



# Research Involving Cognitively Impaired Adults

## **Background**

Arizona statutes do not establish standards for determining whether a cognitively impaired adult can make and communicate health care treatment decisions. A person meets the clinical standard for being incapacitated if they are:

“Impaired by reason of mental illness, mental deficiency, mental disorder, physical illness or disability, chronic use of drugs, chronic intoxication or other cause...to the extent that he lacks sufficient understanding or capacity to make or communicate responsible decisions concerning his person.” [A.R.S. § 14-5101](#).

## **Definitions**

**Cognitively Impaired:** Having either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders), an organic impairment (e.g., dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests.

**Incapacitated Adults:** Under Department of Health and Human Services (DHHS) and Food and Drug Administration (FDA) regulations, a “legally authorized representative” (LAR) means “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.” Unless the IRB has waived the requirement to obtain consent, when research involves an adult who does not have the capacity to consent, consent must be obtained from a LAR. Because Arizona does not have a state statute that specifically addresses who may function as a LAR for research participation, in accordance with federal regulations and guidance from the Office of Human Research Protections (OHRP), the UA has established that the informed consent laws applicable to clinical care in Arizona will be followed to determine who may function as a LAR for research. Under Arizona law, where an adult lacks the capacity to consent to clinical care, the LAR of the subject will be determined by the following order of priority:

- 1) A court-appointed legal guardian who has been granted “general” guardianship or “guardian of the person” (but not a guardian granted only guardianship over financial matters) may provide surrogate consent for research participation. This would not apply if a court has revoked or suspended a guardian’s authority. The investigator should obtain a copy of the court order appointing the individual as the guardian and should maintain the copy with the research records.
- 2) An agent under an individual’s health care power of attorney (HCPOA) may provide surrogate consent for research participation. A HCPOA is effective following a physician’s determination that the individual lacks adequate capacity to make her/his own health care decisions. This would not apply if the HCPOA expressly limits the agent’s authority to consent to research or for the types of procedure(s) involved in the research. The



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investigator should obtain a copy of the HCPOA and should maintain the copy with the research records. Note that a Durable Power of Attorney under A.R.S. 14- 5501 et seq. does NOT confer authority to the agent to consent to health care decision-making, unless it expressly includes the authority to consent to health care.

### **Guidance**

It is generally recommended in the clinical setting that a physician with appropriate clinical training determine capacity. Consultation with a psychiatrist or psychologist may be advisable in some situations but is not required when treatment is for conditions unrelated to the subject's mental health.

In the event there is neither a court-appointed guardian nor an agent under a HCPOA, surrogate consent for research may be given by other individuals listed below, in order of priority, unless there is evidence that the subject did not want the individual to act as his or her surrogate:

- 1) The subject's spouse, unless the subject and spouse are legally separated.
- 2) An adult child of the subject. If the subject has more than one adult child, the investigator shall seek the consent of a majority of the adult children who are reasonably available for consultation.
- 3) A parent of the subject.
- 4) A brother or sister of the subject.

Beyond the categories described above, others may not give surrogate consent for research enrollment. Institutional custodians or caretakers are not LARs unless they meet the requirements above.

Where an individual does not have the capacity to decide whether to participate in research, primary consent will be obtained from the LAR. However, there may be occasions when it is possible to seek the assent of the subject, in addition to the consent of the LAR. The IRB will determine whether assent of the subject is a requirement, and if so, whether the plan for assent is adequate. For research involving cognitively impaired adults, submit the *Appendix for Cognitively Impaired Individuals* in eIRB for IRB review.

For research outside Arizona, a determination of who meets the DHHS and FDA definitions of "legally authorized representative" is to be made with consultation with the UA Office of General Counsel and other legal counsel as UA Office of the General Counsel deems necessary.

A LAR may **not** consent for the individual to participate in research if:

- 1) The LAR knows, or upon reasonable inquiry ought to know, that any aspect of the research protocol is contrary to the religious beliefs or basic values of the prospective subject, whether expressed orally or in writing.
- 2) Two or more persons who qualify as LARs and have equal decision-making priority inform the principal investigator or attending physician that they disagree with each other as to participation of the prospective subject in the research.



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The investigator conducting the research knows that the prospective subject has expressed disagreement about participating in the research.