


2 BACKGROUND

- 2.1. "Children" means:
 - 2.1.1. 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.
- 2.2. "Assent" means:
 - 2.2.1. A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
- 2.3. "Permission" means:
 - 2.3.1. The agreement of parent(s) or guardian to the participation of their child or ward in research.
- 2.4. "Parent" means:
 - 2.4.1. A child's biological or adoptive parent.
- 2.5. "Guardian" means:
 - 2.5.1. An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care. 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.
 - 2.5.1.1. 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. [F.S. 743.0645]
- 2.6. For purposes of this guidance any person who is under the age of 18 generally is unable to consent for themselves. Several important exceptions exist under Florida Chapter 743 that effectively treat children as adults and gives them the capacity to consent to their own medical care and to participate in research. They include the following:
 - 2.6.1. An unwed pregnant minor may consent to the performance of medical or surgical care or services relating to her pregnancy by a hospital or clinic or by a physician.
 - 2.6.2. An unwed minor mother may consent to the performance of medical or surgical care or services for her child by a hospital or clinic or by a physician.
 - 2.6.3. Any minor who is married, or who has been married, to perform all acts they could do if not a minor.
 - 2.6.4. Certified unaccompanied homeless youths.
 - 2.6.5. Any minor who has been adjudicated as an adult and is in custody or under the supervision of the Department of Corrections.
 - 2.6.6. Any minor aged 16 or older, who has been allowed via circuit court judge to remove the disabilities of nonage.

3 GUIDANCE

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