



KESSLER FOUNDATION

Policies and Procedures Manual *IRB*

SUBJECT: Substituted (Surrogate) Consent	POLICY # 5034
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PURPOSE

Kessler Foundation will accept substituted or surrogate consent in certain human subject research studies, from persons with specific, defined relationships with the research subject. This policy describes the procedures to be followed in obtaining surrogate consent.

POLICY STATEMENT, BACKGROUND AND DEFINITIONS

I. Policy Statement and Background:

It is the policy of Kessler Foundation and its Institutional Review Board (IRB) to protect the right to autonomy of all human subjects who participate in research studies. It is also the policy of Kessler Foundation and its IRB 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 provides a mechanism to allow them to participate in IRB-approved research studies. The purpose of this Policy is to confirm that Kessler Foundation will accept substituted or surrogate consent in certain human subject research studies, from persons with specific, defined relationships with the research subject. This policy describes the procedures to be followed in obtaining surrogate 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 the researcher to obtain the legally effective informed consent of the subject or the subject's legally authorized representative prior to the subject's participation in medical research. Federal law defers to state law in determining which class of surrogate is legally authorized to give surrogate consent. New Jersey 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.

New Jersey statutory law (26:14-5) authorizes surrogate consent and prioritizes potential surrogates. The priority of surrogates given in the NJ statute is incorporated into this policy in Section III A, below.

II. Definitions:

The following definitions relate to issues involving surrogate informed consent:

- A. Best Interests: This is the standard to be used by surrogate decision makers to guide health care decisions when the subject's specific values and wishes are unknown. The surrogate, together with the health care team, uses this standard to determine the optimal outcomes for subjects and the interventions most likely to produce them. In making that determination, the surrogate must also take into account the subject's cultural, ethnic, and religious perspectives.
- B. Competency: In relation to decision-making capacity, competency is a legal determination, made by a court of law, that a subject has the requisite capacities to make a medical decision. This is in contrast to the term "decision-making capacity" that is a clinical determination made by the investigator.
- C. Decision Making Capacity: Decision-making capacity for health care has four major components: (1) understanding; (2) appreciating; (3) formulating; and (4) communicating. The first two components represent the subject's ability to understand and appreciate the nature and expected consequences of each health care decision. This includes understanding the known benefits and risks of participating in a research study, as well as any reasonable alternative options, including not participating in the research. The latter two components represent the ability to formulate a judgment and communicate a clear decision concerning health care. As used in this policy, "capacity" is a clinical determination made by the practitioner, in contrast to "competency," which is a legal determination made by a court of law.
- D. Legal Guardian: A person appointed by a court of appropriate jurisdiction to make health care decisions for an individual who has been judicially determined to be incompetent. The appointment may be of limited duration. Under Kessler Foundation policy, legal guardians have the same authority to make health care decisions as any surrogate authorized under this policy. *Note: Financial or other types of limited guardianship do not always include the authority to make health care decisions.*
- E. Immediate Family: A relative (18 years of age or older) of the patient who may act as a surrogate in the following order of priority: spouse, domestic partner, adult child (18 years or older), parent, sibling, adult grandchild (18 years or older).
- F. Substituted Judgment: The standard to be used by surrogate decision makers who have specific knowledge of the subject's values and wishes pertaining to health care choices. This standard requires the surrogate decide, based on what the subject would have wanted if he or she were capable of expressing those preferences. That decision may not necessarily

coincide with what the surrogate and health care team otherwise would consider optimal for the patient.

- G. Surrogate Decision Maker (“Surrogate”): An individual authorized to make health care decisions on behalf of a subject who lacks decision-making capacity.

LIMITATIONS, PROCEDURES AND GUIDELINES

I. Diminished Capacity; Limitations

For purposes of this policy, persons with “diminished capacity” means individuals who are unconscious, comatose, cognitively impaired, 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. 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.

II. Determination of Subject’s Ability to Provide Informed Consent in a Research Study

- A. The investigator will be responsible for determining whether an individual subject can provide informed consent.
- B. If applicable, the investigator will clearly document in the research record the reason for the subject’s inability to provide informed consent.
- C. A licensed and qualified physician not otherwise involved in the research will confirm the subject is incapable of giving informed consent.
- D. The investigator will apply and document any additional safeguards as directed by the IRB.
- E. In order to provide additional safeguards to insure the rights of the subjects are protected, the investigator will also provide for the witnessing of informed surrogate consent by an adult third party and will complete independent documentation of the informed consent process.

III. Individuals Able to Provide Effective Surrogate Consent for Participation in Research Studies

- A. The following individuals may be considered capable of providing surrogate consent, in the following descending order of priority:
 - 1. the guardian of the subject who has the authority to make health care decisions for the subject;
 - 2. the healthcare representative of the subject pursuant to an advance directive for health care;
 - 3. the spouse or civil union partner, as applicable, of the subject;
 - 4. the domestic partner of the subject;
 - 5. an adult son or daughter of the subject;
 - 6. a custodial parent of the subject;
 - 7. an adult brother or sister of the subject;
 - 8. an adult grandchild of the subject;

9. an available adult relative with the closest degree of kinship to the subject.
- B. With respect to an individual from whom an investigator seeks to obtain surrogate 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 Kessler Foundation IRB to assist in the resolution of the matter.
 - C. With respect to an individual from whom an investigator seeks to obtain surrogate 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.
 - D. When there are two or more available persons who may give surrogate consent pursuant to Section III A and who are in the same level of priority, consent will 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.
 - E. When there are two or more available persons who are in different orders of priority pursuant to Section III A, refusal to consent by a person who is a higher priority surrogate will not be superseded by the consent of a person who is a lower priority surrogate.
 - F. If there are no individuals in a higher level of priority, then the investigator will ascertain the following information from the potential surrogate consentor: (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.
 - G. The investigator will clearly document the actions required by this section ("Limitations, Procedures and Guidelines") in the research records.
 - H. 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.

IV. Responsibilities of the Authorized Individual in the Surrogate Consent Process

- a. 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.

- b. If the surrogate agrees to enroll the subject in the research study in question, the surrogate will be required to sign the consent form in the appropriate place provided. As stated: "I, (*name of surrogate*), as the (*relationship to patient*) of (*name of patient*), do consent to the participation of the above person in this research study. I further state that all good faith effort has been made to contact all others in my level of priority to review this decision with them, and that no dissenting opinion exists among them."

V. Education and Role of the Surrogate

- A. Surrogates must receive education from the investigator about their role (including the decision-making considerations described in sections IV A and V B 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 his/her 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.
- B. Whenever possible, surrogates should make their decisions based on substituted judgment, reflecting the views of the research subject 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.

VI. Requirement for Re-Consent

- A. 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 will obtain the legally effective informed consent of the subject for continued participation in the research.
- B. 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.

VII. Training

- A. All investigators who obtain surrogate consent must first complete all educational training as may be required by the Kessler Foundation .

RESOURCES & REFERENCES

The National Bioethics Advisory Commission, *Research Involving Persons with Mental Disorders That May Affect Decision making Capacity* (December 1998).

Research Involving Persons with Mental Disorders That May Affect Decision making Capacity - a report and recommendations of the National Bioethics Advisory Commission

NIH (1999) Research Involving Individuals with Questionable Capacity to Consent: Points to Consider.

OPRR. Protecting Human Research Subjects: Institutional Review Board Guidebook (1993)
http://ohrp.osophs.dhhs.gov/irb/irb_chapter6.htm

OHRP Requirements

45 CFR 46.111 (a) (3)
45 CFR 46.111(b)
45 CFR 46.107
45 CFR 46.408
45 CFR 46:109(b)(c)

FDA Requirements

21 CFR 50.20
21 CFR 50.27
21 CFR 50.55
21 CFR 56.107
21 CFR 56.111(b)

NJ PL 2008, Ch. 12 Title 26:14-1 Access to Medical Research Act

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VERIFICATION OF SPOUSE OR DOMESTIC PARTNERSHIP STATUS

With respect to an individual from whom an investigator seeks to obtain surrogate consent to enroll a subject in a research study, and who claims to be a spouse or domestic partner but has a different last name than the subject, the investigator is responsible for verifying that such individual qualifies as a spouse or domestic partner for purposes of this policy. Spouse or domestic partnership status will be verified by obtaining three (3) of the following pieces of supporting documentation:

1. Joint mortgage or lease ()
2. Designation by one of the spouses/domestic partners of the other spouse/partner as primary beneficiary under a life insurance policy ()
3. Designation by one of the spouses/domestic partners of the other spouse/partner as primary beneficiary of retirement benefits ()
4. Designation by one of the spouses/domestic partners of the other spouse/partner as primary beneficiary under a will ()
5. Joint ownership of an automobile, joint bank account or joint credit account ()

Notwithstanding the foregoing, an individual may verify that he or she is the spouse of the subject by providing a valid marriage certificate without the need for the investigator to obtain copies of three of the above-listed documents. ()

In the case of a same-sex domestic partnership, domestic partnership status may be demonstrated by obtaining a copy of an Affidavit of Domestic Partnership from a Local Registrar of Vital Statistics in any municipality in the State of New Jersey (without the need to obtain copies of three of the above-listed documents), under which each domestic partner confirms joint responsibility for each other's common welfare and the sharing of financial obligations. ()

Copies of the documents obtained as part of the process of verifying spouse or domestic partnership status will be maintained in the research records, along with a copy of this Verification form which contains check-offs for each document that has been obtained and which has been signed and dated by the investigator and the spouse/domestic partner.

Investigator Print Name

Spouse/Domestic Partner Print Name

Signature of Investigator

Signature of Spouse/Domestic Partner

Date

Date