



Research Involving Adults with Decisional Impairment

Background

This Policy governs research involving individuals with decisional impairment. 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 individuals who have lost capacity to make decisions because of clinical situations such as unconsciousness. Research involving individuals 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. Individuals, 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. As such, these individuals 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 person, consent must be obtained from a legally authorized representative, as determine by state or local law.

This policy will outline the extra procedural safeguards that Children's Hospital has deemed necessary to guard against the possible exploitation of individuals with decisional impairment.

Policy and Procedures

Selection of Subjects

It is Children's Hospital policy that absent extenuating circumstances, individuals 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 Children's Hospital that individuals with decisional impairment will not be enrolled in research that: (1) involves greater than minimal risk and no prospect of direct benefit to individual 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 individuals with decisional impairment should be enrolled in the research study and the specific steps to be taken to protect the individuals.

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 individuals 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 Individual is Competent to give Informed Consent to Research

A person 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 benefits, risk and 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 The Clinical Investigation Policy and Procedure Manual under "Informed Consent/Permission/Assent Process."

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 an individual's competence will be addressed.

Determination of Assent

If the research subject is unable to consent, the individual's assent, and particularly his dissent, should be considered. The process by which one determines whether an individual 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 an individual 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 research subject cannot give his consent, and has not expressed his 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 persons. Currently, "legally authorized representative" is not defined in federal or Massachusetts state law. Based on guidance, Children's Hospital Boston has decided to allow consent from the following persons, in order of preference:

- (1) a court-appointed guardian who has clear authority to make health care decisions;
- (2) a person designated as a health care agent under a valid health care proxy, with express authority to consent to research or make health care decisions inclusive of the proposed;
- (3) a durable power of attorney with express authority to consent to research or make health care decisions inclusive of the proposed research;
- (4) family members: competent spouse, competent parent, or adult child (in order of preference). Any other family members involved in the care of a patient wishing to consent to research will be evaluated on a case-by-case basis. Questions regarding the use of family members may be directed to the Office of General Counsel or the Director of Clinical Research Compliance.

Guardians, health care proxies, and durable power of attorneys should attach the appropriate documentation when signing consent forms for research.

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

If a child turns 18 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. If there is no court appointed guardian, the same policies for legally authorized representatives set forth above apply. A new consent document would need to be signed with the appropriate legal guardian or the individual providing surrogate consent.

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 Office of Clinical Investigation or 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

Section G "Surrogate Consent for Adults without Sufficient Decision Making Capacity to Effective Exercise Their Right to Informed Consent" in the "Informed Consent/Permission/Assent Process" policy

Document Attributes

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