Decisionally-impaired Adults

Modified: March 2019

Background:

Researchers may not be aware of who can provide legally effective informed consent when the subject is a decisionally-impaired (e.g. incapacitated, 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.

1. What are the requirements the IRB must ensure when reviewing a protocol that involves adult subjects who may lack 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.

2. Is there any additional informed consent and research record 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
of the LAR to the subject that allows the LAR to provide consent for the subject along with the steps that were taken to obtain consent in order of priority. Further, unless the IRB has approved a waiver of documentation of consent, informed consent must be documented by the use of a written consent form approved by the IRB and signed and dated by the subject or the subject’s LAR. Consent is an ongoing process. Should a subject enrolled in an active IRB approved protocol regain capacity, the subject must be re-consented.

3. Under Florida law, who can determine whether a subject is decisionally-impaired?

Involving decisionally-impaired subjects in research is a complex issue. 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.

Per Florida Law, 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.

4. Who can provide informed consent for research 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.

Those classes of persons are listed in the statute and in the policy in order of priority:

- Judicially appointed guardian
- Spouse
- Adult child
- Parent
- Adult sibling
- Other adult relative
• Close friend of patient
• A licensed clinical social worker

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.

The IRB may, in its discretion, determine the last three classes of persons listed in the statute (other adult relative, close friend of patient, and licensed social worker) may not serve as proxy based on the nature of the study. For instance, they may not be permitted to consent in a non-therapeutic study or a study with increased risk and little benefit.

5. **What is the difference between a designated health care surrogate and a proxy?**

<table>
<thead>
<tr>
<th>Health Care Surrogate vs. Proxy</th>
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<tbody>
<tr>
<td>Both have the same level of authority to make health care decisions</td>
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<tr>
<td>Both must be competent adults</td>
</tr>
<tr>
<td>Health Care Surrogate</td>
</tr>
<tr>
<td>Designated in writing signed by the principal and two adult witnesses.</td>
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<tr>
<td>Continues to make decisions until authority is revoked by patient or by court order</td>
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</table>

6. **What if most of the potential subjects in a research study will eventually become incapacitated?**

If subjects in your study will likely become incapacitated over the course of the study, confirm whether or not they have a designated health care surrogate. If not, researchers should provide the subject with a copy of the [UFHealth Designation of Health Care Surrogate](#) form. Even if a subject has consented on his or her own accord, a designated representative would be ready to step in as the LAR if the subject’s ability to assess his or her own needs and interests becomes compromised during the study. Subjects
should understand that this is a general designation for all health care decisions, and not limited to decisions regarding the research study.

Upon signing the form, the principal may stipulate whether the authority of the surrogate to make health care decisions or to receive health information is exercisable immediately without the necessity for a determination of incapacity or only upon the principal’s incapacity.

7. If a subject becomes incapacitated during the study, does the LAR need to reconsent?

Only if there is a change in the protocol procedures, or new information becomes available, requiring reconsent of all subjects.

8. What if the subject becomes incapacitated during the study, and no surrogate has been established?

9. First, determine if the subject still meets inclusion criteria. If not, withdraw the subject. If the subject still meets inclusion criteria, determine who the proxy will be in accordance with Question 4. If there is a change in the protocol procedures, or new information becomes available, requiring reconsent of all subjects, the proxy must reconsent for the subject. **Who can provide informed consent for research 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 LARs 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 LAR.