



ST. JOHN HOSPITAL & MEDICAL CENTER

Regulatory Requirements for Pediatric Research Pediatric Risk Checklist

Minimal Risk: A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological tests.

Special risk/benefit determinations need to be discussed and documented by the IRB:

Level of Risk	Risk of Harm Category	Requirements for Children's Participation
Level 1:	No greater than minimal risk, with or without a potential for direct benefit to the child.	<ul style="list-style-type: none">• Adequate provisions need to be made for obtaining assent of children.• Permission (informed consent) of one parent.
Level 2	Greater than minimal risk with prospects of direct benefit for each subject.	<ul style="list-style-type: none">• Adequate provisions need to be made for obtaining assent of children.• Permission (informed consent) of one parent.
Level 3	Greater than minimal risk with no prospect of direct benefit to the child, but likely to yield generalizable knowledge about the child's disorder or condition	<ul style="list-style-type: none">• Adequate provisions need to be made for obtaining assent of children.• Permission (informed consent) of both parents.