

Institutional Review Board (IRB) Policies & Procedures Manual



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Research Involving Adults with Decisional Impairment

Purpose

This policy governs research involving adults with decisional impairment and outline the extra procedural safeguards that Boston Children's Hospital has deemed necessary to guard against the possible exploitation of adults with decisional impairment.

Policy

Decisional Impairment is defined as: Persons who have impaired ability to make decisions as a result of intellectual or mental health challenges as well as adults who have lost capacity to make decisions because of clinical situations such as unconsciousness.

Research involving adults with decisional impairment challenges a fundamental principle of research ethics: that research subjects provide informed consent prior to and during their participation in a study. Adults whose decision-making capability has been restricted, in whole or in part, by disease, mental illness, or other circumstances, may not be legally competent to give informed consent. This may also include temporary situations, such as being unconscious or sedated. As such, these adults may be especially vulnerable to coercion, undue influence, and exploitation. Federal Regulations require that extra procedural safeguards be established to protect this vulnerable population and that if consent cannot be obtained from the decisionally impaired, adult consent must be obtained from a legally authorized representative, as determine by state or local law.

Procedures

Selection of Subjects

It is Boston Children's Hospital policy that absent extenuating circumstances, adults with decisional impairment may only be enrolled in:

1. research that does not involve more than minimal risk; or
2. research that involves greater than minimal risk but presents the prospect of direct benefit to the individual.

It is the general position of Boston Children's Hospital that adults with decisional impairment will not be enrolled in research that:

1. involves greater than minimal risk and no prospect of direct benefit to subjects, but will likely yield generalizable knowledge about the subject's disorder or condition, or
2. any other research not otherwise approvable.

A principal investigator seeking an exception to these general principles may request such exception to the IRB, with a description of why adults with decisional impairment should be enrolled in the research study and the specific steps to be taken to protect the adults.

What to Include in a Protocol Submission to the IRB?

A protocol submission to the IRB must establish the level of decision-making ability necessary to consent. This determination is based on the level of risk that the subject will be exposed to, with higher risk protocols requiring a greater level of understanding. Further, the protocol must describe in detail how competency will be assessed, who will be performing the assessments, and what that professional's relationship is to the individual and the research team.

Obtaining Informed Consent

Once the IRB has approved enrolling adults with decisional impairment in a research study, the principal investigator must determine the best manner in which to get informed consent for each study participant. The principal investigator must ensure the individual can give informed consent or assent or a legally authorized representative that can consent for the individual.

Determining Whether an Adult is Competent to give Informed Consent to Research

An adult is legally competent to give informed consent to research when s/he has the:

1. ability to receive and understand information;
2. ability to process information;
3. ability to appreciate the situation and its consequences;
4. ability to weigh potential benefits, potential risk and other alternatives;
5. ability to make and communicate a decision; and
6. ability to appreciate the difference between research and treatment.

More information concerning the aspects of informed consent can be found in IRB Policy and Procedure Manual policies about **Consent and Assent/Parental Permission**.

Given the varying degrees of decisional impairment, the assessment to determine competency for consent can be complex. General competency measures such as the Clinical Dementia Rating, the Mini Mental Status Exam, or the Activities of Daily Living Scale may be helpful to establish a baseline understanding of an individual's competency. Other types of assessments may also exist. However, these metrics should not be the sole mode of evaluation. In some protocols, especially those that contain significant risk, a formal psychiatric or medical assessment may be warranted. Open-ended interviews focusing on how the risks, benefits, and alternatives to the study apply to the subject personally may be used to supplement a more formal evaluation.

Investigators may consider a two-part consent process:

1. an assessment of comprehension and recall (understanding in a strictly factual sense the parameters of the study); and

2. a test of personalized understanding (how the specific benefits, harms, alternatives, and consequences of this study apply to the individual subject's situation).

The assessment process must ensure that potential subjects fully comprehend the difference between individualized treatment and research and between a clinician and clinical investigator. Subjects must recognize that they are consenting for research and not treatment.

In order to strengthen the integrity of the enrollment process, consideration should be given to using an independent professional (someone who is not part of the research team) to assess a potential subject's competency to give informed consent. In general, if the research involves more than minimal risk procedures, use of an independent professional is strongly recommended. The IRB application should include how a subject's competence will be addressed.

Determination of Assent

If the research subject is unable to consent, the subject's assent, and particularly dissent, should be considered. The process by which one determines whether a subject is capable of providing assent must be included in the research protocol. The IRB will also consider assent when reviewing the protocol and make a determination as to whether it is required as part of the review process. This determination should be based on an advanced understanding of the level of decision-making ability necessary to assent. For instance, the researcher should identify what concepts and risks are so central to the protocol that a subject must understand them in order to understand the research protocol more generally. This assent analysis could take the form of a checklist that seeks to identify whether the participant understands various key terms and concepts behind the study, along with the potential risks and benefits of the study. These metrics, and the participant's response to them, should be documented in the study participant's research record.

Determining Who May Consent for Incapacitated or Decisionally Impaired Subjects

If the adult research subject cannot give their consent, and has not expressed their dissent, then a surrogate decision maker must be found to consent in the subject's place. Federal law allows a legally authorized representative to consent for research on behalf of decisionally impaired adult, based on the laws of the jurisdiction in which the research is conducted (e.g., local or state law). Federal regulations also provide that if there is no applicable law in the jurisdiction where the research is conducted addressing this issue, then a legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

Unless the IRB has waived the requirement to obtain consent, based on federal and state laws and regulations, Boston Children's Hospital will approve the following individuals for obtaining a consent for research on behalf of decisionally impaired adults:

1. a court-appointed guardian (e.g., an individual, organization, or agency) who has clear authority to make health care decisions;

2. a person designated as a health care agent under a valid health care proxy, provided that the healthcare proxy includes language with express authority to consent to research or make health care decisions inclusive of the proposed;
3. a durable power of attorney that includes healthcare decision making authority that also has language that allows express authority to consent to research; or
4. a responsible party under the provisions of Massachusetts state law (Chapter 201D, Section 16), which authorizes a health care provider to rely upon the informed consent from a responsible party if a health care proxy or power of attorney has not been executed. For purposes of this policy as applied to research purposes only, this would include allowing a competent spouse, competent parent, or adult child (in order of preference) to provide consent. The research team must investigate and determine that neither of the three previous categories of individuals have been previously appointed for the research subject prior to obtaining consent from a “responsible party.” Any other responsible party involved in the care of a patient wishing to consent to research will be evaluated on a case-by-case basis. Questions regarding who is a responsible party may be directed to the Office of General Counsel or the Director of Clinical Research Compliance,

Research team members are required to use this order and must document, in the research record, the process in which an appropriate legally authorized representative was determined. Guardians, health care proxies, and durable power of attorneys should provide a copy of their appropriate documentation when signing consent forms for research, to be retained in the patient’s medical record.

Children who Begin Research as Children and Become Adults, but are Decisionally Incapacitated During the Course of the Study

If a child turns eighteen during the course of a study, and the study involves continuing diagnostic/therapeutic procedures, or any form of research intervention, informed consent must be obtained from the now adult in order to remain in the research. If the now adult subject is decisionally impaired, the investigator is required to consider and follow the consent policies set forth above. Parents do not automatically maintain the ability to consent for the now adult study subject unless they have been appointed by the court as the subject’s legal guardian. A new consent document would need to be signed with the appropriate legally authorized representative, regardless of whether it is the same person (e.g., a parent/guardian) that signed the consent form when the subject was under the age of eighteen.

Involvement of a Decisionally Impaired Adult in a Protocol where the IRB has not Considered the Above Referenced Special Protections

An investigator may wish to enroll a decisionally impaired adult subject in a protocol when it was not anticipated that decisionally impaired subjects would be enrolled. In this situation, the investigator and IRB have not had the opportunity to consider the special protections listed above and consider the arrangements necessary for the informed consent process. In these circumstances the investigator is to contact the IRB Office and the Office of General counsel to discuss the situation and consider any special necessary

arrangements in order to include the subject in the trial. The issues and principles listed above will be considered in determining whether it is appropriate to include the subject in the research.

Related Content

IRB Policies

Consent and Assent/Parental Permission.

Document Attributes

Title	Research Involving Adults with Decisional Impairment		
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