In an effort to uphold the principle of respect for persons and to protect vulnerable populations who may participate in research, Einstein IRB sets forth this policy to help ensure the protection of potential research subjects who are adults and who may have diminished consent capacity.

Definitions:

"Consent Capacity" is 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” is a demonstrated limitation in an individual’s ability to perform any of the above enumerated functions.

In the following two research situations plans for enrolling subjects with diminished capacity, including a description of how and by whom capacity will be evaluated, must be specified in the protocol and approved by the IRB in advance.

1. A research protocol specifically intended to study individuals with diminished capacity (e.g. Alzheimer’s disease; mental retardation; delirium).
2. A research protocol conducted in an environment (e.g. nursing home, ICU, ER) or on a population group (e.g. schizophrenic patients, intoxicated patients) in which it can be reasonably anticipated that some potential subjects will have diminished capacity, either permanently or at some time during the study.

N.B. On occasion, an individual with diminished capacity may volunteer or be recruited to participate in a research study being conducted among the general population. It is the responsibility of the PI to assure that consent to participate has been obtained with appropriate consideration of each individual’s capacity to consent.

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 subjects will not have capacity to consent (e.g. permanent vegetative state), and in such instances capacity assessment may not be required. Examples of different types of diminished capacity include:

- no capacity (e.g. permanent vegetative state)
- permanent (e.g. mental retardation)
- temporary (e.g. delirium)
- fluctuating (e.g. schizophrenia)
- diminishing (e.g. 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 diminished capacity should be to respect the capacity they may retain by assuring their participation in the decision process at the appropriate level.
In general, 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. When special expertise is required, the IRB application must indicate by name which appropriately qualified person(s) will be assessing capacity to consent and the credentials establishing their qualification. The protocol must also describe the tools that will be used for assessment of capacity.

When enrolling populations at risk of diminished 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.

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 Subject**

Adults who have diminished capacity and may not be able to evaluate the complexity of a specific research project, may retain the capacity to appoint a surrogate decision-maker and should be encouraged to do so. In this case, the potential subject may specify in a formal health care proxy form that his/her health care agent may consent to research. Potential subjects who already have a health care proxy form should update the form to include consent to research.

**Selection of a Surrogate by the Investigator**

When the potential research participant lacks capacity and the potential participant does not have capacity to appoint a surrogate, the IRB may authorize consent from a health care agent or another person according to the following hierarchy, derived from New York’s Family Health Care Decisions Act (FHCDAA):

- Health care agent (the health care proxy may contain specific wishes regarding research)
- A court-appointed guardian (authorized to make health care decisions)
- The patient’s spouse or domestic partner
- The patient’s adult child (son or daughter 18 years or older)
- The patient’s parent
- The patient’s brother or sister (18 years or older)

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.

For studies that offer potential benefit to participants lacking consent capacity, and in certain studies that are minimal risk, and must be conducted on an urgent basis, the IRB may consider the option of permitting a surrogate of lower status in the hierarchy to grant surrogate consent when surrogates of higher status are not reasonably available. The use of this process must be explicitly approved by the IRB.

The protocol must describe how the research team will locate members of the hierarchy and state clearly the lowest level of the hierarchy that will be used.

The process for surrogate selection and level of surrogate must be approved by the IRB.

**Participants at Risk of Losing Consent Capacity**

---

1 Exceptions from this hierarchy may be approved by explicit request to the IRB.
Consent capacity can be affected by disorders with progressive or fluctuating courses. In cases where a subject’s cognitive condition is expected to deteriorate or fluctuate, it may make sense to re-evaluate consent capacity (and, as appropriate, strategies for consent enhancement) at several intervals during the study, especially in long-term studies that may involve multiple phases. In addition, such changes in clinical status may affect, for example, the risk/benefit considerations, appropriate alternatives to study participation, and 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. 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 subjects may be experiencing heightened impairments, e.g., an individual with schizophrenia who is refusing medication or acute drug intoxication. In all cases, respecting a subject’s right to withdrawal from a research study is a continuation of the initial consent process, and consideration should be given to ensuring that diminished capacity does not limit this right.

**Adult Research Participant’s Assent and Dissent**
Adults whose capacity is impaired may still be able to comprehend some aspects of the research study. Assent is the affirmative agreement to participate by the potential research participant. When a potential research participant 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 a potential research participant 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 potential research subject. In general, the dissent of a potential research participant will be respected; overriding a research participant’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 a potential subject’s dissent and this will be determined on a case-by-case basis.

The researcher should clearly state how the assent process will occur and how assent and dissent will be documented.

In cases where the research participant is unable to provide assent or dissent, enrollment of the individual in research will be based on surrogate consent.

**Research Subject Advocates**
If a research subject advocate is proposed by an investigator, the investigator should provide a description of the research subject advocate’s role and function. Often, a research subject advocate acts on behalf of participants to ensure their protection during a study. The advocate can address questions or concerns with regard to confidentiality, privacy, safety, research ethics, the process of informed consent, or the rights of subjects. The IRB reserves the right to require a research subject advocate in certain cases.

**Research Participants who Regain Capacity**
If the research participant regains capacity, written consent from the research participant must be obtained.

**Research with Special Populations**
Potential research participants with mental retardation, patients involuntarily admitted to psychiatry, or developmental disabilities may be enrolled in research only after conferring with general counsel.

**Category of research:**
The following categories of research may include persons with diminished capacity:
Studies that are minimal risk
Subjects with diminished capacity may be enrolled in studies with minimal risk even if the research offers no direct benefit to subjects. Minimal risk means that the probability and magnitude of harm or discomfort (including privacy risks) anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

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 individual subjects in such studies (i.e., the subject without capacity is not expected, such as a patient with senile dementia for an oncology study) may be made to the IRB. The IRB Chair may approve such individual subjects with 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 subjects who have the capacity to consent, then only subjects with capacity may be enrolled. If the research addresses a significant clinical issue related to diminished capacity that can only be done with patients who lack capacity to consent, researchers should approach the IRB 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.

In all cases the final decision to include subjects with diminished capacity to consent is to be made by the Einstein IRB.