CARILION MEDICAL CENTER INSTITUTIONAL REVIEW BOARD
Standard Operating Guidelines

Title: 5.3: Informed Consent Process: Use of Legally Authorized Representative	
Original Date: April 2006	**Date of Last Revision:** 2-15, 8-23
Primary Sponsor: Human Research Protections Office	**Approved By:** Director of the Human Research Protections Office

Objective:

To describe the use of legally authorized representatives in authorizing human subjects research when a prospective human subject has been determined incapable of making an informed decision about whether to participate in research.

General Description:

Federal regulations that govern research involving human subjects define a legally authorized representative as 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. 45CFR46.102(i) and 21CFR50.3(l)

Virginia law § 32.1-162.16 defines a legally authorized representative in the following specified order of priority for adults: (a) the agent appointed under an advance directive, as defined in § 54.1-2982, executed by the prospective subject, provided the advance directive authorizes the agent to make decisions regarding the prospective subject's participation in human research, (b) the legal guardian of a prospective subject, (c) the spouse of the prospective subject, except where a suit for divorce has been filed and the divorce decree is not yet final, (d) an adult child of the prospective subject, (e) a parent of the prospective subject when the subject is an adult, (f) an adult brother or sister of the prospective subject or (g) any person or judicial or other body authorized by law or regulation to consent on behalf of a prospective subject to such subject's participation in the particular human research.

For the purposes of this guideline, a legally authorized representative for category (g) above includes an attorney in fact appointed under a durable power of attorney, to the extent the power grants the authority to make such a decision. The attorney in fact should not be employed by the person, institution, or agency conducting the human research. No official or employee of the institution or agency conducting or authorizing the research is qualified to act as a legally authorized representative.

Procedure:

For Subjects Who Are Carilion Patients

In order for a legally authorized representative to give informed consent for a prospective adult human subject to take part in human subjects research, the prospective human subject must be found to be incapable of making an informed decision as defined in § 54.1-2982. This means that the prospective adult subject is unable to understand the nature, extent or probable consequences of the

proposed research or is unable to make a rational evaluation of the risks and benefits of alternatives to the proposed research.

If the prospective adult subject is unconscious or experiencing a profound impairment of consciousness due to trauma, stroke, or other acute physiological condition, a physician caring for the prospective subject must document that the prospective subject is incapable of making an informed decision for that reason. If the patient is incapable of making an informed decision due to other reasons, a physician caring for the patient as well as a second physician or clinical psychologist must document in writing that the prospective subject is incapable of making an informed decision. The second opinion shall be made by a clinician not otherwise currently involved in the treatment of the prospective subject. The Carilion consent template includes guidance on the written consent documentation requirements. For guidance on how researchers can assess a prospective subject's decision- making capacity, please see SOG 5.6.

For Subjects Who Are Not Carilion Patients

In order for a legally authorized representative to give informed consent for a prospective adult human subject to take part in human subjects research, the prospective human subject must be found to be incapable of making an informed decision. This means that the prospective adult subject is unable to understand the nature, extent or probable consequences of the proposed research or is unable to make a rational evaluation of the risks and benefits of alternatives to the proposed research.

Documentation that the prospective subject is incapable of making an informed decision to take part in the research study must be made in writing by a research team member who is a physician or licensed clinical psychologist after personal examination of the subject. Whenever the proposed research could significantly affect the prospective subject's clinical treatment, the prospective subject's primary care provider or current treating clinician will be consulted about the subject's participation in research.

How to Document Lack of Decision Making Capacity for Research Subjects

In addition to the above information specific to whether subjects are or are not Carilion patients, whenever it is likely that a significant number of prospective adult subjects for a research study will not be capable of making an informed decision, the researcher should provide the Carilion Clinic IRB with written assurance that a) a legally authorized representative will not be allowed to consent to research if it is known the research is contrary to the religious beliefs or basic values of the prospective subject; b) no prospective subject will be enrolled in the research if the prospective subject is protesting taking part in the research; c) no prospective subject will be enrolled in the research if two or more legally authorized representatives of equal decision-making priority disagree about participation of the prospective subject in the research.

Limitations on LAR Consent

A legally authorized representative may not consent to non-therapeutic research for an adult subject unless it is determined by the IRB that such non-therapeutic research will present no more than a minor increase over minimal risk to the human subject. A legally authorized representative may not consent to participation in human research on behalf of a prospective adult subject if the legally authorized representative knows, or upon reasonable inquiry ought to know, that any aspect of the human research protocol is contrary to the religious beliefs or basic values of the prospective subject, whether expressed orally or in writing. A legally authorized representative may not consent to participation in human research involving non-therapeutic sterilization, abortion, psychosurgery or admission for research purposes to a facility or hospital.

Notwithstanding consent by a legally authorized representative, no person shall be forced to participate in any human research if the investigator conducting the human research knows that participation in the research is protested by the prospective subject. In the case of persons suffering from organic brain diseases causing progressive deterioration of cognition for which there is no known cure or medically accepted treatment, the implementation of experimental courses of therapeutic treatment to which a legally authorized representative has given informed consent shall not constitute the use of force.

If two or more persons who qualify as legally authorized representatives and have equal decision-making priority inform the principal investigator or attending physician that they disagree as to participation of the prospective subject in human research, the subject shall not be enrolled in the human research that is the subject of the consent.

For research involving children, the parent or the child's legal guardian is authorized to give permission for the child's participation in research. See SOG 3.6 Vulnerable Populations.

IRB Considerations

To approve a study allowing an LAR to provide informed consent on behalf of a decisionally-impaired adult, the IRB shall take into account the following considerations.

- The PI plans to/has requested to enroll adults who are not capable of providing consent.
- The PI indicates that an appropriate Legally Authorized Representative will be asked to give consent on behalf of the incapacitated adult.
- The PI indicates that all eligible subjects will require an LAR OR that some subjects may be able to provide assent or even consent for themselves
- The PI describes a plan and includes documents to assess capacity and solicit the consent for continued participation for adult subjects who will or may regain decision making capacity.
- A written or script-supported consent document (or other information relevant to the research) will be provided to the research participant accompanied by a consent conversation, as applicable.
- The circumstances of the consent process provide the prospective participant or the LAR sufficient opportunity to consider whether to participate.
- The circumstances of the consent process minimize the possibility of coercion or undue influence.
- The person communicating information to the participant or the LAR during the consent process will provide that information in language understandable to the participant or the representative.

It is the responsibility of the principal investigator to indicate a plan and justification for enrolling subjects who are not capable of providing legally recognized informed consent. The IRB is responsible for approving the enrollment of individuals unable to provide consent, as well as the use of an LAR in protocol-specific circumstances according to this policy.