

Department: UAMS Institutional Review Board
Policy Number: 17.13
Section: Special Populations
Effective Date: February 25, 2005
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SUBJECT: Legally Authorized Representatives

POLICY

Some (potential) subjects are unable to provide their own consent for participation in the research, due to diminished functional abilities or not having reached the age of majority under Arkansas law. For these (potential) subjects, a legally authorized representative may be designated to provide consent/permission for research participation on the potential subject's behalf, and to continue to confirm consent throughout study participation, as long as the incapacity persists or until the (potential) subject reaches the age of majority. The legally authorized representative shall be someone designated in accordance with this policy.

DEFINITIONS

Diminished Functional Abilities: Substantial impairment of cognitive functions (such as attention, comprehension, memory and intellect), communication abilities or other abilities that affect capacity to make and express a decision regarding participation in a research study. Such condition may be either temporary or permanent.

Health care: Any care, treatment, service or procedure to maintain, diagnose, treat or otherwise affect an individual's physical or mental condition.

(Potential) subject: Refers to both the individual prior to the obtaining of an agreement to participate in the research, and to an enrolled research subject.

PROCEDURE

A. Research involving healthcare. The following individuals may provide consent for research involving healthcare on behalf of individuals with diminished functional abilities or who have not reached the age of majority under Arkansas law:

1. Any parent, whether an adult or a minor, for his or her minor child. "Child" as used here includes biological or adopted children. Stepparents cannot provide consent/permission for a stepchild they have not formally adopted.
2. Any guardian, conservator, or custodian appointed pursuant to a court order, for his or her ward or other charge.
3. A minor who is married, emancipated, or incarcerated may consent for him/herself.
4. A person designated in writing by an adult individual as having authority to make health care decisions for the individual, such as a health care proxy, health care agent, or durable power of attorney for healthcare.
5. Any person designated, orally or in writing to the supervising healthcare provider, as a surrogate by an adult or an emancipated minor.
6. In the absence of an alternate decision maker designated by the individual, a person designated as a surrogate decision maker by the individual's supervising healthcare provider in the individual's medical record.

B. Research that does not involve healthcare. The following individuals may provide consent for research that does not involve healthcare on behalf of individuals with diminished functional abilities or who have not reached the age of majority under Arkansas law:

1. Any parent, whether an adult or a minor, for his or her minor child. "Child" as used here includes biological or adopted children. Stepparents may not provide consent/permission for a stepchild they have not formally adopted.
2. Any guardian, conservator, or custodian, for his or her ward or other charge.
3. A minor who is married, emancipated, or incarcerated may consent for him/herself.
4. A person designated in writing by an adult individual as having authority to make decisions for the individual, such as a power of attorney, OR to make health care decisions for the individual, such as a health care proxy, health care agent, or durable power of attorney for healthcare.
5. Any person designated, orally or in writing to the supervising healthcare provider, as a surrogate by an adult or an emancipated minor.
6. In the absence of an alternate decision maker designated by the individual, a person designated as a surrogate decision maker by the individual's supervising healthcare provider in the individual's medical record.

C. For all research:

1. No person who is the subject of a protective order or other court order directing that person to avoid contact with the (potential) subject may serve as the (potential) subject's surrogate.
2. UAMS Medical Center Policy ML.1.01, Informed Consent, provides more information about designating a surrogate in the healthcare setting. Healthcare providers are to follow all relevant policies when designating surrogates.

REFERENCES:

Ark. Code Ann. §§ 20-6-101 et. seq

UAMS Medical Center Policy ML.1.01, Informed Consent

AAHRPP Elements I.1.G, II.3.F, II.4.A, II.4.B, III.1.C, III.1.F

AAHRPP Tip Sheet: State and Local Law