Definition

Children are persons who have not attained the legal age (18) for consent to treatments or procedures involved in the research, under applicable law of the jurisdiction in which the research will be conducted. The secretary of the DHHS has set 18 as the age of adulthood in the absence of other guidelines.

Informed Consent

The general requirements for obtaining informed consent, the elements to be included, and the provisions for waivers all apply to research involving children as subjects. The regulations require that the assent of the child be solicited when, in the judgment of the IRB, they are capable of providing assent. The process of obtaining informed consent for children is complicated by the issues of the child’s age, ability to understand, and the relationship with the parents or guardians. When evaluating consent procedures for children the following guidelines are generally applied:

Parental Consent

For research involving children under 18 years of age, investigators must obtain written consent from at least one parent or guardian for participation of the child in the project. If the project involves more than minimal risk, as described below, signatures of both parents or guardians will be required.

Child’s Assent

Children are legally unable to give consent either orally or in written form to participate in a research activity. From about middle school onward, children can comprehend a properly written form requesting their consent. Therefore, a written assent from the child (in addition to a required written parental/guardian consent) may become appropriate. While written assent is not legally binding, it does provide an optional documentation of the subject’s being “informed” of the research activity.

The assent explanation should be worded to match the reading comprehension level of the children. Elementary school age children should provide oral assent to participate. The explanations to the children should match the level of comprehension of the children being solicited for research participation. A script copy of the explanation to be given should be provided to the IRB.
Some of the criteria defining exempt research change when children are the subjects of research. The following research is categorized as exempt:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices such as
   (a) research on regular and special education instruction strategies; or
   (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) if information taken from those sources is recorded in such a manner that subjects cannot be identified (directly or through identifiers linked to the subjects).

3. Research involving the observation of public behavior so long as the investigator does not participate in the activities being observed. Observations must be recorded in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subject. Moreover, the observations recorded about the individual, if they became known outside the research, should not place the subjects at risk of criminal or civil liability or be damaging to the subject’s financial standing or employability. Finally, the research should not deal with sensitive aspects of the subject’s own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified (directly or through identifiers linked to the subjects).

Although categorized as exempt for adults, surveys and interviews with children must be reviewed by IRB members and are categorized for either expedited or full board review.
Research Categories Involving Children

The regulations define four categories of research involving children. Each category addresses a different order of risk and benefit for the child. As such, each category also has special review criteria. These criteria are in addition to the review criteria applied by the IRB to adult projects.

1. Minimal Risk: Minimal risk means that the risks of harm anticipated in the proposed research are no greater than those ordinarily encountered in daily life or during the performance of routine physical psychological examinations or tests. If the proposed research involves only minimal risk, then it may be approved if the project makes adequate provisions for soliciting assent of the children and permission of their parents or guardians.

2. Greater than Minimal Risk with Direct Benefits: The IRB may approve a project in which the procedure or intervention offer the child subject greater than minimal risk if there is the prospect of direct benefit to the child, and if it meets the following criteria.

   (a) The risk must be justified by the anticipated benefits to the subject;

   (b) The relationship of the anticipated benefit to the risk is at least as favorable as that presented by available alternative approaches; and

   (c) The project makes adequate provision to solicit the child’s assent and permission of parents or guardians.

3. Greater than Minimal Risk with No Direct Benefit: If a project offers the child subject greater than minimal risk without prospect of direct benefit from the intervention or procedure, then the IRB may approve it only if it meets the following criteria:

   (a) The risk represents only a minor increase over minimal risk;

   (b) The intervention or procedure presents experiences to the child subject that are reasonably commensurate with those inherent in actual medical, dental, psychological, social, or educational situations;

   (c) The intervention or procedure is likely to yield generalizable knowledge about the subject’s disorder or condition, information which is of vital importance for understanding or ameliorating the subject’s disorder or condition; and

   (d) The project makes adequate provision to solicit the children’s assent and permission of the parents or guardians.
4. Research Not Otherwise Appropriate: Research that the IRB cannot approve under one of the above categories may be permitted if it meets stringent criteria. This category of research is extremely rare. If you feel that your research project does not meet any of the above categories, please contact the IRB office for guidance.