Series 503 Populations with Limited Decision Making Capacity | Institutional Review Board

The Institutional Review Board from Series 503 of Populations with Limited Decision Making Capacity

I. Definitions & Scope

Assent: A positive indication of willingness to participate in a study.

Capacity to consent: The ability to provide legally effective consent to enroll in a research study.

Diminished or fluctuating functional abilities: Substantial impairment of cognitive functions (such as attention, comprehension, memory and intellect), communication abilities or other abilities that affect capacity to make and express a decision regarding participation in a study that may be temporary, permanent, or change over time.

Dissent: Any expression of unwillingness to participate in a study or component of a study, including refusal to undergo a procedure involved in the study.

Legally Authorized Representative: (LAR) an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

Minimal Risk: Defined, based on DHHS regulations, as studies for which, "the probability and magnitude of harm or discomfort 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."

Research conducted with individuals with limited, questionable, or fluctuating decision making capacity must be designed in such a way as to provide additional protections to these populations. Conducting research involving participants who cannot consent to enroll because of a physical or psychological condition is vital to the expansion of knowledge that can benefit the lives of those and similarly situation individuals, and this kind of research must be designed with care. Participants who cannot consent to enrollment in research due to a legal deficiency also deserve additional protections. In all cases, research with these populations should only occur when they are necessary to the design of the research and are among the population that stands to benefit from the outcomes of the research.

When feasible, researchers should make efforts to support or enhance prospective participants' ability to consent. Some individuals who are not capable of consenting under routine consenting procedures might be capable when special measures are adopted. Such methods include:

1. designing a stepwise consent process, which involves a waiting period between each phase of the process: capacity assessment, initial presentation of information, and obtaining consent;
2. enhanced presentation of consent information during initial presentation and/or immediately prior to obtaining consent, including:
    a. repetition of information (especially misunderstood information),
    b. both oral and written presentation of information,
    c. multi-media presentation of information,
    d. interactive questioning, and
    e. written study summaries;
3. continuous dissemination of consent information throughout the course of the study; and

4. conducting the consent process in an environment in which the participant is comfortable.

II. Incapacity Due to Age

1. Children
   Legally speaking, children -- or those who have not yet reached the age of 18 in most jurisdictions in the U.S. -- are “incompetent” to enter into contracts and give legally effective informed consent. For this reason, informed consent from a legal guardian (often a parent) is required for the involvement of children in a research study, absent a waiver consistent with the provisions articulated in SOP 502. Children should still be given an opportunity to assent to the research, even where a waiver is applied, where their age, maturity, and comprehension skills would permit them to understand the nature of the research and what it is they might be agreeing to. Generally speaking, a seven year old neurotypical child is considered capable of assenting to most research procedures. In school settings especially, it is very common for researchers to request an “opt-out” informed consent process. This requires a waiver of informed consent in most cases. Children who reach the age of majority while they are still human subjects in the research should be given an opportunity to give their own legally effective informed consent to continue on with the study. Researchers who are working with children likely to reach the age of majority during the conduct of the study must articulate a plan for obtaining the informed consent of these individuals, or must obtain a waiver of informed consent for their continued inclusion in the study.
2. The Elderly
   Being elderly does not mean that an individual does not have the capacity to render legally effective informed consent. Age, on its own, is not an acceptable justification for seeking informed consent from someone other than the participant themselves. However, participant age is one factor that researchers should consider when developing a plan to ensure that the party they are seeking informed consent from is the party legally able to give it. The primary focus should be on capacity: attention, intellect, comprehension, memory, and ability to communicate. Advanced age might be an indicator that the research team should carefully consider issues of capacity.

III. Individuals with Limited Capacity

Functional abilities exist along a continuum, and prospective adult participants can have greater or lesser ability because of various physical and psychological conditions. The extent and nature of impairment may vary based on the nature of the condition and on factors specific to individual participants. However, prospective adult participants with limited (not complete) impairments to functional abilities are presumed to be capable of providing consent to enroll and participate in a research study unless there is substantial evidence that they are not capable. Researchers should not consider the mere presence of a condition that leads to diminished functional abilities as indicative of a lack of capacity to consent.

When the recruitment plan includes individuals who are likely to have impairment to their functional abilities, the capacity of such prospective participants to consent to enroll in the study in question should be assessed on an individual basis prior to their enrollment. Research with these populations should target individuals with the least amount of impairment necessary to achieve the aims of the study.

Various approaches to assessing prospective participants’ capacity to consent to enroll in a study are appropriate, depending on the nature of the research. The assessment methodology should increase in rigor as the degree of risk associated with participation and extent of likely impairment to prospective participants’ functional abilities increase. One or more individuals with relevant expertise should be identified to evaluate prospective participants’ capacity to consent and make an objective determination regarding the capacity to consent of each participant. In most instances, this will be a member of the research team, but for studies involving a high degree of risk to participants it might be necessary to engage an independent evaluator. Methods to assist with evaluators’ determinations include:

1. conducting clinical interviews with prospective participants and asking them to describe aspects of the study;
2. using standard psychological and neuropsychological screening tests; and
3. utilizing a formal instrument for assessing capacity to consent in clinical research.

Cognitive tests and competence assessment instruments alone cannot provide the basis of the evaluator's determination regarding a participant's capacity to consent, and should at most supplement or support the evaluator's expert judgment.

IV. Individuals with Complete Incapacity

Due to the nature of their physical or psychological conditions, some prospective participants will not be capable of assenting to their participation in research (for example, participants whose condition involves extended loss of consciousness). However, for any prospective participant incapable of providing consent, but capable of communicating their preferences regarding participation, researchers should make reasonable efforts to offer information regarding the procedures that they will undergo and ensure that their participation is willing. Researchers should outline, in their protocol submissions, a plan for obtaining the assent of adult participants who cannot consent, when appropriate. The content of these procedures will depend on the degree of risk and extent of likely impairments to participants' functional abilities and should increase in rigor as risk and functional abilities increase. Mere lack of objection by participants should not be interpreted as assent. Moreover, the dissent of a participant, whether communicated orally or otherwise, should be respected. If a participant expresses dissent only to a component of a study and not to participation in the study as a whole, researchers might return at a later point and see whether the participant is willing to undergo the procedures involved in that component. However, if a participant dissents repeatedly to participation in a component of a study, they should be withdrawn from that component and, if necessary, from the study. If a dissenting participant cannot be withdrawn from a study or component of a study for safety reasons, they should be able to receive the intervention, but should be withdrawn from the research, if possible.

V. Working with the Legally Authorized Representative

Some participants deemed incapable of providing consent might be capable of appointing a legally authorized representative, and should be encouraged to appoint one if the participants are incapable of rendering legally effective informed consent. From time to time, a prospective participant may not be able to consent or designate a legally authorized representative to enroll in research. When research has direct therapeutic benefits to participants, it can sometimes be appropriate to explore ways to enroll a participant who would like to assent to the research. In those cases, the Office of General Counsel should be consulted, and the OGC representative should deliver to the IRB, in writing, a plan for enrolling such participants in research. The USU IRB suggests using a hierarchy similar to the one here:

1. a person designated by the individual, while retaining the decisional capacity to do so, to make decisions for them regarding participation in research;
2. a person designated by the individual, while retaining the decisional capacity to do so, to make decisions for them regarding non-research health care decisions;
3. the individual's legal guardian with authority to make health care decisions for them;
4. the spouse, or individuals such as domestic partners or people joined via a civil union;
5. an adult son or daughter;
6. a parent;
7. an adult brother or sister; or
8. an adult who has exhibited special care and concern for the prospective research participant.

If two similarly situated LARs appointed through this method disagree about enrolling a prospective participant in research, that individual should not be enrolled.

VI. Fluctuating Capacity

Some conditions might cause functional abilities to fluctuate over time, or to decrease gradually over the course of the study. When the participant recruitment plan includes individuals likely to experience fluctuating functional abilities or functional abilities that will decrease over time, the following considerations should be worked in to the study plan and represented in the submitted materials for review. Those considerations include whether:

- procedures have been described for reevaluating participants' capacity to consent over the course of the study;
- such participants are asked to designate an individual to serve as a legally authorized representative, if necessary;

- individuals identified as potential legally authorized representatives are involved in the consent process;
- such participants are asked to document their wishes regarding participation in the study;
- the consent process plans to avoid, if feasible, periods during which prospective participants are likely to experience greater than normal impairment to functional abilities (for example, due to changes in participants' medication schedules, acute intoxication or episodic increases in the severity of the symptoms associated with their conditions);
- there are procedures for obtaining the consent of any participant who is initially judged incapable of providing consent, but regains the capacity to consent.