

## **POLICY ON INFORMED CONSENT OF CHILDREN**

This policy applies to all research involving children as subjects, conducted or supported by the Department of Health and Human Services and/or The University of Texas at Tyler. In addition to this policy, refer to UT Tyler's Protection Of Children Involved In Research for any research involving human subjects under the age of 18 years.

### **I. Definitions**

(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.

### **II. Age Requirements for Assent**

Due to variations in child development maturity levels, these are to serve as guidelines.

- For children 6 years of age and under: No actions, parental consent only
- For children 7-12 years of age: Child must be able to provide verbal agreement in addition to parental consent; if child verbally disagrees, no coercion must take place by parent or other
- For children 13-17 years of age: Written assent by child and written consent by parent required

### **III. Documentation means of the Assent shall be established by the IRB**