

INSTITUTIONAL REVIEW BOARD GUIDELINES FOR
CATEGORIES OF RESEARCH INVOLVING MINORS AND PROTECTIONS AS
REQUIRED BY THE 45 CFR 46

Category of Research	Additional Protections
A. Research not involving more than minimal risk (45 CFR 46.404)	If appropriate, assure adequate provisions are made for soliciting assent of children and permission of parents or guardians.
B. Research involving grater than minimal risk but presenting the prospect of direct benefit to individual child participants (45 CFR 46.405)	IRB must determine that: <ul style="list-style-type: none"> • The research risk is justified by the anticipated benefits to participants; • The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches, and; • Adequate provisions are made for soliciting the assent of children and permission of their parents or guardians.
C. Research involving grater than minimal risk and no prospect of direct benefit to individual participants but likely to yield generalizable knowledge about the participant's disorder or condition (45 CFR 46.406)	An IRB may approve the research only if it finds: <ul style="list-style-type: none"> • The risk represents a minor increase over minimal risk; • The research presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected dental, psychological, medical, social or educational situation; • The research is likely to yield generalizable knowledge about the participant's disorder or condition that is of vital importance for understanding or ameliorating it, and; • Adequate provisions are made for soliciting the assent of children and permission of their parents or guardians.
D. Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children (45 CFR 46.407)	An IRB must find that: <ul style="list-style-type: none"> • The research presents a reasonable opportunity to further understanding, prevention or alleviation of a serious problem affecting the health or welfare of children, and; • The DHHS Secretary will convene a panel of experts in pertinent disciplines to review the research.