

SOP: LARs, Children, and Guardians				
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1 PURPOSE

- 1.1 This policy establishes how to determine which individuals meet the following DHHS and FDA definitions:
 - 1.1.1 Legally Authorized Representative
 - 1.1.2 Children
 - 1.1.3 Guardian

2 REVISIONS FROM PREVIOUS VERSION

- 2.1 None

3 POLICY

- 3.1 Unless the IRB has waived the requirement to obtain consent, when research involves adults unable to consent, permission must be obtained from a Legally Authorized Representative.
 - 3.1.1.1 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:
 - 3.1.1.2 An attorney in fact under a durable power of attorney. [Florida Statute §765.204]
 - 3.1.1.3 A designated Health Care Surrogate as defined in Florida Statute §765.202.
 - 3.1.1.4 In the absence of a Health Care Surrogate, the following individuals in the following order of priority:
 - 3.1.1.5 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;
 - 3.1.1.6 The subject's spouse;
 - 3.1.1.7 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;
 - 3.1.1.8 A parent of the subject;
 - 3.1.1.9 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;
 - 3.1.1.10 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
 - 3.1.1.11 A close friend of the subject.
 - 3.1.1.12 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

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be reviewed by the facility's bioethics committee. Documentation of efforts to locate proxies from prior classes must be recorded in the patient record.

- 3.1.2 For all other research:
 - 3.1.2.1 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.
 - 3.1.3 For research outside Florida, a determination of who is a Legally Authorized Representative is to be made with consultation from legal counsel.
 - 3.2 DHHS and FDA's Subpart D applies to all research involving children.
 - 3.2.1 When research is conducted in Florida all individuals under the age of 18 years are children. Exceptions exist for pregnant females under the age 18, who are considered adults until they deliver. Post delivery, they are considered minors again. Contact legal counsel for more information.
 - 3.2.2 For research outside Florida, a determination of who is a child is to be made with consultation from legal counsel.
 - 3.3 Unless the IRB has waived the requirement to obtain consent, when research involves children consent may only be obtained from biologic or adoptive parents or an individual legally authorized to consent on behalf of the child to general medical care¹. Before obtaining permission from an individual who is not a parent, contact legal counsel.
- 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 45 CFR §46.102, 45 CFR §46.402
 - 7.2 21 CFR §50.3

¹ This is the DHHS and FDA definition of “guardian”