University of Central Florida	**SOP:** Legally Authorized Representatives, Children, and Guardians				
	NUMBER	DATE	AUTHOR	APPROVED BY	PAGE
	HRP-012	12/10/2012	T. Bechert	S. Dziegielewski	1 of 3

1 PURPOSE

1.1 This policy provides legal council's opinion of which individuals meet the following DHHS and FDA definitions when the research is conducted in Florida:

1.1.1 Legally authorized representative

1.1.2 Children

1.1.3 Guardian

2 REVISIONS FROM PREVIOUS VERSION

2.1 Minor revisions for AAHRPP accreditation; replaces version dated 09/23/2009.

3 POLICY

3.1 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.

3.2 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.

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

3.3.1 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, provided 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:

3.3.1.1 An attorney in fact under a durable power of attorney. [Florida Statute §765.204]

3.3.1.2 A designated Health Care Surrogate as defined in Florida Statute §765.202.

3.3.1.3 In the absence of a Health Care Surrogate, the following individuals in the following order of priority:

3.3.1.3.1 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;

3.3.1.3.2 The subject's spouse;

3.3.1.3.3 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;

3.3.1.3.4 A parent of the subject;

3.3.1.3.5 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;

3.3.1.3.6 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

3.3.1.3.7 A close friend of the subject.

3.3.1.3.8 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. Decisions to withhold or withdraw life-prolonging procedures will be reviewed by the facility's bioethics committee. Documentation of efforts to locate proxies from prior classes must be recorded in the patient record.

3.3.2 For all other research:

3.3.2.1 An attorney in fact under a durable power of attorney. [Florida Statute §765.204]

3.3.2.2 The judicially appointed guardian of the subject who has been authorized to consent to research.

3.4 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.

3.5 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 meet this definition. When research is conducted in Florida all individuals under the age of 18 years meet this definition with the following exceptions:

3.5.1 Emancipated minors. The State of Florida considers a child emancipated and therefore able to give consent on behalf of him/herself in the State of Florida if:

3.5.1.1 The child has had the disability of nonage removed by a circuit court [Florida Statute §743.015].

3.5.1.2 The child is married or has been married, including one whose marriage is dissolved, or who is widowed. [Florida Statute §743-01].:

3.5.2 Individuals between 18 and 20 years of age when the research procedures involve the consumption of alcohol.

3.6 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.

3.7 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.

4 RESPONSIBILITIES

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

5 PROCEDURE

5.1 None.

6 MATERIALS

6.1 None.

7 REFERENCES

7.1 None