Grand Valley State University Institutional Review Board (IRB)	
Title: *Research Involving Children*	
Section: 812.	This policy and procedure supersedes those previously drafted
Approved by HRRC: 09/13/2011 Revised 04/08/2014; 10/28/2014 Revised by HRRPPC: 03/28/2018 Revised by IRBPPC: 04/16/2024	Approved by RIO/HRPA: 09/23/2011 Revisions approved on 04/08/14; 10/28/2014 Revisions approved by AIO/RIO: 04/16/2018 Revision approved by AIO/RIO: 3/16/2020 Revision approved by AIO/RIO: 08/30/2024
Effective Date: 08/30/2024	
Related documents: *710: Assessing Risk to Research Participants* *720: Assessing Risk to Vulnerable Participants* *813: Research Involving Participants with Questionable Consent Capacity and/or Legally Authorized Representatives* *820: Waivers, Alterations and Exceptions to Informed Consent Process and Documentation*	

Policy

For non-exempt research involving children, permission from the parent, guardian, or other legally authorized representative of the child is required, unless waived by the IRB. This permission must be free from coercion and undue influence, obtained in accordance with applicable laws and acquired through culturally appropriate means.

Children are not capable of providing informed consent but may provide informed assent. Assent is not merely the absence of refusal or objection; affirmative agreement to participate is required, unless assent is waived by the IRB. The FWA agreement between GVSU and the DHHS does not include the subparts including subpart D, Protection of Children. However, the IRB generally follows the protections in subpart D and at its discretion may waive or alter the assent requirement under certain circumstances as provided in the regulations 45 CFR 46 subpart D. See also *IRB Policy 820: Waivers, Alterations and Exceptions to Informed Consent Process and Documentation.*

Procedures

1. Determinations for Research Involving Children
    a. Determinations related to research involving children must be voted on separately from the vote for approval of the protocol for both expedited and full-board protocols under review.
    b. For protocols being reviewed under expedited review procedures, all reviewers, as well as the Chair reviewing the protocol, must agree with the determinations. If consensus cannot be reached for one or more of the required determinations, the protocol requires full-board review.
    c. For protocols being reviewed under full board review, determinations will be made by majority vote.

2. Categories of Research Involving Children

a. Research not involving greater than minimal risk: The IRB may approve 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, guardians, or other legally authorized representatives.

b. Research involving greater than minimal risk and has the prospect of direct benefit to the individual participants: The IRB may approve research in which the IRB finds that greater than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual participant, or by a monitoring procedure that is likely to contribute to the participant's well-being, only if the IRB finds that:

    i. The risk is justified by the anticipated benefit to the participants;

    ii. The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches; and,

    iii. Adequate provisions are made for soliciting the assent of the children and permission of their parents, guardians, or legally authorized representatives.

c. Research involving greater than minimal risk and has no prospect of direct benefit to individual participants, but is likely to yield generalizable knowledge about the participant's disorder or condition: The IRB may approve research in which the IRB finds that greater 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 participant, or by a monitoring procedure which is not likely to contribute to the well-being of the participant, only if the IRB finds that:

    i. The risk represents a minor increase over minimal risk;

    ii. The intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

    iii. The intervention or procedure is likely to yield generalizable knowledge about the participants' disorder or condition which is of vital importance for the understanding or amelioration of the participants' disorder or condition; and,

    iv. Adequate provisions are made for soliciting assent of the children and permission of their parents, guardians, or legally authorized representatives.

d. Research not meeting the requirements of the above categories: The IRB generally may not approve research that does not meet the requirements of categories outlined in Procedures 2.a, 2.b, or 2.c above. However, the IRB may approve the research only if:

i. 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,

ii. For research funded by the Department of Health and Human Services (DHHS) or subject to FDA regulation: The Secretary of DHHS or the Commissioner of Food and Drugs as applicable, 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. The research in fact satisfies the requirements of §46.404, §46.405, or §46.406, as applicable, or,
2. The following:
    a. The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
    b. The research will be conducted in accordance with sound ethical principles; and,
    c. Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in §46.408.

3. Determining Whether a Prospective Research Participant is a Child
    a. Federal regulations place limitations on the types of research that can be approved to include children, and the processes for approving that research.

    b. Further, when research has been approved to include children, federal regulations describe who must provide informed consent before a child can be enrolled in the research, and provide requirements for obtaining the assent of the child. In addition, these regulations state that the determination of whether an individual is a child is to be determined by "applicable law", which typically means state or local statutes, regulations or cases.

    c. For research participants located in Michigan, several exceptions to the age of majority apply. ("Age of majority" is the legal age at which a person is considered an adult.) Children aged 14-17 can consent for themselves without parent permission or notification to parents in certain situations, including:

        i. When a child participating in research is emancipated, the individual's participation in the research is no longer subject to parental or guardian permission.

        ii. When the research is focused on outpatient mental health treatment, excluding pregnancy termination referral services and the use of psychotropic drugs.

iii. Additional circumstances allowed under Michigan state law. Researchers are encouraged to visit https://www.michigan.gov/mde/services/special-education/funding/medicaid/parental-consent-resources for further information.

d. For research participants located outside of Michigan, the requirements for parental permission are based on the legal definition of a child in the locality where the participant is located. Participants who may be considered children in their home locality do not require parental permission if they are located in Michigan and have attained the age of majority in this state (18 years). Likewise, a participant under 18 years of age and located in Michigan would generally need parental permission to participate in research, even if the participant would be considered an adult in their home locality.

4. Assent of the Child

a. In determining whether children are capable of assenting, the IRB will consider the ages, maturity, and psychological state of the targeted 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. When the IRB determines that assent is required, it will also determine whether and how it should be documented.

b. In many cases, the IRB expects children seven (7) years of age and older to provide assent when participating in non-exempt research. If a child aged seven or older dissents from participating in research, even if his or her parents, guardians, or legally authorized representatives have granted permission, the child's refusal prevails. The IRB may waive its assent requirements if the research intervention or procedure has the potential of direct benefit to the child and is available only in the context of research.

c. The IRB has the authority to determine the appropriate manner, if any, of documenting a child's assent based on such considerations as the nature of the research activity, the information collected, and the child's age, maturity, and degree of literacy. If children are involved in research in which a consent form would have been used if the participants were adults, it is generally appropriate to use a similar (age appropriate) form to document a child's assent.

d. Voluntary participation requires that assent be an on-going process. Initial assent from a child does not imply that a child may be coerced or forced to comply with ongoing research activities.

5. Parent/Guardian/Legally Authorized Representative Permission

a. The permission of the parent(s), guardian(s), or other legally authorized representative(s) is generally required before the child may be approached to assent to participate in the research.

b. The following circumstances dictate who may give permission for enrolling children in research.

   i. At the discretion of the IRB, the permission of one parent may be sufficient for enrolling a child in research if:
      1. the research is minimal risk or
      2. the research holds the prospect of direct benefit to the child.

   ii. If the research is ***a slight increase over minimal risk*** **and** ***holds no prospect of direct benefit*** to the child, both parents must give 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. An exception may be made if a court grants sole decision-making authority to one parent, or if some person or agency other than the parent has been assigned legal authority over the child.

   iii. If the research ***holds more than a slight increas***e ***ove***r ***minimal risk*** **and** ***holds no prospect of*** direct benefit to the child, the research may not be approved unless the provisions detailed above in 2.d have been satisfied.

   iv. An adult who has been authorized as a guardian for some purposes is not automatically authorized to permit a child to participate in research. Guardian powers are explicitly specified by the terms of a court order and may or may not include authorization to permit enrollment in research studies. The authority to make health care decisions is not necessarily the same as the authority to consent to a child's participation in research.

c. If a researcher is a mandated reporter by state or federal law and required to report known or suspected child abuse or neglect, this must be disclosed and explained in the parental permission form.

6. Children Who Are Wards of the State

   a. Children who are wards of the state or a specific agency, institution, or entity can be included in minimal risk research and research that is greater than minimal risk with the prospect of direct benefit (categories outlined in Procedures 2.a and 2.b above). The IRB will make the determinations identified above related to parent permission and assent requirements.

   b. Children who are wards of the state or a specific agency, institution, or entity can be included in research falling under the categories outlined in Procedures 2.c and 2.d above ***only if*** such research is:

i. Related to their status as wards; or

ii. Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards.

c. Under conditions b(1) or b(2) above, the IRB requires appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child. Individuals may serve as advocate for more than one child. The advocate shall be an individual who has the background, experience, and commitment to act in the best interests of the child for the duration of the child's participation in the research and who is not otherwise associated with the research, the researchers(s), or the guardian organization.

7. When a Child Becomes an Adult during Research

a. In Michigan the age of majority is 18 years, but a child may be emancipated by court order or while on active military duty before age 18. When a child participating in research reaches the legal age of majority or is otherwise emancipated, the individual's participation in the research is no longer subject to parental or guardian permission. However, unless initial requirements for obtaining informed consent were waived by the IRB, the researcher must obtain and document legally and ethically valid informed consent from the now-adult participant *before* any further interactions or interventions with the participant may occur. This consent is required regardless of the level of detail provided in the assent document.

b. If the now-adult participant has cognitive impairment such that the parent(s) or guardian(s) will retain legal decision-making authority for the participant, the researcher must document this status in the research records and follow the provisions in IRB Policy 813: *Research Involving Participants with Questionable Consent Capacity and/or Legally Authorized Representatives*.

Guidance

Parental Permission and Assent Requirements based on Level of Risk and Potential for Direct Benefit

Level of Risk	Parental Permission Requirement	Assent Requirements	Waiver
Not greater than minimal risk with the prospect of direct benefit and similar benefit available outside the context of the research	1 parent, unless otherwise determined by the IRB (Procedures 5.b.i)	Required, unless otherwise determined by the IRB (Procedures 4.a and 4.b)	Permission and/or assent may be waived if permitted under IRB Policy 820: *Waivers, Alterations, and Exceptions to Informed Consent*
Not greater than minimal risk with the prospect of direct benefit and benefit	1 parent, unless otherwise determined	Not required	

only available within the context of the research	by the IRB (Procedures 5.b.i)		*Process and Documentation*
Not greater than minimal risk with *no* prospect of direct benefit	1 parent, unless otherwise determined by the IRB (Procedures 5.b.i)	Required, unless otherwise determined by the IRB (Procedures 4.a and 4.b)	
Greater than minimal risk with the prospect of direct benefit and similar benefit available outside the context of the research	1 parent, unless otherwise determined by the IRB (Procedures 5.b.i)	Required, unless otherwise determined by the IRB (Procedures 4.a and 4.b)	
Greater than minimal risk with the prospect of direct benefit and benefit only available within the context of the research	1 parent, unless otherwise determined by the IRB (Procedures 5.b.i)	Not required	
Slight increase over minimal risk with *no* prospect of direct benefit	2 parents, unless conditions are met under Procedures 5.b.ii	Required, unless otherwise determined by the IRB (Procedures 4.a and 4.b)	
Otherwise unapprovable research (greater than minimal risk with no prospect of direct benefit)	2 parents, unless otherwise determined by the IRB (Procedures 5.b.iii)	Required, unless otherwise determined by the IRB (Procedures 4.a and 4.b)	