

**Children’s Hospital Institutional Review Board
Information Sheet
Assent and Parental Permission - Table**

The table outlines the requirements for assent and parental permission based on the category of research with children as defined in the federal regulations.

CATEGORY OF RESEARCH	ASSENT FROM THE CHILD	PARENTAL PERMISSION
<p>§46.404 Research Not Involving Greater Than Minimal Risk. <u>Examples</u></p> <ul style="list-style-type: none"> • Additional blood is taken for research at the time of a clinically indicated blood draw. • Questions of a non-sensitive nature are asked, e.g., activities of daily living. 	<p>Assent must be obtained unless the child is incapable of providing assent, or the research intervention holds out the prospect of clear benefit that is available only in the context of the research.</p>	<p>Permission from one parent is sufficient.</p>
<p>§46.405 Research Involving Greater Than Minimal Risk, But the Prospect of Direct Benefit to Individual Subjects Is Present. <u>Examples</u></p> <ul style="list-style-type: none"> • Use of an investigational device that holds promise. • All patients receive active treatment in a treatment study. 	<p>Assent is not required if the intervention is available only in the context of the research. The IRB will request that written assent be obtained from adolescents 14 and older unless the adolescent is incapable of providing assent because of their condition.</p>	<p>Permission from one parent is sufficient.</p>
<p>§46.406 Research Involving Greater Than Minimal Risk and No Prospect of Direct Benefit to Individual Subjects, But Likely to Yield Generalizable Knowledge About the Subject's Disorder or Condition. <u>Examples</u></p> <ul style="list-style-type: none"> • A Phase I investigational new drug study. • A study using invasive placebo controls. 	<p>Assent is required.</p>	<p>Permission from both parents is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or the child has a guardian, or belongs to a single-parent family where only one person has legal responsibility for the care, custody and financial support of the child.</p>

Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life, or during the performance of routine physical or psychological examinations or tests. The definition is indexed to healthy children.

Benefit: A valued or desired outcome; an advantage.