Department: UAMS Institutional Review Board
Policy Number: 17.2
Section: Special Populations
Effective Date: July 31, 2002
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SUBJECT: Persons with Diminished Functional Capacity

POLICY

Adult subjects are routinely viewed as capable of consenting to enroll and participate in research. Subjecting unimpaired participants to risks associated with IRB-approved research is ethically permissible when the participants decide that doing so is in their interests or in line with their values and provide consent. However, functional abilities exist along a continuum, and can fluctuate due to various physical and psychological conditions. These conditions can include, but are not limited to, acute or chronic medical conditions, and psychiatric, neurologic, developmental, or behavioral disorders. Prospective adult participants with impaired functional abilities are presumed to be capable of giving consent to enroll and participate in a research study unless there is substantial evidence they are not capable. People with diminished functional capacity may be less likely to understand the purpose or voluntary nature of research, to anticipate reasons against their participation, or to express their wishes than participants with unimpaired functional abilities. Investigators and the IRB shall ensure that appropriate measures to safeguard subjects' rights, safety, and welfare are in place if subjects with diminished functional abilities may be enrolled.

DEFINITIONS

Assent: A positive indication of willingness to participate in a research study
Diminished functional abilities/capacity: 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.
Capacity to consent: The ability to provide legally effective consent to enroll in a research study.
Health care: Any care, treatment, service, or procedure to maintain, diagnose, treat, or otherwise affect an individual's physical or mental health condition.
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.

PROCEDURE

A. Research that is expected to include persons with diminished functional abilities 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.
B. Research with people who have diminished functional capacity must fall in to one of two categories:
    1. The proposed research is minimal risk. The investigator must demonstrate to the IRB that there is a compelling reason to include cognitively impaired individuals as subjects. Cognitively impaired individuals must not be subjects in research simply because they are readily available.
    OR
    2. The research presents a potential of direct benefit to the participant. Cognitively impaired individuals may not be subjects in research that is greater than minimal risk, unless that research has a potential to directly benefit the subject and the potential benefits outweigh the potential risks.
C. Investigator responsibilities when proposing research involving persons with diminished functional capacity include:
    1. Provide a plan to assess the capacity to consent before and during the research. The plan should indicate an individual with relevant expertise will evaluate prospective participants' capacity to consent and make an objective determination regarding each participant's capacity to consent. Any additional methods used to assist with these evaluations, such as conducting interviews, screening tests, or formal assessment instruments, should also be described, noting that cognitive tests and competence assessment instruments alone cannot provide the basis of the evaluator's determination, and should at most supplement or support the evaluator's judgment.

2. If capacity to consent is likely to be found lacking, provisions to obtain the permission of an appropriate LAR should be made. See IRB Policy 17.13 for information about LARs.
3. If feasible, researchers should try to support or enhance prospective subjects' ability to consent. Methods such as designing a multi-step consent process (capacity assessment, presentation of information, obtaining consent to each step separated by a certain period of time) or enhanced presentation of consent information using materials other than written consent form may be appropriate.
4. For participants incapable of providing consent, but capable of communicating a preference regarding participation, the PI should make reasonable efforts to provide information about the research and ensure that the participant is willing to join the study.
5. Describe in the submission any additional safeguards that are in place to protect the rights and welfare of subjects with diminished functional capacity.

D. IRB responsibilities when reviewing and approving research involve persons with diminished functional ability include:
   1. The IRB may only approve research involving persons with diminished functional ability when the following conditions are met:
      a. The research cannot reasonably conducted without these subjects' participation
      b. The proposed research has all necessary safeguards in place to protect the rights and welfare of the cognitively impaired subjects.
      c. The informed consent process and document are appropriate for these subjects, and include provisions for assessing potential subjects' ability to provide their own consent and for seeking consent from an LAR, as appropriate.
   2. The IRB should consider whether to require investigators to solicit prospective subjects' assent, keeping in mind that the dissent of a subject should always be respected.
   3. Assessing whether subjects' functional capacity may fluctuate during research participation, and if so, whether appropriate measures are in place to ensure subjects' rights, safety, and welfare are protected throughout participation.
   4. The IRB should consider the following elements when reviewing research involving people with diminished functional abilities:
      a. Whether the population targeted for recruitment represents the population with the least degree of impairment to functional abilities compatible with the study's aims.
      b. The possibility the subjects may be unusually sensitive to the possible risks of the research.
      c. The results of any previous research involving the experimental intervention in animals or humans with unimpaired functional abilities.
      d. Whether the proposed method of assessing capacity to consent is appropriate to the research (the assessment methodology should increase in rigor as the degree of risk and the extent of impairment to subjects' functional ability increase)
      e. Whether assent from participants should be sought and, if so, the proposed method for doing so is appropriate
      f. Whether knowledge to be likely to be gained through the study will improve the understanding of the condition, disease or behavior affecting the participant population
      g. Compensation for participation is appropriate and is being provided to the appropriate person (i.e. monetary payments should be given to the participant or to an individual who regularly manages the participants' finances, if participants do not manage their own expenses.

REFERENCES

45 CFR 46.111(a)(3)
21 CFR 58.111(a)(3)
AAHRPP Element II.4.A, II.4.B, III.1.C, and III.1.F
AAHRPP Tip Sheet 26, *Reviewing Research Involving Adult Participants with Diminished Functional Abilities Related to Capacity to Consent*