

# Selecting a Legally Authorized Representative Policy

## Scope

Mayo Clinic Human Research Protection Program

Research for which the Mayo Clinic IRB serves as the IRB of Record Purpose

## Policy

Federal regulations (45 C.F.R.46.116; 21 C.F.R. 50.20) require that researchers obtain and document the informed consent of the subject or the subject's legally authorized representative before involving a subject in any research, unless the IRB has waived the requirement for informed consent.

Office for Human Research Protection (OHRP) and Food and Drug Administration (FDA) regulations state that designation of a subject's legally authorized representative is to be determined by "applicable law" (45 C.F.R. 46.102(c); 21 C.F.R. 50.3(l)), which typically means state or local statutes, regulations or cases. OHRP guidance states that it would consider an individual to be a subject's legally authorized representative for research as long as that state or local law provides a "reasonable basis" for allowing that individual to provide informed consent for the subject.

## Applicable Law

The Mayo Clinic IRB will consider applicable laws and may consult with legal counsel when deciding who can serve as an LAR for subjects of proposed research under the laws of the jurisdiction in which the research is conducted (e.g., local or state law). This includes situations in which the Mayo Clinic IRB serves as the IRB of Record for a Relying Organization in a jurisdiction other than the jurisdictions of the three major Mayo Clinic campuses. An acceptable LAR in these jurisdictions is as follows:

## Arizona

There is no law in Arizona that specifically addresses legally authorized representatives for research purposes. Therefore, researchers should seek informed consent for research that involves health care procedures (diagnostic testing, use of drugs and/or devices) in accordance with state law for surrogate decision makers for health care treatment (Arizona Revised Statutes 36-3231). Under this law, researchers must make a reasonable effort to locate and follow the directions of the following individuals, in order of priority:

- The subject's health care agent, as designated in a valid health care power of attorney;
- The subject's court-appointed guardian, if appointed for the express purpose of making health care treatment decisions;
- The subject's spouse (unless the subject and spouse are legally separated);
- An adult child of the subject (if more than one, the majority of the adult children who are reasonably available);
- A parent of the subject;
- If the subject is unmarried, the subject's domestic partner;
- A brother or sister of the subject;

- A close friend of the subject, who has exhibited special care and concern for the subject, who is familiar with the subject's health care views and desires and who is willing and able to become involved in the subject's health care and act in the subject's best interest.

If the research does not involve health care procedures and the IRB has not waived the requirement for informed consent, consult with the IRB or Legal Department.

## **Florida**

There is no law in Florida that specifically addresses legally authorized representatives for research purposes, but Florida law states that surrogate laws for clinical care also apply to "experimental treatments" that have been approved by the IRB. Therefore, researchers should seek informed consent for research that involves health care procedures (diagnostic testing, use of drugs and/or devices) in accordance with state law for surrogate decision makers for health care treatment (Florida Statutes 765.401). Under this law, researchers must locate and follow the directions of the following individuals, in order of priority (only moving to the next level if such a person is not reasonably available, willing or competent to act):

1. The subject's health care surrogate (sometimes also referred to as the health care power of attorney), as designated in a valid written health care advance directive; or
2. In the absence of a written designation, the health care proxy as specified in the order below:
  - a. The subject's judicially-appointed guardian;
  - b. The subject's spouse;
  - c. An adult child of the subject (if more than one, the majority of the adult children who are reasonably available);
  - d. A parent of the subject;
  - e. An adult sibling of the subject (if more than one, the majority of the adult siblings who are reasonably available);
  - f. An adult relative of the subject who has exhibited special care and concern for the subject, who has maintained regular contact with the subject and who is familiar with the subject's activities, health, and religious or moral beliefs;
  - g. A close adult friend of the subject who has exhibited special care and concern for the subject, and presents an affidavit stating that he or she is a friend of the subject who is willing and able to become involved in the subject's health care, has maintained such regular contact with the subject so as to be familiar with the subject's activities, health and religious or moral beliefs.
3. If the research does not involve health care procedures and the IRB has not waived the requirement for informed consent, consult with the IRB or Legal Department.

## **Minnesota**

Except for individuals under a civil commitment\* order, there is no law in Minnesota that specifically creates a hierarchy of legally authorized representatives for research purposes. It is generally accepted that surrogates have the same authority in research as in the clinical setting.

If the individual has appointed a health care agent (sometimes referred to as a health care power of attorney), or if there is a judicially-appointed guardian, that individual would generally be considered the legally authorized representative.

In the absence of a health care surrogate or judicially-appointed guardian, the closest adult relative would generally be considered the legally authorized representative. If there is more than one individual with the same degree of kinship, it is recommended that all such individuals jointly serve the role.

Because these guidelines are analogous to the guidelines that apply in the clinical setting, it is advised that they be utilized only in situations where the research holds out a prospect of direct benefit to the subject. For other situations, consult with the IRB or Legal Department.

\*A person under civil commitment is prohibited from giving consent to participate in a psychiatric clinical drug trial unless the court allows the patient to give consent to participate in a specific psychiatric clinical drug trial. (Minnesota Statutes 253B.095, subd. 1)

## Legal Counsel

Legal counsel is available to assist the Mayo Clinic Institutional Review Board (IRB), and Mayo Clinic researchers and study teams regarding the:

- Applicability of federal and state laws involving human subjects research,
- Resolution of any legal issues related to research regulations involving human subjects, and the
- Resolution of conflicts among applicable laws within (or outside) the jurisdiction where the organization resides.

Contact information for Mayo Clinic Legal Counsel is available on the Legal Department website: <http://intranet.mayo.edu/charlie/legal/resources-and-topics/research-2/>

## Policy Notes

N/A

## Related Procedure(s)

N/A

## Related Document(s)

N/A

## Definitions

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

## References

21 CFR 50.3(1) *Protection of Human Subjects - Definitions*

45 CFR 46.102(c) *Protection of Human Subjects - Definitions*

Arizona Revised Statutes 36-3231

Florida Statutes 765.401

Minnesota Statutes 253B.095, subd. 1

**Owner**

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**Contact**

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**Revision History**

<b>Date</b>	<b>Synopsis of Change</b>
February 27, 2018	Schedule Review: Update to new template, no other changes at this time due to AAHRPP accreditation cycle.
2/18/2016	Scheduled Review: 1) Added Revision History and 2) Updated link for Mayo Clinic Legal Counsel