CARILION MEDICAL CENTER INSTITUTIONAL REVIEW BOARD
Standard Operating Guidelines

Title: 5.6: Informed Consent Process: Decision Making Capacity Assessment for Adults	
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Objective:

To establish guidelines for when and how to assess prospective adult research subjects for decision-making capacity.

General Description:

As a general rule, all adults, regardless of their diagnosis or condition, are presumed to be capable of making an informed decision about participating in a research study. That is, they can incorporate information about a potential study through the consent process, weigh the study procedures and potential risks and benefits using their own values and personal priorities, and come to a decision about whether or not they choose to participate. These adults are able to provide legally effective informed consent to participate in a research study because the person understands the difference between treatment and research, understands the risks and benefits of participating in a specific research study, appreciates the consequences of participating or not participating, and is able to make and communicate a decision about participation or non-participation. However, there are individuals whose ability to incorporate the information needed for such a choice may be impaired to the extent that they may not be capable of providing legally effective informed consent for research.

This guideline is to be used by researchers and the Institutional Review Board for projects where the design of the study is expected to recruit from populations with disorders known to be associated with impairment of decision-making capacity. Also included are examples of post-consent assessment instruments that can be used to help document decisional capacity. The guideline applies to a broad range of conditions that comprise diminished decision-making capacity. Examples include healthy individuals in shock (temporary decisional impairment), those born with severe intellectual disabilities (permanent decisional impairment), individuals with age-related dementia (progressive decisional impairment), individuals with mental illnesses such as schizophrenia (fluctuating capacity), and individuals under the influence of certain drugs (temporary and/or fluctuating capacity). Excluded from this guideline are pediatric subjects as well as planned emergency research without informed consent since there is separate guidance for these areas.

Procedure:

Basic Principles

The IRB will consider the following principles in reviewing research applications:

- Studies involving subjects with cognitive impairment can be approved only if justified and appropriate additional safeguards are in place.

- 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 decisional capacity.
- 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.

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:

- Understanding: Understanding information relevant to the decision, such as nature and purpose of the study, potential risks and benefits.
- Appreciation: Applying the information to one's own situation and condition
- Reasoning: To incorporate the information with personal priorities, values, potential consequences, and alternatives
- Expression: Expressing 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.

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, all of whom 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 the subject's legally authorized representative (LAR). This person may act on behalf of the subject for consent purposes. (Information about the order of authority to provide consent on behalf of another adult for participation in clinical research presenting the prospect of therapeutic benefit to the subject can be found in SOG 5.3.) For such a study, assessment of the degree of decisional incapacity of the subject may not be required apart from determining that the subject met eligibility criteria for study participation. For all such study participants, surrogate consent would be required.

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

- When there is IRB-mandated re-consent after changes to a protocol. In such cases, if a subject who initially met criteria for having adequate decisional capacity now does not reach that threshold, the subject would be removed from the study, or consent obtained from the subject's LAR if the protocol is IRB approved for surrogate consent.

- When some or all of the study participants can be expected to improve while on study to the extent that they re-acquire the capacity to provide legally effective informed consent. In such cases, the subject would be asked to agree to continued study participation.

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 and the criteria for identifying subjects with diminished capacity. Formal and less formal assessments are allowable, and which is more appropriate will depend on the specific protocol in question.

Less formal assessments may include routine clinical assessments. For example, "normal" scores on standardized cognitive screening tests, such as a score of 24 or higher on the Mini-Mental State Examination (MMSE). It may also be appropriate to include the clinical assessment of a researcher familiar with the disorder under study, which would include ways in which professionals make judgments about capacity in routine interactions. This approach would need to be supplemented by a discussion by the study team with the subject about the study to ensure understanding, such as "What are we going to be doing as part of this study?" In some cases, study design may actively exclude subjects with significant cognitive impairment, and include screening assessments.

More formal assessments may include:
- A standardized assessment of decisional capacity, such as the MacArthur Competence Assessment Tool – Clinical Research (MacCAT-CR).
- A post-content quiz demonstrating the subjects' knowledge of critical elements in the informed consent document. Quiz questions could include 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 who score less than perfect on the initial presentation, educational procedures may be used to facilitate their understanding, including a more detailed discussion of the items they have difficulty recalling. The quiz can then be repeated. Examples of post-content quizzes include the "Aid to Capacity Evaluation" or ACE and the University of California, San Diego Brief Assessment of Capacity to Consent (UBACC).
- Screening tests, performed after obtaining initial informed consent, may be used as assessments of cognitive status. For example, if a subject scores ≤ 23 on the Mini-Mental State Examination, they would be considered to have impaired cognition, and so will either be excluded or surrogate consent sought, dependent on the study protocol.

Other alternatives exist and will be considered by the IRB, such as the Hopkins Competency Assessment Test (HCAT), a brief instrument for evaluating the capacity of patients to give informed consent. 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.

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 the cognitively impaired adult's affirmative agreement to participate in the research. Mere failure to object should not, absent affirmative agreement, be construed to be assent.

Assent to participate in research by an adult with diminished decision-making capacity (for whom a legally authorized representative will provide informed consent) is to be obtained when, in the judgment of the IRB, the adult is capable of providing assent. In determining whether proposed subjects are capable of assenting, the IRBs will take into account the condition and

psychological/emotional states of the adults involved. If a person with decisional impairment is capable of exercising some judgment concerning the nature of the research and participation in it, the investigator should obtain the subject's assent in addition to the consent from the legally authorized representative. The IRB's determination of the proposed subjects' capacity to assent may apply to all or only some of the adults to be involved in a proposed research activity.

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 is not a necessary condition for proceeding with the research if the IRB finds and documents that either of the following is true:

- The capability of some or all of the adults is so limited that they cannot reasonably be consulted; or
- 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.

Assent should include the key elements of informed consent. The assent discussion and information should be provided in language appropriate for an adult with diminished decision-making capacity, based on the nature of the study and the expected ability of the prospective subjects to understand the purpose and the procedures involved in the research.

When the assent of an adult with diminished decision-making capacity is required, the IRB must determine the appropriate method, if any, of documenting assent. This decision should be based on considerations such as the length and complexity of the research and the adult's condition and psychological/emotional state.

Generally, when documentation of assent is required an assent form similar to the consent document signed by the legally authorized representative is used. Alternatively, based on the condition of the adults and nature of the research, for some studies investigators may add a signature line for assent to the consent document that legally authorized representatives will sign. The IRB can also approve assent forms on a case-by-case basis in other formats that satisfy requirements for obtaining and documenting assent.

When assent is not documented by use of a form as described above, documentation of assent may be limited to verifying that assent took place using a witness or other method. Alternatively, the IRB may decide that documentation of assent is not warranted. If verbal assent will be obtained, the IRB must review a written description of the information (i.e., a "script") that will be provided to subjects during the assent process.

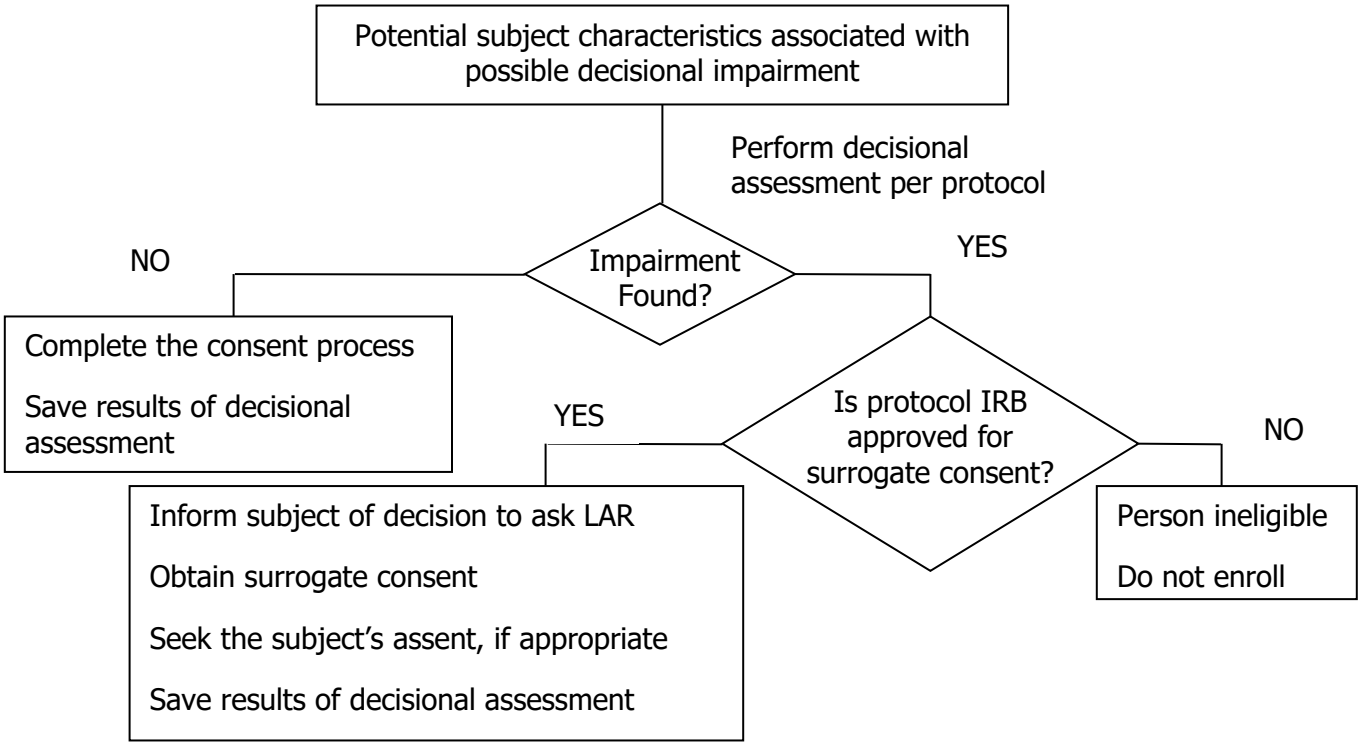
Documentation Requirements

- Protocol Summary: When appropriate, the investigator should indicate that the protocol targets populations wherein impaired decisional capacity is unlikely, and that during the clinical interview, any subjects who appear to have impaired capacity will be excluded. If the protocol targets subjects, some of whom may exhibit impairment, the procedures for assessing decisional capacity must be described. Any assessment tools to be used (such as post-content quizzes) must be included with the application.

- 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.

What if a potential subject fails to demonstrate adequate decisional capacity?
If a subject does not reach the threshold for decisional capacity as described in the protocol summary, the subject may not be eligible for the study. 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. See flow diagram below.

A subject must have the right not to participate or to withdraw from study participation. 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 since all other potentially beneficial therapy has been exhausted.



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:

- 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.
- 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. 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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