

Children's Hospital Institutional Review Board

Information Sheet

Regulations for Research with Children

When conducting research with children it is important to keep in mind that the federal regulations that protect human research participants include additional protections for children. Research with children is divided into four categories, based on level of risk and prospect of benefit posed by the research. The four categories are:

1. **Research not involving greater than minimal risk**
Minimal risk means that 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.
2. **Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects**
For this category the IRB must determine that:
 - The risk is justified by the anticipated benefit to the child.
 - The benefit anticipated is at least as favorable as that available through alternative approaches.
3. **Research involving greater than minimal risk and no prospect of direct benefit to the individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition**
For this category the IRB must determine that:
 - Risks represent a minor increase over minimal risk.
 - The intervention presents experiences that are reasonably commensurate with those inherent in the child's actual or expected medical, dental, psychological, social or educational situations.
 - Intervention is likely to yield generalizable knowledge about the child's disorder or condition, which is of vital importance for the understanding or amelioration of the disorder or condition.

For all research the IRB must determine that adequate provisions have been made to obtain the assent of the child participant and the permission of the parent or guardian.

4. **Research not otherwise approvable which presents an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of children**
The research may not be approved by the local IRB. It is referred to the Secretary of the Department of Health and Human Services (DHHS) for review by a panel of experts with the opportunity for public review and comment.