

Informed Consent and Legally Authorized Representatives for Research

This Policy is Applicable to the following sites:

Big Rapids, Continuing Care, Corporate, Gerber, Ludington, Outpatient/Physician Practices, Priority Health, Reed City, SH GR Hospitals, SHMG, United/Kelsey, Zeeland

Applicability Limited to:	N/A
Reference #:	2053
Version #:	2
Effective Date:	04/09/2015
Functional Area:	Administrative Operations, Research
Department Area:	Research

1 PURPOSE

This Policy establishes who may consent to research on behalf of individuals who do not have capacity to make their own health care decisions.

2 SCOPE

This Policy applies to individuals involved in human subject research conducted at or supported by any of the Spectrum Health entities listed above (collectively, "Spectrum Health").

Research is *conducted at* Spectrum Health if patients of Spectrum Health are potential subjects in the research, or if the research activities involve the use of space, facilities, materials, personnel or other resources of Spectrum Health.

Research is *supported by* Spectrum Health if it is funded through direct or indirect financial support from Spectrum Health or through any grant, contract, or other arrangement between Spectrum Health and a third party, including, but not limited to, a foundation or corporate research sponsor.

3 BACKGROUND

- 3.1 Informed consent for participation in research involving human subjects is governed by state and federal laws and regulations. If an individual cannot consent to be a participant in human subject research because of age or lack of decision-making ability, a *legally authorized representative* may consent to that individual's participation in research in accordance with this Policy.

- 3.2 The term “*legally authorized representative*” means an individual or judicial authority or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the research.

- 3.3 Michigan law currently does not define who may serve as a “*legally authorized representative*” for *research purposes*. However, when an individual has authority under Michigan law to serve as a subject’s legally authorized representative for health care and medical decision making purposes, it may be reasonable and appropriate—*under the circumstances*—for that person to also make decisions related to the subject’s participation in research.

- 3.4 The laws and requirements for consent by legally authorized representatives are different, depending on whether the prospective subject is an adult or a child (i.e., under 18 years of age, or a “minor”).

4 POLICY

4.1 *Legally Authorized Representatives for Adult Patients*

- 4.1.1 If an adult patient is unable to make or communicate health care decisions because of physical or mental illness, age, disability, substance abuse, trauma or coma, or other physical or mental condition, a *legally authorized representative* may—*depending on the circumstances*—consent on behalf of the patient to the patient’s participation in research. The determination of a patient’s ability to make health care decisions must be made in accordance with applicable law and Spectrum Health policies—i.e., the attending physician must assess and document the patient’s condition and ability to make decisions, and a second physician or a psychologist must concur with and document this assessment.

- 4.1.2 Michigan law does not specifically define who may qualify as a legally authorized representative with the authority to consent to an adult patient’s participation in research. Where the research involves *an intervention that might benefit the patient*, it is reasonable to permit someone who could consent to medical care for that patient to also consent to the patient’s participation in research.

- 4.1.3 Consistent with Michigan law* regarding consent for medical care, the following individuals—*in descending order of priority*—may act as a legally authorized representative and make decisions related to the patient’s participation in the research project:
 - 4.1.3.1 The individual identified in a written patient advocate designation (as defined by, and in accordance with, Michigan law). This may also be referred to as an “*advance directive*” or a “*durable power of attorney for health care*.”

 - 4.1.3.2 A guardian or conservator with the authority to make health care decisions for the patient.

 - 4.1.3.3 The spouse of the patient.

 - 4.1.3.4 An adult son or daughter of the patient.

- 4.1.3.5 An adult grandchild of the patient.
- 4.1.3.6 A parent of the patient.
- 4.1.3.7 An available adult relative familiar with the patient and with the closest degree of kinship to the patient.

*(*NOTE: If the patient has a terminal illness, depending on the situation Michigan law may specify a different order of priority for individuals with decision-making capacity. Consult with legal counsel to determine whether these special provisions apply).*

- 4.1.4 The Institutional Review Board (IRB) determines when the use of a legally authorized representative to obtain consent for the patient's participation in a proposed research study is appropriate. The researcher(s) and the patient's legally authorized representative are responsible for honoring any of the patient's previously expressed wishes concerning participation in research (i.e. past medical decisions, past research participation experiences, and previously expressed desires to participate or not participate in research). Special consideration should be given to a written patient advocate designation or other written records or documentation of the patient's wishes with respect to medical decisions or research participation.
- 4.1.5 If an adult patient regains the ability to provide legally effective informed consent after his/her participation in a research study has begun, and the study intervention(s) or interaction(s) are continuing (e.g., collection of individually identifiable health information), the patient can remain in the study only after he/she provides informed consent, unless the IRB grants a waiver of consent.

4.2 *Legally Authorized Representatives for Children*

- 4.2.1 Under federal regulations, "*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. In Michigan, individuals under 18 years of age are considered "*children*," and are unable to give legally effective consent to treatment or participation in research.
- 4.2.2 There are two components of informed consent when the research involves children: (1) permission (consent) of the child's legally authorized representative, e.g., parent (biologic or adoptive) or legal guardian;¹ and (2) the child's "*assent*," or affirmative agreement to participate in the research study.
- 4.2.3 *Consent.* Pursuant to federal regulations, the IRB must determine whether and to what extent consent is required for a child's participation in research.

¹ A "legal guardian" is an individual or official appointed through state or local law, a court order, or upon the death of a parent (or current guardian) through the parent's (or guardian's) will to have custody of the child, either temporarily or permanently, with the associated rights to make decisions on behalf of the child, including medical/health care decisions.

- 4.2.3.1 If the IRB determines that the research does not involve greater than minimal risk, or the research involves greater than minimal risk but presents the prospect of direct benefit to individual subjects, the IRB *may* determine that consent of only *one* parent is necessary.
- 4.2.3.2 In general, *both* parents must consent when the IRB determines that the research involves greater than minimal risk and there is no prospect of direct benefit to individual subjects, *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 (see “*Special Situations*” below).
- 4.2.3.2 Research designed for a participant population for which parental or guardian consent is not a reasonable requirement to protect research participants (e.g. neglected or abused children), and that are not subject to oversight of the Food and Drug Administration (FDA), the IRB *may* waive the consent requirements.
- 4.2.4 *Special Situations – Parent/Guardian Consent.*
- 4.2.4.1 *Divorced Parents.* A parent with legal custody of the child can consent to the child’s participation in research. Legal custody may be held by both parents, in which case the consent of both parents should be obtained; however, the consent of one parent is generally sufficient.
- 4.2.4.2 *Step-Parent.* Generally, a step-parent does not have legal authority to give consent for a child’s participation in research. However, if the step-parent has been given power of attorney with delegated parental rights, the step-parent may give legally effective consent for research purposes. The power of attorney must be in writing and must clearly state that it applies either to all parental rights or specifically to the right to consent to medical treatment.²
- 4.2.4.3 *Foster Care.* A probate court, child placement agency, Department of Social Services or a foster parent may consent to medical treatment for a child under his/her/its care and jurisdiction. However, Michigan law does not specifically grant the foster parent or agency the ability to consent to the child’s participation in research. If a child in foster care is a potential subject, consult with legal counsel to determine whether the child may participate in research and who may consent on the child’s behalf.
- 4.2.4.4 *Legal Guardian.* A legal guardian of a child has—in most cases—the rights of a parent, including the right to consent to the child’s participation in research. A copy of the guardianship papers must be reviewed and retained in the child’s record.
- 4.2.5 *Special Situations – When a Minor Can Consent.* Under the following circumstances, Michigan law permits a minor child (i.e., an individual under 18 years of age) to give

² The written power of attorney must also include the name of the custodial parent, the child’s name, name of the person receiving the authority (i.e., the step-parent), the signature of the custodial parent, a date and witness signature.

legally effective consent to medical care and treatment; it may also be appropriate for a minor, under one of these circumstances, to give consent to participate in research:

4.2.5.1 The minor is “*emancipated*.” Under Michigan law, an “emancipated minor” is a person who is either:

4.2.5.1.1 Validly married/widowed/divorced;

4.2.5.1.2 On active military duty; or

4.2.5.1.3 Emancipated by court order. (*NOTE: Documentation evidencing the court order should be placed in the minor’s record*).

4.2.5.2 The research procedures are limited to the following:

4.2.5.2.1 Mental health services on an outpatient basis (excluding use of psychotropic drugs), so long as the minor is at least fourteen (14) years of age;³

4.2.5.2.2 Services for a sexually transmitted disease or HIV;⁴

4.2.5.2.3 Substance abuse related services (i.e., for alcohol or other drugs);⁵ or

4.2.5.2.4 Prenatal or pregnancy (except pregnancy termination).⁶

4.2.6 *Assent.*

4.2.6.1 The IRB will determine whether children proposed to be included in a research study are capable of providing assent and whether assent should be required for the study. The IRB will take into account the ages, maturity, and psychological state of the children involved. This determination may be made for all children to be involved in research under a particular protocol, or for each child.

³ The minor’s parent or guardian (or other person acting in loco parentis) cannot be informed of the services without the consent of the minor, unless the mental health professional treating the minor determines that there is a compelling need for disclosure based on a substantial probability of harm to the minor or to another individual, and if the minor is notified of the mental health professional’s intent to inform the minor’s parent or guardian (or person in loco parentis). MCL 330.1707.

⁴ For medical reasons (as determined by the treating physician), the parent or guardian *may*, but is *not required* to, be informed of the services given to the minor. MCL 333.5127.

⁵ See above. MCL 333.6121.

⁶ See above. MCL 333.9132.

4.2.6.2 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(s) 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 may not be a necessary condition for the research. Even where the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement (in accordance with federal regulations).

4.2.4 *Subjects Who Reach Age 18 During the Study.* If a legally authorized representative (i.e., parent or guardian) consents to a child's participation in a research study, the child reaches age 18 while participating in the study (and is otherwise capable of providing legally effective consent), and the study intervention(s) or interaction(s) are continuing (e.g., collection of individually identifiable health information), the individual can remain in the study only after he/she provides informed consent (unless the IRB grants a waiver of consent).

4.3 *Documentation.* Documentation establishing an individual's authority to act as a legally authorized representative on behalf of an adult or a child, such as Letters of Guardianship, patient advocate designation or advance directive, must be retained in the research record.

If it is unclear whether an individual has authority to act as a legally authorized representative for research purposes, or in the event of a dispute or disagreement as to a subject's participation in research, contact legal counsel for the Spectrum Health Research Department at (616) 391-3050.

1. Revisions

Spectrum Health reserves the right to alter, amend, modify or eliminate this policy at any time without prior written notice.

2. References

45 CFR §46.102, 45 CFR §46.402, 45 CFR §46.408
21 CFR §50.3, 21 CFR §50.55
MCL 330.1707
MCL 333.5127
MCL 333.5653
MCL 333.6121
MCL 333.9132
MCL 700.2103
MCL 700.3206
MCL 700.5506 to 700.5515
MCL 722.4

3. Policy Development and Approval

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- 4. Keywords**
research, human subjects, consent, capacity, legally authorized representative, sh-admin-res-021