Albert Einstein College of Medicine

Enrolling Adults with Varying Decision-Making Capacity in Research

I. Purpose

This Procedure describes the enrollment and consent process for enrolling and assessing adults with varying decision-making capacity in human research.

II. Scope

This Procedure applies to all human research conducted under the auspices of the Einstein Institutional Review Board ("IRB").

III. Definitions

Assent: An individual's affirmative agreement to participate in research obtained in conjunction with permission from the individual's legally authorized representative. Mere failure to object should not be considered assent.

Consent Capacity: an adult's ability to understand information relevant to making an informed, voluntary decision to participate in research. This includes the ability to understand the purpose of the research and the procedures involved, to appreciate medical and other consequences of research (including risks and benefits), and to understand the alternative to enrollment in the study. It also includes the ability to decide and effectively communicate a choice about participation.

Diminished Capacity: a demonstrated limitation in an individual's ability to perform any of the above functions.

IV. Procedure

The inclusion of people with varying decision-making capacity in a research study must be approved by the IRB. The protocol must include a description of how and by whom consent capacity will be evaluated. Examples of research situations that may include people with varying decision-making capacity include the following:

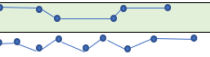
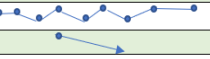
1. A research protocol specifically intended to study people with varying decision-making capacity (e.g., Alzheimer's disease, delirium, certain cognitive conditions).
2. A research protocol conducted in an environment (e.g., nursing home, ICU, ER) or on a population group (e.g., patients with schizophrenia; patients who are intoxicated) in

which it can be reasonably anticipated that some potential individuals may have varying decision-making capacity, either permanently or at some time during the study.

Determining Capacity of an Adult Research Participant

Consent capacity is rarely an all-or-nothing situation. Capacity is best understood as occurring along a continuum from complete capacity to no capacity whatsoever. In some cases, it is obvious that potential individuals will not have the capacity to consent (e.g., comatose or non-responsive state). In such instances, capacity assessment may not be required. Examples of different types of diminished capacity include:

- no capacity (e.g., comatose or non-responsive state)
- chronic (e.g., intellectual disability spectrum)
- temporary (e.g., delirium)
- fluctuating (e.g., schizophrenia)
- diminishing (e.g., Alzheimer's disease)

CAPACITY	EXAMPLE	IMAGE
No capacity	Comatose or non-responsive	
Chronic	Intellectual disability spectrum	
Temporary	Delirium	
Fluctuating	Schizophrenia	
Diminishing	Alzheimer's disease	

Consent capacity is also decision specific. It depends on the nature and complexity of the study, the study procedures, and the decision-making process. The goal of the consent process for any study involving people with varying decision-making capacity should be to respect the capacity they may attain by ensuring their participation in the decision-making process at their appropriate level.

The assessment of a potential research participant's capacity should be made by staff who have been appropriately trained to evaluate capacity. In some cases, an adequate determination of capacity will require special expertise. If the individuals are Montefiore Medical Center patients, the assessment and documentation of decision-making capacity must comply with Montefiore clinical policies on informed consent.

When enrolling populations at risk of diminishing or fluctuating consent capacity, researchers should incorporate a formal process for capacity evaluation into the protocol's enrollment and screening process, along with a mechanism for securing surrogate consent as appropriate.

The protocol must describe the tools that will be used for assessment of capacity. Investigators may choose the appropriate assessment tool for their study. Two commonly used tools include the MacArthur Competence Assessment tool and the University of California, San Diego Brief Assessment of Capacity to Consent (UBACC).

Surrogate Consent for Adult Research Participation

Appointment of a Surrogate by the Individual

While people with varying decision-making capacity may not be able to evaluate the complexity of a specific research project, they may retain the capacity to appoint a surrogate decision-maker and should be encouraged to do so. If the individual retains the capacity to choose from among

appropriate surrogates, as listed in the New York State hierarchy below, their choice should be respected.

Selection of a Surrogate by the Investigator

For research conducted in New York State, the IRB may authorize surrogate consent from a health care agent or another person according to the following hierarchy, derived from New York's Family Health Care Decisions Act (FHCDA)[1]:

- An individual who is designated as a representative/agent through a health care proxy signed by both the individual and the appointed representative/agent. For a healthcare proxy to be effective, it must have been signed at a time when the individual had decision-making capacity. In addition, the health care proxy must not specifically prohibit research.
- A court-appointed guardian authorized to make health care decisions
- The individual's spouse or domestic partner
- The individual's adult child (son or daughter 18 years or older)
- The individual's parent
- The individual's brother or sister (18 years or older)
- A close relative or friend (A close relative or friend is any person 18 years or older who is a close friend of the individual or a relative of the individual other than a spouse, adult child, parent, brother, or sister. The close friend/relative must present a signed statement indicating that they have maintained regular contact with the individual and are familiar with the individual's activities, health, and religious or moral beliefs).

For research conducted outside of New York State, the categories of persons who may act as legally authorized representatives will be considered by the IRB in accordance with applicable state or local law.

Surrogate consent for research should be based on the expressed preferences of the potential research participant, when known, or consistent with his/her prior behavior, beliefs, and values, when preferences are not known.

The process for surrogate selection and level of surrogacy must be approved by the IRB. The IRB has the discretion to limit the classes of persons who may act as the legally authorized representative for a given study, given that each class of persons may have varying degrees of understanding of the wishes of the impaired individual regarding research participation. In general, the higher the level of risk of the research protocol and the lower the prospect of direct benefit, the closer (kinship/relationship) the legally authorized representative should be to the individual participating in the research.

Individuals at Risk of Losing Consent Capacity

Consent capacity can be affected by disorders with progressive or fluctuating courses. In cases where an individual's cognitive condition is expected to deteriorate or fluctuate, it may make sense for researchers to review consent capacity during the course of the study. In addition, such

[1] For exceptions to this hierarchy, contact the Office of Human Research Affairs ("OHRA") for guidance.

changes in clinical status may affect, for example, the risk/benefit considerations, appropriate alternatives to study participation, and the need for additional safeguards or monitoring.

When consent capacity could diminish during the course of a study, it may be most appropriate to transition to surrogate consent and decision-making. In these cases, involving at the start of the study, an individual who could serve as a surrogate, later on, may be most prudent, and the individual's wishes regarding participation in the study should be documented. For individuals with conditions that bring about fluctuating levels of consent capacity, it is important to consider the timing of the assessment and consent; it may make sense to time the initial consent carefully to avoid periods when prospective individuals may be experiencing heightened impairments (e.g., an individual with schizophrenia who is refusing medication). In all cases, respecting an individual's right to withdraw from a research study is a continuation of the initial consent process, and consideration should be given to ensuring that varying decision-making capacity does not limit this right.

Individual's Assent and Dissent

People with varying decision-making capacity may still be able to comprehend some aspects of the research study. The researcher should clearly state how the assent process will occur and how assent and dissent will be documented.

Assent is the affirmative agreement to participate by the individual. When an individual is capable of providing assent, he/she will only be enrolled in a research study if he/she assents and has a consenting surrogate. If an individual assents but a surrogate does not provide consent, the individual will not be enrolled in the study.

Dissent is any objection to participation by the individual. In general, the dissent of an individual will be respected; overriding an individual's dissent would only be considered in cases where there is a prospect of direct benefit, which is only available in the research context. The IRB will determine when it is appropriate to override an individual's dissent, and this will be determined on a case-by-case basis.

In cases where an individual is unable to provide assent or dissent, enrollment of the individual in research will be based on surrogate consent. The individual's inability to provide assent should be documented. The individual's ability to assent should be re-evaluated, and there should be a process for re-evaluation at certain intervals, as appropriate to the research protocol.

Research Participants who Regain Capacity

If the individual regains capacity, written consent must be obtained prior to continued participation in research. A professional team will make the decision regarding regaining capacity.

Assessing Decisional Capacity Within the Context of Research

The following categories of research may include people with varying decision-making capacity:

Studies that are minimal risk
People with varying decision-making capacity may be enrolled in studies with minimal risk even if the research offers no direct benefit to the individual.

Studies that involve a minor increase over minimal risk and a prospect of direct benefit
The risks must be reasonable in relation to the prospective benefits. Full IRB review is required. The IRB may recommend additional safeguards.

Studies that involve a minor increase over minimal risk and no prospect of direct benefit
The risks must be reasonable in relation to an assessment of the scientific merit and probability that the study will further the understanding of the etiology, prevention, diagnosis, pathophysiology, or alleviation or treatment of a condition that specifically affects the research population. Full IRB review is required. The IRB may recommend additional safeguards.

Studies that involve greater than minimal risk with a prospect of direct benefit
The prospect of direct benefit must only be available in the context of research, and standard treatment may not be withheld. Full IRB review is required. Requests to enroll individuals in such studies may be made to the IRB via a protocol exception request. The IRB Chair may approve such individuals with the consultation of general counsel.

Studies that involve greater than minimal risk with no direct benefit
If the research protocol can be carried out by enrolling only individuals who have the capacity to consent, then only individuals with capacity may be enrolled. If the research addresses a significant clinical issue related to varying decision-making capacity that can only be done with individuals who lack capacity to consent, researchers should approach the Office of Human Research Affairs ("OHRA") to see if the study is permissible. The risks must be reasonable in relation to an assessment of the scientific merit and probability that the study will further the understanding of the etiology, prevention, diagnosis, pathophysiology or alleviation or treatment of a condition that specifically affects the research population. Full IRB review is required.

V. Effective Date

Effective as of: July 1, 2020

Revised as of: July 24, 2023

VI. Procedure Management and Responsibilities

Einstein's Office of Human Research Affairs is the Responsible Office under this Procedure. The Executive Dean is the Responsible Executive for this Procedure. The OHRA Director is the Responsible Officer for the management of this Procedure.