

Michigan State University Human Research Protection Program	
<i>Subject: Special Categories of Research Subjects</i>	
<i>Sub-Topic: Children</i>	
<i>Section: 6-8-C</i>	<i>This policy and procedure supersedes those previously drafted.</i>
<i>Reviewed by: IRB, URC, UGC, MSU Legal Counsel</i>	<i>Approved by: Vice President of Research and Graduate Studies, 4-21-2005</i>
<i>Related Sections: 6-4-C</i>	

Policy

As a general rule, the Institutional Review Board (IRB) does not approve research involving children if the research and its objectives can be met by using adults. When the research can only be appropriately conducted using children, special consideration must be given to safeguarding their interests and to protecting them from harm. Special provisions of the federal regulations on human subject research govern research involving children (45 CFR 46 subpart D, 21 CFR 50 subpart D).

The vulnerability of children participating in research calls for special consideration, including consent procedures. See Section 6-4-C, "Parental Consent and Child Assent", of the HRP Manual for policies and procedures.

Definitions

The following definitions are pertinent to the special area of research with human subjects involving children.

Definitions

Child

DHHS: "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."(45 CFR 46.402(a))

FDA: "children means persons who have not attained the legal age for consent to treatments or procedures involved in clinical investigations, under the applicable law of the jurisdiction in which the clinical investigation will be conducted." (21 CFR 50.3(o))

In Michigan, a child is a person who:

1. has not yet reached the age of 18; and
2. has not been emancipated by court order; and
3. has not been emancipated by operation of law under any of the following circumstances:
 - a. marriage;

- b. active duty with the armed forces of the United States.

Michigan law states that an emancipated minor has the rights and responsibilities of an adult (with certain exceptions), including the right to authorize his or her own preventive healthcare. Although it is a reasonable inference, Michigan law does not explicitly state that emancipated minors may consent to participation in research. Thus, the IRB, with input from the MSU Office of the General Counsel, may choose not to approve research that relies solely on the consent of an emancipated minor.

Parent

DHHS & FDA: "Parent means a child's biological or adoptive parent." (45 CFR 46.402(d), 21 CFR 50.3(p))

Guardian

DHHS: "guardian means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care." (45 CFR 46.402(e))

FDA: "guardian means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care when general medical care includes participation in research. For purposes of subpart D of this part, a guardian also means an individual who is authorized to consent on behalf of a child to participate in research." (21 CFR 50.3(s))

In Michigan, a guardian is a person who:

1. has accepted a written parental appointment to be a guardian and there are no surviving, capacitated parents with parental rights; or
2. has accepted a court appointment to be a guardian.

For purposes of the DHHS regulations, a guardian does not include a limited guardian unless the limited guardianship expressly allows the guardian to consent to medical care.

For purposes of the FDA regulations, a guardian does not include a limited guardian unless the limited guardianship expressly permits the guardian to consent to participation in research

Emancipated - a legal status conferred upon persons who have reached the age of 18 or who have not yet attained the legal age of competence as defined by state law (for such purposes as consenting to medical care), but who are entitled to treatment as if they had, by virtue of assuming adult responsibilities, such as marriage or serving on active duty in the military, or by virtue of a court order.

Assent

DHHS: "Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent." (45 CFR 46.402(b))

FDA: "Assent means a child's affirmative agreement to participate in a clinical investigation. Mere failure to object may not, absent affirmative agreement, be construed as assent." (21 CFR 50.3(n))

Permission

DHHS: "Permission means the agreement of parent(s) or guardian to the participation of their child or ward in research" (45 CFR 46.402(c))

FDA: "Permission means the agreement of parent(s) or guardian to the participation of their child or ward in a clinical investigation. Permission must be obtained in compliance with subpart B of this part and must include the elements of informed consent described in § 50.25." (21 CFR 50.3(r))

Classification

Research involving children is classified into four categories of research:

1. **Research not involving greater than minimal risk (45 CFR 46.404).** Research of this nature requires adequate provisions for soliciting the assent of the children and the permission of their parent(s) or guardian(s).
2. **Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects (45 CFR 46.405).** Research of this nature is approvable by the IRB if: a) the risk is justified by the anticipated benefit to the subject; b) the relationship of risk to benefit is at least as favorable as any available alternative approach; and c) adequate provisions are made for soliciting the assent of the children and the permission of their parent(s) or guardian(s).
3. **Research involving greater than minimal risk that has no prospect of direct benefit to individual subjects, but is likely to yield generalizable knowledge about the subject's disorder or condition (45 CFR 46.406).** The IRB is able to approve research in this category provided: 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 experiences; c) 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 subject's disorder or condition; and d) that adequate provisions are made for soliciting assent of the children and the permission of their parent(s) or guardian(s).
4. **Research not otherwise approvable which presents an opportunity to understand, prevent or alleviate a serious problem affecting the health or welfare of children (45 CFR 46.407).** The IRB must find 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 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 1) that the research in fact satisfies the conditions of [§46.404](#), [§46.405](#), or [§46.406](#), as applicable, or (2) the following 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 iii) adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in [§46.408](#)