

**RESEARCH INVOLVING HUMAN PARTICIPANTS UNABLE TO CONSENT-  
SURROGATE CONSENT**

<b>SOP #:</b>	<b>505</b>	<b>VERSION #:</b>	<b>1</b>	<b>EFFECTIVE DATE:</b>	<b>5/1/09</b>	<b>SUPERSEDES DOCUMENT:</b>	<b>/ /</b>
<b>THIS POLICY PERTAINS TO:</b>			<b>ALL RESEARCH SUBMITTED TO THE IRB</b>				
<b>RESPONSIBILITY FOR EXECUTING POLICY:</b>		<b>ASSOCIATE VICE PRESIDENT FOR RESEARCH AND ECONOMIC DEVELOPMENT, IRB CHAIRPERSON, IRB VICE CHAIRPERSON, IRB MEMBERS</b>					
<b>LAST REVIEWED ON:</b>		<b>/ /</b>	<b>RESULTS:</b>	<b>REVISED</b>			
<b>APPROVAL AUTHORITY:</b>		<b>Associate Vice President for Research and Economic Development</b>					
<b>APPROVED BY:</b>					<b>DATE:</b>	<b>/ /</b>	

**1. POLICY**

Research involving subjects who are mentally ill or subjects with impaired decision-making capacity warrants special attention. Research involving these populations frequently presents greater than minimal risk, may not offer direct medical benefit to the subject, and may include a research design that calls for washout, placebo or symptom provocation. In addition, these populations are considered to be vulnerable to coercion. Provisions must be made to obtain legally effective informed consent prospectively from each research participant or permission for the participants legally authorized representative.

**2. SPECIFIC POLICY**

**2.1 Definitions**

**Surrogate Consent:** Obtaining from a surrogate decision maker (*a person appointed to represent or act on behalf of another*) the valid informed consent to participate in research for an adult subject who is cognitively impaired, lacks capacity, or suffers a serious or life-threatening disease.

**Health Care Agent:** The health care agent is the individual named in a Durable Power for Health Care Decision Maker (DPAHC) executed by the subject while the subject had decision-making capacity. The health care agent acts on the subject’s behalf to make health care decisions, including enrolling the subject in a research study, when the subject is unable to provide consent. A Health Care Agent is considered a Legally Authorized Representative.

**Court-appointed guardian:** A legal guardian has been appointed by a court to make decisions for an individual who has been judicially judged to be incompetent. A court-appointed guardian is considered a Legally Authorized Representative.

**Next-of-Kin:** In the following order: spouse, adult child (18 years or older), parent, adult sibling (18 years or older), grandparent, or adult grandchild (18 years or older). This list contains the only surrogate entities who are allowed to provide consent for research purposes. This is only used when the adult participants who are incompetent or lack decision-making capacity, AND do not have a valid Court-appointed guardian or health care agent. The next-of-kin should be an adult who has exhibited special care and concern for the patient and who is familiar with the patient’s personal morals and values.

**Legally Authorized Representative (as defined by FDA and DHHS regulations):** An individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

FDA regulation at 21 CFR 50.20 states that no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.

HHS regulation at 45 CFR 46.116 states that if a subject is not legally competent to consent to participate in a study, the federal regulations require that a legally authorized representative consent for the subject.

## **2.2 Investigators Responsibilities**

2.2.1 Investigators must apply to the IRB for use of surrogate consent that is specific to the particular study being reviewed.

- Surrogate consent may be considered only in research studies relating to the cognitively impaired, lack of capacity, or serious or life-threatening disease and conditions of the research.
- Upon approval of the IRB for use within a specific protocol, the Investigator shall apply the use of surrogate consent on a case by case basis.

2.2.2 If an adult participant is identified and is incompetent or lacks decision-making capacity for healthcare decisions and consent:

- The treating physician, the consulting physician(s) and/or other involved members of the healthcare team must document in the medical record;
  - The basis for their determination that the patient lacks decision-making capacity;
  - The identity of the legal authorized representative and if none, the next-of-kin. (A copy of the legal form authorizing the durable power of attorney etc. must be maintained in the research records.)
  - The process by which the participant was enrolled or declined to be enrolled in the research.

## **2.3 IRB Guidelines**

2.3.1 Surrogate consent is a protocol specific request of the Investigator, and must be reviewed and approved accordingly by the IRB:

- Surrogate consent may be considered only in research studies relating to the cognitively impaired, lack of capacity, or serious or life-threatening disease and conditions of the research.
- The IRB membership should include at least one member who is familiar with the population to be recruited.
- The IRB shall utilize consultants as necessary to assure appropriate expertise. Such consultant's may not vote with the IRB or contribute to the quorum.
- The IRB will consider whether and when to require a reassessment of the participants decision making capacity, periodic reconsenting of the participants, and the study's renewal period.

## **2.4 Criteria for IRB approval:**

Incompetent persons or persons with impaired decision making capacity are the only suitable research subjects. Competent persons are not suitable for the proposed research. The Investigator must demonstrate to the IRB that there is a compelling reason to include incompetent individuals or persons with impaired decision-making capacity as subjects. Incompetent persons or persons with impaired decision making capacity must not be subjects in research simply because they are readily available.

Favorable risk/benefit ratio. The proposed research entails no significant risks, tangible or intangible or, if the research presents some probability of harm, there must be at least a greater probability of direct benefit to the participant. Incompetent people or persons with impaired decision making capacity will not be subjects of research that imposes a risk of injury unless that research is intended to benefit that subject and the probability of benefit is greater than the probability of harm.

Voluntary participation. In situations where the potential research subject is incompetent to provide informed consent, the Investigator should still attempt to obtain assent from the potential subject. Some persons may resist participating in a research protocol that has been approved by their representatives. Under no circumstances may subjects be forced or coerced to participate.

Well-informed representatives. Procedures have been devised to assure that participant's representatives are well informed regarding their roles and obligations to protect incompetent subjects or persons with impaired decision making capacity. Health care agents (appointed under Durable Power of Attorney for Health Care) must be given descriptions of both proposed research studies and the obligations of the person's representatives. They must be told that their obligation is to try to determine what the subject would do if competent, or if the subject's wishes cannot be determined, what they think is in the incompetent person's best interest.

## **2.5 IRB Determination and Documentation**

The IRB shall make a determination in writing of each of the criteria listed above. If these criteria are met, the IRB may approve the inclusion of incompetent subjects or subjects with impaired decision making capacity in research projects on the basis of informed consent from legally authorized representatives or in none exists, next-of-kin.

## **3. RESPONSIBILITY**

The IRB Chairperson or IRB Coordinator is responsible for providing the Investigator with guidance to ensuring the rights and welfare of the participant.

The IRB Chairperson and IRB Members are responsible for the review of the project, consent, and assent, and for ensuring all safeguards are in place using the Cognitively Impaired/Surrogate Consent Checklist.

The IRB Secretary is responsible for the pre-review of the IRB study submissions to ensure a complete study submission.

## **4. APPLICABLE REGULATIONS AND GUIDELINES**

45 CFR 46.111

45 CFR 46.116 and 46.117

[OHRP Guidance Document: Informed Consent, Legally Effective and Prospectively Obtained](#)

**5. ATTACHMENTS**

SC 505-A Persons Cognitively Impaired or Unable to Consent  
 SC 505-B Checklist for Adults Unable to Consent (Surrogate Consent)

**6. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY**

<b>Who</b>	<b>Task</b>
<i>IRB Chairperson, IRB Coordinator</i>	Provide guidance to Investigators as needed.
<i>IRB Secretary</i>	Provide Cognitively Impaired/Surrogate Consent Checklist to reviewers.
<i>IRB Chairperson, IRB Coordinator, IRB Secretary</i>	Select appropriate Primary Reviewers. Obtain Consult if needed.
<i>Primary Reviewers (IRB Members)</i>	Use Checklist for assistance in reviewing the study. Review study and determine if all safeguards are in place.
<i>IRB Secretary</i>	Send correspondence to Investigator as appropriate.