

HAC Policies and Procedures

Cognitively Impaired

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Cognitively Impaired Persons

A cognitively impaired person is defined as having either:

- 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. In addition, persons under the influence of or dependent on drugs or alcohol, suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.

The major ethical concern in research involving individuals with these types of disorders or impairments is that their disorders may have an impact on their capacity to understand the information presented as well as their ability to make a truly informed decision about participation in the research. Some individuals with such disabilities may be residents of institutions responsible for the individual's total care and treatment. This dependence on the institution may have an impact on their ability to voluntarily participate in research (e.g., these individuals may agree too readily to requests for their "cooperation" or may be vulnerable to perceived or actual pressures for fear of being denied services.)

The HAC must review several areas and their potential for coercion when reviewing research involving cognitively impaired persons:

- Are these individuals the primary population for this research?
- Are there adequate protections for privacy and confidentiality of information?
- How are issues of consent and competence addressed?

There should be specific evidence of individuals' incapacity to understand and to make a choice before they are deemed unable to consent.

What if you have a cognitively impaired subject?

A surrogate whose *primary* interest is the patient's welfare may give informed consent if conditions are met for cognitively impaired subjects.

What Should You Do When The Question Of Competency Is Unclear?

Competency is commonly judged by the subject evidencing a choice with regard to research participation, through factual understanding of issues including the rational manipulation of information as well as the appreciation of the nature of the research project. If competency is an issue, it must be acknowledged in the DRP and the procedures used to evaluate competency must be described in detail. The Department of Psychiatry and Health Behavior has a documented policy in place to address these issues.

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Will The HAC Require Any Additional Safeguards For Cognitively Impaired Subjects?

The HAC may request that a physician not affiliated with the research protocol review and document the competency of the potential subject since there are specific conditions and exceptions to the consent requirements in these situations. Contact the HAC Administrative Office for more details.

What If You Are Considering A Study Where Subjects Will Lose Competency Over Time (e.g., Alzheimer's Disease, Dementia, etc.)?

The DRP should include how these issues will be addressed.

Who Do I Contact if I Have Any Questions?

For additional guidance, contact the HAC Administrative Office at HAC@mcg.edu or call the following extensions:

(706) 721-8397 for PIs whose last names begin with A-G

(706) 721-3110 for PIs whose last names begin with H-P

(706) 721-1482 for PIs whose last names begin with Q-Z

Although the above listing indicates the staff's primary PI assignments, all HAC Administrative Office staff can answer your questions. There may be situations when your questions may require consultation with the HAC or OHRP leadership.