

## 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. No individual who lacks decision-making capacity may participate in VA Research until the IRB has reviewed and approved that individual's, or that class of individuals', participation in a given study
- B. Criteria for Decision-Making Capacity
  1. An individual is presumed to have decision-making capacity unless any one or more of the following apply:
    - a) It has been documented by a qualified practitioner in the individual's medical record in a signed and dated progress note that the individual lacks capacity to make the decision to participate in the proposed study. *NOTE: The qualified practitioner may be a member of the research team*
    - b) The individual has been ruled incompetent by a court of law
  2. If there is any question as to whether or not a potential adult subject has decision-making capacity, and there is no documentation in the medical record that the individual lacks decision-making capacity, and the individual has not been ruled incompetent by a court of law, the investigator must consult with a qualified practitioner (who may be a member of the research team) about the individual's decision-making capacity before proceeding with the informed consent process.
- C. Temporary or Fluctuating Lack of Decision-Making Capacity. Individuals, who because of a known condition, are at high risk for temporary (e.g., head trauma) or fluctuating (e.g., schizophrenia) lack of decision-making capacity must be evaluated by a qualified practitioner (who may be a member of the research team), to determine the individual's ability to provide informed consent. This evaluation must be performed as described in the IRB-approved protocol. If the individual is deemed to lack decision-making capacity at the time of their participation in the study, a legally authorized representative (LAR) must provide informed consent. If the subject regains decision-making capacity, the investigator or designee must repeat the informed consent process with the subject, and obtain the subject's permission to continue with the study.
- D. Criteria for Enrollment. Individuals who lack decision-making capacity may be enrolled in protocols if:
  1. The proposed research entails:
    - a) No greater than minimal risk to the subject as determined by the IRB; or
    - b) If the research presents some probability of harm, there must be at least a greater probability of direct benefit to the subject or
    - c) Greater than minimal risk and no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition that is of vital importance for the understanding or amelioration of the subject's disorder or condition.

2. The disorder (e.g., Alzheimer's) leading to the individual's lack of decision-making capacity is being studied, whether or not the lack of decision-making itself is being evaluated (e.g., an individual who lacks decision-making capacity as the result of a stroke can participate in a study of cardiovascular effects of a stroke), but only if the study cannot be performed with only persons who have decision-making capability.
  3. The subject of the study is not directly related to the individual's lack of decision-making capacity, but the investigator can make a compelling argument for including individuals who lack decision-making capacity in the study (e.g., transmission of methicillin-resistant *Staphylococcus aureus* (MRSA) infections in a nursing home where both individuals with, and those without, decision-making capacity are affected).
- E. IRB Determination. If the criteria in D. above are met, the IRB may approve the inclusion of individuals who lack decision-making capacity in research studies on the basis of informed consent from legally authorized representatives (LARs) as described in F. below.
1. Before approving the study, the IRB must:
    - a) Ensure the study includes appropriate procedures for respecting dissent;
    - b) Consider whether or not the study needs to include procedures for obtaining assent; and
    - c) Determine whether any additional safeguards need to be used (e.g., consent monitoring).
  2. The IRB must document its deliberations and the criteria in D. above it used to approve inclusion of individuals who lack decision-making capacity in the IRB minutes or IRB protocol file.
- F. Surrogate Consent
1. Investigators' Responsibilities for Surrogate Consent. Investigators must:
    - a) Provide the IRB with a description of the procedures to ensure that subjects' LARs are well informed regarding their roles and obligations to protect persons who lack decision-making capacity
    - b) Provide information (i.e., informed consent process and HIPAA authorization) to the subjects' LARs that would ordinarily be required to be made to the subjects themselves if they had decision-making capacity
  2. LARs
    - a) **Authorized Person.** The following persons are authorized to consent on behalf of persons who lack decision-making capacity in the following order of priority (38 CFR 17.32(e)):
      - (1) Health care agent (i.e., an individual named by the individual in a Durable Power of Attorney for Health Care (38 CFR.17.32(a)(iii));
      - (2) Legal guardian or special guardian;

- (3) Next of kin in this order: a close relative of the patient 18 years of age or older, in the following priority: spouse, child, parent, sibling, grandparent, or grandchild; or
    - (4) Close friend.
  - b) Responsibilities of LARs. LARs are acting on behalf of the potential subjects, therefore:
    - (1) LARs must be told that their obligation is to try to determine what the subjects would do if able to make an informed decision.
    - (2) If the potential subject's wishes cannot be determined, the LARs must be told they are responsible for determining what is in the subjects' best interests.
    - (3) LARs generally assume the same rights and responsibilities as the individuals who lack decision-making capacity in the informed consent process.
3. Dissent or Assent. If feasible, the investigator must explain the proposed research to the prospective research subject even when the surrogate gives consent. Although unable to provide informed consent, some persons may resist participating in a research (i.e., if they dissent) protocol approved by their representatives. Under no circumstances may a subject be forced or coerced to participate in a research study even if the LAR has provided consent.

**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.               |
| 1.2, 05/02/11     | 1.1, 9/21/09       | Updated for revised VHA Handbook 1200.05, date 10/15/2010. Changed approval to the Human Protections Administrator. |