Rutgers Guidelines for Surrogate Consent

The following guidance provides direction on obtaining from a surrogate decision maker the valid informed consent to participate in research for an adult who is cognitively impaired, lacks capacity, or suffers a serious or life-threatening disease.

I. Investigator Responsibilities:

A. IRB Approval:

The investigator must apply to the IRB for use of surrogate consent that is specific to the particular study being reviewed. Upon approval by the IRB, the investigator shall apply the use of surrogate consent on a case-by-case basis within that protocol.

1. New Studies: An investigator must indicate in the IRB Application for Initial Review that the protocol will utilize a surrogate consent process and must provide a complete description of the Investigator’s plan to obtain the surrogate’s consent as by completing Appendix H, the Surrogate Consent Process Addendum. An investigator must receive IRB approval prior to implementation of surrogate consent procedures for a specific study.

2. Ongoing Studies: If an investigator decides to utilize the surrogate consent process for a Study that has already received IRB approval, a Request for Modification Form as well as a completed Appendix H, the Surrogate Consent Process Addendum must be submitted to the IRB. An investigator must receive IRB approval for this modification prior to implementation of surrogate consent procedures for a specific study.

B. Determination of Incapacity:

1. Whenever possible, investigators will attempt to obtain informed consent directly form the subject.

2. If the subject has an advance directive for healthcare and has indicated that s/he does not wish to participate in a research study, the potential subject must not be included in the study.

3. A determination that the subject is unable to consent, as well as the extent of the incapacity and the likelihood that s/he will regain decision-making capacity, must be made by an attending physician with no connection to the study. This determination must be documented by the attending physician making the determination.

For purposes of this section, inability to consent shall mean that a subject is unable to voluntarily reason, understand, and appreciate the nature and consequence of proposed health research interventions, including the subject’s diagnosis and prognosis, the burdens, benefits, and risks of, and alternatives to, any such research, and to reach an informed decision.

4. The investigator must assure that the determination of incapacity is promptly given to the subject and to at least one person at the highest category reasonably available on the list of surrogates in subsection C3 below.

C. Identification of Surrogate:

1. If the investigator believes that a subject lacks decision-making capacity, (See Section
2. If the subject expresses resistance or dissent to participation or to the use of a surrogate for consent, the investigator must exclude the subject from the study.

3. Surrogate informed consent may be obtained from an authorized representative with reasonable knowledge of the subject, who shall include any of the following persons, in the following descending order or priority:

   i. the guardian of the subject with the authority to make health care decisions;
   ii. the health care representative pursuant to an advance directive for health care;
   iii. the spouse or civil union partner;
   iv. a domestic partner
   v. an adult son or daughter;
   vi. a custodial parent;
   vii. an adult brother or sister;
   viii. an adult grandchild; or
   ix. an available adult relative with the closest degree of kinship.

4. The investigator must make a good faith effort to contact the individual at the highest level of priority. These efforts should be documented. Potential surrogates must be advised that if a higher-ranking surrogate is identified at any time, the investigator whenever feasible will defer to the higher-ranking surrogates’ decision regarding the subject’s participation in the research.

5. The investigator must assure that if one of two or more available persons in the same order or priority expresses opposition to the participation of the subject in the study, the investigator must exclude the subject from the study.

6. The investigator must assure that when two or more available persons are in different orders of priority, refusal to consent by a potential surrogate who is of a higher priority controls and cannot be superseded by the consent of a person who is of a lower priority.

D. Obtaining Surrogate Consent:

1. Surrogates for a potential research subject may not receive financial compensation for providing consent.

2. Surrogates must review, sign and date the Surrogate Self-Certification Form and the IRB-approved Surrogate Consent Form prior to providing surrogate consent for study participation.

3. The investigator or designee must orally review each element included in the Surrogate Consent Form with the surrogate. This oral review must be in non-technical terms and in a language in which the surrogate is fluent.

4. The investigator must assure that a copy of the Surrogate Consent Form is given to the surrogate.

E. If a Subject Regains Cognitive Ability

In the event that a subject regains the cognitive ability to consent to participation in the study, the Investigator must assure that the subject is promptly consented using standard consent procedures.
F. Documentation

1. The principal investigator must use a study-specific, IRB-approved Surrogate Consent Form and ensure that:

   a. the principal investigator or his/her designee signs and dates the Surrogate Consent Form.

   b. the subject’s surrogate signs and dates the Surrogate Consent Form.

   c. the Surrogate Consent Form is signed and dated by a witness who is not the subject, the subject’s guardian, surrogate, or member of the research team, and who can attest that the requirements for informed consent to the study have been satisfied.

2. In all cases involving the use of a surrogate, the principal investigator, or his/her IRB-approved designee obtaining surrogate consent shall file a completed Surrogate Consent Form in both the medical and research records.

3. The determination of a subject’s incapacity to consent to study participation by the physician making the determination must be documented and retained in both the medical and research records. This documentation must be retained as part of the permanent source documents for the IRB-approved study.

II. IRB Responsibilities:

   A. In order to approve the use of a surrogate in a study, the IRB must make a determination and document that the research relates to the cognitive impairment, lack of capacity, or serious physical or behavioral conditions and life-threatening diseases of the research subjects and either:

   1. offers the prospect of direct benefit to the subject, provided that the IRB has determined that the risk is justified by the anticipated benefits and that the relation of the anticipated benefit to the risk is at least as favorable to the subject as that presented by available alternative approaches. If a currently recognized treatment exists, the subject, guardian, or surrogate shall be presented with the choice of the recognized treatment and the research protocol;

   or

   2. does not offer the prospect of direct benefit to the subject, provided that the IRB has determined that it: (1) is likely to yield generalizable knowledge about the subject’s disorder or condition; (2) by its very nature cannot be conducted without the participation of decisionally incapacitated persons; and (3) involves no more than a minor increase over minimal risk. “Minimal risk” means that the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine psychological exams or tests.

   B. The IRB must ensure that all of the following elements are specified in the approved Surrogate Consent Form in nontechnical terms and in a language in which the subject or the subject’s guardian or authorized representative is fluent:

   1. an explanation of the procedures to be followed in the study and any drugs or devices to be utilized, including:
a) the purposes of the procedures, drugs, or devices;

b) the use of placebo controls, when applicable;

c) the process by which persons will be assigned to control groups.

2. an explanation of any potential direct benefits to the subject. If no such direct benefits are reasonably expected, that fact should be made clear.

3. a description of any attendant discomfort and reasonably foreseeable risks to the subject.

4. a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

5. an estimate of the expected duration of the study.

6. the name, institutional affiliation, and address of the person or persons actually performing and primarily responsible for the conduct of the study;

7. an offer to answer any inquiries concerning the study or the procedures involved; and

   a) whom to contact for answers to pertinent questions about the study;

   b) whom to contact in the event of a study–related injury; and

   c) contact information for the institutional review board; and

   d) the name, address, and phone number of an impartial third party, not associated with the research to whom the subject/surrogate may address complaints.

8. instruction to the subject or surrogate that he/she is free to withdraw consent and discontinue participation in the study at any time, without prejudicing the subject’s medical treatment outside the study;

9. a statement regarding the Investigator’s plan to safely remove a subject from the study and any consequences of abruptly ending participation in the study;

10. the name of the sponsor or funding source, if any, or manufacturer if the study involves a drug or device, and the organization, if any, responsible for the general direction of the study; and

11. the material financial stake or interest, if any, that the investigator or research institution has in the study. (For purposes of this section, “material” means $10,000 or more in securities or other assets valued at the date of disclosure, or relevant cumulative salary or other income.)

C. The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

   1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;

3. The research could not practicably be carried out without the waiver or alteration; and

4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.