

## Special Protections for Children as Research Subjects

### **I. DEFINITION OF A CHILD FOR PURPOSE OF CONSENT**

By regulatory definition, children are persons who have not attained the legal age for consent to treatments or procedures involved in research, under applicable law of the jurisdiction in which the research will be conducted. Under Alabama law, a minor is a person younger than 19 years old, unless such a person has been emancipated ([Code of Alabama, Section 26-1-1](#)).

### **II. OBTAINING CONSENT AND ASSENT TO PARTICIPATE**

Research conducted under the auspices of BSC in which children, as defined above, are participants will be reviewed by the IRB in accordance with [45 CFR 46, Subpart D](#), which generally requires the consent of at least one parent or a legal guardian and the assent of the child.

### **III. DEFINITION OF A PARENT OR GUARDIAN**

A parent, for purposes of consent, means either a child's biological or adoptive parent. A guardian is an individual who is authorized under applicable state or local law to exercise the powers and responsibilities of a parent regarding the minor's health, support, education, or maintenance and to consent to the general medical care of the minor.

### **IV. RESEARCH IN A STATE OTHER THAN ALABAMA**

If the proposed research involves children in another state as participants, the laws of the state where the research occurs will apply. Researchers should specify the location of research and, if conducted in a state other than Alabama, assure compliance with relevant state laws and local ordinances.

### **V. OBTAINING CONSENT FROM COLLEGE STUDENTS WHO HAVE NOT REACHED AGE OF MAJORITY**

Investigators need to be aware that the age of majority in Alabama places many college students in the legal category of minor children unable to provide informed consent to participate in research. Where students are offered the opportunity to participate in multiple research projects as a component of a class or classes at BSC the IRB will consider approval of consent procedures where a single, global consent to participate in any of the research opportunities presented during a term is obtained from parents or guardians. All research projects for which such global consent is obtained must pose no more than a minimal risk of harm to participants. Assent must then be obtained from minor students for each individual research project in which the opportunity to participate is offered and accepted. No student legally classified as a minor will be a participant in research unless both the consent of a parent or guardian and the assent of the student are obtained.