1. PURPOSE

1.1. This policy describes the University of Florida’s determination of which individuals are:

1.1.1. Legally Authorized Representatives (LARs)
1.1.2. Children
1.1.3. Guardians

2. POLICY

2.1. Under DHHS and FDA regulations a “legally authorized representative” means 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.

2.2. When research involves adults unable to consent, permission must be obtained from a legally authorized representative, unless the IRB has waived the requirement to obtain consent.

2.3. When research is conducted in Florida, the following individuals meet this definition:

2.3.1. For research involving health care procedures, consent may be sought from the following individuals for purposes of enrolling a subject with limited autonomy into a human research study, when appropriate the Principal Investigator obtains documentation from the participant’s attending physician, clinician, therapist or counselor, or an impartial third party, that the subject is not capable of giving informed consent, and obtains consent from one of the following:

2.3.1.1. An attorney in fact under a durable power of attorney. [§765.204, Florida Statutes]
2.3.1.2. A designated Health Care Surrogate. This designation must be in writing. [§765.202, Florida Statutes]
2.3.1.3. In the absence of a Health Care Surrogate or Durable Power of Attorney, the following individuals may act as proxy in the following order of priority [§765.401, Florida Statutes]:

2.3.1.3.1. The judicially appointed guardian of the subject or the guardian advocate of the person having a developmental disability as defined in s. 393.063, who has been authorized to consent to medical treatment;
2.3.1.3.2. The subject’s spouse;
2.3.1.3.3. An adult child of the subject, or if the subject has more than one adult child, a majority of the adult children who are reasonably available for consultation;
2.3.1.3.4. A parent of the subject;
2.3.1.3.5. The adult sibling of the subject or, if the subject has more than one sibling, a majority of the adult siblings who are reasonably available for consultation;
2.3.1.3.6. An adult relative of the subject who has exhibited special care and concern for the subject and who has maintained regular contact with the subject and who is familiar with the subject's activities, health, and religious or moral beliefs; or
2.3.1.3.7. A close friend of the subject.
2.3.1.3.8. A clinical social worker licensed pursuant to chapter 491, or who is a graduate of a court-approved guardianship program. Such a proxy must be selected by the provider's bioethics committee and
must not be employed by the provider. If the provider does not have a bioethics committee, then such a proxy may be chosen through an arrangement with the bioethics committee of another provider. The proxy will be notified that, upon request, the provider shall make available a second physician, not involved in the subject's care to assist the proxy in evaluating treatment. Documentation of efforts to locate proxies from prior classes must be recorded in the patient record.

2.3.1.4. Health Care Surrogates and Proxies may not consent to [§765.113]:

2.3.1.4.1. Abortion
2.3.1.4.2. Sterilization
2.3.1.4.3. Electroshock therapy
2.3.1.4.4. Psychosurgery; or
2.3.1.4.5. Experimental treatments that have not been approved by an IRB in accordance with the Common Rule

2.3.2. For all other research:

2.3.2.1. An attorney in fact under a Durable Power of Attorney. [§765.204, Florida Statutes]
2.3.2.2. The judicially appointed guardian of the subject who has been authorized to consent to research.

2.4. For research outside Florida, a determination of who meets the DHHS and FDA definitions of "legally authorized representative" is to be made with consultation from legal counsel.

2.5. Under DHHS and FDA regulations "children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted. Subpart D of the DHHS must be applied if and only if an individual involved in the research meets this definition. When research is conducted in Florida all individuals under the age of 18 years meet this definition with the following exceptions:

2.5.1. Emancipated minors. The State of Florida considers a minor emancipated and therefore capable to give consent on behalf of him/herself if:

2.5.1.1. The minor has had the disability of nonage removed by a circuit court [§743.015, Florida Statutes].
2.5.1.2. The minor is married or has been married, including one whose marriage is dissolved, or who is widowed. [§743.01, Florida Statutes].
2.5.1.3. The minor is unwed and pregnant

2.5.1.3.1. An unwed pregnant minor may consent to the performance of medical or surgical care or services relating to her pregnancy and such consent is valid and binding as if she had achieved her majority.
2.5.1.3.2. An unwed minor mother may consent to the performance of medical or surgical care or services for her child and such consent is valid and binding as if she had achieved her majority.

2.5.2. Unemancipated minors. In Florida, minors may independently consent to the following treatments or procedures:

2.5.2.1. Medical examination or treatment for STDs, including HIV testing. [§384.30, Florida Statutes]
2.5.2.2. Voluntary admission to a substance abuse treatment facility. [§397.501, Florida Statutes]

2.5.2.3. Donating blood without compensation. [§ 743.06, Florida Statutes]

2.6. For research outside Florida, a determination of who meets the DHHS and FDA definitions of “children” is to be made with consultation from legal counsel.

2.7. Under DHHS and FDA regulations a “guardian” means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care. When research involves children and parental permission is required, consent may only be obtained from parents (biologic or adoptive) or a guardian as defined by DHHS and FDA regulations. When research is conducted in any jurisdiction and permission for a child to participate in research is to be obtained from an individual other than biological or adoptive parents, the individual providing such permission must provide written documentation of the legal ability to consent to the child’s general medical care. A copy of this documentation is to be kept with the consent document in the investigator’s files.

2.7.1. In Florida, “Medical care and treatment” includes ordinary and necessary medical and dental examination and treatment, including blood testing, preventive care including ordinary immunizations, tuberculin testing, and well-child care, but does not include surgery, general anesthesia, provision of psychotropic medications, or other extraordinary procedures. [§ 743.0645]

2.7.2. In addition to the natural or adoptive parent, legal custodian, or legal guardian, the following individuals may consent to medical care and treatment [§743.0645]:

2.7.2.1. A Health Care Surrogate
2.7.2.2. A person who possesses a power of attorney specifically authorizing medical consent on behalf of the minor
2.7.2.3. The stepparent
2.7.2.4. The grandparent of the minor
2.7.2.5. An adult brother or sister of the minor
2.7.2.6. An adult aunt or uncle of the minor

3. RESPONSIBILITIES

3.1. Investigators are to follow this policy when obtaining permission for adults unable to consent for themselves, or for children to take part in research.

4. REFERENCES