

Department: UAMS Human Research Advisory Committee
Policy Number: 17.3
Section: Special Populations
Effective Date: July 31, 2002
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SUBJECT: Economically and Educationally Disadvantaged

Normal volunteers may be considered vulnerable subjects particularly if they are members of economically or educationally disadvantaged populations. Normal subjects may be unduly influenced by an offer of monetary compensation particularly if it appears excessive in relation to the effort required. They may feel coerced by one-on-one personal recruitment by a person in authority, their physician for example. Educationally or economically disadvantaged persons may feel pressured to agree to volunteer for fear of losing health or other benefits [21CFR56.111(b); 38 CFR56.111(a)(3); 45 CFR46.111(a)(3)].

Guidelines for the HRAC:

1. Research involving normal volunteers should involve low or minimal risk and any foreseeable risks must be minimized. Justification must be provided for involving normal volunteers in protocols involving greater than minimal risk.
2. The manner in which normal volunteers will be contacted and recruited for participation must be specified.
3. Advertisements or scripts must be submitted to the HRAC for review prior to beginning the study. (General announcements or advertisements should be used rather than person-to-person recruitment.)
4. The manner in which the confidentiality of the data collected will be protected must be specified.
5. There must be a statement in the informed consent that participation is voluntary and that the subject has the choice of not participating.
6. The issue of costs to the research subject must be specifically addressed. There must be no medical costs to the participant.
7. Any known or unknown long-term risks to the participant must be addressed in the consent form.
8. There must be a specific plan regarding compensation for injury that might result from participation in the research.