**Decisionally-impaired Adults**

Modified: January 2017

**Background:**

Researchers may not be aware of who can provide legally effective informed consent when the subject is a decisionally-impaired (e.g. incapacitated, incompetent, unconscious, or developmentally disabled adult. Most often, when a subject is unable to consent for him or herself, it is assumed a parent, spouse, or adult child are authorized to provide consent, but that may not be the case. This document provides specific guidelines to be followed for obtaining consent, when the potential subject is decisionally-impaired.

**Q: What are the requirements when an adult subject lacks capacity to consent to the research?**

In order to approve research under the federal regulations, the IRB must determine that subject selection is equitable and therefore must be “particularly cognizant” of the special problems of research involving vulnerable populations including “mentally disabled persons” and determine that additional safeguards have been included in the study to protect the rights and welfare of these subjects. There is no definition of “mentally disabled persons” nor are there additional safeguards codified in the regulations.

Both HHS and FDA Regulations (§46.116 and §50.20, respectively) require the investigator to obtain the legally effective informed consent of the subject or the subject’s legally authorized representative ("LAR") before involving the subject in research.

Additionally, both HHS and FDA regulations define an LAR as "an individual or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedures involved in the research." (45 CFR 46.102; 21 CFR 50.3). Federal law does not preclude another party from consenting for a subject to be enrolled in a research study provided the individual consenting is authorized to do so under State Law. Florida statutes and VA regulations specify who can consent for decisionally-impaired adults.

**Q: Is there any additional documentation required?**

Investigators should indicate in the research protocol and applicable IRB submission that decisionally-impaired adults will be enrolled in the research and describe the provisions for obtaining and documenting consent in accordance with Florida Law and/or VA regulations. The IRB must review and approve the inclusion of decisionally-impaired adults prior to enrolling such subjects in a study. The IRB will determine on a protocol-by-protocol basis the requirements for consent of the LAR and assent of the subject.

For FDA regulated research, obtaining consent from the LAR must be deemed feasible before the use of a test article unless the exceptions under 21 CFR 50.23 are met and reported to the IRB in accordance with IRB policy. The investigator must document in the medical and/or research record the relationship...
Under Florida law, who can determine whether a subject is decisionally-impaired?

Under Florida law, an individual is presumed to be capable of making health care decisions for him or herself unless he or she is determined to be incapacitated. Incapacity may not be inferred from the person's voluntary or involuntary hospitalization for mental illness or from her or his mental retardation. Nor does the presence of a mental disorder like Schizophrenia, or a neurodegenerative disease diagnosis such as Alzheimer's negate the presumption of capacity for informed consent.

If an individual's capacity to make healthcare decisions for herself or himself or provide informed consent is in question, the attending physician must evaluate the individual's capacity and document the process in the individual's medical record. If the physician concludes that the individual lacks capacity, the physician must also enter that conclusion in the individual's medical record. If the attending physician has a question as to whether the individual lacks capacity, another physician must also evaluate the individual's capacity, and if the second physician agrees that the individual lacks the capacity to make health care decisions or provide informed consent, the determination must be documented in the individual's medical record. Note, a finding that an individual lacks capacity to make health care decisions should not be construed as a finding that the individual lacks capacity for any other purpose, or that the lack of capacity is permanent.

Q: Who can provide consent for the decisionally-impaired adult under Florida law?

While not specific to research, Florida Law addresses surrogate consent to medical procedures that are considered applicable to consent for research participation. Under Florida Law, several classes of persons can consent for decisionally-impaired adults. Those classes of persons and the associated statutes are found in HRP Policy 021 on Legally Authorized Representatives.

They are listed in the policy in order of priority. In the absence of a Durable Power of Attorney or Health Care Surrogate, consent may be sought from a Proxy. A Proxy, or substitute decision-maker, may consent to experimental treatment, provided that experimental treatment has been approved by an IRB and the Proxy reasonably believes the decisionally-impaired adult would have made the same decision under the circumstances.

However, Proxy consent must be sought first from the person at the top of the list. Only if that option is not reasonably available, willing, or competent to consent, does the next option apply, and so on down the list. If the first reasonably available person refuses consent, however, that refusal is final. Note refusal to consent and unwillingness to consent are different. An individual may be unwilling to act as Proxy, thus the next person on the list should be contacted. However, once an individual agrees to act as Proxy, and that individual refuses to consent, that refusal is final.
Researchers must indicate in both the IRB submission and the informed consent form who consent will be sought from, again, starting at the top of the list. If the list is partial, it must still reflect the order required by Florida Law. For example, Health Care Surrogate and Durable Power of Attorney may be listed but a Proxy cannot be listed unless all the options before a Proxy are also listed.

Q: Who can provide consent for the decisionally-impaired adult when the VA is involved?

When conducting VA Research, under appropriate conditions, investigators may obtain consent from the LAR of a subject (Surrogate Consent). VHA 1200.5 is more restrictive than Florida Law, specifically listing the relatives of a subject who can provide surrogate consent for research. VA Requirements must be applied for VA Research.

VA policy recognizes as legally authorized representatives in order:

1. Durable Power of Attorney for Health Care. Persons appointed as health care agents under a durable Power of attorney for Health care;

2. Court appointed Guardian;

3. Next of Kin in the following order: spouse, adult child, parent, and adult sibling Surrogate consent may be used only when the prospective subject is determined to be incompetent and both of the following are true:

   a. the subject is determined to be incompetent by either (a) the practitioner, in consultation with the chief of service or chief of staff appropriate medical evaluation, or (b) a legal determination. This definition of incompetence is not limited to the legal definition but may also be a clinical judgment that a person lacks the capacity to understand the circumstances of participating in research and to make an autonomous decision; and

   b. that there is little or no likelihood that the subject will regain competence within a reasonable period of time. Incompetent subjects must not be coerced to participate. When feasible, researchers should explain the proposed research to the potential, incompetent subject. Researchers should inform the IRB how they will obtain/document the subject’s assent to participate in the research. Disclosures that would normally be made to a competent subject must be made to the incompetent subject’s legally authorized representative.