

Requirements for Assent and Parental Permission

When children are involved in research, the protocol generally must require the permission of the parent(s) and the assent of the child, if the IRB determines that the proposed child subject pool may be capable of providing assent. Factors that the IRB considers in determining whether all or some of the children may be capable of assenting to participation in a study include: (i) the nature of the research, (ii) the children's age, status, and condition (*e.g.* whether the children can comprehend and appreciate what it means to be a volunteer for the benefit of others), (iii) the children's experience and knowledge of clinical treatment (such as being a patient or being treated for illnesses of varying degrees of severity), and (iv) the maturity and psychological state of the proposed subjects.

When the IRB determines that assent is required, it also determines that the provisions for obtaining and documenting assent are adequate. The child should be given an explanation of the proposed research procedures, the purpose of the research, and any discomforts, in a language that is appropriate to the child's age, experience, maturity, and condition. Children should be asked if they wish to participate in the research, particularly if the research is not likely to be of any benefit to the children as subjects. A particular child subject's capacity to assent must be evaluated on an individual basis by a knowledgeable professional. If appropriate, the IRB may require that either an IRB member or an advocate for the child be present during the assent in order to verify the child's understanding and may require that a parent or close family member be present during the research.

The IRB may exercise its discretion to permit research without the assent of a child who is capable of assenting only if the investigator provides a satisfactory explanation of why the child subject's assent will not be obtained and the research offers the child the possibility of a direct benefit which is available only in the context of the research.

The signature of one parent is sufficient when the research is in categories 1 or 2 identified above. The signature of both parents is required if both parents are available and the research is in categories 3 or 4 identified above. This requirement may be waived if one parent is deceased, unknown, incompetent, or when one parent has sole legal responsibility for the care and custody of the child. In some cases, the IRB may determine that the requirement for parental consent is inappropriate. Examples may include research involving older adolescents and treatment for which they may, under applicable law, consent on their own behalf (*e.g.* treatment for sexually transmitted diseases or drug abuse). In other research (*e.g.* research on child abuse or neglect), there may be serious doubt as to whether the parents' interests adequately reflect the child's interests. In such types of research the children who are the research subjects should be given the full opportunity for informed consent as if they are adults, or the Principal Investigator should propose alternative procedures for protecting the rights and interests of children asked to participate.