

Policy and Procedures for Assessing Capacity To Consent for Research

I. Policy

A. When to assess capacity for research consent All persons having reached the age of majority 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 are:

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

When there is an indication that capacity for consent may be diminished the subject's capacity to consent should be evaluated using the standards and procedures described below and the results should be recorded on the Capacity Assessment Record (CAR).

B. Standards for capacity Even when there is an indication of diminished capacity, the presumption of capacity remains. As indicated on the CAR, there are four different standards that might be used to assess capacity⁶. They are listed in a rough order of ascendancy. *It is the policy of the UC Davis Alzheimer's Disease Center to accept a subject as competent to consent to research only when the person is judged capable with regard to all 4 standards¹.*

Standard 1. Did the RC "make a choice"? *"This standard focuses on the presence or absence of a decision, and not on the quality of the decision"*⁶

This is simply a question as to whether the subject can evidence a choice. If the subject offers a consistent choice about participating in the study this standard is met. If the subject's choice is ambiguous, either because it is inconsistent or unclearly demonstrated, then the standard is failed.

Standard 2. Did the participant show "understanding"? *"This standard requires memory for words, phrases, ideas, and sequences of information, and also comprehension of the fundamental meaning of information about treatment."*⁶

A subject need not demonstrate complete or comprehensive understanding of the study in order to meet this standard. However, verbatim recitation of fact without evidence of comprehension is not sufficient either. Consider whether or not the potential subject grasps sufficient information to form the basis for a reasoned decision. If the subject comprehends and

remembers (even with assistance) a) that participation is voluntary, b) the major procedures c) main risks and d) benefits, then this standard is met. Failure on any element (a-d) means this standard is failed.

Standard 3. Did the RC show "reasoning/rational reasons"? *"This standard tests the capacity to use logical processes to compare the benefits and risks of various treatment options and weigh this information to reach a decision."*⁶

The core of this standard is the ability to logically compare risks and benefits in order to reach a rational decision regarding participation. To meet this standard the subject needs to demonstrate the ability to consider both risk and benefit in relation to each other and use the information in a logical manner to come to a decision.

Standard 4. Did the RC show an "appreciation" of the personal risks/benefits of the study? *"This standard emphasizes the patients' awareness of the consequences of a treatment decision: its emotional impact, rational requirements and future consequences"*⁶

Appreciation seems to imply something more than an intellectual understanding, and incorporates an affective judgment of the impact of study participation in the context of the particular individual in his or her particular situation. Meeting standard 3 would seem to generally suffice for meeting this standard as long as the subject has a realistic understanding of his or her circumstances.

C. Assent: Subjects who are not capable of consent to research still must assent to research in order to take part. Assent implies willingness or, minimally, lack of objection to taking part. It does not imply understanding. An interpretable statement from the subject regarding assent must be taken as valid regardless of the subject's level of confusion or dementia. Thus, a statement such as "whatever my daughter says is OK with me" is fine. The demonstration of assent need not be verbal. Passive lack of objection is acceptable in an alert patient. Indications of distress such as crying or attempts to escape the situation should be taken as refusals to assent to the study.

II. Procedures

A. Who should assess capacity? The evaluation of capacity should be done by a clinician who is experienced in the evaluation of dementia. Capacity must be assessed based on a direct examination of the subject; the report of others will not suffice.

B. Methods Capacity judgments may be made after routine clinical mental status examination when, in the examiner's opinion, the patient is severely demented and one or more standards is unquestionably failed. When there is any doubt, capacity should be specifically assessed in the course of attempting to obtain informed consent.

The routine assessment of capacity should begin with the examiner reviewing the informed consent form with the subject in the normal manner used to obtain consent. The simplified study summary, approved by the IRB, should be used as an aide, to emphasize and remind subjects of

major points. When the examiner has reviewed the study, he or she should ask the subject to explain the major elements of the study. Those elements are a) this is a research study (not routine treatment), b) participation is voluntary, c) study procedures, d) risks, e) benefits. In addition, as described in the standards above, the subject needs to make a rational choice based on an appreciation of the facts. *The subject can use the simplified study summary to answer the questions.* Based on the subject's responses the examiner should then make a final judgment about capacity for consent.

The consent process and capacity assessment should be recorded using the Capacity Assessment Record (CAR). Although the CAR requires that the evaluator make a decision with regard to each standard, there is no need to methodically evaluate each standard in every case. The evaluator may focus on any or all of them, as seems appropriate given what is known about the potential subject. Thus, it may quickly be clear that a severely demented patient cannot meet standard 2. The evaluator may then move directly to the issue of assent. Or, it may be clear that a subject with mild AD meets standards 1-3, and it is only 4 that is at issue. The reasons for your decision on each item should be documented, however briefly, using the CAR.

C. Suggested questions: The sequence of questions given below is given for illustrative purposes and to show how particular questions may be used to assess capacity with regard to particular standards for capacity. They pick up at the point that review of the consent form has been completed. This is not a script; clinical judgment remains the best guide for what to ask.

1. "Now I'd like to ask you some questions about study. Are we offering you your usual medical care, or are we asking you to be in a research study?"
2. "Must you take part in this study, or is it OK to say 'no'?"
3. "Tell me the main things that you would do in this study"
4. "Tell me the main risks of this study"
5. "Tell me the benefits of this study."
6. " Will this study mainly help you or others?"
7. "Considering the risks and benefits we have discussed, would you like to take part in this study?"
8. "Why?"

D. Relating questions to standards The suggested questions are repeated below, annotated to as to illustrate their relationship to the standards for capacity.

[Questions 1-6 pertain to standard 2 (Understanding). The subject need not know every detail in order to meet this standard, but neither does a rote recitation or reading of fact without comprehension suffice. If the subject does not understand 1 or more of these key elements about the study, standard 2 is failed.]

1. "Now I'd like to ask you some questions about study. Are we offering you your usual medical care, or are we asking you to be in a research study?"

2. "Must you take part in this study, or is it OK to say 'no'?"

3. "Tell me the main things that you would do in this study"4. "Tell me the main risks of this study"

5. "Tell me the benefits of this study."

6. " Will this study mainly help you or others?"

7. "Considering the risks and benefits we have discussed, would you like to take part in this study?" *[failure to respond in a consistent, unambiguous manner indicates that standard 1 is failed]*

8. "Why?" *[This is the single most important question for assessing standards 3 (Rational Reasons) and 4 (Appreciation). With regard to standard 3, if the answer indicates a balancing of risk and benefit, even if vague, this standard can be met. For example, "I'd like to help and there's not much to lose" might be sufficient, especially if other questions had indicated you that the subject had a reasonable idea of what the risks were. An answer that refers only to benefit should be questioned by pointing out there are risks. For example, if someone said "It seems like a good idea" you might ask "but what about the risks of the study?". If they can in response say something sensible that acknowledges the study's risks, this standard would be met. If they appeared not to understand that any risks were attached to the study, this standard would not be met. The greater the risks, the more specific must be the subject's consideration of those risks. In a pharmaceutical trial subjects must acknowledge that the extent of risk is not entirely defined and that there is some potential for serious adverse events.*

Standard 4 is usually met if standard 3 is met. The key difference is that the appreciation standard requires relating the facts to one's own situation; thus, patients with an impaired sense of reality might fail standard 4 while meeting standard 3. If a subject is delusional or anosagnostic then they may be unable to relate information that they correctly understand to their own personal situation. Thus, for example, an amnesic patient may deny memory loss and so believe that although a study would be good for someone with memory loss that it is not a good idea for him. Or, for example, a patient might recognize that a drug carried special risk for people with diabetes, but might fail to comprehend that she is diabetic. Under such circumstances these patients might be fail only standard 4.]

D. Documentation Record your actions and decisions using the CAR. This goes to the patient's chart, where it becomes part of his or her research records.

E. Summary of Process

1. Review Informed consent form with patient. Use the simplified study summary. If he or she cannot participate, then they lack capacity and no further assessment is needed.
2. Question the subject about the study using the simplified study summary.
3. Based on that, decide whether or not the subject has capacity.
4. If the subject has capacity and agrees to the study, have them sign the consent form.
5. If the subject lacks capacity or has marginal capacity, ask for the patient's assent to participate.
6. If the subject assents, and the subject's legally authorized representative consents, have both the subject and the representative sign the consent form.
7. Document the process using the CAR.
8. CAR and consent forms go to the chart.

III. References

1. Bioethics Interest Group *Expert Panel Report to the National Institutes of Health (NIH) Research Involving Individuals with Questionable Capacity to Consent: Ethical Issues and Practical Considerations for Institutional Review Boards (IRBs)*
http://www.nih.gov/sigs/bioethics/reports/exec_sum.htm
2. Cahill M, Wichman A. Research involving persons with cognitive impairments: results of a survey of Alzheimer disease research centers in the United States. *Alzheimer Dis Assoc Disord* 2000;14:20-7.
3. Cherniack EP. Informed consent for medical research by the elderly. *Exp Aging Res* 2002;28:183-98.
4. Etchells E, Darzins P, Silberfeld M et al. Assessment of patient capacity to consent to treatment. *J Gen Intern Med* 1999;14:27-34.
5. Kim SY, Karlawish JH, Caine ED. Current state of research on decision-making competence of cognitively impaired elderly persons. *Am J Geriatr Psychiatry* 2002;10:151-65.
6. Marson, et al. (1994) *ADAD*, 8, suppl. 4:5-18.
7. Marson DC, Cody HA, Ingram KK, Harrell LE. Neuropsychologic predictors of competency in Alzheimer's disease using a rational reasons legal standard. *Arch Neurol* 1995;52:955-9.
8. Marson DC, Hawkins L, McInturff B, Harrell LE. Cognitive models that predict physician judgments of capacity to consent in mild Alzheimer's disease. *J Am Geriatr Soc* 1997;45:458-64.

IV. Attachments

1. Template for simplified study summary
2. Capacity Assessment Record
3. Study summary for "The Reliability of MRI Measurements Made with Two Different Scanners."