

 <b>JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH</b>	<b>Human Research Protection Program Policies &amp; Procedures</b>	
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Title: <b>Decisionally Impaired Subjects</b>	Date Effective June 8, 2005	Supercedes P&P dated November 29, 2004

## Background

Individuals whose decision-making capacity is restricted, wholly or in part, due to illness, mental disability or other circumstances may be incapable of making informed judgments about whether to participate, or continue participation, in a study. The Common Rule requires that additional safeguards be in place to protect the rights and welfare of individuals who may be subject to undue coercion or undue influence, including mentally disabled persons. There are, however, no additional DHHS regulations that specifically concern protection of subjects who are unable to make informed decisions due to cognitive impairment or another disability.

The CHR considers such persons to be vulnerable and in need of additional protections. It has developed the following policy based on the NIH guidance entitled: *Research Involving Individuals with Questionable Capacity to Consent: Points to Consider*.

The policy includes, but is not necessarily limited to, the following categories of studies:

- *Psychiatric studies*, where it is anticipated (but not presumed) that patients may be or become decisionally impaired;
- *Clinical protocols involving medical conditions* that often (but not always) render a person physically unconscious or decisionally impaired (i.e. stroke, unstable or serious cardiac conditions, shock, mental status changes due to fever/infections or other reversible conditions, emergency, trauma, ICU research, drug abuse, etc.); and
- *All other research* that may include subjects who might experience fluctuating decisional capacity (due to dementia, emotional distress, illness, etc.).

The policy is relevant for both adults (for consent) and minor children (for assent).

## JHSPH Policy and Procedures

It should not be assumed that incapacitated or decisionally impaired subjects are incapable of giving valid initial or ongoing consent. Investigators who will conduct studies in which the decision-making capacity for some or all of the subjects is impaired, either prior to enrollment or during the course of the study, should address the following points in their research plan.

### Selecting Subjects and Obtaining Their Consent

- The research should be conducted on subjects who have the capacity to consent before being conducted on subjects who are not able to give consent.
- No person who has the capacity to consent may be enrolled in a study without his or her informed consent, or assent if the subject is a child.
- Persons who have been determined to lack capacity to consent should not be enrolled in research that is not likely to result in direct benefit to them, unless the research presents no more than minimal risk.
- Research protocols should include a thorough justification of the research design to be used, including a description of the prospective benefits and of procedures designed to minimize risks to subjects. The evaluation of benefits should distinguish possible direct medical benefits to the subject from other types of benefits.
- Studies that are designed to provoke symptoms, to withdraw subjects rapidly from therapies, to use placebos or to expose subjects to inappropriate risks must be thoroughly justified.
- The research plan should describe procedures for assessing a subject's capacity to consent and the circumstances in which consent will be sought from the legally authorized representative(s) recognized by the State in which the research will be conducted. (See also [Proxy consent](#) in *The Informed Consent Process*)
- For research protocols that present greater than minimal risk, CHR may require that an independent, qualified professional assesses the potential subject's capacity to consent. The protocol should describe who will conduct the assessment and the nature of the assessment. CHR will permit investigators to use less formal procedures to assess a potential subject's capacity, if there are good reasons for doing so.
- Investigators should consider a two-part consent process when appropriate: first an assessment of comprehension and recall, and second a test of understanding. When potential subjects are capable of making informed decisions about participation, they may accept or decline participation without involvement of any third parties.
- Any objection to enrollment or continued participation in a research protocol by a potential or actual subject must be respected.
- An investigator, acting with a level of care and sensitivity that will avoid the possibility or the appearance of coercion, may approach people who previously objected to participate or continue in a study, to ask whether they have changed their minds.
- A person who has been determined to lack capacity to consent to participate in a research study must be notified of that determination before permission may be sought from his or her legally authorized representative to enroll that person in the study. Capacity should be determined in relation to the task. If permission is given by an authorized representative to enroll such a person in the study, the potential subject must be notified. Should the person object to participating, their objection must be respected.
- If a research subject has fluctuating or limited decision-making capacity, or is likely to become incapacitated, investigators should establish and maintain communication with

involved caregivers, consistent with the subject's level of autonomy and the need for confidentiality.

## Checklist

A [Decisionally Impaired Subjects Checklist](#) is available. This should be completed and included with each research application that will involve decisionally impaired subjects.

## Definitions

**Cognitively Impaired:** *Having a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders), an organic impairment (e.g., dementia), or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, seriously or terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.*

**Competence:** *Technically, a legal term used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. Competence may fluctuate as a function of the natural course of a physical or mental illness, response to treatment, effects of medication, and general physical condition.*

**Incompetence:** *Often a synonym for incapacity. In a research setting: lacking sufficient ability, knowledge, or psychological capacity to consent to research.*

**Decisionally Impaired:** *Lacking or having compromised decision-making capacity owing to cognitive impairment.*

**Decision-making Capacity:** *Often defined in state statutes – generally understood as the ability to understand the choice(s) presented, to appreciate the implications of choosing one alternative rather than another, and to make and communicate a choice.*

**Incapacity:** *Refers to a person's mental status. It is the inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. Often used as a synonym for incompetence.*

**Informed consent:** *An agreement to participate in research that is made voluntarily by an individual with legal and mental competence and the capacity to understand the information transmitted and its implications, after having been informed of the physical, psychological and personal risks and potential benefits entailed by a research protocol. Informed consent is usually demonstrated by signing a consent form, but it may be oral (under specific criteria approved by an IRB) (45 CFR 46.116)*

**Legally Authorized Representative:** *An individual, judicial or other body authorized under applicable law to consent on behalf of a prospective participant to that individual's participation in research (21 CFR 50.3(l))*

**Vulnerable subjects/participants:** *Individuals who lack the capacity to provide informed consent or whose willingness to participate in research may be unduly influenced by others.*

## RESOURCES & REFERENCES

The National Bioethics Advisory Commission, *Research Involving Persons with Mental Disorders That May Affect Decision making Capacity* (December 1998). [Research Involving Persons with Mental Disorders That May Affect Decision making Capacity - a report and recommendations of the National Bioethics Advisory Commission](#)

NIH (1999) [Research Involving Individuals with Questionable Capacity to Consent: Points to Consider.](#)

OPRR. Protecting Human Research Subjects: Institutional Review Board Guidebook (1993) [http://ohrp.osophs.dhhs.gov/irb/irb\\_chapter6.htm](http://ohrp.osophs.dhhs.gov/irb/irb_chapter6.htm)

*OHRP Requirements*      45 CFR 46.111 (a) (3)  
   45 CFR 46.111(b)  
   45 CFR 46.107  
   45 CFR 46.408  
   45 CFR 46:109(b)(c)

*FDA Requirements*      21 CFR 50.20  
   21 CFR 50.27  
   21 CFR 50.55  
   21 CFR 56.107  
   21 CFR 56.111(b)

*AAHRPP Element*      Element II.4.D