	<b>SOP: LARs, Children, and Guardians</b>		
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**1 PURPOSE**

1.1 This SOP 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 SOP Statement**

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 When research is conducted in the State of Texas the following individuals meet this definition:


- 3.1.1.1 Legal guardian with the authority to made decisions regarding medical treatment
- 3.1.1.2 Person designated as a surrogate decision-maker by the patient in a medical power of attorney or Advance Directive
- 3.1.1.3 In the absence of either of the above, an individual from the following list, in order of priority, who is available after a reasonably diligent inquiry, may consent on behalf of the subject:
  - Spouse (including common law spouse)
  - Adult child who has the waiver and consent of all other qualified adult children to act as the sole decision-maker
  - A Majority of the reasonably available adult children
  - Parents
  - Individual clearly identified to act for the subject by the subject before the subject became incapacitated
  - Nearest living relative
  - A member of the Clergy

3.1.2 For research outside the State of Texas 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.

When research is conducted in the State of Texas all individuals under the age of 18 years are children. Exceptions exist for:

- 3.2.1 Individuals under 18 years of age on active duty with the armed services of the United States of America
- 3.2.2 Individuals 16 years of age or older, residing separate and apart from his/her parents, managing conservator, or guardian (with or without consent and regardless of duration), and managing his/her own financial affairs (regardless of the source of the income)
- 3.2.3 Individuals under 18 years of age seeking the diagnosis and treatment of an infectious, contagious, or communicable disease that is required by law or a rule to be reported by the licensed physician or dentist to a local health officer or the Texas Department of Health, including all diseases within the scope of Section 81.041, Health and Safety Code
- 3.2.4 Individuals under 18 years of age who are unmarried and pregnant and the research involves treatment related to the pregnancy, other than abortion
- 3.2.5 Individuals under 18 years of age seeking an examination and treatment for drug or chemical addiction, drug or chemical dependency, or any other condition directly related to drug or chemical use
- 3.2.6 Individuals under 18 years of age serving a term of confinement in a facility of the Texas Department of Criminal Justice
- 3.2.7 Contact legal counsel for more information.

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3.2.8 For research outside the State of Texas, 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 care<sup>1</sup>. Before obtaining permission from an individual who is not a parent, contact legal counsel.

3.4 When research is conducted in Texas the following individuals are Guardians in accordance with state law:

3.4.1 A person who is appointed by the court to protect for the person of one who does not have the capacity to protect his or her own interests.

**4 RESPONSIBILITIES**

4.1 Investigators are to follow this SOP 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

7.3 AAHRPP I.1.G, I-9, II.4.B

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<sup>1</sup> This is the DHHS and FDA definition of “guardian”