Decatur Memorial Hospital

INSTITUTIONAL REVIEW BOARD
SOP 206: Special Populations - Decisionally Impaired

POLICY
Potential study participants who lack the ability to make and communicate medical treatment decisions may still participate in a clinical trial if a Legally Authorized Representative is identified.

PURPOSE
To provide guidance and direction for assessment and documentation of decisional capacity and obtaining valid informed consent for participation in a clinical trial from a Legally Authorized Representative (LAR) decision-maker when an adult potential study participant lacks decisional capacity.

DEFINITIONS

Decisional Capacity: The ability to understand and appreciate the nature and consequences of a decision regarding medical treatment or forgoing life-sustaining medical treatment and the ability to reach and communicate an informed decision in the matter as determined by the physician investigator. Decisional capacity may change over the natural course of an illness, response to treatment, effects of medications, general physical health and other factors. Therefore, mental status will be re-evaluated periodically.

Lack of Decisional Capacity: Having an uncontrolled psychiatric disorder (e.g., psychosis), an organic impairment (e.g. dementia), or developmental disorder (e.g., intellectual disability) that affects cognitive function to the extent that capacity for judgment and reasoning is significantly diminished. Others including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, and persons with severe physical disabilities may also lack the ability to make decisions in their best interests.

Legally Authorized Representative (LAR): An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective study participant to participate in the clinical trial.

PRCOEDURES

1. Presumption of Competence

1.1 As a general rule, all adults, regardless of their diagnosis or condition, should be presumed competent to consent to research unless there is evidence of serious lack of decisional capacity that would impair reasoning or judgment. Physicians and providers routinely review medical history and assess all patients for alertness and ability to communicate. Even patients who have a diagnosed mental disorder may be perfectly able to understand the matter of being a voluntary clinical trial participant, and quite capable of consenting to or refusing participation. A mental disability alone should not disqualify a person from consenting to participate in research. There should be specific, documented evidence of individuals' incapacity to understand and to make a choice before they are deemed unable to consent.

2. Questionable Impairment

2.1 If providers suspect a study participant has compromised decisional capacity, the following questions will be provided as a guide to further assess the need for an LAR:

2.1.1 Does the potential study participant understand the required elements of informed consent by answering the following questions:

2.1.1.1 What is your present medical condition?

2.1.1.2 What is the treatment that is being recommended for you?

2.1.1.3 What do you and your doctor think might happen to you if you decide to accept the recommended treatment?

2.1.1.4 What do you and your doctor think might happen if you decide not to accept the recommended treatment?

2.1.1.5 What are the alternatives available (including no treatment) and what are the probable consequences of accepting each?

2.1.2 Does the potential study participant assign personal values to the risks and benefits of intervention?

2.1.2.1 Assigning personal values can be assessed by commands made by the potential study participant (e.g. I don't like the side effects of diarrhea. Is there medication for breakthrough pain? Can I have medication for nausea? Even if I don't benefit, it may help future generations.)

2.1.3 Is the potential study participant able to think through information rationally?

2.1.4 Is the potential study participant's decision-making capacity stable?

2.1.4.1 The stability of the choice can be determined by repeating a question several minutes later.

2.2 If the physician investigator finds the potential study participant lacks decisional capacity, an LAR must be identified, documented and involved in the consent process. If an LAR cannot be identified, then the potential participant will not be enrolled in a clinical trial.

2.3 Per routine medical practice, all providers routinely assess patients' continued decisional abilities at follow-up visits and prior to re-consent to ensure decisional capacity has not diminished over time and that the study participant recalls study involvement. Reassessment may include tests that evaluate comprehension, and the methods used are at the physician investigator's discretion.

3 Use of a Legally Authorized Representative

3.1 Every attempt should be made to identify a surrogate highest on the priority lists below:

3.1.1 <u>For Illinois</u>: Types of LAR for potential study participants are listed in order of priority below.

3.1.1.1 Court-appointed guardian, or proxy designed by durable power of attorney

3.1.1.2 Spouse or civil union partner

3.1.1.3 Any adult son or daughter

3.1.1.4 Either parent

3.1.1.5 Any adult brother or sister

3.1.1.6 Any adult grandchild

3.1.1.7 A close friend (requires affidavit); or

3.1.1.8 Guardian of the estate

3.1.2 <u>For Missouri</u>: Legal guardian, attorney-in-fact, then family member in the following order of priority:

3.1.2.1 Spouse

3.1.2.2 Adult child

3.1.2.3 Parent

3.1.2.4 Adult brother or sister; or

3.1.2.5 Relative by blood or marriage

SCOPE

This SOP applies to all members of the research team.