



<b>Policy Name: Research Involving Children</b>			
Approved			Date: 11/01/08
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## I. POLICY

- A.** The IRB will consider the potential benefits, risks, and discomforts of research involving children within the context of the justification for inclusion of children in the research. For example, why are those children specified by the inclusion/exclusion criteria being enrolled in the research? Will this defined population directly benefit from the research? Would the risks be better managed by refining the exclusion criteria? The IRB will consider the circumstances of the children to be enrolled in a study, e.g. their health status, age, and ability to understand their involvement, as well as potential benefit to the subjects, other children with the same disease/condition, or society as a whole. (OHRP Guidance, 2005).
- B.** The IRB will decide which of four risk categories defined by federal regulations [45CFR 46(d) and 21CFR 50.51-50.54] apply to any study enrolling children other than exempt research.
- C.** Minimally, an adult parent with legal custody of a child or an adult awarded legal custody of a child must give informed consent for a child to be enrolled in research. A child 12 years of age or older must give documented “assent” to be enrolled in research. The assent will be documented on the informed consent document. An “emancipated minor” must provide documentation of his/her financial independence such as a rental lease or bank account in his/her name before consenting as an adult to participate in research [45 CFR 46 Subpart D Additional DHHS Protections for Children Involved as Subjects in Research]
- D.** The IRB may decide that both parents must give informed consent for a child to be enrolled in research. The IRB will require that both parents must give informed consent for a child to enroll in research if the research is assessed by the IRB to be category 3 or category 4 unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal custody of a child [45CFR 46.408(c)]. The regulations make two parents the default and one is appropriate if the IRB determines it is so and the research falls into the first two “categories”.
- E.** Under certain circumstances, to protect the welfare of the minor, the convened IRB board may chose to waive parental consent. An example would be a study involving child abuse in which parental consent would be

ill-advised. In circumstances where parental consent is waived, a child subject advocate must be assigned to protect the children who would participate as participants in the research.

## II. DEFINITIONS

Definitions for the following terms used in this section may be found in HRPP Guide Section 1.3 Definitions Terms:

### A. Children

## III. CHILDRENS RESEARCH CATEGORIES

- A. **Category I [45 CFR 46.404 and 21 CFR 50.51] = research not involving greater than minimal risk to the children.** To approve this category, the IRB must make the following determinations: 1) the research presents no more than minimal risk to the children; and 2) adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.
- B. **Category II [CFR 46.405 and 21 CFR 50.52] = research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child subjects involved in the research.** To approve this category, the IRB must make the following determinations: 1) the risk is justified by the anticipated benefits to the subjects; 2) the relation of the anticipated benefit to the risk presented by the study is at least as favorable to the subjects as that provided by available alternative approaches; and 3) adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.
- C. **Category III [45 CFR 46.406 and 21 CFR 50.53] = research involving greater than minimal risk and no prospect of direct benefit to the individual child subjects involved in the research, but likely to yield generalizable knowledge about the subject's disorder or condition.** To approve this category, the IRB must make the following determinations: 1) risk of the research presents a minor increase over minimal risk; 2) the intervention or procedure presents experiences to the child subjects that are reasonable commensurate with those inherent in their actual, or expected medical, dental, psychological, social, or educational situations; 3) the intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding or amelioration of the disorder or condition; and 4) adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians.
- D. **Category IV [45 CFR 46.407 and 21 CFR 50.54] = research that the IRB believes does not meet the conditions of the other categories**

**but 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.** This category of research requires a federal level of review by the Secretary, Health and Human Services, or designee and the Commissioner of FDA who will request the review by a panel of experts in pertinent disciplines and call for public review and comment.

#### **IV. PROCEDURES**

- A.** The “Special Subject Populations –Children” checklist will be used as a guide for IRB evaluation and will be completed by the primary reviewer.
- B.** During the initial review of a protocol involving children, the IRB assigned primary reviewers will designate the appropriate risk category as defined above and give a brief rationale for the category selected.
- C.** The Board will determine the appropriate research category as part of the motion relative to approval of a protocol involving children; the rationale for this categorization will be documented in the Board meeting minutes.
- D.** If the research is determined to fit category I or II, the IRB will decide if the consent of one parent is adequate or if the consent of both parents is required. This decision will be documented in the IRB meeting minutes.
- E.** If the research is determined to fit category III or IV, the documented consent of both parents will be required unless the Board stipulates documented consent from one parent is acceptable; the rationale for this decision will be documented in the IRB meeting minutes

#### **V. REFERENCES**

- A.** [Special Subject Populations Checklist – Children](#)