

Pediatric Assent

Because children cannot legally give consent, federal regulations require the permission of their parents and, with the exception of very young children in some treatment protocols, the assent (affirmation agreement) of the child-subject.

Assent has generally been divided into three categories depending upon the age of the child-subject. The commonly accepted rule of thumb is that children under the age of 7 are too young to assent; those children between 7 to 12 should be capable of assenting; and children over the age of 12 should be able to participate fully in the consent process (i.e., giving assent and documenting that decision in writing). Parents or guardians, however, may provide permission for their child to participate in a research study. For research with very young children (preschool and under), only the parent's permission is typically needed.

For teenagers, a single form that both the minor and the parent(s) sign may be adequate. For children in between (7-12), two forms are generally advisable; one consent that is written at a basic level for the child (as a script for oral presentation or for reading), and a more detailed form for the parent's understanding and signature. Furthermore, to the extent that they are able, children should be asked about their willingness to participate. Information about the research study must be presented to children at their developmental level, so they can understand what is being asked of them. The combination of assent (agreement) of the minor subject and permission of the parent or legal guardian is recognized by the federal regulations as an adequate substitute for consent.