



# OFFICE *of* RESEARCH & GRADUATE STUDIES

## **HRPP Guidance on Children, Legal Guardians, and Legally Authorized Representatives**

These guidelines establish how to determine which individuals meet the following Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) definitions:

- Children
- Guardian
- Legally Authorized Representative

### **Scope and Definitions**

**Children:** DHHS and FDA Subpart D applies to all research involving children. When the research takes place in Texas, all individuals under the age of 18 years are children, with exemptions listed below.

**Guardian:** Individuals are considered guardians when they are a person appointed by a court to protect a person who does not have the capacity to protect their own interests.

**Legally Authorized Representative:** 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 (LAR) defined below.

### **Exceptions to the Definition of Children**

1. Individuals under 18 years of age on active duty in the armed services of the United States of America.
2. Individuals 16 years of age or older, residing separately and independent of parents/guardian/managing conservator, and managing their own financial affairs.
3. Individuals under 18 years of age seeking the diagnosis or treatment of an infectious, contagious, or communicable disease that is required by law or a rule to be reported by a licensed health care provider to a local or state department of health, including diseases within the scope of Section 81.041 of the Health and Safety Code.
4. Individuals under 18 years of age who are unmarried and pregnant, and the research involves treatment related to pregnancy, other than abortion.
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.
6. Individuals under 18 years of age who are serving a term of confinement in a facility of the Texas Department of Criminal Justice.
7. For research outside the State of Texas, a determination of who is a child will be made with consultation from the UIW Office of Legal Counsel.

### **Legally Authorized Representatives**



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1. A legal guardian with the authority to make decisions regarding medical treatment.
2. A person designated as a surrogate decision-maker by the patient in a medical power of attorney or advanced directive.
3. In the absence of 1. and 2. above, an individual from the following list may consent on behalf of the subject:
  - a. Spouse/common law spouse
  - b. Adult child who has the waiver and consent of all other qualified adult children to act as the sole decision-maker.
  - c. A majority of the reasonably available adult children
  - d. Parents.
  - e. Individuals clearly identified to act for the subject by the subject before the subject became incapacitated.
  - f. Nearest living relative.
  - g. A member of the clergy.

### **Responsibilities**

Investigators are to follow these guidelines when obtaining permission for adults unable to consent or children to participate in research.

### **References**

1. [45 CFR 46.102](#)
2. [45 CFR 46.402](#)
3. [21 CFR 50.3](#)

### **Contact**

Should you have any questions contact the Human Research Protection Program by phone at (210) 805-3555 or by email at [hrpp@uiwtx.edu](mailto:hrpp@uiwtx.edu).