Department: UAMS Institutional Review Board

Policy Number: 17.13

Section: Special Populations Effective Date: February 25, 2005

Revision Dates: NA

SUBJECT: Legally Authorized Representatives

Purpose: To describe who meets the criteria of a legally authorized representative and in what types of research under Arkansas law.

Policy:

1. In Arkansas, in addition to other persons as may be authorized and empowered, the legally authorized representative for another person, for purposes of providing consent for research involving surgical or medical treatments or procedures, not prohibited by law, which might be suggested, recommended, prescribed or directed by a licensed physician, is any one the following:

- Any parent, whether an adult or a minor, for his minor child or adult child of unsound mind. Child as used here includes biological, adopted, step or foster children. The father of an illegitimate child, however, cannot consent for the child solely on the basis of parenthood;
- 2. Any person standing in loco parentis, whether formally serving or not;
- Any guardian, conservator, or custodian, for his ward or other charge under disability;
- 4. Any adult for a minor sibling or adult sibling of unsound mind:
- 5. If an authorized parent is absent, any maternal grandparent and, if the father is an authorized parent, any paternal grandparent, for a minor grandchild or for an adult grandchild of unsound mind;
- 6. Any married person, for a spouse of unsound mind; or
- 7. Any adult child, for their mother or father of unsound mind.

Important Note for CAVHS research. The VA regulations and handbook define legally authorized representative differently than Arkansas law and have additional requirements for cognitively impaired subjects. Please see IRB Policy 17.2 for further discussion.

In Loco parentis means one who puts him/herself in the situation of a lawful parent by assuming the obligations incident to the parental relation without going through the formalities necessary to a legal adoption.

Unsound Mind means and includes the inability to perceive all relevant facts related to one's condition and proposed treatment so as to make an intelligent decision based thereon, regardless of whether the inability is only temporary or has existed for an extended period of time or occurs or has occurred only intermittently and whether or not it is due to natural state, age, shock or anxiety, illness, injury, drugs or sedation, intoxication, or other cause of whatever nature. An individual shall not be considered to be "of unsound mind" for the purposes of this subchapter based solely upon the fact of his refusal of medical care or treatment.

"Other persons as may be authorized and empowered" would include an attorney-infact designated in a durable power of attorney for "health care". For purposes of the health care power of attorney statute, the term "health care" means "any care, treatment, service, or procedure to maintain, diagnose, treat, or provide for the patient's physical or mental health or personal care." An agent appointed under a power of attorney for health care would take precedence over any person listed above.

Court-appointed guardians also would be "authorized and empowered" to act on behalf of others, such as a minor or on behalf of a person of "unsound mind."

2. For **any other type of research**, there is no legally authorized representative specifically designated under Arkansas law. The research may be conducted, therefore, **only if** it meets the waiver criteria of 45 C.F.R. § 46.116(d) (outlined in policy 15.3, section 1.1) **and** is not FDA-regulated.