

Obtaining and Documenting Assent from Children

Parental consent is usually a prerequisite to the recruitment of human research participants who are children. However, parental consent constitutes only half of the consent process. Assent, the agreement of a child to participate in research, is the second component of the informed consent procedure for children.

The means of obtaining assent from children must be appropriate for the age ranges and levels of mental development found within the proposed participant pool. The National Commission for the Protection of Human Subjects of Biomedical and Social Science Research expects that assent be requested from children who are 6 years of age or older. However, for children between the ages of 6 and 18, the appropriate method for obtaining assent will vary. The following guidelines were proposed during a panel discussion sponsored by the National Institutes of Health:

Age 6-7

A simple oral description of the child's involvement is given to the participant and verbal assent is requested. The procedure may be documented on the informed consent form by the presence of the signature of a witness.

Age 8-13

A more complete oral description of the research (in layman's terminology) is given to the participant. Verbal assent is requested. The procedure may be documented on the informed consent form by the signature of a witness.

Above age 13

flexibility in the methods for obtaining assent from children is universally recognized. Because a single method of obtaining assent may not be appropriate for all potential participants, investigators may need to be prepared to use different approaches with different participants. As in any consent process, the primary concern is that the participant is able to understand the explanation that is presented. The need for a witness to document verbal assent procedures is dependent upon the complexity of the research and the risks to the participant.