Department: **UAMS Institutional Review Board**
Policy Number: **17.2**
Section: **Special Populations**
Effective Date: **July 31, 2002**
Revision Dates: **February 8, 2005; June 24, 2004; October 10, 2002**

SUBJECT: Cognitively Impaired Persons

Policy: Additional safeguards must be in place to protect the rights and welfare of participants that may be vulnerable to coercion or undue influence such as those that are cognitively impaired. Individuals with psychiatric, cognitive, or developmental disorders, or those who are substance abusers may have limited capacity to understand the information presented and may not be able to make a reasoned decision about participation. Research that is expected to include cognitively impaired participants must address how determinations will be made as to whether a participant has impaired decision making capacity to consent both before and during the research and how those participants will be protected.

DEFINITIONS

Cognitively Impaired (also known as Unsound Mind): 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" based solely upon the fact of his refusal of medical care or treatment.

Health care: Any care, treatment, service, or procedure to maintain, diagnose, treat, or provide for the patient's physical or mental health or personal care.

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. See Policy 17.13 for Arkansas LAR Policy.

For Research involving, or having the potential to involve, non-VA cognitively impaired participants, INVESTIGATORS MUST:

Provide a proposed plan to assess the capacity to consent before and during the research. If capacity to consent is likely to be found lacking and the research involves surgical or medical treatments and/or procedures that might be prescribed by a licensed physician, provisions to obtain the permission of an appropriate LAR should be made. Policy 17.13 should be consulted for the list of appropriate LARs.

Procedure:

For Research involving, or having the potential to involve, VA cognitively impaired participants, INVESTIGATORS MUST:

Provide a proposed plan to assess the capacity to consent before and during the research in accordance with VA requirements. If capacity to consent is likely to be found lacking and the research involves surgical or medical treatments and/or procedures that might be prescribed by a licensed physician, provisions should be made to obtain the permission from an attorney-in-fact designated in a durable power of attorney for health care, or from next-of-kin in the following order: spouse, adult child (18 years or older), parent, adult sibling (18 years or older), grandparent, or adult grandchild (18 years or older). Do not use the LARs listed at 17.13. For VA research, only those listed here are allowed to grant surrogate permission.

IRB RESPONSIBILITIES WHEN INVOLVING VA RESEARCH

IRBs may only approve research involving persons with impaired decision-making capability when the following conditions apply:

1. Only incompetent persons or persons with impaired decision making capacity are suitable as research subjects. The investigator must demonstrate to the IRB that there is a compelling reason to include incompetent individuals or persons with impaired decision-making capacity as subjects. Incompetent persons or persons with impaired decision-making capacity must not be subjects in research simply because they are readily available.
2. The proposed research entails no significant risks, tangible or intangible, or if the research presents some probability of harm, there must be at least a greater probability of direct benefit to the participant. Incompetent people or persons with impaired decision-making capacity are not to be subjects of research that imposes a risk of injury, unless that research is intended to benefit that subject and the probability of benefit is greater than the probability of harm.
3. Procedures have been devised to ensure that participant's representatives are well informed regarding their roles and obligations to protect incompetent subjects or persons with impaired decision making capacity. When appropriate, the IRB should consider whether other health care providers ought to be consulted to ensure that proposed research procedures will not be detrimental to ongoing therapeutic regimens The LAR must be given descriptions of both proposed research studies and their obligations as a LAR. They must be told that their obligation is to try to determine what the subject would do if competent, or if the subject's wishes cannot be determined, what they think is in the incompetent person's best interest.

The IRB must make a determination in writing of each of the criteria listed above If these criteria are met, the IRB may approve the inclusion of incompetent subjects or subjects with impaired decision-making capacity in research projects on the basis of informed consent from a VA Approved LAR. Although incompetent to provide informed consent, some persons may resist participating in a research protocol approved by their representatives. Under no circumstances may subjects be forced or coerced to participate.

IRB CONSIDERATIONS WHEN INVOLVING NON-VA RESEARCH may be allowed in two situations.

1) As described above for VA Research; or

2) Where proposed research involves greater than minimal risk but where the purpose of the research is therapeutic with respect to individual subjects and where the risk is commensurate with the degree of expected benefit.

The IRB should consider whether to require investigators to solicit prospective subjects' "assent" (the willingness and, to the extent possible, knowledgeable participation of those unable to give legally valid consent). The IRB should also determine whether an incompetent person's refusal to participate in research should override consent given by a LAR.