

Michigan State University Human Research Protection Program	
<i>Subject:</i> Informed Consent	
<i>Sub-Topic:</i> Parental Permission & Child Assent	
<i>Section:</i> 6-4-C	<i>This policy and procedure supersedes those previously drafted.</i>
<i>Reviewed by: IRB, URC, UGC, MSU Legal Counsel; Revision reviewed by HRPP Director, Sr. Asst. VP Regulatory Affairs, VPRGS.</i>	<i>Approved by: Vice President of Research and Graduate Studies, 4-21-2005; Revision approved by the Vice President of Research and Graduate Studies on 7-5-2006.</i>
<i>Related Sections:</i> 6-8-C, 8	

Policy

Federal regulation 45 CFR 46.408 and 21 CFR 50.55 require that when children are involved in research the assent of the child when practical and the permission of the parent(s) or guardian(s), be obtained. While children may legally be unable to give informed consent, they do possess the ability to assent to or dissent from participating in research. Consequently, when practical, children should be asked whether or not they want to participate in the proposed research, particularly if the research: a) does not involve interventions likely to be of benefit to the subjects; and b) the children can comprehend and appreciate what it means to be a volunteer for the benefit of others.

Permission by parents or guardians must be documented in accordance with the requirements of federal regulation 45 CFR 46.117 and/or 21 CFR 50.27. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient, if consistent with state law, for research to be conducted under the research categories 45 CFR 46.404, 45 CFR 46.405, 21 CFR 50.51, or 21 CFR 50.52. Where research is covered by 45 CFR 46.406, 45 CFR 46.407, 21 CFR 50.53 or 21 CFR 50.54 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 when only one parent has legal responsibility for the care and custody of the child (45 CFR 46.408(b), 21 CFR 50.55(e)). See "Children", Section 6-8-C of the HRP Manual for the categories of research that apply to children.

Except in highly unusual circumstances, such as when a child is too ill or young to give assent or possibly in the case of emancipated minors, the IRB expects that investigators will obtain the assent of children and the permission of their parent(s) or guardian(s) to participate in proposed research. When investigators propose to obtain assent verbally, a script of the assent language and content must be included with the investigator's IRB application.

For research subject to DHHS regulations, parental permission may be waived if the following conditions are met

- 1) "The research involves no more than minimal risk to the subjects;"
- 2) "The waiver or alteration will not adversely affect the rights and welfare of the subjects;"
- 3) "The research could not practicably be carried out without the waiver or alteration;" and
- 4) "Whenever appropriate, the subject will be provided with additional pertinent information after participation." (45 CFR 46.116(d))

Waiver of parental permission is not permissible under the above conditions for research subject to FDA regulations.

In circumstances where obtaining parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children), the IRB may waive the consent requirements of 45 CFR 46.116 provided that the rights and welfare of the children who will be participating in the proposed research will be protected by an adequate alternative mechanism, and provided that the waiver is not inconsistent with federal, state, or local law. While the design of the alternative mechanism depends on the nature of the proposed research, it must take into account the risks and anticipated benefits to the subjects, and the subjects' age, maturity, status, and condition. Waiver of parental permission is not permissible under the described conditions for research subject to FDA regulations.

In most cases, once parental permission has been granted the agreement (assent) of the child is required. In most circumstances children age eight and above should be given an opportunity to provide a signed assent. Younger children may provide an oral assent. Assent documents or scripts must be reviewed and approved by the IRB. The assent document should be written in age-appropriate language. Even when parental permission has been secured, a child may decline to participate and researchers should respect the child's decision. In addition to evaluating the assent language, the IRB will examine the assent process. The IRB will consider whether the assent will be obtained in the presence of parents. If assent will be obtained in the presence of parents, the IRB will evaluate whether this is appropriate.

School officials and/or teachers do not have the authority to give consent for the participation of children in research studies. Only a parent or guardian may allow a child, with the child's assent, to participate in research.

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))

Regulatory Requirements

DHHS: 45 CFR 46.408 "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, when 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 where 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 §46.116 of Subpart A.”
- “(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 §46.116 of Subpart A, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404 or §46.405. Where research is covered by §46.406 and §46.407 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 when only one parent has legal responsibility for the care and custody of the child.”
- “(c) In addition to the provisions for waiver contained in §46.116 of Subpart A, 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 would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.”

“(d) Permission by parents or guardians shall be documented in accordance with and to the extent required by §46.117 of Subpart A.”

“(e) When the IRB determines that assent is required, it shall also determine whether and how assent must be documented.”

For projects to which FDA regulations and policies apply - 21 CFR 50.55 “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 D, the IRB must determine that adequate provisions are made for soliciting the assent of the children when in the judgment of the IRB the children are capable of providing assent.”

“(b) In determining whether children are capable of providing assent, the IRB must 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 clinical investigations under a particular protocol, or for each child, as the IRB deems appropriate.

“(c) The assent of the children is not a necessary condition for proceeding with the clinical investigation if the IRB determines:”

“(1) That the capability of some or all of the children is so limited that they cannot reasonably be consulted, or”

“(2) That the intervention or procedure involved in the clinical investigation 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 clinical investigation.”

“(d) Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement if it finds and documents that:”

“(1) The clinical investigation involves no more than minimal risk to the subjects;”

“(2) The waiver will not adversely affect the rights and welfare of the subjects;”

“(3) The clinical investigation could not practicably be carried out without the waiver; and”

“(4) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.”

“(e) In addition to the determinations required under other applicable sections of this subpart D, the IRB must determine that the permission of each child’s parents or guardian is granted.”

“(1) Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient, if consistent with state law, for clinical investigations to be conducted under § 50.51 or § 50.52.”

“(2) Where clinical investigations are covered by § 50.53 or § 50.54 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 when only one parent has legal responsibility for the care and custody of the child if consistent with State law.”

“(f) Permission by parents or guardians must be documented in accordance with and to the extent required by § 50.27.

“(g) When the IRB determines that assent is required, it must also determine whether and how assent must be documented.”

In addition, Section 6-8-C, “Children” of the HRP Manual should be utilized to review the additional approval criteria for approval of projects involving children. This policy examines the issue of child assent and parental consent only.

Implementation

The IRB requires the investigator to address the issue of consent within the initial application.

For modifications to an approved project, the investigator should also provide an explanation of the consent process, including a description of whether assent will be obtained.

The project will be reviewed as specified by the initial application, revision or renewal procedures. See applicable sections of Section 8 of the HRP Manual for specific policies and procedures.

Review and Documentation

Reviewer(s) shall review the description and materials and determine if the appropriate criteria have been satisfied. If the reviewer has any questions, a reviewer comment will be sent to the investigator addressing the issue(s).

If the reviewer(s) determine that the requirements for permission by parents or guardians and for assent by children have been satisfied, the IRB member or the IRB chair will document that the conditions have been met and why the materials met the criteria. A standard form shall be used for documentation.

For full board review protocols, the discussion and documentation shall be recorded in the minutes of the IRB meetings.