# Determination of Minimal Risk for Child Research

**Section 404 of the regulations allows the IRB to approve research if the IRB finds that the risks of the research are no more than minimal.**

Three of the four categories of human research involving children may be approved by an Institutional Review Board (IRB). The four categories differ from one another according to the level of risk involved, the prospect of direct benefit to the research subjects, and the anticipated research findings. For all four categories, the proposed research activity must satisfy the requirements for parental or guardian permission and child assent. Depending on the category, additional conditions must be met in order for the IRB to approve the research activities.

The three categories **approvable by an IRB** are:

a. Section 404 of the regulations allows the IRB to approve research if the IRB finds that the risks of the research are no more than **minimal**. The regulations rely on the definition of "**minimal risk**" provided in Subpart A of the regulations, as follows:

   - **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 (45 CFR 46.102(i))

---

b. Section 405 of the regulations allows the IRB to approve research if the IRB finds that:
   - more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject or by a monitoring procedure that is likely to contribute to the subject's well-being;
   - the risk is justified by the anticipated benefit to the subjects; and,
   - the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.

c. Section 406 allows the IRB to approve research if the IRB finds that:
   - more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is not likely to contribute to the well being of the child;
   - the risk represents a minor increase over minimal risk;
   - the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations; and,

- the intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition.

d. The fourth category of approvable research involving children is identified in Section 407, and requires the IRB to make certain findings and refer the proposed research activity to the Secretary of HHS for further review and approval.