IRB Policy and Implementation Instructions for Obtaining Consent in Instances When the Subject is Unable to Provide Consent (Proxy/Surrogate Consent)

Introduction:

Researchers at The University of Chicago and elsewhere have been vexed by the problem of conducting studies in situations where the patient is unable to consent to participation in a research project. Such situations include many protocols in the Intensive Care Unit, the Emergency Department, the Psychiatry Department, and those involving patients with dementia. Recent changes in both federal regulations and state laws have partially remedied this situation. Researchers working in such areas now have new options for proceeding with protocols, even if the patient is unable to consent. Amendments to the Health Care Surrogate Act and the Medical Patient Rights Act provide a legal basis in the State of Illinois for the use of proxy consent in research (see Appendix for legal background).

Proxy consent should involve all the same considerations that informed consent from a competent patient involves. It also involves identifying the proper surrogate and ensuring that the research decision reflects the wishes of the subject, if known or, if not known, the best interests of the subject. In addition, the IRB will be concerned about whether the research could be accomplished in situations involving the consent of a competent patient, and will consider whether the intervention is likely to offer therapeutic benefit to the subject of the study. The IRB will always view these considerations as paramount.

Implementation:

The University of Chicago believes in the importance of the informed consent process and believes that subjects should be given every opportunity to provide their consent. Understanding, however, that medical circumstances may preclude a subject from participating in the consent process, the University of Chicago and University of Chicago Medical Center IRBs will implement the following procedures to consider requests for surrogate consent in keeping with the Medical Patient Right Act and the Health Care Surrogate Act.

A. Protocol submission and review:

1. Researchers wishing to utilize surrogate consent will be asked to provide additional information regarding this population in addition to completing the IRB Protocol Submission Form in full.
2. The IRB will utilize the prioritized listing of surrogates in the Health Care Surrogate Act in evaluating protocols requesting to use surrogate consent. The priority order specified by the Act is as follows: 1) subject's guardian; 2) subject's spouse; 3) any adult son or daughter of the subject; 4) either parent of the subject; 5) any adult brother or sister of the subject; 6) any adult grandchild of the subject; 7) a close friend of the subject; and 8) the subject’s guardian of the estate.
3. In determining whether to approve the use of surrogate consent in a particular protocol, the IRB will consider such factors as whether the research could be done without using surrogate consent or whether the proposed intervention offers direct benefit to the subjects of the research.

B. Procedures for Surrogate Consent:

1. The attending physician must determine that the subject lacks decisional capacity.

2. An attempt should be made to determine whether there is an operable and unrevoked living will, durable power of attorney for health care, or declaration for mental health treatment ("Advance Directive") which is applicable to the subject's decision about whether to participate in the research. Surrogate consent should be invoked only in cases when, after reasonable inquiry, no Advance Directive applies or, despite efforts to contact the person authorized in an Advance Directive, that person is unavailable.

3. The researcher must attempt to identify a surrogate of the highest priority. (Note: If there is more than one surrogate of the highest priority and there is a disagreement between them, majority rules. If there is disagreement and no majority, consult with the Ethics Consult Service or the Office of Medical Legal Affairs.)

4. The University of Chicago/UCMC Health Care Surrogate Act Certification Concerning Research must be used in all instances of surrogate consent. The certification shall be placed in the subject's medical record and a copy attached to the research consent form or, if written consent is not required, kept with the subject research records.

5. The consent process with the surrogate should include a discussion with the attending physician and an inquiry into the extent to which the surrogate is able to speak for the subject. Following the requirements of the Health Care Surrogate Act, this discussion should emphasize the surrogate's ability to make a decision that would conform as closely as possible to what the subject would have done or intended under the circumstances. The surrogate should take into account evidence that includes the subject's personal, philosophical, religious, and moral beliefs and ethical values relative to the purpose of life, sickness, medical procedures, suffering and death.

6. In circumstances in which the subject's wishes are unknown after reasonable efforts to discern them, the decision shall be made on the basis of the subject's best interests as determined by the surrogate decision maker. In determining the subject's best interests, the surrogate shall weigh the burdens and benefits of the proposed research and shall take into account any other information, including the views of family and friends, that the surrogate decision maker believes the patient would have considered if able to act for herself or himself.

7. The surrogate should express his/her decision to the researcher in the presence of an adult witness (at least 18 years of age.)
8. *The University of Chicago/UCMC Health Care Surrogate Act Certification Concerning Research* attached to the consent form should document the surrogate decision making process described in points 5, 6 and 7.

9. The subject should be made aware of the research and the identity of the surrogate as soon as feasible. If the subject objects and the surrogate is not a court-appointed guardian, the subject should be withdrawn from the research.

10. The surrogate will have the same rights as the subject to receive information on the research, to withdraw consent for further participation, etc.