# Consenting Individuals with Impaired Decision-Making Capacity

**Please provide any feedback regarding this scenario in the comment form below or by clicking here.**

The objective of this use case is to demonstrate a possible scenario within a researcher-initiated longitudinal cohort study in which recruitment activities target special populations, specifically cognitively impaired individuals. The research focuses on issues unique to this population and involves no more than minimal risk to the research participants.[1] The purpose of this scenario is to examine the unique requirements around consent and enrollment of decisionally impaired individuals.

Some participants may not be able to consent for a number of reasons, including, but not limited to, mental disorders, neurological disorders, medications, substance abuse, head trauma, etc. Therefore, these participants' capacity or competency to consent may fluctuate or change over time. The protocol should also address prospective participants that had the capacity or competency to consent at the initial enrollment phase, but may experience a change in capacity or competency for reconsent that requires the involvement of a legally authorized representative (LAR) or suspension/termination of their participation in the study.

The research team may need to include some method to make a determination on a prospective participant's capacity to consent in the protocol if the IRB determines additional safeguards are necessary. The protocol can include any of the following methods to determine a prospective participant's capacity to consent:

- Qualified independent party to assess the decisional capacity of the potential research participant
- Independent entity to monitor the consent process
- Standardized assessment of cognition of capacity to consent. The assessment may ask the prospective participant to demonstrate that they understand the purpose of the study, procedures, potential risks and benefits, alternatives to participation, etc.
- Informational or educational techniques
- Waiting period to allow the prospective participant additional time to consider all component of the study
- Proxy consent
- Assent in addition to proxy consent

The protocol should also include a statement of rationale for administering any of the assessments described above. These might include:

- Intent to study characteristics of decisionally impaired individuals
- Intent to study general population with members who may develop impairment

The research team should also determine if a potential participant has been declared legally incapacitated or legally incompetent in their state. Participants deemed legally incapacitated or legally incompetent are not considered competent and therefore cannot legally give their consent to participate in a research study.

The team will need a process to determine who should be appointed to make data-sharing decisions on behalf of patients who cannot make this determination themselves (guidelines related to LARs).

The study protocol will need to inform the LAR how they can withdraw consent for the participant at any time during the study. The research team should also be aware of fluctuations in the patient's status throughout the study. Participant capacity to consent should re-evaluated as necessary or as outlined in the study protocol. If a decisionally impaired participant no longer requires an LAR to consent for them, the research team should acquire consent directly from the participant.

**Questions:**

- Is the research team obligated to remove data at a patient's request if they decide not to reconsent to a study their LAR had consented them into previously? What is the research team's obligations with respect to data collected in the interim when the patient no longer required an LAR/proxy and was contacted to reconsent?
- Are there issues associated with cooperative consent (e.g., assent of participant with consent of proxy)?
- Are the questions/tests for decisional impairment described above sufficient to verify privacy concerns?

| Title | Response |
|---|---|
| Description | Participant that is or may become decisionally impaired is consented into a longitudinal study. The participant's capacity to consent changes over the course of the study. |
| Primary actor /participant | Research team, participant, LAR or proxy |
| Support actor /participant | Information systems |

| | |
|---|---|
| Preconditions | • At the time of initial record release approval, all parties obtain all legally required authorizations for health data linkage and transfer.<br>• Data requests use unique identifiers to protect the identity of patients so they cannot be re-identified.<br>• The data exchange will be funded by a research agency.<br>• Capacity to consent will be determined by someone qualified to assess decisional capacity.<br>• Participants will be asked to demonstrate that they understand the purpose of the study, procedures, potential risks and benefits, alternatives to participation, and can indicate a choice to participate in the research.<br>• Participant capacity to consent will be re-evaluated as necessary.<br>• If the participant lacks the capacity to consent, the consent of a Legally Authorized Representative will be sought.<br>• If the participant lacks the capacity to consent, the participant's assent will be sought. |
| Postconditions | Data will be made available to researchers for uses in a manner that is compliant with legal concerns and ethical concerns of the research team. |
| Alternative | A patient that has the capacity to consent becomes decisionally impaired, and their LAR is unaware they are enrolled in a research study. |
| Considerations | A participant's status as decisionally competent may change over the course of the study, but this is unknown at the outset, so it must be accounted for in development of the study protocol |
| Data Elements Considered | Not specified |
| Purpose of the Data Collection | Research |
| Purpose of Data Use | Analysis under a specific IRB approved research protocol |
| Terms of Transfer to the Data Holders | Direct consent from participants to researcher |
| Terms of Transfer to Researchers | IRB approval |

[1] The Common Rule indicates that research should involve cognitively impaired subjects only when they comprise the only appropriate subject population, the research focuses on an issue unique to this population, and it involves no more than minimal risk.

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