

	CHILD ASSENT			
	P & P	VERSION DATE	REPLACES P & P	PREVIOUS VERSION DATE
	6.02	02.07.2020	5.9	03.25.2019

Assent is a child’s affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. In any research project in which children are subjects, adequate provisions for soliciting assent must be described in the IRB application and included in the consent form. Following an explanation of the study in language appropriate for the age group, assent should be obtained unless it is determined by the investigator that the child is not capable of providing assent. In most circumstances, written assent (unless documentation is waived by the IRB) should be obtained from any child seven years of age or older. However, in making this determination, the child’s age, maturity, and psychological state must be taken into consideration. For children from the ages of 7 to 13 years of age, a separate assent form should be developed using language appropriate for this age-group. For children from 14 to 17 years of age an assent line may be used on the informed consent document of the study. If assent is not obtained as required by the IRB, then the reasons for not obtaining assent must be fully documented. This documentation must be particularly thorough in the case of research that is non-therapeutic in nature and/or does not hold out the prospect of direct benefit to the child.

The IRB may determine that as a group the children asked to participate in a research project are incapable of providing assent, and this requirement may be waived by the IRB. If the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children, and is available only in the context of the research, the IRB may determine that the assent of the children is not a necessary condition for proceeding with the research.