*Please refer to the UIC HSPP policy* [*Decisionally and Cognitively Impaired Subjects*](https://go.uic.edu/irb0854) *for definitions, University policies and procedures, and information regarding federal, state, and local laws. The IRB expects all investigators who recruit and enroll decisionally-impaired subjects to be aware of, and to comply with, any applicable laws and regulations regarding the involvement of decisionally-impaired subjects in research.*

**I. Research Title:**

**II. Risk Level of Research**

**A.** Does this research meet the definition of minimal risk\*?

Yes – *skip to Section III.*

No

1. Will the research be of direct benefit to the subject?

Yes –*skip to Section III.*

No

2. If the research does not offer direct benefit, will the research likely contribute generalizable knowledge about the subject’s condition or disorder that will yield important data for the understanding or management of the condition or disorder?

Yes – *Proceed to Section III.*

No – **STOP.** Decisionally-impaired subjects may not be included in this research.

*\* Minimal risk* means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

*If the research is greater than minimal risk, the IRB may require an independent assessment or expert to make a determination as to the ability of the subject to consent. The IRB may also determine that additional safeguards are necessary to protect the subject.*

**III. Decisionally-Impaired Subject Population**

**A.** Describe the type and range of impairment of subjects to be included in this research:

**B.** 1.Explain why decisionally-impaired subjects should be recruited and enrolled into this research. *(If the purpose of the research can be achieved by including competent subjects, the IRB requires compelling justification for the inclusion of decisionally-impaired subjects.)*

2. Describe the criteria and/or measurements to be used in determining decisional impairment. Include any testing or measurement instruments with this submission.

3.a. Indicate who will assess the range of impairment, and the initial and on-going decision-making capacity of subjects to:

* Understand relevant information, such as research procedures, risks, and benefits
* Appreciate their participation in the research and its likely consequences
* Think through information rationally
* Provide informed consent

Principal Investigator

Other members of the research team

Qualified practitioner who is not a member of the research team.

b. Describe the qualifications of the person(s) above to assess the subject’s range of impairment and decision-making capacity:

c. Provide an outline of the training that the above personnel will receive regarding how to obtain informed consent and assent from decisionally-impaired subjects and/or LARs:

4. Will institutionalized subjects be recruited or enrolled into the research?

No

Yes – Justify the recruitment of an institutionalized population and explain why non-institutionalized subjects are not appropriate for this research:

5. Is the research likely to change, alter, or otherwise interfere with the decisionally-impaired subject’s existing therapy or regimens?

No

Yes – Justify any changes or alterations to the decisionally-impaired subject’s existing therapy or regimens:

6. Will the prospective subject’s physician or other health care providers be consulted before the decisionally-impaired subject is recruited or enrolled into the research?

No – Explain:

Yes – Explain:

7. Are any of the investigators the prospective subject’s physician or health care provider?

No

Yes – Explain how each investigator will clearly distinguish his/her role as a clinician from his/her role as an investigator:

**IV. Procedures to Obtain Informed Consent/Assent**

* For decisionally-impaired subjects, the consent of the individual’s LAR **must** be obtained and assent **should** be obtained from the decisionally-impaired subject.
  + **Under Illinois law, authorized LARs may be (by priority ranking):**

**(1) the agent listed in a valid advance directive** (for example, in a power of attorney for health care or a declaration for mental health treatment)**,**

**(2) the legal guardian of the decisionally-impaired subject, or**

**(3) a surrogate, as defined by Illinois law and are specific to health care**. Surrogates, as defined by Illinois law and specific to health care, from highest-priority to lowest-priority:

• subject’s guardian of the person

• subject’s spouse

• any adult son or daughter of the subject

• either parent of the subject

• any adult brother or sister of the subject

• any adult grandchild of the subject

• a close friend of the subject

• subject’s guardian of the estate

**A.** 1. Explain how the LAR(s) will be identified, how their authority to give consent for the prospective subject ascertained, and how their role and obligation to protect the subject will be documented. Consider that the LAR(s) must understand their obligation to act in the best interest of the subject.

2. Will legal records regarding the authority of each LAR (including, but not limited to, advance directives, court orders, guardianship documents, wards of the state documentation) be reviewed by the investigator and/or copies collected from each LAR?

No -Provide justification for NOT reviewing or collecting LAR documentation:

Yes

**B.** 1.a. Provide a detailed explanation of the procedures to be used to solicit the assent or assess the dissent of decisionally - impaired subjects and how this will be documented.

N/A – A waiver of subject assent is requested; proceed to 2.a.

b. Detail the proposed additional safeguards that will be put into place to ensure that decisionally-impaired subjects understand and freely volunteer to participate in the research (for example, plans for on-going evaluation of the subject’s assent, observation of behaviors that may be viewed as indicators of assent or dissent, independent witness observation of the assent process, involvement of a subject advocate). **Special attention should be paid to avoiding coercion or undue influence of the potential decisionally-impaired subjects**.

c. Will the subject’s right to dissent from participation in the study be respected in all cases, even when the LAR has consented?

No - Describe and justify the circumstances when it will not be honored:

Yes

d. If enrolling decisionally-impaired subjects whose primary language is not English, explain how and who will be responsible for conducting/overseeing the assent process.

2.a. Justify the request for a waiver of subject assent for decisionally-impaired subjects:

N/A – A waiver of subject assent is not being requested; proceed to C.

b If a waiver of assent is requested, explain what assent processes or procedures will ensure the subject’s autonomy and right to justice are respected and how the subject’s right to dissent from participation will be handled. *(Note that when the research offers the subject the possibility of a direct benefit that is important to the health or well-being of the subject and is available only in the context the research, the IRB may determine that a subject’s dissent, which should normally be respected, may be overruled by the subject’s LAR.)*

**C. Fluctuating or Changing Capacity to Consent**

1. Is the subjects’ decision-making capacity likely to fluctuate or change (decrease or increase) during the study?

No

Yes - Provide a plan for periodic re-assessment of the subject’s capacity to provide consent and re-consenting the subject or LAR of decision-making capacity improves or is impaired:

**D. Research involving medical interventions/interactions**

N/A – This research does not involve a medical intervention or interaction and the surrogate Act is not relevant.

The Illinois Surrogate Act requires the clinician/Investigator to:

* Document the determination of a lack of decisional capacity in the health care record, including the cause, nature, and duration of the impairment;
* Inform the surrogate that the surrogate’s decision regarding the subject should conform as closely as possible to what the subject would have done or intended under the circumstances;
* Document the decision of the surrogate in the health care record, including a witness’ signature;
* Record the name, address, phone number, and relationship of the surrogate to the subject in the health care record;
* Inform the subject of the identify of, and any decisions made by, the surrogate, when feasible; and
* Withdraw the surrogate, or any decision made by the surrogate, if the subject objects.

1. Describe how the above Surrogate Act requirements will be met in this research: