

Grand Valley State University Institutional Review Board (IRB)	
Title: <i>Informed assent and parental permission</i>	
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	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
Effective Date: 05/01/2018	
Related documents: 710: <i>Assessing risk to research participants</i> 720: <i>Assessing risk to vulnerable participants</i> 813: <i>Research involving participants with questionable consent capacity and/or legally authorized representatives</i> 820: <i>Waivers, alterations and exceptions to informed consent process and documentation</i> G-9: <i>Guidance on age of majority in US and foreign countries</i>	

Policy

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

Minors 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. The FWA agreement between GVSU and the DHHS does not include the subparts including subpart D, Protection of Minors. 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 *ORCI Policy 820: Waivers, alterations and exceptions to informed consent process and documentation*.

Procedures

1. Assent of the Minor

- a. In many cases, the IRB requires the assent of children seven (7) years of age and older when participating in non-exempt research. If a minor aged seven or older dissents from participating in research, even if his or her parents or guardian have granted permission, the minor’s refusal generally prevails. The IRB may waive its assent requirements if the research intervention or procedure has the potential of direct benefit to the minor and is available only in the context of research.
- b. The IRB has the authority to determine the appropriate manner, if any, of documenting a minor’s assent based on such considerations as the nature of the research activity and the information collected, the minor’s age, maturity, and degree of literacy. If minors 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 minor's assent.

- c. Voluntary participation requires that assent be an on-going process. Initial assent from a minor does not imply that a child may be coerced or forced to comply with any research activities, unless the nature of the research allows parent/guardian permission to override the minor's lack of assent (see table providing *Parental Permission and Assent Requirements* based on Level of Risk and Potential for Direct Benefit in the **Guidance** section of this policy below).
- *Note:* 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.

2. Parent/Guardian Permission

- a. The permission of the parent(s) or other legally authorized representative is required before the minor may be approached to assent to participate in the research. For research participants located outside of Michigan, the requirements for parental permission are based on the legal definition of a minor in the locality where the participant is located. Participants who may be considered minors 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.
- b. The following circumstances dictate who may give permission for enrolling minors in research.
 - i. At the discretion of the IRB, the permission of one parent may be sufficient for enrolling a minor in research if:
 - 1. the research is minimal risk or
 - 2. the research holds the prospect of direct benefit to the minor
 - ii. If the research is ***a slight increase over minimal risk and holds no prospect of direct benefit*** to the minor, 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 [45 CFR 46.408]. 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 minor (See *Note* below).

- iii. If the research ***holds more than a slight increase over minimal risk and holds no prospect of*** direct benefit to the minor, the research may not be approved without special written petition to the secretary of DHHS. Contact the IRB for details.

[See chart below under Guidance]

- *Note:* Researchers should *not* assume that an adult who has been authorized as a guardian for some purposes is automatically authorized to permit a minor 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 minor's participation in research.

3. Minors Who Are Wards of the State

- a. Under 45 CFR 46.409, minors who are wards of the state or a specific agency, institution, or entity can be included in research that is greater than minimal risk and holds no anticipated potential for direct benefit to the participant, but is likely to yield generalizable knowledge about the participant's disorder or condition and research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children ***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 subjects are not wards.
- b. Under conditions (1) or (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.

4. When a Minor Becomes an Adult during Research

- a. In Michigan the age of majority is 18 years, but a minor may be emancipated by court order, marriage, or while on active military duty before age 18. When a minor 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.

Guidance

Waiver of parental permission and 46.408(c) and (e) Requirements for permission by parents or guardians for assent by children

408(c): The IRB may waive the requirements for obtaining parental or guardian permission if either of the following 2 conditions is met:

1. The IRB makes and documents the required findings under either 45 CFR 46.116 (c) or (d) [the “practicability conditions”]
OR
2. The IRB determines that a research protocol is designed to study conditions in children or a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects (for example, neglected or abused children) AND the following two additional criteria are also met:
 - (a) An appropriate mechanism is in place to protect the children,
AND
 - (b) The waiver is not inconsistent with federal, state or local law.

The choice of an appropriate substitute mechanism (for example, appointing a child advocate or assent monitor) for protecting children participating in research would depend on the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and the child’s age, maturity, status, and condition.

Note that the IRB may waive the requirement for obtaining parental or guardian permission under 45 CFR 46.408(c) even if the research involves more than minimal risk to the child subjects.

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

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

Level of Risk	Parental Permission Requirement	Assent Requirements	
Not greater than minimal risk (\leq min. risk) with the prospect of direct benefit and similar benefit available outside the context of the research	1 parent, unless conditions are met under 46.608(c)	required	Permission and/or assent may be waived if requirements are met under 45 CRF 46.116(d).
Not greater than minimal risk (\leq min. risk) with the prospect of direct benefit and benefit only available within the context of the research	1 parent, unless conditions are met under 46.608(c)	not required	

Not greater than minimal risk (\leq min. risk) with <i>no</i> prospect of direct benefit	1 parent, unless conditions are met under 46.608(c)	required	
Greater than minimal risk ($>$ min. risk) with the prospect of direct benefit and similar benefit available outside the context of the research	1 parent, unless conditions are met under 46.608(c)	required	
Greater than minimal risk ($>$ min. risk) with the prospect of direct benefit and benefit only available within the context of the research	1 parent, unless conditions are met under 46.608(c)	not required	
Slight increase over minimal risk (slightly $>$ min. risk) with <i>no</i> prospect of direct benefit	2 parents, unless conditions are met under 46.408(b) or (c)	required	
Otherwise un-approvable research ($>$ slight increase over min. risk w/no prospect of direct benefit)	2 parents, unless conditions are met under 46.408(b) or (c)	required	