Office of the Secretary, Education

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

ED conducts or funds research that the IRB does not believe meets the requirements of §97.404, §97.405, or §97.406 only if—

(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; and

(b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either that—

(1) The research in fact satisfies the conditions of §97.404, §97.405, or §97.406, as applicable; or

(2)(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children; and

(ii) The research will be conducted in accordance with sound ethical principles; and

(iii) Adequate provisions are made for soliciting the assent of children and