

§ 97.402

(c) The exceptions, additions, and provisions for waiver as they appear in § 97.101(c) through (i) are applicable to this subpart.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e-3, 3474; and 42 U.S.C. 300v-1(b)).

§ 97.402 Definitions.

The definitions in § 97.102 apply to this subpart. In addition, the following definitions also apply to this subpart:

(a) *Children* are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

(b) *Assent* means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

(c) *Permission* means the agreement of parent(s) or guardian to the participation of their child or ward in research.

(d) *Parent* means a child's biological or adoptive parent.

(e) *Guardian* means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e-3, 3474; and 42 U.S.C. 300v-1(b)).

§ 97.403 IRB duties.

In addition to other responsibilities assigned to IRBs under this part, each IRB shall review research covered by this subpart and approve only research that satisfies the conditions of all applicable sections of this subpart.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e-3, 3474; and 42 U.S.C. 300v-1(b)).

§ 97.404 Research not involving greater than minimal risk.

ED conducts or funds research in which the IRB finds that no greater than minimal risk to children is presented, only if 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 § 97.408.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e-3, 3474; and 42 U.S.C. 300v-1(b)).

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

ED conducts or funds research in which 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, only if 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 § 97.408.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e-3, 3474; and 42 U.S.C. 300v-1(b)).

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

ED conducts or funds research in which 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 which is not likely to contribute to the well-being of the subject, only if the IRB finds that—

(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 that 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 § 97.408.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e-3, 3474; and 42 U.S.C. 300v-1(b))

§ 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;

(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 the permission of their parents or guardians, as set forth in § 97.408.

(Authority: 5 U.S.C. 301; 20 U.S.C. 1221e-3, 3474; and 42 U.S.C. 300v-1(b))

§ 97.408 Requirements for permission by parents or guardians and for assent by children.

(a) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine that adequate provisions are made for soliciting the assent of the children, if in the judgment of the IRB the children are capable of providing assent. In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the

children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the children and is available only in the context of the research, the assent of the children is not a necessary condition for proceeding with the research. Even if the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement under circumstances in which consent may be waived in accord with § 97.116.

(b) In addition to the determinations required under other applicable sections of this subpart, the IRB shall determine, in accordance with and to the extent that consent is required by § 97.116, that adequate provisions are made for soliciting the permission of each child's parent(s) or guardian(s). If parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under § 97.404 or § 97.405. If research is covered by §§ 97.406 and 97.407 and permission is to be obtained from parents, both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or if only one parent has legal responsibility for the care and custody of the child.

(c) In addition to the provisions for waiver contained in § 97.116, if the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), it may waive the consent requirements in subpart A of this part and paragraph (b) of this section, provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State, or local law. The choice of an appropriate mechanism depends upon the nature