

## **Research with Children**

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. Whenever feasible, appropriate studies should be conducted on animals, adults and older children before young children are involved as research participants. In reviewing protocols, the IRB will consider the degree of risk inherent in the proposed research and the methods for obtaining the assent of the children and the permission of parents or legal guardians.

Investigators, when developing protocols, must ensure the informed consent process is clear that there is no prospect of benefit to the individual participant, and that the assent and permission are voluntary and uncoerced with no implication of obligation.

### **Who is a child according to federal regulations?**

"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 (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#subpartd>). In most cases, these are individuals under the age of 18 years. However, there are state regulations that identify age of consent. Please check to make sure you are compliant with your local regulations.

### **Obtaining consent and assent for participation**

In almost all cases, written consent from a parent or legal guardian must be obtained if the research involves children under the age of 18. In cases where child abuse is an issue, the requirement for parental consent can be waived.

Documentation of assent is required for participants between the ages 7 and 18 years of age unless the participant is incapable, either mentally or emotionally, of being reasonably consulted about participating. The assent form, submitted to the IRB for review, should include a simplified version of the elements of informed consent, such as an explanation, at a level appropriate to the child's age, maturity and condition, of the procedure(s) to be used, their meaning to the child in terms of discomfort and inconvenience, and the general purpose of the research.

(NOTE: Participants under the age of 18 will need to complete an Assent form; a separate parental consent form is required for these participants providing parental permission to participate)

### **Exempt research with minor children (under age of 18)**

Research with children is eligible for exemption from IRB review involving these situations: 1) normal educational practices in commonly accepted educational institutions, 2) educational testing, and 3) observation in public settings. These activities fall under exemption categories (1) and (2), with the following provisions:

46.101(b)(1): Research conducted in established or commonly accepted educational settings, involving normal educational practices; such as (i) research on regular and special education instructional strategies, (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods. All data collected must be compiled as "groups of students" with no possible way to identify individuals, or compromise privacy or confidentiality.

46.101(b)(2): Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) also applies to children. Information must be obtained and recorded in such a way, that subjects cannot be identified.

Research and procedure involving surveys (such as longitudinal studies), interview procedures (of ethnographic nature) or observations of public behavior where the investigators participate in the activities being observed does NOT meet exemption classification. In these cases, investigators are involved in an intervention and/or interaction where privacy may be compromised.

**Research Compliance Office**  
<http://ors.umkc.edu/research-compliance>

**Waiver of Parental/Guardian Permission**

By regulatory definition, "children" are persons who have not attained the legal age for consent to treatments, procedures, or other activities involved in research. Since children are considered a vulnerable population, the IRB imposes additional protections on research involving children, in accordance with the 45 CFR Part 46, Subpart D. This includes the investigator obtaining permission of parent(s) or guardian(s) through the consent process and assent of the child, and the IRB being able to make certain findings based on the level of risk and benefit of the research. Consent from a parent or guardian must always be an affirmative agreement to participate or to give permission for one's child to participate in research.

The IRB may waive parental or guardian permission if:

- the regular conditions for waiver of consent are met (see [45 CFR 46.116\(c\)](#) or [46.117\(d\)](#)); or
- the study focuses on a condition for which parental or guardian permission is not a reasonable requirement to protect the children and an appropriate mechanism is substituted, e.g. is of such private and sensitive nature that it is not reasonable to require permission, (for example, adolescents in studies concerning treatment of sexually transmitted disease); or
- a subject population for which parental or guardian permission is not a reasonable requirement to protect the children and an appropriate mechanism is substituted, e.g. is such that parental permission is not a reasonable requirement to protect the participants, (for example abused or neglected children). ([45 CFR 46.408](#))

**Research that does not pose greater the minimal risk**

A waiver of the requirement for parental or guardian permission may be requested by the researcher in studies that do not pose greater than minimal risks to the subjects. In such research, prior parental notification could then be used as one mechanism for meeting the requirement in 46.408(c) that an "appropriate mechanism for protecting the children who participate as subjects in research is substituted." Researchers will be required to provide a detailed plan for fully informing parents/guardians about the potential study and document that the research meets the criteria found in 46.116(d). A letter or packet of information sent home to parents or guardians with information about the study (for example, with students as part of regular school mailings) would satisfy parental notification. The IRB may accept an alternative mechanism to protect the child participants (i.e., appoint a qualified child advocate). In accordance with the federal regulations, the IRB requires that the investigator obtain the assent of the children, if the children are capable of providing assent, and it is not waived. The IRB also needs to know how the affirmative assent of the child will be documented, e.g., signature on assent forms, documented by the investigator, or other.

In certain situations, studies that may have a risk/benefit ratio where the benefit is high and will make a positive impact on the life and welfare of the children population involved. In these cases, researchers may be interacting with subject groups where parents or guardians have a lower response rate and do not send in consent forms, even after repeated attempts. In other extreme cases, a parent or guardian may not have the capability or knowledge to decide what is in a child's best interests.

**Classroom or school based research**

Research is ordinarily NOT suitable for a waiver of permission if it involves any of the following issues:

- Parental political affiliations or beliefs
- Mental or psychological problems
- Sexual behavior or attitudes
- Illegal, antisocial, or self-incriminating behavior
- Appraisals of other individuals with whom the minor has a familial relationship
- Relationships legally recognized as privileged (lawyers, doctors, clergy), or
- Religious affiliations or beliefs.

**More than minimal risk research**

In situations where the protocol involves more than minimal risk, parental consent alone may NOT be sufficient. One cannot obtain a waiver of parental consent for research that involves more than minimal risk unless the research involves issues of child abuse or neglect or other situations where obtaining parental permission might increase the risks to the child participants. In such cases parental consent may be waived. However, the investigator must supply an appropriate mechanism and justification for obtaining consent from someone serving as an advocate for the child.