When do You Need Parental Permission for Research with Children?

An Institutional Review Board (IRB) may waive the requirements for obtaining parental or guardian permission if it makes and documents the findings under either 45 CFR 46.116(c) or (d). However, the FDA does not allow the waiver for parental permission for research involving an FDA-regulated product.

1 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 and during the performance of routine physical and psychological examinations or tests.

2 Must be reviewed by the Secretary

3 The IRB may waive the requirement for informed consent if,
   A) The research involves minimal risk to subjects,
   B) The waiver or alteration will not adversely affect the rights and welfare of subjects;
   - AND -
   C) The research could not practically be carried out without the waiver or alteration, and whenever appropriate, the subjects will be provided with additional pertinent information after participation.