



**45 CFR 46.404 and 21 CFR 50.51**

**Research not involving greater than minimal risk.**

...the IRB find that no greater than minimal risk to children is presented...the IRB finds that adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians as set forth in §46.408 or §50.55.

**45 CFR 46.405 and 21 CFR 50.52**

**Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.**

...the IRB find that more than minimal risk to children is presented by an intervention or procedure that that holds out the prospect of direct benefit for the individual subject, or by monitoring procedure that is likely to contribute to the well-being of the subject...the IRB finds that:

- (a) The risk is justified by the anticipated benefit to the subjects;
- (b) The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; *and*
- (c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in §46.408 or §50.55.

**45 CFR 46.406 and 21 CFR 50.53**

**Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subjects' disorder or condition.**

...the IRB find 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...the IRB finds:

- (a) The risk represents a minor increase over minimal risk;
- (b) 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;
- (c) 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; *and*
- (d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in §46.408 or §50.55.

**45 CFR 46.407 and 21 CFR 50.54**

**Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.**

...the IRB does not believe [the research] meets the requirements of 46.404, 46.405 or 46.406...

- (a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
- (b) The Secretary, after consultation with a panel of experts...and following opportunity for public review and comment has determined either:
  - the research will be conducted in accordance with sound ethical principles;
  - (1) The research...satisfies §46.404, §46.505, §46.406 or §50.51, §50.52 or §50.53 or;
  - (2) The following:
    - (i) The research presents a reasonable opportunity to further understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
    - (ii) The research will be conducted in accordance with sound ethical principles;
    - (iii) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in §46.408 or §50.55.