do not supersede more restrictive or specific local requirements or policies.

Exclusion from Study or Use of Surrogate Consent

A key choice in study design is whether to 1) exclude people who cannot consent for themselves or 2) include them with surrogate consent from the subject's legally authorized representative.

Note: You must regard a prospective subject's objection or resistance to study participation ? in any way or at any time ? as a refusal or withdrawal and honor this request immediately, even if a surrogate or the study investigator disagrees with the decision.

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

For some studies in which there is potential direct benefit to subjects, it may be unethical to exclude individuals with impaired decisional capacity. In other studies that may have no direct benefits for subjects, it may be necessary to enroll these individuals in order to answer scientific questions. In such cases, surrogate consent may be sought if it is justified and conforms to state law and UCOP guidance on surrogate consent in research [3].

Other possible options

In limited circumstances, studies may be approved for waiver of all consent (see IRB's guidance on Waiving Informed Consent [8] and Research in Emergency Settings [7]).

Decisional Capacity Assessment for Research

No single set of standards for defining and implementing assessment of decisional capacity has received universal acceptance by experts in the field.

Per UCOP guidance [4], investigators should "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. "MacCA T-CR: MacAtihur Competence Assessment Tool for Clinical Research. Professional Resource Press, 20QI]"*

You should specify who will conduct the decisional capacity assessment, the method(s) of assessment and criteria for identifying incapable subjects. Use the info below to formulate your plan to assess decisional capacity. A less formal procedure to assess potential subjects? capacity may be permitted if a formal assessment is not feasible or necessary.

What is "decisional capacity"?

This term refers to a potential participant?s ability to make a meaningful decision about whether or not to participate in a study.

"Decisional capacity" in the research context has been interpreted by the American Psychiatric Association as including the following elements

1. Ability to understand relevant information;
2. Ability to appreciate the situation and its likely consequences;
3. Ability to manipulate information rationally [i.e., to reason]; and
4. Ability to evidence a choice.

Other sources, e.g., UCSD's "Decision-Making Capacity Guidelines" and the UCSF Memory and Aging Center?s "Capacity to Consent" policies, offer variations of the above list.

- **?Decisional capacity? versus ?competence?**: ?Decisional capacity? should not be

confused with the concept of ?competence.? Incompetence is a legal determination made by a court of law. However, someone who was judged legally incompetent to handle their own financial affairs might still retain sufficient decision-making capacity to make a meaningful choice about taking part in a study. As well, a person with normal cognitive functioning (i.e., legally competent) might be put into circumstances where their decision-making capacity is temporarily impaired by severe pain or overwhelming anxiety.
- **Decisional capacity is study specific and situation specific.** 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 under duress.

When is an explicit assessment of decisional capacity necessary?

1. Studies intended to include cognitively impaired subjects:

- **More than minimal risk**: If a study involves more than minimal risk [9] and target subjects can reasonably be expected to have diminished decision-making capacity, 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 IRB may still require such assessment if it believes that it is appropriate to safeguard the subjects? welfare.

2. Studies not intended to include cognitively impaired subjects:

Potential subjects who are found to have diminished capacity **must be excluded** unless the IRB has approved the use of surrogate consent [3] from legally authorized representatives for the study in question.

- **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**: If there are indications of potentially diminished capacity in an individual subject, assessment of decisional ability may need to be done.

Who should assess capacity?

In general, the consent assessor should be a researcher or consultant familiar with dementias 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).

What are some 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.

If a study anticipates usingsurrogate consent[3] from legally authorized representatives, the method of assessment must be specified in the IRB Application. Review the UCOP guidance[4] for additional information.

Forms and Instruments

- The UCSF Memory & Aging Center?s policy and procedure on Capacity to Consent and ?Capacity Assessment Record for Research Informed Consent (CAR)? (copyright Daniel Marson) are very detailed and clear.
- 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).
- A post-consent quiz documenting the subjects? knowledge of critical elements in the consent form may be used. (See linked samples at end of UC San Diego's Decision-Making Capacity Guidelines [10].)
- Study investigators may develop alternative procedures for evaluating decision-making capacity.

Additional Methods

Assessment standards and instruments: The potential research subject may be evaluated on the four elements or standards for decisional capacity listed above (or others if proposed and approved by the IRB). The individual?s capacity to understand all of these concepts may not be necessary in order to consent to participate in a particular research protocol?greater capacity is required for higher risk protocols. One or more of the decisional capacity assessment forms or instruments discussed above may be used

Review of consent documents with the subject: The assessor may review the IRB-approved consent form with the prospective subject in the normal manner used to obtain consent. A simplified study summary may be used as an aid to emphasize/remind subjects of major points.

Capacity assessment: The assessor can ask the prospective subject to explain the main elements of this study and indicate 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 consent capacity: These questions pick up at the point that consent form review has been completed. They are examples only ? clinical judgment remains the best guide for what to ask.

- 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.

Additional Safeguards

As noted above, the IRB considers decisional capacity assessment the primary safeguard for prospective subjects with cognitive impairments. Depending on the study and the level of risk involved, the IRB may require additional safeguards, including use of an independent monitor; special informational or educational techniques; use of waiting periods to decide about participation; and/or assent in addition to surrogate permission for subjects who do not have decisional capacity to consent for themselves.

What are some indications of potentially diminished capacity for consent?

The following are usually considered indications of potentially diminished capacity, although many individuals with these conditions may have sufficient capacity to consent:

- a diagnosis of dementia or cognitive impairment;
- presenting for an evaluation of dementia or cognitive impairment;
- a report, in medical records or from a family member or person well acquainted with the subject, that the subject has symptoms of dementia or cognitive impairment;
- psychotic symptoms, bizarre or abnormal behavior exhibited by the individual;
- an abnormal degree of confusion, forgetfulness, or difficulties in communication that is observed in the course of interacting with the individual.

What info regarding the decisional capacity assessment should I submit to IRB?

The IRB Application and consent form should present information on rationale for including individuals with cognitive impairments, risk level, etc., as discussed above. In regard to the decisional assessment procedures, describe the following in the IRB Application (at a minimum):

1. Who will conduct the assessment,
2. The method by which prospective subjects? decisional capacity will be evaluated, and
3. The criteria for identifying incapable subjects.

If a standardized decisional capacity instrument is to be used, submit a copy of the instrument tailored to the specific protocol. Likewise, submit copies of any other instruments to be used (e.g., post-test questionnaire, form or method developed by the investigator).

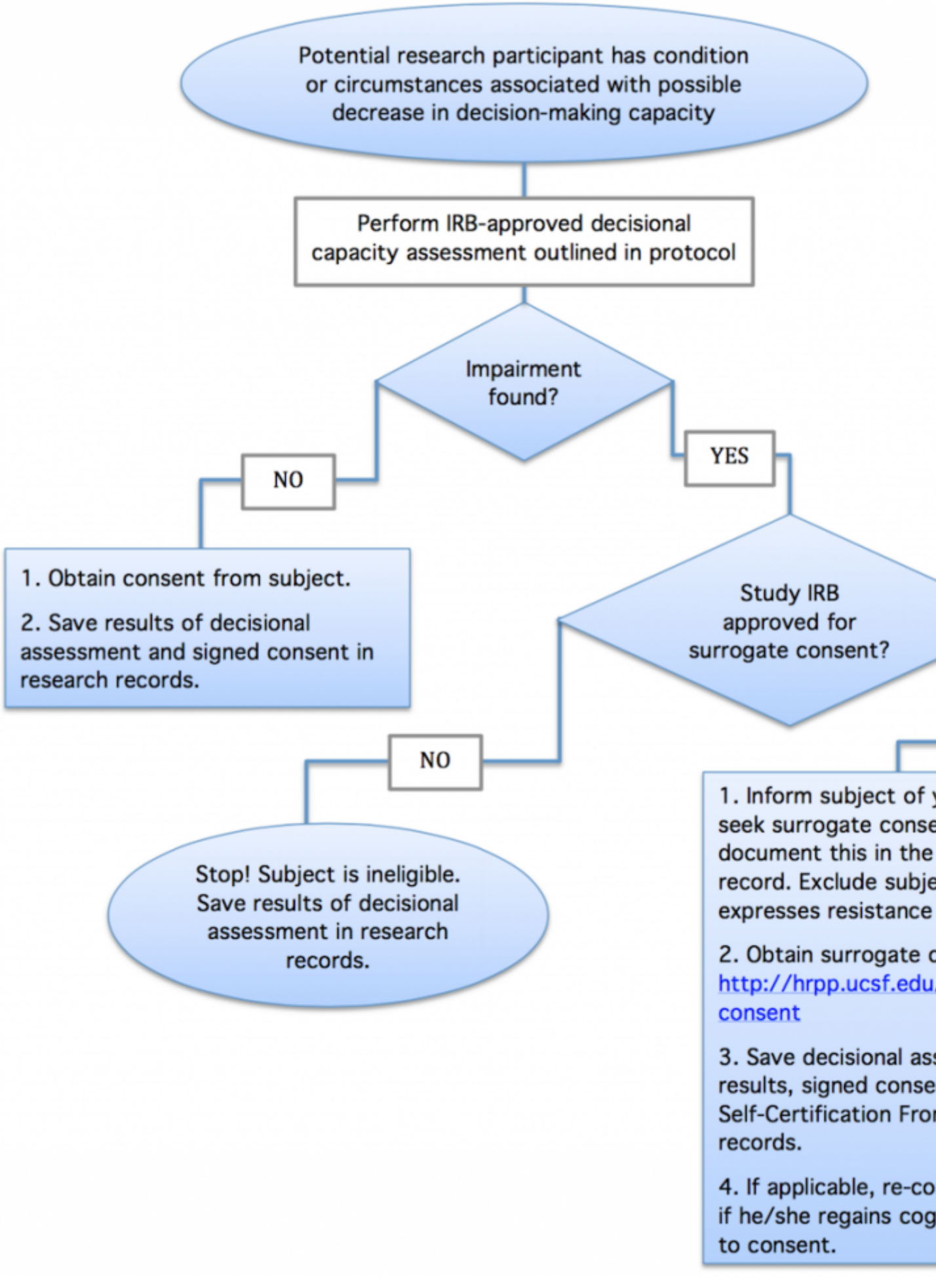
How do I document the decisional capacity determination in the research file?

Save copies of all completed instruments/forms for that individual and other relevant documents used in the process (including, of course, any consent forms) in each participant?s research file.

Decisional Capacity Assessment Flowchart

This flowchart outlines the steps to take when a decisional capacity assessment is needed.

This chart is adapted from UCSD's Decision-Making Capacity Guidelines [5].


Potential research participant has condition or circumstances associated with possible decrease in decision-making capacity
Perform IRB-approved decisional capacity assessment outlined in protocol
Impairment found?
NO
YES
1. Obtain consent from subject.
2. Save results of decisional assessment and signed consent in research records.
Study IRB approved for surrogate consent?
NO
Stop! Subject is ineligible. Save results of decisional assessment in research records.
1. Inform subject of y
seek surrogate conse
document this in the
record. Exclude subje
expresses resistance
2. Obtain surrogate c
http://hrpp.ucsf.edu/
consent
3. Save decisional ass
results, signed conse
Self-Certification Fro
records.
4. If applicable, re-co
if he/she regains cog
to consent.

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Links
[1] http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.111
[2] http://www.leginfo.ca.gov/pub/01-02/bill/asm/ab_2301-2350/ab_2328_bill_20020912_chaptered.html
[3] http://irb.ucsf.edu/surrogate-consent
[4] http://www.ucop.edu/research-policy-analysis-coordination/_files/srrgte_cnsnt_guide.pdf
[5] http://irb.ucsd.edu/decisional.shtml
[6] http://irb.ucsf.edu/children-and-minors-research
[7] http://irb.ucsf.edu/research-emergency-settings
[8] http://irb.ucsf.edu/waiving-informed-consent
[9] http://irb.ucsf.edu/levels-review
[10] https://irb.ucsd.edu/decisional.shtml