
Yale University Institutional Review Boards

IRB Policy 340 Participation of Individuals with Impaired Consent Capacity

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Scope

This policy defines the heightened safeguards that all researchers must employ in order for a Yale IRB to approve the participation of adult individuals with impaired consent capacity in biomedical, behavioral, and social science research.

Policy Statement

IRBs and investigators must operate according to the principles that individuals with impaired consent capacity who are recruited for or enrolled in research studies must be treated in a manner commensurate with their special status. Research involving these individuals should employ additional safeguards as appropriate to the study and the participant population in order to protect their rights and welfare.

Reason for the Policy

It is important, necessary, and in keeping with the Belmont principles of beneficence and justice to include individuals with impaired consent capacity as participants in research projects. A number of conditions associated with decisional impairment, such as stroke and Alzheimer's disease, afflict ever-increasing numbers of our citizens and impose growing burdens on those individuals, their families, and society. Scientifically and ethically appropriate research involving these individuals is critical to illuminate the underlying disease mechanisms that lead to these conditions and to identify promising treatments. To be most useful and free of bias, that research must include individuals with severe and chronic forms of these disorders as well as those exhibiting minimal impairment. Engaging individuals in research who cannot consent for themselves or whose decision-making capacity may be compromised or may fluctuate over time may result in their inability to protect their own self-interests. Therefore, additional safeguards must be implemented, as required in 45 CFR 46.111(b) and 21 CFR 56.111(b).

Definitions

Assent

An individual's affirmative agreement to participate in research. This should be sought in addition to the consent of a legally authorized representative or surrogate when the individual is sufficiently cognitively capable of understanding the nature of his or her participation in a research study. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Impaired Consent Capacity

A compromised capacity to understand information related to the research and to make a reasoned decision about initial or continuing participation in research that may preclude the individual from providing legally effective consent. Such impairment or compromised capacity may be temporary,

permanent, or may fluctuate. Examples of individuals who may have impaired consent capacity include women in active labor, individuals who have suffered a stroke or other acute and severe illness, individuals under the influence of drugs or alcohol, individuals experiencing considerable pain, individuals under extreme emotional distress (e.g., learning of a newly diagnosed life threatening or terminal illness for self or loved one, anticipating imminent major surgery), and individuals suffering from cognitive disorders or mental disorders. Impaired consent capacity as defined in this policy is distinct from legal incompetence.

Legal Incompetence

Legal incompetence refers to a designation of status that has been adjudicated in a court proceeding, and it often refers to an inability to manage one or more significant areas of life such as business or monetary affairs. An individual who is designated as legally incompetent often will have impaired consent capacity in terms of consenting to research but, in some circumstances, will maintain capacity for informed consent. Equally important, an individual may be legally competent, but still have impaired consent capacity.

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.

Research Advance Directive

A document used to indicate willingness to continue to participate in a research study or in future studies. In filling out an advance directive, the participant, who at the time is capable of consenting, provides consent to document his/her willingness to continue to participate in the research study in the future or in other future studies during which it is likely that the participant will not be capable of providing consent. An advance directive may also be used to allow the participant to name an individual that the participant would like to act as his/her surrogate to provide permission for the participant's continuation in a current study or enrollment in a future study, in addition to the participant's assent.

Surrogate Permission

Permission for an individual to participate in research given by an appropriate surrogate (e.g., next of kin – spouse, parent, child, sibling) when an individual is assessed as not capable of providing fully informed and legally effective consent.

Therapeutic Misconception

The belief that research studies are intended to benefit the participants who enroll in them and that an individual is asked to participate in a research trial as part of his or her clinical care.

Policy Sections

340.1 IRB Considerations

IRBs reviewing projects involving adult participants with impaired consent capacity must include one or more members or consultants who are familiar with the conditions that may affect the prospective participant's capacity to provide consent and with the concerns of the population being studied. IRBs should consider whether it is necessary to consult with or to have in attendance a special representative familiar with the disorder and capable of addressing concerns specific to the subject population (45 CFR 46.107; 21CFR 56.107(a)).

The IRB will approve research projects which propose to include individuals with impaired consent capacity only after consideration of safeguards in addition to the requirements for approval described in the IRB Review Policy. (See Checklist 340 CH. 1, Points to Consider.)

Appropriateness of Inclusion

Individuals who have been found to have impaired consent capacity may be enrolled in research **only when** the IRB finds that their participation in the study is justified, and appropriate additional safeguards are in place to protect them, such as, where appropriate and feasible, provisions for surrogate permission or an advance directive.

Furthermore, the IRB must find that their participation in research:

- Presents no more than minimal risk; or
- Presents greater than minimal risk, provided that IRB finds that:
 - The risks are justified given the potential benefits of the research either to the participants or to the development of generalizable knowledge to benefit the participants' class of individuals.

Justification for Inclusion

Whenever possible, research should be designed to include only those individuals who are capable of consenting for themselves. In some studies, however, where benefit is likely, it is abundantly more ethical and in line with the Belmont principles to include individuals with impaired consent capacity. In other studies, even those without potential (or likely) benefit to participants, the only way to answer the scientific aim may be to include such individuals in the research.

Investigators proposing research targeting adult individuals with impaired consent capacity as participants must provide IRBs with a thorough justification for their proposed research design, including how capacity will be assessed, plans to include surrogate permission, plans for subject assent (where appropriate) and a description of the procedures that are designed to minimize risks to participants. IRBs must consider whether the protocol includes a reasonable rationale for inclusion of individuals with impaired consent capacity as a target population.

Risk:Benefit Assessment

A research study specifically designed to include individuals with impaired consent capacity must have as its goal either to study treatment designed to directly benefit the individual, or the development of important generalizable knowledge regarding the disease or condition of the targeted population. The IRB's deliberations shall include consideration of the nature and degree of anticipated impairment of the targeted study populations, the risk level of the proposed study, and the potential for direct benefit to the study participants.

340.2 Investigator Obligations

Requisite Expertise

The investigator must ensure that the individual who is responsible for determining whether a potential participant has the capacity to consent has the appropriate expertise necessary to determine and monitor the participant's capacity initially and on an ongoing basis. The determination is made by individual observation of and interaction with the potential participant. The determination may be made by an investigator or by another professional who has appropriate expertise. It may also include opinions from one or more caregivers.

Assessment of Capacity to Provide Consent

Research studies designed to involve individuals with impaired consent capacity must include a means to assess a potential participant's capacity to provide consent and the criteria for identifying individuals who are impaired. At a minimum, this assessment must include a method to evaluate the potential participant's ability to understand the relevant study information, e.g., the nature of the research and its likely consequences, to process information about the research rationally, and to communicate a choice clearly as to whether or not he/she wishes to participate.

The method(s) used to assess capacity to provide initial and continued consent vary and therefore must be commensurate with the level of risk to the participant and the complexity of the research. Less formal methods to assess the potential participants' capacity—including, for example, the ways professionals often make judgments about capacity in routine interactions—may be permitted if a formal assessment is not feasible or necessary. The assessment of capacity to provide consent is required regardless of risk.

The assessment method must allow for a repeat assessment of the capacity to consent if the potential participant's condition changes or is expected to change. Measures to assess the capacity to provide initial and continued consent could include the use of consent quizzes; the participation of a consent monitor, subject advocate, or independent clinician in the consent process; and the design of the consent process to include several meetings between the potential participant and the investigator. Subsequent assessment for capacity to provide continuing consent is especially important upon the introduction of a new or different intervention along the course of research; e.g., a biopsy or spinal tap. (See Procedure 340 PR. 1, Assessment of Capacity to Consent.)

Consent and Assent Concerns

1. Individuals who are temporarily impaired due to environmental or other factors (e.g., women in advanced and active labor, individuals under the influence of drugs or alcohol, individuals under extreme emotional distress) should not be asked to participate in research until they regain their sound decision-making ability and can provide consent. However, in the event that the research is designed to study individuals in precisely those situations and/or states of mind, whenever practical, investigators should design the research project so that participants will be appropriately consented and enrolled prior to the temporary decisional impairments. The use of an advance directive may be appropriate in this circumstance. If this is not feasible, the consent of the individual should be sought once the individual regains capacity. Investigators must respect the wishes of the individual, should the individual object to the use of his/her research information, and research data will be excluded from the study.
2. For research contemplating enrolling participants who are not able to provide informed consent at the outset of the study, and where an advance directive is not possible due to their condition, permission from a surrogate for their participation must be approved by the IRB (see Informed Consent Policy). Participants enrolled in research without their consent must be offered the opportunity to consent to or withdraw themselves (and their study information or samples) from the research once they regain capacity. Investigators must respect the decision of the participant.
3. For research involving participants who are able to provide informed consent at the outset of the study, but who are expected to have fluctuating, limited, or diminishing capacity to provide continuing consent during the course of the study, special procedures should be implemented to assure that participants' rights and safety are continually protected. Such processes could include the timing of study procedures to avoid periods of heightened vulnerability; where possible, advance directives to document the participant's intent and attitude toward research participation at the time the research participant is capable of decision-making; or the use of an independent monitor. In addition, providing assistance with completing health care representative forms which would allow that representative (an LAR) to consent to medical and research procedures for patients on an indefinite basis may be appropriate.
4. Assent must be sought when the individual is sufficiently cognitively capable of understanding the nature of his or her participation in a research study and capable of communicating. Where assent is required, mere failure to object may not, absent affirmative agreement, be construed as assent. The prospective participant's objection to participate in any way, at any time, must be taken as a refusal or withdrawal and be honored, even if the surrogate consentor or the study doctor disagrees with the decision.

However, for some studies, withdrawal may still require research interventions such as tapering off of medication or other important procedures to protect participant safety and well-being. Withdrawal consequences should be made explicit in the consent and assent forms.

5. Individuals with impaired capacity to consent may be especially vulnerable to therapeutic misconception. Therefore, investigators should be especially careful to make participants and their families or caretakers aware of the differences between individualized treatment versus research and the separate and distinct roles of the clinician and the research investigator.

340.3 Surrogate or Legally Authorized Representative

Absent a participant-designated or state-specified legally authorized representative (LAR) for research decision-making, investigators may engage and IRBs may approve as surrogates individuals who are specified in state statutes as LARs for medical decision-making or, in the absence of such statutes, individuals who would normally provide consent for medical care under prevailing, commonly accepted clinical practices. Participant assent must also be obtained whenever possible.

The IRB shall consult with Institutional legal counsel regarding the categories of surrogates eligible to serve as LARs in different situations.

The IRB shall adhere to Connecticut state statutes that explicitly prohibit court-appointed guardians of mentally retarded individuals from giving permission for their wards to participate in research unless certain stringent terms and conditions are met (CGS Sec. 45a-677(e)).

340.4 Additional Safeguards

The IRB may require additional safeguards depending on the protocol and the level of potential risk to the participants involved. Such safeguards may include the use of an independent monitor and/or assessor; special informational or educational techniques; or the use of waiting periods to afford participants and their surrogates more time to decide about participation.

Related Information

340 PR.1 Assessment of Capacity to Consent

340 CH. 1 Points to Consider

Contacts

Subject	Contact	Phone
Biomedical Studies involving Individuals with Impaired Consent Capacity	Human Investigation Committee	785.4688 ysmhic@yale.edu
Social or Behavioral studies involving Individuals with Impaired Consent Capacity	Human Subjects Committee	436-3650 human.subjects@yale.edu
Surrogate or Legally Authorized Representative	Office of the General Counsel	432-4949

Roles and Responsibilities

Human Investigation Committee

HIC I, HIC II, HIC III and HIC IV serve as the four Institutional Review Boards or IRBs for biomedical human research conducted at Yale University.

Human Subjects Committee

The HSC is responsible for the review and oversight of social and behavioral human research.

Office of the General Council

The OGC serves as legal advisor to the Yale community.