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<th>Michigan State University</th>
<th>Human Research Protection Program</th>
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<td><strong>Subject:</strong> Informed Consent</td>
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<td><strong>Sub-Topic:</strong> Parental Permission &amp; Child Assent</td>
<td>This policy and procedure supersedes those previously drafted.</td>
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<td><strong>Section:</strong> 6-4-C</td>
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Approved by: Vice President of Research and Graduate Studies, 4-21-2005. Revision 1 approved by VP Research & Graduate Studies on 7-5-2006. Revision 2 approved by VP Research & Graduate Studies on 3-9-2008. Revision 3 approved by VP Research & Graduate Studies on 5-6-2008. Revision 4 approved by VP Research & Graduate Studies on 7-21-2011. Revision 5 approved by Assistant VP Regulatory Affairs on 3-28-2013.

| Related Sections: 6-8-C, 8, 8-2, 8-3 |

Additional provisions of the federal regulations on human subject research govern research involving children (45 CFR 46 subpart D, 21 CFR 50 subpart D) and the Michigan State University (MSU) Institutional Review Board (IRB) follows these provisions. 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 does not involve interventions likely to be of benefit to the subjects and the children can comprehend and appreciate what it means to be a volunteer for the benefit of others.

**Parental Permission**
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. The IRB shall determine whether permission of one parent is sufficient or if permission of both parents is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for care and custody of the child. 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 the Human Research Protection Program (HRPP) Manual 6-8-C “Children” for the categories of research that apply to children.
For research subject to U.S. Department of Health and Human Services (DHHS) regulations (45 CFR 46), 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 U.S. Food and Drug Administration (FDA) regulations (21 CFR 50, 21 CFR 56).

If parental permission is waived, the IRB may consider whether parents should be provided with notification about the research study. The IRB may also consider whether parents should be given an opportunity to “opt” their child out of participating in the study. In either case, a waiver of consent must be granted if parental permission will not be obtained.

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.

**Assent**

Except in highly unusual circumstances, such as when a child is too ill or young to give assent, the IRB expects that investigators will obtain both the assent of children and the permission of their parent(s) or guardian(s) to participate in proposed research.

The IRB will determine and document that assent is a requirement of all children, some children, or none of the children. If the IRB determines that assent is not a requirement of some children, the IRB determines and documents which children are not required to assent.

If the IRB determines that assent is not a requirement for some or all of the children, the IRB will determine and document one or more of the following:

1. The children are not capable of providing assent based on the age, maturity, or psychological state.
2. The capability of the children is so limited that they cannot reasonably be consulted.
3. The intervention or procedure involved in the research holds out the prospect of direct benefit that is important to the health or well-being of the child and is available only in the context of the research.

4. The assent process can be waived using the criteria for waiver of the consent process.

When investigators propose to obtain assent verbally, a script of the assent language and content must be included with the IRB application. The investigator should maintain a mechanism to track assent.

Provided below are recommended guidelines for age appropriate assent, if assent is required for some or all of the children. The following are guidelines only, and may not be appropriate for every research study involving children or all children in a given study. The IRB should determine for each research study what constitutes age appropriate assent for that research population.

- Ages 5-7: Verbal assent script
- Ages 8-12: Age and language appropriate written assent form
- Ages 13-18: May separately sign the parental permission form

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 can 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**
See HRPP Manual 6-8-C “Special Categories of Research Subjects” for definitions applicable to this policy (child, parent, guardian, emancipated, assent, permission).

**Regulatory Requirements**
The following requirements for parent or guardian permission and child assent must be met to involve children in research. In addition, HRPP Manual 6-8-C “Children” must be utilized to review the additional criteria for approval of research studies involving children. This policy and the regulations provided below include only the requirements for child assent and parental or guardian permission.
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, in accordance with and to the extent that consent is required under part 50, 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 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.”

“(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.”

**Implementation**

The IRB requires that the investigator address the issue of consent, including parental permission and child assent if the research involves children, within the initial application.
For modifications to an approved research study, the investigator should also provide an explanation of the consent process, including parental permission and child assent if the research involves children, within the revision application.

The research study will be reviewed as specified by the initial application, revision, or renewal procedures. See HRPP Manual 8 “Types of Review” for specific policies and procedures.

**Review and Documentation**
Review and approval for research involving children follows the procedures as required by the level of review. See HRPP Manual 8-2 “Expedited Review Procedure” and/or HRPP Manual 8-3 “Full Board Review Procedure” for policies and procedures on review and documentation required for research involving children.