

Research Involving Minors

In Arkansas , “minor” (children) refers to persons under 18 years old and not emancipated. Minors are a special group of research participants, classified as a “vulnerable population” and protected under the Common Rule 45 CFR 46 Subpart D and 21 CFR 50 Subpart D.

Depending on risk level, certain research protocols involving minors may require full board review.

For more information on NIH requirements for inclusion of children in research, see [NIH Inclusion of Children Policy Implementation](#).

Definitions

Assent: Agreement to participate in research by a person under 18 (in Arkansas) who cannot legally provide effective informed consent. *Note: Failure to object does not constitute assent.*

Emancipated Minors: Individuals in which the following persons under the legal age of 18, have the legal rights of adults due to special circumstances, including the right to consent to treatments or procedures involved in research:

1. Persons under the age of 18 on active duty in the military
2. Married persons under 18 years of age

Guardian: An individual authorized under applicable state or local law to consent on behalf of a child to general medical care. *Note: Grandparents or other family members who are not formally appointed as guardians or legal representatives by a court generally do not have the authority to provide consent on behalf of a child without consent by the child’s parents.*

Parent: A child’s biological or adoptive parent.

Permission: The agreement of a parent(s) or legal guardian to the participation of his/her child or ward in research. *Note: Parents/guardians may not give consent on behalf of a child, but rather “permission.”*

Procedures

1. For research protocols involving minors, the IRB must determine that the proposed research meets the special protections for minors specified by federal regulations and this policy, as well as general criteria for human subjects research.
2. One or both parents (or a guardian) must provide permission for a child to participate in research, unless these requirements are waived by the IRB. In most cases, children capable of assent must also express their willingness to participate. For research involving incarcerated and/or pregnant minors, the protocol must provide the necessary

protections for research involving prisoners and/or pregnant women, as well as the requirements for research involving minors.

3. If a minor reaches the legal age of consent while enrolled in research with parental/guardian permission, he/she must provide informed consent (unless waived) to continue participation.
4. In certain situations, children under 18 years of age may legally provide informed consent for some or all of the activities involved in research (e.g., to release information from educational records). In special situations, the IRB may determine that the assent of **some** or **all** minors is not required (e.g., children less than 2 years old). In such cases, the IRB will indicate which part of the population is not required to assent.

Permissible Research Categories

The IRB may approve three categories of research involving minors as described below. For all categories, the proposed research must satisfy UCA IRB requirements for parental/guardian permission and minor assent.

1. Research involving minimal risk
2. Research involving greater than minimal risk *with the prospect of direct benefit* if:
 - the risk is justified by the anticipated benefit to the child **AND**
 - the anticipated benefit to risk ratio is at least as favorable as available alternative approaches.
3. Research involving greater than minimal risk *without the prospect of direct benefit*, but likely to yield generalizable knowledge about the child's disorder or condition if:
 - the risk presents no more than a minor increase over minimal risk,
 - the research involves experiences that are reasonably equivalent to those in the minor's actual (or expected) medical, dental, psychological, social, or educational situations, **AND**
 - the research is likely to yield generalizable knowledge about the minor's disorder or condition that is of critical importance for the understanding or improvement of the disorder/condition.