



ASSESSMENT OF DECISION MAKING CAPACITY IN ADULTS PARTICIPATING IN A RESEARCH STUDY

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Based on the ethical principle of respect for persons as described in the Belmont Report (<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>), individuals should be treated as autonomous agents, and persons with diminished autonomy are entitled to protection.

The principle of respect for persons has two separate concepts: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

In research, respect for persons demands that subjects enter into the research voluntarily and with adequate information to make a choice.

However, there are individuals whose ability to consider the information needed for such a choice may be impaired and they may not be capable of providing legally effective informed consent for research.

The purpose of this policy is to establish guidelines for when and how to assess decision making capacity in adults.

Excluded from this policy are considerations about research studies involving children and prisoners, and emergency use of a drug, device, or biologic without consent.

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

The phrase “decision making capacity” refers to an individual’s ability to make a meaningful, informed decision. It is generally thought to include at least 4 components:^{1, 2}

1. Understanding: Understanding information relevant to the decision, such as nature and purpose of the study, potential risks and benefits.
2. Appreciation: Applying the information to one’s own situation and condition
3. Reasoning: To incorporate the information with personal priorities, values, potential consequences, and alternatives
4. Expression: Expressing (communicating) a choice in a consistent fashion

Decision making capacity is generally considered to be situation- and task-specific, and as such is protocol-specific. For example, a subject may be able to make an informed decision about participating in a study involving a simple procedure, but not a more complex procedure.

Decision making capacity is not synonymous with the legal capacity of competence. Incompetence is a legal determination made in a court of law, although such a determination may consider an individual’s decision making capacity. For example,

someone may be judged legally incompetent to manage their financial affairs, but they may have sufficient decision making capacity to make meaningful decisions about medical treatment or participating in a research study.

B. When is Explicit Assessment of Decisional Capacity Required?

Assessment of capacity must occur in studies where at least a portion of people targeted for enrollment can be expected to have diminished decision making capacity. Such diminished capacity is ordinarily due to impairment in cognition or perception (such as delirium or psychosis).

If a protocol targets subjects for enrollment who would be expected to have diminished decision making capacity (such as people with moderate to severe dementia), the study must require that surrogate consent be obtained from those subjects' legally authorized representative (LAR). This person may act on behalf of the subject for consent purposes. If a protocol targets a subject population that includes the potential for diminished decision making capacity (such as people with a range of intellectual disabilities or mild dementia), a protocol must be in place to assess capacity to determine if consent will be conducted with the subject's LAR or the subject him/herself.

Further information about the order of authority to provide consent on behalf of another adult for participation in clinical research can be found in the HRPP policy titled "The Use of the Legally Authorized Representative in Research Involving a Vulnerable Population of Adult Subjects" on the DUHS IRB web site.

Repeat assessment of decisional capacity would be indicated in two settings:

1. When there is IRB-mandated re-consent after changes to a protocol. In such cases, if a subject has gained or lost capacity, the re-consent process may differ from the initial consent process with respect to use of an LAR.
2. When some or all of the study participants can be expected to improve or decline while on study to the extent that they re-acquire or lose the capacity to provide legally effective informed consent.

C. Procedures for Assessing Decision Making Capacity

A range of methods may be used to assess decisional capacity. The protocol summary should describe how decisional capacity will be evaluated, by whom it will be evaluated, and the criteria for evaluation.

For example, "normal" scores on standardized cognitive screening tests may be used, such as a score of 24 or higher on the Mini-Mental State Examination (MMSE).³ It may also be appropriate to include the clinical assessment of a researcher familiar with the disorder under study.

More formal assessments may include:

1. A standardized assessment of decisional capacity, such as the MacArthur Competence Assessment Tool – Clinical Research (MacCAT-CR).⁴
2. A post-consent quiz demonstrating the subjects' knowledge of critical elements in the informed consent document. Questions could be about the purpose of the study, voluntary nature of the study, ability to withdraw, confidentiality, risks of

the study, or other key elements of consent. For subjects whose understanding is less than perfect, additional procedures may be used to improve their understanding, including a more detailed discussion of the items they have difficulty recalling. The quiz can then be repeated.

3. Someone outside the research team assessing the subject's understanding of the study.

Other methods will be considered by the IRB. As part of a protocol's review process, the appropriateness of the assessment plan will be reviewed. If the plan does not appear rigorous enough for a particular study, adjustments may be required by the IRB.

D. Assent

Adults with diminished decision making capacity may retain sufficient capacity to provide meaningful assent regarding their participation in the proposed research project. Assent is an affirmative agreement to participate in the research. **Absence of an objection or an inability to object should not be considered "assent."**

Assent of the potential subject should be sought by the person obtaining consent. If, in the judgment of the investigator, the adult potential subject retains sufficient decisional capacity to reason that, given his/her personal priorities, he/she does not want to participate in the research, the investigator and the person obtaining consent must honor the potential subject's decision.

But the assent of the potential subject may not be a necessary condition approval of the research if the IRB finds and documents that either of the following is true:

1. The capability of some or all of the adults is so limited that they cannot reasonably provide assent; or
2. The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well being of the adult and is available only in the context of the research.

The requirement for assent of the adult participant also may be waived if the IRB finds and documents that the requirements of 45 CFR 46.116(d) will be met.

E. Documentation Requirements

1. Research Summary: The Research Summary entry for Subject's Capacity to Give Legally Effective Consent should be completed for each study in which informed consent is not waived. Planned enrollment of individuals in research who may lack capacity should describe the need to enroll such individuals to achieve the objectives of the research, as well as the plan for assessing capacity.
2. Research Record: For studies targeting potentially impaired subjects, the decisional capacity assessment must be documented in the study record. Either the completed assessment tool may be included, or documentation of the clinical assessment may be reflected in the study visit note.

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

If the study has been approved by the IRB for use of surrogate consent by the LAR, informed consent must be obtained from the LAR. If the study is not approved for surrogate consent, the subject must be excluded from participation.

A subject must have the right not to participate or to withdraw from study participation without penalty or loss of benefits, either via consent or assent. An LAR's consent for the subject to participate is not sufficient if the subject refuses to participate, unless participation in the study holds out the only prospect for direct therapeutic benefit to the subject, all other potentially beneficial therapy has been exhausted, and the IRB has approved use of an LAR and waiver of assent in this situation.

H. What if an enrolled subject's decisional capacity changes over the course of the study?

If the study permits the enrollment of subjects whose decisional capacity may change, the plan for managing this should be included in the protocol summary. In general, the guiding principles should be 1) obtaining consent directly from the subject when possible, and 2) protecting the subject's right to withdraw. Examples of approaches are included below:

1. Decisional capacity is impaired at enrollment, but the subject is expected to improve: In delirium, subjects may be decisionally impaired at enrollment. Once treated appropriately, typically these subjects improve and regain baseline decision making capacity. Such a study could request authorization for a LAR for initial enrollment, and once a subject improves enough to exhibit adequate decisional capacity, the subject would be asked to complete the consent process and agree to continued participation. If at any time the subject indicates that he/she does not want to continue study participation, the subject would be withdrawn from the study, unless participation in the study holds out the only prospect for direct therapeutic benefit to the subject, all other potentially beneficial therapy has been exhausted, and the IRB has approved use of an LAR and waiver of assent in this situation.
2. Decisional capacity may worsen over time: Long-term longitudinal studies in older populations are associated with the risk that some subjects may acquire cognitive deficits as the study progresses. For subjects who do develop decisional impairment after agreeing to participate, the LAR would become responsible for making medical decisions. In such cases, the protocol summary should state that the LAR will be informed about the study, although formal written consent from the LAR would not be required because consent was initially obtained from the subject. The LAR would have the authority to withdraw the subject from the study if he/she concludes that withdrawal is in the subject's best interest. If a study amendment requires reconsent, written consent from the LAR would be required at that time. The consent form should contain a statement that informs subjects of this, and encourages them to discuss the study with their LAR.

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When research is funded by the NIDILRR and the IRB reviews research that purposefully requires inclusion of children with disabilities or individuals with mental disabilities as research participants, the IRB must include at least one person primarily concerned with the welfare of these research participants.

REFERENCES

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