

Approval Criteria: Decisionally Impaired and Cognitively Impaired Subjects

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POLICY:

- I. It is the policy of the UIC IRB to review, approve, and provide guidance as to ethical considerations to afford additional protections when cognitively and decisionally impaired subjects are involved in human subjects research to uphold their rights and welfare and to prevent coercion or undue influence.
 - II. A UIC investigator applying to conduct a research activity involving decisionally impaired and cognitively impaired subjects in another jurisdiction (i.e., state) must become familiar and provide evidence of compliance to the IRB with all applicable legal, professional, and ethical requirements for the conduct of research involving children for each jurisdiction where the research will be conducted.
 - III. Studies that involve children or other vulnerable populations, are greater than minimal risk and are not conducted in Illinois must be reviewed and approved by an IRB in the appropriate jurisdiction (i.e., state) as well as the UIC IRB.
- IV. Definitions
- A. **COGNITIVELY IMPAIRED:** 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. Others, including persons 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, may also be compromised in their ability to make decisions in their best interests. (Penslar RL, Porter JP. *Institutional Review Board Guidebook*, Chapter 6: Special Classes of Subjects, OHRP, 1993).
 - B. **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. (See terms *Incompetence*, *Incapacity*) Competence may fluctuate as a function of the natural course of a mental illness, response to treatment, effects of medication, general physical health, and other factors.

- Therefore, mental status should be re-evaluated periodically. As a designation of legal status, competence or incompetence pertains to an adjudication in court proceedings that a person's abilities are so diminished that his or her decisions or actions (e.g., writing a will) should have no legal effect. Such adjudications are often determined by inability to manage business or monetary affairs and do not necessarily reflect a person's ability to function in other situations. (Penslar RL, Porter JP. *Institutional Review Board Guidebook*, Chapter 6: Special Classes of Subjects, OHRP, 1993).
- C. 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).
 - D. DECISIONAL CAPACITY: 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).
 - E. 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).
 - F. 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. Often used as a synonym for incompetence. (Penslar RL, Porter JP. *Institutional Review Board Guidebook*, Chapter 6: Special Classes of Subjects, OHRP, 1993)
 - G. INCOMPETENT: A legal term meaning inability to manage one's own affairs. Often used as a synonym for incapacity.
 - H. LEGALLY AUTHORIZED REPRESENTATIVE (LAR): DHHS and the FDA define a legally authorized representative as "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." (46.102(c); 21 CFR 50.3).
- V. UIC policy is guided by OHRP's *Institutional Review Board Guidebook* (Chapter 6 Section D), i.e., "the predominant ethical concern in research involving individuals with psychiatric, cognitive, or developmental disorders [including temporary or

sporadic decisional impairment resulting from substance abuse or trauma] is that their disorders may compromise their capacity to understand the information presented and their ability to make a reasoned decision about participation. Many individuals with disabilities affecting their reasoning powers may be residents of institutions responsible for their total care and treatment. The impact of institutionalization may further compromise their ability to exercise free choice (voluntariness). (These concerns apply both to voluntary patients and those committed involuntarily.)”

VI. This policy and procedure is 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 UIC HSPP has extended application of the concepts of these statutes to research. OPRS staff or IRB members consult with the Office of University Counsel when needed. PIs should contact OPRS with any questions concerning Illinois state law or this policy.

PROCEDURE:

- I. IRB Composition. The IRB must include a member knowledgeable about and experienced with the mentally disabled or cognitively impaired. (Refer to UIC HSPP *Identification and Use of Ad Hoc Consultants* policy).
- II. IRB Approval Criteria.
 - A. The IRB must consider the following points, as adopted from OHRP’s *Institutional Review Board Guidebook* (Chapter 6 Section D), in its review of protocols involving cognitively or decisionally impaired subjects. The findings may be documented either in a review guide or meeting minutes:
 1. The IRB should be aware of any applicable Illinois state law, particularly those relating to consent by family members on behalf of persons incapable of consenting on their own. Note that consent to participation in research may differ from consent to medical treatment. In addition, it should be noted that some federal agencies (including components of the Department of Defense) prohibit the participation of mentally disabled persons in research conducted under their auspices (Adapted from OHRP Guidance on Special Classes of Subjects). Refer to UIC HSPP policy *Informed Consent Process and Informed Consent Documents*. OPRS staff may refer additional questions to the UIC Office of University Counsel.
 2. Research involving cognitively or decisionally impaired subjects should be relevant to the subject’s condition or circumstances. There must be a compelling justification for including the decisionally or cognitively impaired as subjects. Decisionally or cognitively impaired individuals must not be subjects only because they were available.
 3. If the investigator proposes to recruit institutionalized individuals who are decisionally impaired, justification for using that population must be

provided. For example, are noninstitutionalized subjects appropriate for the research and reasonably available? Further, does the research pertain to aspects of institutionalization?

4. 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 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.
5. If more than minimal risk is involved in the research, 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.
6. In reviewing a protocol, the IRB must evaluate:
 - a) How persons authorized to give legally valid consent on behalf of any individuals lacking the capacity to consent will be identified;
 - b) Whether assent of prospective subjects should be required; and
 - c) Whether objections to participation by subjects who lack the capacity to give valid consent can be overridden and, if so, under what circumstances can this occur.
7. The IRB must evaluate whether:
 - a) An advocate or consent auditor should be appointed to ensure that the preferences of potential subjects are elicited and respected; and
 - b) An individual should be designated to ensure the continuing agreement of subjects to participate as the research progresses.
8. The IRB must evaluate whether:
 - a) The patient's physician or other health care provider must be consulted before any individual is invited to participate in the research;
 - b) The research is likely to interfere with ongoing therapy or regimens; and
 - c) The request to participate itself might provoke anxiety, stress, or other serious negative response.
9. The IRB should ensure that:
 - a) 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,
 - b) LARs are given descriptions of the studies; and
 - c) Informed that their obligation is to try to determine what the subject would do if competent.

III. Record Retention. 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.

IV. Informed Consent Process: General Principles.

- A. In most cases, for subjects who have been determined to lack decision making capacity, the consent of the subject's LAR is required and assent should be obtained from the subject.
 - 1. 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.
- B. In order to seek consent from a LAR, 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.
- C. Informed consent for subjects determined to lack the capacity to provide consent should be obtained from a LAR. Because neither the Medical Patient Rights Act nor the Health Care Surrogate Act provides definitive statutory authority for surrogate consent in research studies, the UIC HSPP has developed the following priority list for surrogates, incorporating the stipulations from these 2 statutes and the Mental Health Treatment Preference Declaration Act :
 - 1. Individuals authorized to act on behalf of the subject in the event they are incapacitated in an operable and unrevoked living will under the Illinois Living Will Act, an operable and unrevoked declaration for mental health treatment under the Mental Health Treatment Preferences Declaration Act, or an authorized agent under a power of attorney for health care under the Illinois Power of Attorney Act when the patient's condition falls within the coverage of the living will, the declaration for mental health treatment, or the power of attorney for health care.
 - 2. Subjects' guardian of the person;
 - 3. The subject's spouse;
 - 4. Any adult son or daughter of the subject;
 - 5. Either parent of the subject;
 - 6. Any adult brother or sister of the subject;
 - 7. Any adult grandchild of the subject;
 - 8. A close friend of the subject;
 - 9. The subject's guardian of the estate.

V. Informed Consent Process: Fluctuating Capacity.

- A. 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.
 - 1. 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).

2. 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.
3. The IRB may require an outside witness observe and confirm the consenting process.
4. 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.

VI. Risk and Benefit Considerations.

- A. The IRB must find that appropriate provisions in accordance with the level of risk and the prospect of benefit are made for determining the subject's ability to provide consent or their ability to withdraw, such as the following:
 1. The ability to make a choice;
 2. The ability to understand relevant information;
 3. The ability to appreciate the situation and its likely consequences; and
 4. The ability to think through information rationally.
- B. The research should not impose a risk of harm, unless the research is intended to benefit the subject and the probability of benefit is greater than the probability of harm.
- C. The IRB must consider the items below in making the determination of whether an independent assessor is required to determine the level of decisional incapacity of the subject:
 1. No more than minimal risk:
 - a) The IRB may allow PIs to make the determination as to the disability of the subject to consent.
 2. Greater than minimal risk - and direct benefit:
 - a) The IRB may require an independent assessment or expert to make the determination as to the ability of the subject to consent.
 - b) The independent assessor must be qualified both by educational attainment and professional experience in his or her field in a manner appropriate to the proposed subject population.
 3. Greater than minimal risk - and limited to indirect benefit:
 - a) The IRB must require an independent assessment by an expert to make the determination as to whether the subject is competent to consent.
 - b) The independent assessor must be qualified both by educational attainment and professional experience in his or her field in a manner appropriate to the proposed subject population
 - c) The IRB must determine that the research would be highly valuable to the general field of study when the research is greater than minimal risk and does not offer direct benefit

4. The IRB must consider the degree of ability of the potential subject, the level of risk, and the prospect of benefit to the individual subject.

VII. VA Research.

- A. Research involving persons with impaired decision-making capability may only be approved when the following conditions apply:
 1. The IRB includes at least one member who is an expert in the area of the research. Consideration may be given to adding another member who is a member of the population, a family member of such a person or a representative of an advocacy group for that population.
 2. Only incompetent persons or persons with impaired decision making capacity are suitable as research subjects. Competent persons are not suitable for the proposed research. The investigator must demonstrate to the IRB that there is a compelling reason to include incompetent individuals or persons with impaired decision-making capacity as subjects. Incompetent persons or persons with impaired decision-making capacity must not be subjects in research simply because they are readily available.
 3. The proposed research entails no significant risks, tangible or intangible, or if the research presents some probability of harm, there must be at least a greater probability of direct benefit to the participant. Incompetent people or persons with impaired decision-making capacity are not to be subjects of research that imposes a risk of injury, unless that research is intended to benefit that subject and the probability of benefit is greater than the probability of harm.
 4. Procedures have been devised to ensure that participant's representatives are well informed regarding their roles and obligations to protect incompetent subjects or persons with impaired decision making capacity. Health care agents (appointed under Durable Power of Attorney for Health Care (DPAHC)) and next-of-kin, or guardians, must be given descriptions of both proposed research studies and the obligations of the person's representatives. They must be told that their obligation is to try to determine what the subject would do if competent, or if the subject's wishes cannot be determined, what they think is in the incompetent person's best interest.
- B. The IRB must make a determination in writing of each of the criteria listed above. If these criteria are met, the IRB may approve the inclusion of incompetent subjects or subjects with impaired decision-making capacity in research projects on the basis of informed consent from authorized representatives as defined below.
- C. Both investigators and IRB members must be aware that for some subjects, their decision-making capacity may fluctuate. For subjects with fluctuating decision making capacity or those with decreasing capacity to give consent, a re-consenting process with surrogate consent may be necessary.
- D. Although incompetent to provide informed consent, some persons may resist participating in a research protocol approved by their representatives. Under no circumstances may subjects be forced or coerced to participate.

- E. Under appropriate conditions, investigators may obtain consent from the legally authorized representative of a subject (surrogate consent).
1. Such consent may be obtained from: a health care agent appointed by the person in a DPAHC or similar document; court-appointed guardians of the person, or from next-of-kin in the following order of priority, unless otherwise specified by applicable state law: spouse, adult child (18 years or older), parent, adult sibling (18 years of age or older), grandparent, or adult grandchild (18 years of age or older).
 2. Such consent may be requested and accepted only when the prospective research participant is incompetent or has an impaired decision-making capacity, as determined and documented in the person's medical record in a signed and dated progress note. The determination must be made in accordance with the following requirements or as established by a legal determination.
 - a) The practitioner, in consultation with the chief of service, or COS, may determine after appropriate medical evaluation that the prospective research subject lacks decision-making capacity and is unlikely to regain it within a reasonable period of time.
 - b) Consultation with a psychiatrist or licensed psychologist must be obtained when the determination that the prospective research subject lacks decision-making capacity is based on a diagnosis of mental illness.
 - c) Disclosures required by VHA Handbook 1200.05 to be made to the subject by the investigator must be made to the subject's surrogate.
 - d) If feasible, the practitioner must explain the proposed research to the prospective research subject even when the surrogate gives consent. Under no circumstances may a subject be forced or coerced to participate in a research study.

REFERENCES:

[21 CFR 50.3](#)
[45 CFR 46.102\(c\)](#)
[Illinois Living Will Act](#)
[Illinois Health Care Surrogate Act \(755 ILCS 40/1 et seq.\)](#)
[Medical Practice Act \(410 ILCS 50/3.1\)](#)
[Mental Health Treatment Preferences Declaration Act \(755 ILCS 43/10\)](#)

REVISION LOG:

Version (#, date)	Replaces (#, date)	Summary of changes
1.1, 09/21/09	1.0, 10/15/08	Specified the responsibilities of the investigator when research is being conducted in another state.