1. What is the definition of children?

Federal regulations that provide protection to human research subjects define children as persons who have not attained legal age to consent to treatments or procedures involved in research or clinical investigations. See 21 CFR 50.3(o); 34 CFR 97.402(a); and 45 CFR 46.402(a). However, the same regulations also provide that the legal age to consent, and thus the criteria for defining children, is a function of state and local laws. See 21 CFR 56.103(c) and 45 CFR 46.402(e),(f).

2. What is the definition of a minor?

The legal age for consent is termed the age of majority and is a function of state law, not federal law. Individuals who have not attained the age of majority are termed minors. Under Alabama law, a minor is a person younger than 18 years old, unless such a person has been emancipated.

3. What is an emancipated person?

A person who is 18 years old and is either married or widowed is emancipated by operation of law without the need for any formal action before a court or other authority. A person under the age of 19 years but over the age of 18 years may be emancipated, or “relieved of the disability of nonage,” by order of a juvenile court when such relief is in the best interest of the minor.

4. Do the terms minor and child mean the same thing?

No, the terms minor and child are not synonymous. Under state law a minor may be given the authority to consent to certain treatments or procedures. Therefore, that person would not be classified as a child under the federal guidelines because relevant state law authorizes consent prior to reaching the age of majority. However, that person would still be classified as a minor under state law and would not have authority to consent to any treatment or procedure not specifically authorized by state law.

5. Does Alabama law make such a distinction?

Yes, Alabama law allows certain persons under 18 years to give effective consent for certain defined purposes. A minor who is: (i) 14 years of age or older; or (ii)
has graduated from high school; or (iii) is married, or having been married is divorced; or (iv) is pregnant may give effective consent to any legally authorized medical, dental, health or mental health services. Any minor may give effective consent for any medical services to determine the presence of, or to treat, pregnancy, venereal disease, drug dependency, alcohol toxicity or any reportable disease. Finally, a minor 12 years of age or older who may have come into contact with any sexually transmitted disease as designated by the State Board of Health may give consent to the furnishing of medical care related to the diagnosis or treatment of such disease, provided a duly licensed practitioner of medicine in Alabama authorizes such diagnosis and treatment.

6. What about consent to participate in research?

Although Alabama law permits minors to consent under those circumstances identified above, there is no statute addressing their capacity to consent to procedures purely for research purposes (i.e., where there are no services provided and no treatment is involved). A minor without authority under Alabama law to consent to treatments or procedures involved in research or clinical investigations is a child under applicable regulations. Therefore, when conducted in Alabama, research involving children as defined above will be reviewed in accordance with 45 CFR 46, Subpart D, which generally requires the consent of at least one parent and the assent of the child. The IRB has discretion to consider the ability of adolescents to consent to treatment under state law as a factor in determining whether to waive parental consent on a case by case basis pursuant to 45 CFR 46.408(c). Investigators wishing to use UA students who are not yet 18 years of age in a low-risk study should request a waiver of parental consent from IRB. (It is unlikely that parental permission would be waived for studies of more than low risk.)

Notwithstanding the above, a minor who is the parent of a child who is a prospective participant in research being performed in Alabama may consent to research involving that child or infant (neonate).

7. Must assent always be obtained from children?

No. Assent of a child may be waived if the capability of the child is limited by age, maturity, or psychological state. Investigators should describe and justify the reasons why they believe assent of a child should be waived in the IRB application.

8. What if I conduct research on children/minors outside the State of Alabama?

The rules stated above are solely based on Alabama law. Other states may have different rules concerning the age of majority, emancipation of minors, and the ability of minors to consent to certain treatments or procedures. When research studies are conducted outside the State of Alabama and when such studies contemplate the enrollment of participants who may be classified as children, the investigators and IRB shall seek advice from the UA Office of Counsel regarding the definition of children in the applicable state other than Alabama.
9. If my research involves children, who qualifies as a parent or guardian for purposes of giving consent?

A parent, for purposes of consent, means either a child’s biological or adoptive parent. In some instances, the consent of a guardian may be used in lieu of parental consent. 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. For purposes of research conducted in Alabama a guardian is 1) a person appointed guardian of a child pursuant to the Alabama Uniform Guardianship and Protective Proceedings Act as documented by a valid court order; or 2) a person having legal custody of a child and as documented by court order; or iii) a person acting in loco parentis, regardless of whether such is documented by a court order.

A person acts in loco parentis of a child where the individual voluntarily assumes responsibility for the child’s custody, care, and maintenance even though no court order exists formally appointing the person as the guardian, legal custodian, or adoptive parent of the child.

The Department of Education has additional requirements for research involving children. Parent or guardian access to instructional material used in a research or experimentation program:

- This includes access to all instructional material – including teachers' manuals, films, tapes, or other supplementary material – which will be used in connection with any research or experimentation program or project. These materials must be available for inspection by the parents or guardians of the children engaged in such research.
- Research or experimentation program or project means any program or project in any research that is designed to explore or develop new or unproven teaching methods or techniques.
- Children are persons enrolled in research not above the elementary or secondary education level, who have not reached the age or majority as determined under state law.

10. Are the definitions of “guardian” the same in every state?

No. When research studies are conducted outside the State of Alabama and when such studies contemplate the enrollment of participants who may have guardians who may need to give consent to treatments or procedures involved in research or clinical investigations, the investigators and IRB should seek advice from the UA Office of Counsel on the correct manner to obtain legally effective informed consent for the applicable jurisdiction. The investigator shall ensure that all required consents are obtained before any research involving children as subjects begins.

11. Are the definitions of “Legally Authorized Representatives” the same in every state?

No. Some states name and prioritize the categories of persons who may serve, and these categories and priorities differ from state to state. Other states do not specify
categories of persons or may not prioritize them. Again, seek advice from the UA Office of Counsel if your research involves legally authorized representatives in other states.

12. What does Alabama law say about persons who may serve as Legally Authorized Representatives (LARs)?

Alabama law does not specify who has such authority. Therefore, UA has the discretion to make a reasonable designation of those persons it believes are appropriate for making such decisions. Use the following list, in order of descending priority: A legally appointed guardian, a health care proxy or person authorized to make medical decisions in conjunction with a durable power of attorney; a spouse; an adult child; a parent; next of kin; or a person or agency acting in loco parentis. Investigators should see GUIDANCE: Investigators and Legally Authorized Representatives for additional information.

13. May I use a raffle for a cash prize or other thing of value as a benefit to a subject for agreeing to participate in my study?

No, Alabama law provides that lotteries (i.e. the providing of a thing of value in exchange for a chance to win something of value) are a criminal offense. Therefore, a researcher who desires to make a monetary payment or provide another thing of value to a subject for participating in the research should choose an alternative to entry of the subjects’ names in a raffle or lottery for a prize.