

**DREXEL UNIVERSITY COLLEGE OF MEDICINE
INSTITUTIONAL REVIEW BOARDS**

POLICY ON SUBSTITUTED (SURROGATE) CONSENT

This policy was approved by the IRB on February 16, 2004

1. POLICY STATEMENT AND BACKGROUND

It is the policy of the Drexel University College of Medicine (DUCOM) and its Institutional Review Boards (IRBs) to protect the right to autonomy of all human subjects with the exception of children, who participate in research studies. It is also the policy of DUCOM and its IRBs to protect those with diminished autonomy or reduced capacity to consent. For persons who are not capable of making autonomous choices, the IRB recognizes that substituted consent is necessary in order to offer experimental treatments. The purpose of this Policy is to confirm that the DUCOM will accept substituted (or surrogate) consent in certain human subject research trials, in certain situations, from certain persons; and to describe the procedures to be followed in obtaining substituted consent. The following procedure will be followed when the investigator determines that a potential subject has diminished capacity and seeks consent for that individual's participation in research.

Federal regulations require that the researcher obtain the legally effective informed consent of the subject or the subject's legally authorized representative prior to medical research. Federal law defers to state law to determine which surrogate is legally authorized to give substitute consent. Pennsylvania law requires the informed consent of the subject or the subject's authorized representative before the administration of an experimental medication, the use of an experimental device, or the use of an approved medication or device in an experimental manner. Pennsylvania law also authorizes substituted consent to the performance of experimental biomedical or behavioral medical procedure or participation in any biomedical or behavioral experiment by the subject's court-appointed guardian pursuant to a court order. Finally, Pennsylvania statutory law further authorizes a person named in the subject's power of attorney to consent to medical, therapeutic and surgical procedures.

While Pennsylvania statutory law does not explicitly authorize substituted consent in the absence of a power of attorney or court-appointed guardian, case law strongly supports substituted consent by close family members when patients lack capacity to make medical decisions. When the subject is unable to give informed consent, the subject's close family member or significant partner is in the best position to determine the wishes of the subject regarding participation in therapeutic research.

2. LIMITATIONS, PROCEDURES AND GUIDELINES

2.1 Diminished Capacity; Limitations

For purposes of this policy, persons with "diminished capacity" means individuals who are unconscious, comatose or otherwise incapable of giving informed consent, as determined by the investigator and another duly licensed and qualified physician not otherwise involved in the research. Substituted consent shall not be permitted under this policy for mentally retarded individuals, unless authorized by a court having jurisdiction over such matters, individuals diagnosed with a mental illness, or minors. In addition, surrogate consent will only be permitted in cases where there is either minimal risk of harm to the patient or, where there are more than

minimal risks, where the prospect of direct benefit to the patient justifies the risks involved, as determined by the IRB.

2.2 Determination of Subject's Ability to Provide Informed Consent in a Research Study

2.2.1 The investigator shall be responsible for determining whether an individual subject can provide informed consent.

2.2.2 If applicable, the investigator will clearly document in the research record the reason for the subject's inability to provide informed consent.

2.2.3 The investigator shall apply and document any additional safeguards as directed by the IRB.

2.2.4 In order to provide additional safeguards to insure that the rights of the subjects are protected, the investigator shall also provide for the witnessing of informed surrogate consent by an adult third party, and shall complete independent documentation of the informed consent process.

2.3 Individuals Able to Provide Effective Surrogate Consent

2.3.1 The following individuals may be considered capable of providing surrogate or substituted consent, in the following descending order of priority:

- a. A health care proxy appointed by the subject in a power of attorney;
- b. A court-appointed guardian authorized to consent to the subject's participation in the protocol in a current court order;
- c. Spouse or domestic partner;
- d. Adult child;
- e. Adult grandchild;
- f. Natural or adoptive parent;
- g. Grandparent;
- h. Adult brother or sister.

2.3.2 With respect to an individual from whom an investigator seeks to obtain substituted consent and who claims to be a spouse or domestic partner but has a different last name than the subject, the investigator will be required to verify that relationship through the use of the Verification form attached to this policy. If, after completing the verification procedure, the investigator remains uncertain as to whether a spouse or domestic partner relationship exists, then the investigator is to contact the DUCOM Office of the General Counsel to assist in the resolution of the matter.

2.3.3 With respect to an individual from whom an investigator seeks to obtain substituted consent, the investigator will ascertain from that individual whether there are any individuals in a higher level of priority and, if so, the investigator will be required to obtain the consent of the individual in the higher level.

2.3.4 When there are two or more available persons who may give surrogate informed consent pursuant to Section 2.3.1 and who are in the same level of priority, consent shall not be considered as having been given if any of those persons expresses dissent. The investigator must make reasonable attempts to contact those in the highest level of priority either by telephone or in person before obtaining consent from any individual in a lower level of priority.

2.3.5 When there are two or more available persons who are in different orders of priority pursuant to Section 2.3.1, refusal to consent by a person who is a higher priority surrogate shall not be superseded by the consent of a person who is a lower priority surrogate.

2.3.6 If there are no individuals in a higher level of priority, then the investigator will ascertain from the individual from whom the investigator seeks to obtain substituted consent (a) whether there are other individuals within the same level of priority, and (b) if so, whether the individual believes he or she may consent on behalf of all other individuals within that level of priority or whether he or she would first like to discuss the matter with such other individuals.

2.3.7 The investigator will clearly document the actions required by this Section 2 in the research records.

2.3.8 Under this policy, individuals capable of providing surrogate or substitute consent are also considered capable of providing authorization for use and disclosure of the subject's Protected Health Information ("PHI") under the Health Insurance Portability & Accountability Act of 1996 ("HIPAA") and its implementing regulations.

2.4 Responsibilities of the Authorized Individual in the Surrogate Consent Process

2.4.1 The surrogate should base his or her decision on the subject's expressed wishes or, if unknown, what the subject would have desired in light of his or her prognosis, values and beliefs. In the event of a disagreement among potential surrogates within the highest level of priority, the investigator may attempt to reach consensus through discussions with the potential surrogates. If consensus is not reached, the subject will not be enrolled in the study.

2.4.2 Any person serving as a surrogate for purposes of providing consent pursuant to this policy may not receive any compensation or consideration of any kind for serving as surrogate or providing the consent.

2.5 Education and Role of the Surrogate

2.5.1 Surrogates must receive education from the investigator about their role (including the decision-making considerations described in 2.4.1 and 2.5.2 of this policy), the cognitive and health status of the research participant, as well as all material aspects of the study in which the participant may be involved before their consent may be requested. Before a surrogate may provide consent for an individual to participate in a research study, the surrogate must be informed of the (i) risks and benefits, (ii) alternatives, (iii) expected outcomes, and (iv) rights and obligations of a research subject. The process of informed consent should not be abbreviated or circumscribed because consent is being obtained from a surrogate; to the contrary, the research is to be explained to the surrogate as completely and comprehensively as it normally would be if the research subject was being consented. Such education must be clearly documented in the research records.

2.5.2 Whenever possible, surrogates should make their decisions based on substituted judgment, reflecting the views of the individual expressed while capable of making decisions. Best interest standards should be used if the values of the individual are not known. It is important that the surrogate consider the potential subject's prior statements about and reactions to medical issues, when applicable to the study, and all facets of the potential subject's personality with which the surrogate is familiar -- with particular reference to his or her relevant philosophical, theological, and ethical values -- in order to extrapolate what decision the potential subject would make.

2.6 Requirement for Re-Consent

2.6.1 If at any time after the subject is enrolled in a study through surrogate consent, he or she regains the capacity to provide informed consent, the investigator shall obtain the legally effective informed consent of the subject for continued participation in the research.

2.6.2 Decision-making capacity of subjects may fluctuate. The consent process should be ongoing and involve the surrogate if at any time the investigator believes that the subject is unable to provide informed consent for continuing in a research project in which the subject initially gave informed consent.

2.7 Emergency Use of Surrogate Consent

2.7.1 Section 7.4 of the Drexel University College of Medicine Guidelines for Biomedical and Behavioral Research Involving Human Subjects provides for the immediate and emergency use of a test article outside the research environment. Such use is not considered research. If a research protocol has not been reviewed by the IRB under those requirements, no subject deemed by the investigator to be unable to give informed consent may be entered into the research without re-review by the IRB of an amended protocol.

2.8 Training

2.8.1 All investigators who obtain surrogate consent must first complete any educational training as may be required by the DUCOM Office of Research.