

## Rush University Medical Center Policies and Procedures

Policy Number: RA-IRB-208

Category Name: Research

Title: Research Involving Adults with Questionable Capacity to Consent

Type: Policy and Procedure

Dated: 12/2011

Applies To: Rush Investigators/Study Staff, Rush IRB Members and Rush IRB Administrative Staff.

### Policy

**Investigators must evaluate a subject's capacity to consent in all research. Consent capacity can be impaired, for example, by mental disorders, emotional distress, neurological disorders such as stroke or dementia, metabolic impairments, psychoactive medications, substance abuse, and head trauma. It is important to recognize that in some situations, these conditions may produce substantial impairment of capacity, while in other situations they may not affect an individual's understanding of key informed consent elements. In research involving such conditions, it is important that Investigators determine whether a prospective subject's diminished decision-making capacity affects his or her capability to provide informed consent.**

**Additionally, in such situations the Rush IRB must determine what additional safeguards and monitoring may be needed, paying particular attention to the disorder under study, the study population, and human subjects protections. An IRB may decide that additional efforts are needed to enhance a prospective subject's ability to provide informed consent.**

### Definitions

**Cognitively Impaired:** Having any condition that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Examples include but are not limited to, persons with an acute psychiatric disorder, developmental disorder, under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps. Cognitive impairment occurs when problems with thought processes occur. It can include loss of higher reasoning, forgetfulness, learning disabilities, concentration difficulties, decreased intelligence, and other reductions in mental

functions. Cognitive impairment may be present at birth or can occur at any point in a person's lifespan.

**Competence/Incompetence:** Legal terms, as adjudicated in court proceedings, 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.

**Decisional Capacity (or Capacity to Consent):** In Illinois, "the ability to understand and appreciate the nature and consequences of a decision regarding medical treatment or forgoing life-sustaining treatment and the ability to reach and communicate an informed decision in the matter as determined by the attending physician." (755 ILCS 40/10).

**Incapacity:** Refers to a person's mental status and means inability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice.

**Legally Authorized Representative:** 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. If a surrogate decision maker is necessary, such an individual must be an adult who (i) has decisional capacity, (ii) is available upon reasonable inquiry; (iii) is willing to make medical treatment decisions on behalf of a patient who lacks decisional capacity and (iv) is identified by the attending physician in accordance with the provisions of the Illinois Health Care Surrogate Act in the following order of priority:

- the patient's (subject's) guardian;
- the patient's (subject's) spouse;
- the adult son or daughter of the patient (subject);
- the parent(s) of the patient (subject), consistent with 21 CFR 50, Subpart D, and 45 CFR 46, Subpart D;
- any adult brother or sister of the patient (subject);
- any adult grandchild of the patient (subject);
- a close friend of the patient (subject);
- the patient's (subject's) guardian of the estate

RUMC Policy #OP-0029 indicates that a legal representative may also include a durable power of attorney identified in writing by an adult patient (subject).

**Close Friend:** In Illinois, "Any person 18 years of age or older who has exhibited special care and concern for the patient and who presents an affidavit to the attending physician stating that he or she (i) is a close friend of the patient, (ii) is willing and able to become involved in the patient's health care, and (iii) has

maintained such regular contact with the patient as to be familiar with the patient's activities, health, and religious and moral beliefs. The affidavit must also state facts and circumstances that demonstrate that familiarity.” (755 ILCS 40/10).

**Guardian:** DHHS and the FDA define a guardian as an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care. In Illinois, the term Guardian “means a court appointed guardian of the person who serves as a representative of a minor or as a representative of a person under legal disability.” In Illinois, a variety of guardianship appointments exist and the investigator should take care to document that the guardian’s representation of the ward is within the scope of their authority: limited guardianship, plenary guardianship, guardian of the person, guardian of the estate, and temporary guardianship. (Health Care Surrogate Act, 755 ILCS 40).

Procedure:

Temporary or permanent cognitive or decisional impairment may result from a variety of conditions. The IRB should attempt to distinguish between people who have a condition that might cause temporary impairment and people who are impaired. Regardless of the reason for impairment, the IRB should apply the same safeguards when considering approval of research involving persons who might not be able to make informed decisions.

Generally agreed upon principles hold that (a) research involving cognitively or decisionally impaired subjects should be relevant to the subject’s condition or circumstances; (b) research involving cognitively or decisionally impaired persons should not be done if the research question(s) could be answered by involving capable persons; (c) decision making capacity should be tested and documented in studies involving impaired persons; (d) persons who might lose the capacity to consent during the research should appoint a surrogate who can approve continuing participation.

The PI must propose adequate procedures for evaluating the mental status of prospective subjects to determine whether they are capable of consenting. Determination of capacity to consent or inability to withdraw may be made by asking the subject specific questions about the research that he or she must answer, through a standardized measure and/or consultation with another qualified professional in accordance with the level of risk and the prospect of benefit. The PI must explain and the IRB must determine whether these procedures are appropriate both to the subject population and the nature of the proposed research.

In reviewing a protocol, the IRB must also evaluate:

- How persons authorized to give legally valid consent on behalf of any individuals lacking the capacity to consent

- (legally authorized representative or LAR) will be identified;
- Whether assent of prospective subjects should be required; and whether objections to participation by subjects who lack the capacity to give valid consent can be overridden and, if so, under what circumstances this can occur.
  - Whether an individual should be designated to ensure the continuing agreement of subjects to participate as the research progresses.
  - If the patient's physician or other health care provider must be consulted before any individual is invited to participate in the research;
  - If the research is likely to interfere with ongoing therapy or regimens; and
  - If the request to participate itself might provoke anxiety, stress, or other serious negative response.

If the research presents more than minimal risk to subjects, the IRB must determine whether the risk is justified by the anticipated benefits to the participating subjects and the importance of the knowledge that may reasonably be expected to result.

The IRB should also ensure that procedures have been devised to ensure that the subject's LAR is well informed regarding his or her role and obligations to protect the subject, including consideration of what the subject would do if capable to consent for themselves.

The PI should obtain and keep all legal records related to authority to consent, including advance directives, court orders, guardianship documentation, and applicable documentation as to wards of the state.

### **Informed Consent**

In most cases, for subjects who do not meet the criteria for capacity to consent, the consent of the subject's LAR is required and assent should be obtained from the subject.

In research where there is potential for direct benefit to the subject, the IRB may waive the requirement to obtain assent; however, consent from the LAR must be obtained, except where the FDA exemptions for one-time emergency use or emergency research are met.

In order to seek consent from a LAR that is a guardian or durable power of attorney, the PI must obtain a copy of the documents certifying that the subject is unable to make decisions; a copy of the advance directives or other applicable document, if applicable; the court order, if applicable; or any other evidence that the person believed to be the LAR has this authority.

Since capacity to consent or the ability to withdraw may fluctuate, the IRB must evaluate the process for continued verification of understanding and willingness to participate by the subject.

The consent procedures should describe a plan for protecting individuals who may lose their capacity to provide consent or their ability to withdraw while participating in research activities (such as an advocate or an ombudsman).

If a LAR provides initial consent to the research and during the research the subject is determined to be capable of providing informed consent, the PI must obtain consent from the subject.

The IRB may require an outside witness observe and confirm the consenting process.

The IRB may request the PI to obtain from the subject a valid advance directive in instances where incapacity of the subject may be expected to occur during the period of study conduct, either as a result of the research or expected progression of the subject's condition.

#### Reference

21 CFR 50.3  
45 CFR 46.102(c)

This policy is guided by OHRP's *Institutional Review Board Guidebook* (Chapter 6 Section D) and "Research Involving Individuals with Questionable Capacity to Consent: Points to Consider" Issued in November 2009 by the Office of Extramural Research of the National Institutes of Health.

This policy and procedure is also based on the following Illinois state laws: the Illinois Health Care Surrogate Act (755 ILCS 40/1 et seq.), the Mental Health Treatment Preference Declaration Act (755 ILCS 43/10), and the Medical Practice Act (410 ILCS 50/3.1).

These statutes, other than the Medical Practice Act, relate to medical treatment decisions; however, the Rush IRB has extended application of the concepts of these statutes to research. IRB Administrative staff or IRB members may consult with the Office of Legal Affairs when needed. PIs should contact IRB Administrative staff with any questions concerning Illinois state law or this policy.

**Last reviewed: 12/23/2011**