



MCW Office of Research Standard Operating Procedure

LEGALLY AUTHORIZED REPRESENTATIVES (LAR): WHO CAN CONSENT ON BEHALF OF AN ADULT SUBJECT WITH DECREASED DECISIONAL ABILITY?

Unit: Human Research Protections Program (HRPP), Office of Research

Applies to: Faculty and Staff involved in human research

PURPOSE:

When Investigators identify they will enroll individuals who may have decreased or lack decisional ability, they should include in their application how they will consent these individuals, as outlined in *IRB SOP: Projects with Subjects Likely to Manifest or Develop Decreased Decisional Ability*.

This procedure outlines the process for determining the need for a Legally Authorized Representative (LAR) to consent on behalf of a subject in a research project. To define the criteria that is used to determine who meets the legal and regulatory requirements to function as a LAR.

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 procedure(s) involved in the research. (45 CFR 46.102 (c)) (21 CFR 50.3 (1))

Decreased Decisional Ability: Defined as persons who evidence decreased ability to understand, communicate, reason, and/or decide. The impairment may be due to disorders of a psychiatric, organic (including those suffering from delirium or degenerative brain diseases), developmental (e.g., intellectual disability), substance misuse (e.g., those under the influence of or dependent on drugs or alcohol), or other nature that affects cognitive or emotional functions. Trauma patients, for example, may transiently lack decisional ability due to debilitating pain, taking medication to relieve debilitating pain, having strong medication side effects, or having trouble communicating.

Applicable law: Within the United States, state law dictates who may serve as an LAR from one state to the next. Outside the United States, other legal systems prevail. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the non-research context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

Advanced Medical Directive: A document expressing a person's treatment preferences and the designation of a surrogate decision-maker if a person should become unable to make medical decisions on their own behalf.

Health Care Proxy: a person or organization with the power to represent or serve in the place of another; a legal document in which an individual designates another person to make health care decisions if he or she is rendered incapable of making their wishes known. The health care proxy has the same rights to request or refuse treatment that the individual would have if capable of making and communicating decisions.

Health Care Power of Attorney (HCPOA): Declarations by patients, made in advance of a situation in which they may be incompetent to decide about their own care, stating their treatment preferences or authorizing a third party to make decisions for them.

PROCEDURE:

1. When Investigators identify they will enroll individuals who may have decreased or lack decisional ability, they should include in their application how they will consent these individuals, as outlined in *IRB SOP: Projects with Subjects Likely to Manifest or Develop Decreased Decisional Ability*.
2. Once the Investigator determines the need and appropriateness to use an LAR in the consenting process for the proposed project, they should use the following steps in determining who a subject's LAR is:
 - a. **Court Appointed Guardian:** Determine if there is a court-appointed guardian with the power to make decisions on behalf of the patient who is incompetent to do so, always under the court's supervision. Guardianship may or may not include health care or research decisions, because legal competency is different than incapacity to give informed consent. Therefore, the presence or absence of guardianship is only a factor to be considered, and does not resolve the question of "who can give informed consent?" In these situations, the investigator should always consult with the MCW General Counsel. The guardian of an adult patient should not give informed consent on behalf of the patient until the investigator has determined that the patient lacks capacity to consent.
 - b. **HCPOA:** If there is no guardian, next determine if the patient has a HCPOA to someone else under Wisconsin law. This power allows the proxy to make health care decisions when the patient is incapable of communicating his/her wishes. Health care providers can presume a HCPOA was created by the individual when that individual had the capacity to make such an agreement, unless the provider has reason to know that the individual lacked capacity at the time the HCPOA was signed. One person serving as HCPOA over another cannot (under Wisconsin law) consent to:
 - Admission to a mental health treatment facility,
 - Experimental mental health research,
 - Psychosurgery,
 - Electroconvulsive treatment, or
 - "Drastic mental health procedures"Therefore, in the absence of guidance or case law on what these terms mean, investigators should never rely on a person serving as HCPOA for any mental health research requiring clinical treatment absent consultation with the MCW General Counsel.
 - c. **Next of Kin:** Finally, if there is no guardian and does not have a HCPOA, solicit consent from a next of kin (in the following order):
 - i. Spouse,
 - ii. Adult child,
 - iii. Parent,
 - iv. Adult sibling,
 - v. Grandparent,

- vi. or adult grandchild

Do not advance to a subsequent category (e.g., adult child) unless you have established that there is no one occupying the preceding category (e.g., spouse). Document each of these determinations to justify the choice of "next of kin."

The investigator cannot ask an adult child to serve as "legally authorized representative" if the subject is married. If the spouse cannot be contacted, or if the spouse declines to consent, then no one else may consent on behalf of the subject without an opinion from the MCW General Counsel.

Likewise, the investigator cannot ask an adult sibling to serve as "legally authorized representative" if the subject is married, or has an adult child, or a living parent. If those other parties cannot be contacted, or if they decline to consent, then the adult sibling may not consent on behalf of the subject.

If there are several persons in a single LAR category (e.g., several adult children, or several adult siblings), the investigator may use his/her discretion in choosing the most appropriate "legally authorized representative." If several persons in the same LAR category (e.g., adult children) disagree about project participation, the investigator would be wise to not enroll the subject or work toward consensus.

- 3. Within the eBridge SmartForm application, Investigators should describe the process they will use to determine a subject's LAR, to allow the IRB committee to review the process and its appropriateness for the project and project population.

REFERENCES:

45 CFR 46.102(c)

21 CFR 50.3 (1)

SUPPORTING DOCUMENTS:

IRB SOP: Research with Subjects Likely to Manifest or Develop Decreased Decisional Ability

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