

**Institutional Review Board (IRB)**

**GUIDELINES FOR USE OF LEGALLY AUTHORIZED REPRESENTATIVES**

**1. Overview**

The State of Missouri has enacted legislation that outlines how research participants unable to consent for themselves may be enrolled in research studies. The guidelines below are to be used when consent of a legally authorized representative is used to enroll adult research participants.

**2. Definitions**

**Legally Authorized Representative (LAR):** An individual, judicial, or other body authorized under applicable law to consent on behalf of a prospective subject to the subject’s participation in the procedure(s) involved in the research.

**Attorney in Fact/Power of Attorney:** A written, formal or legal document exists authorizing a person to act as the agent or attorney of another person. If an Attorney in Fact/Power of Attorney exists, he/she should be asked to consent on behalf of a prospective subject.

**Minimal Risk Studies:** A study is minimal risk if the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life, or in the routine medical, dental, or psychological examination of a healthy person.

**3. Who Should Act as LAR**

Consent should be obtained in accordance with [**Missouri Revised Statutes**](http://www.moga.mo.gov/mostatutes/stathtml/43100000641.HTML)**,** Chapter 431, General Provisions as to Contracts, Section 431.064.1.

Experimental treatment, tests, and drugs, consent to administer by third party--life-threatening emergencies, consent by whom.

1. When an adult person, because of a medical condition, is treated by a teaching hospital for a medical school accredited by the American Osteopathic Association or the American Medical Association and such person is incapable of giving informed consent for an experimental treatment, test or drug, then such treatment, test or drug may proceed upon obtaining consent of a legal guardian, attorney-in-fact, or a family member in the following order of priority:
	1. [Attorney in Fact/Power of Attorney]
	2. Spouse, unless the patient has no spouse, or is separated, or the spouse is physically or mentally incapable of giving consent, or the spouse's whereabouts is unknown or the spouse is overseas;
	3. Adult child;
	4. Parent;
	5. Brother or sister;
	6. Relative by blood or marriage.

This priority order is to be followed without deviation.

1. Nothing in this section shall authorize such legal guardian, attorney-in-fact, or family member to consent to treatment in contravention to such incapacitated person's expressed permission regarding such treatment.
2. In a life-threatening emergency, consent of such an incapacitated person to any research program or experimental procedure shall not be required when the institutional review board responsible for the review, approval, and continuing review of the research activity has approved both the research activity and a waiver of informed consent and has both found and documented that the requirements for an exception from informed consent requirements for emergency research, as provided under Part 50 of Title 21 or Part 46 of Title 45 of the Code of Federal Regulations, as amended, have been satisfied.

Details about the LAR determination process should be captured in a note-to-file and kept with the consent document in the research records.

Minimal Risk Studies:

The Missouri statute applies to studies of “experimental treatment, tests, and drugs”. However, studies that are minimal risk in nature may use a more flexible LAR process. If a power of attorney/attorney in fact exists, consent should still be obtained from that person. Otherwise, in determining the order of who can provide consent, the Missouri statute should be followed, but, if a spouse is not generally available, **after documented attempts to contact the spouse**, investigators may proceed down the list and obtain consent from one of the others on the list.

This scenario ONLY applies to minimal risk studies. Below is recommended notation for the use of a non-spouse LAR in minimal risk studies.

**SAINT LOUIS UNIVERSITY**

**documentation for the Use of a**

**Non-Spouse Legally authorized representative**

**MINIMAL RISK RESEARCH**

*Instructions: The notation below may be written in a summary note-to-file or this notation may be printed and filed with the consent form.*

Participant’s record was reviewed.

Study team determined that participant has a capable spouse.

Unable to reach spouse after \_\_\_\_\_ attempts.

Consent provided by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Relationship to Participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (e.g. adult child, parent, brother or sister or relative by blood or marriage).

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of Principal Investigator Date

or Research Team Member

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Print Name of Principal Investigator

or Research Team Member