Human Research Protection Program Procedures

IV. Basic Procedures for Human Research Protections

U. Obtaining Consent on Behalf of Adults Who Lack Decision-Making Capacity

(45CFR46.101 (e) (f); 45CFR46.102 (c); 45CFR46.402(d) (e); 21CFR50.3(l); 21CFR50.3(o); 21CFR50.3(s); 21CFR56.103(c)

(1) Conditions to be satisfied

The following conditions must be satisfied when it is anticipated that adults who lack decision-making capacity might be enrolled in a research protocol:

a. The research should either:
   • Offer the prospect of direct benefit to the research subject; a placebo controlled study may qualify if the IRB is persuaded that there is no generally accepted treatment for the condition being studied; or
   • Offer the prospect of yielding generalizable knowledge about the subject’s disorder or condition which is of vital importance for the understanding or amelioration of the subject’s disorder or condition and expose the research subject to no greater than minimal risk.
   • The research design provides additional safeguards to protect the rights and welfare of adult subjects unable to consent to research.

b. Consent must be obtained from a legally authorized representative (see (2) below).

c. A person not directly involved in the medical care of the subject must participate in the consent process. The role of this person is to assure that the rights of the prospective research subject are protected and reinforce the various elements of informed consent.
including, but not limited to, understanding that: the primary purpose of the project is to answer a research question and not treat the patient; participation is voluntary; and declining to participate will not affect any other care the patient may be need or be entitled to receive. This person may be a research nurse, a member of the IRB, a patient advocate, or other person knowledgeable about protection of human research subjects. It is anticipated that details for complying with this requirement will be established during a dialog between the members of the IRB and the investigator and incorporated into the final version of the protocol.

d. The protocol must be considered at a convened meeting of the IRB, and the IRB’s assessment of the risks and benefits of participation in the study will be noted in the minutes of a convened meeting. The IRB may seek advice from the UnityPoint Health System Law Department regarding potential liability issues presented by a protocol.

e. If the protocol targets individuals who lack decision making capacity at the time of consent, then it may be reviewed at intervals of 6 months or less.

f. When researchers are likely to approach adults who lack the ability to consent, the IRB evaluates whether:
   - The proposed plan for the assessment of the capacity to consent is adequate.
   - Assent of the participant is a requirement, and, if so, whether the plan for assent is adequate.

(2) **Legally authorized representative**
Consent for research will be obtained from a person or entity legally authorized to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

**Implementation.** In Iowa, legally authorized representatives include: Substitute medical decision-making board [Iowa Code 135.29]; guardian for minor or person with impaired decision-making capacity [Iowa Code 633.562, 633.552]; attorney-in-fact, guardian, spouse, adult child, parent, adult sibling [641 Iowa Admin Code 857, Durable power of attorney for health care , Iowa Code 144B.2, 144B.3, 144.B.5].
(3) **Assent of subject**

When research involves decisionally-impaired persons, the IRB will consider whether the assent of the subject should be sought, when in the judgment of the IRB the subjects are capable of providing assent, and such assent will meaningfully add to the respect of the subjects’ autonomy. This judgment may be made for all subjects to be involved in research under a particular protocol, or for each subject, as the IRB deems appropriate.

(4) **If a subject regains decisional capacity**

A research subject who regains decisional capacity will be fully informed of the nature of the protocol and the conditions under which he or she was enrolled. The subject’s continued participation in the protocol will be solicited using the normal process for obtaining informed consent. A subject who objects to participation in the project may request that none of the information obtained about the subject be used for research and such a request will be honored if practicable.