

**University of Kentucky**  
**IRB Policy on Children in Research**

D22.0000

If you are proposing research involving individuals under the age of 18, read the requirements described below, mark the appropriate selection in the space provided on the General Information Sheet [[Form A](#)], and complete [Form W](#) and include it with your application.

Children are considered a vulnerable research population because their intellectual and emotional capacities are limited and they are legally incompetent to give valid consent. Special procedures and considerations are, therefore, required by the federal regulations for the review of research involving children. A copy of the federal regulations governing research involving children may be obtained from the Office of Research Integrity, 315 Kinkead Hall, 859-257-9428 and is included in the [IRB Resource Guide](#).

Whenever feasible, appropriate studies should be conducted on animals, adults and older children before young children are involved as research subjects.

The Institutional Review Board is required to consider the degree of risk inherent in the proposed research and the methods for obtaining the assent of the children as well as the permission of parents or guardians. The IRB's policy with respect to obtaining permission from the parents or guardians and assent from children is specified below:

1. Parental permission must be obtained if the research involves children under the age of 18 unless the individuals are legally emancipated or the IRB waives the requirement. A written form must be used to document parental permission. The permission process and form must include the elements of informed consent set forth in federal regulations and outlined in the informed consent template included in the IRB expedited and full review applications [Form C]. The parental permission form should be written from the perspective of a parent being informed about what their child is being asked to experience (i.e., "Your child is being asked...", "Your child will...").
2. Subjects 6 years of age or older should be involved in the decision to participate in a research project unless the requirement for assent is waived (see below for conditions of waiving assent).

The Investigator should at a minimum provide an explanation to the children about the proposed research procedures in language appropriate to the child's age, maturity and condition (i.e., assent script). See Form D in the [IRB Application](#) for instructions and a sample assent form containing appropriate elements.

3. Unless the requirement is waived by the IRB, documentation of assent is required for subjects aged 12-17. The child should be given an explanation, at a level appropriate to the child's age, maturity and condition, of the procedures to be used, their meaning to the child in terms of discomfort and inconvenience, and the general purpose of the research. In most cases, a written assent form should be used to document assent. A copy of the assent form must be submitted to the IRB for review. The form should include a simplified version of the elements of informed consent (see Form D in the [IRB Application](#) for instructions and a sample assent form containing appropriate elements).
4. For clinical research, individuals under the age of 18 may possibly be considered emancipated in accord with state law. For a complete definition of emancipated minors, see the section on *Emancipated Individuals* in the Informed Consent SOP. Legal counsel makes a determination whether subjects in a study meet state requirements for being legally emancipated. Investigators should contact Katherine Adams in Legal Counsel at 859-257-2936 or [kadams@uky.edu](mailto:kadams@uky.edu) before submitting the IRB application to the IRB.

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The IRB may waive its requirements for obtaining or documenting assent if the IRB determines:

1. Capability of the child is limited such that (s)he cannot be reasonably consulted;
2. The children are not capable of providing assent based on the age, maturity or psychological state); or
3. The research intervention or procedure(s) involved hold out a prospect of direct benefit that is important to the health or well-being of the children, and is available only in the context of the investigation; or
4. a) the research involves no more than minimal risk to the participants; and  
b) the waiver will not adversely affect the rights and welfare of the participants; and  
c) the research could not practicably be carried out if assent was required; and  
d) when appropriate, pertinent information is provided after participation.

If the IRB determines any of the above criteria are met and waive the requirement for obtaining assent, the IRB determines and documents which children are not required to assent.

The IRB policy for waiving parental/guardian permission is summarized below.

1. The IRB may waive the requirements for parental/guardian permission in non-FDA regulated studies if the conditions outlined in 45 CFR Subpart D 45.408(c) or 45 CFR 46.116(c)(d) are met. (See ORI/IRB Informed Consent SOP)
2. IRB cannot waive parental/guardian permission for FDA regulated studies.
3. The IRB may determine that permission of one parent is sufficient if the research is not greater than minimal risk or greater than minimal risk but presents the prospect of direct benefit to individual subjects. For all other risk categories of research, permission of both parents or guardians are required unless one parent is not reasonably available, deceased, unknown, legally incompetent, or when only one parent has legal responsibility for the care and custody of the child.

Federal regulations specify that the conditions for approval of research involving children vary in accord with four federally mandated categories of research based on degree of risk. Also, federal regulations have additional requirements for studies that involve children who are wards of state. The IRB applies the federal regulations when conducting review of studies involving children. The investigator addresses the federal requirements by completing Form W in the IRB expedited and full applications. The ORI maintains Protocol Specific Training materials that summarize the federal requirements. They are included in the IRB Survival Handbook and on the ORI website.

### Exemptions

The IRB may determine that some research involving children can be exempt from the federal policy for the Protection of Human Subjects. Research that involves children and falls into categories under [45 CFR §46.101\(b\)\(1\)](#) and (b)(3) through (b)(6) may be found to be exempt. However, the exemption category under [45 CFR §46.101\(b\)\(2\)](#), pertaining to survey or interview procedures or observations of public behavior, does not apply to research involving children, except for research involving public behavior when the Investigator does not participate in the activities being observed.

### State Law

State and local law must be followed when they provide additional protections beyond those provided by federal regulations. For assistance with applying state law to research involving children, contact the University of Kentucky's legal counsel at (859) 257-2936.

For research conducted outside the state of Kentucky, the Principal Investigator (PI) is responsible for identifying the applicable state law(s) to determine which individuals are "children" or "guardians" (the PI should contact legal counsel if unable to identify applicable state law(s)). The PI provides the information to UK legal counsel for review and determination prior to approval by the IRB

Definitions for "child/children", "legally authorized representative", "emancipated", "guardian", "assent", and "permission" are included in the IRB/ORI Informed Consent Standard Operating Procedure (SOP) which is available on the ORI [website \[www.research.uky.edu/ori/human/SOPs\\_&Policies.htm#3\]](http://www.research.uky.edu/ori/human/SOPs_&Policies.htm#3).