

§ 46.402 Definitions.

The definitions in § 46.102 of the pre-2018 Requirements and the 2018 Requirements, as applicable, shall be applicable to this subpart as well. In addition, as used in this subpart:

- (a) *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.
- (b) *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.
- (c) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.
- (d) *Parent* means a child's biological or adoptive parent.
- (e) *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

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