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| **Department:** | **UAMS Institutional Review Board** |
| **Policy Number:** | **17.6** |
| **Section:** | **Special Populations** |
| **Effective Date:** | **July 31, 2002** |
| **Revision Date:** | **August 24, 2004; February 15, 2016** |

**SUBJECT: Minorities**

Federal regulations require the equitable selection of subjects [45 CFR 46.111(a)(3)]. In addition, NIH requires that applicants for all research grants, cooperative agreements, and contracts involving human subjects include minorities (and women) in study populations "so that research findings can be of benefit to *all* persons at risk of the disease, disorder or condition under study; special emphasis should be placed on the need for inclusion of minorities and women in studies of diseases, disorders and conditions which disproportionately affect them." Investigators must provide a "clear compelling rationale for their exclusion or under- representation" Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources.

The inclusion of minorities in research is important, both to ensure that they receive an equal share of the benefits of research and to ensure that they do not bear a disproportionate burden. Most diseases affect all population groups, minority and non-minority alike. For generalizability purposes, investigators must include the widest possible range of population groups. Sometimes, however, minorities are subject to a differential risk. Some research, for example, relates to conditions that specifically affect various minority groups (*e.g*., sickle cell anemia or Tay Sachs disease), so that involvement of the relevant minority groups is imperative. Other research focuses on characteristics of diseases or effectiveness of therapies in particular populations (*e.g*., HIV transmission, treatment for hypertension), and may also concern conditions or disorders that disproportionately affect certain racial or ethnic groups. Exclusion

or inappropriate representation of these groups, by design or inadvertence, would be unjust. Further, to the extent that participation in research offers direct benefits to the subjects (in HIV research, for example, the receipt of a promising new drug), under representation of minorities

denies them, in a systematic way, the opportunity to benefit.

**IRB Considerations:** Research designs that include diverse study populations are highly desirable. The UAMS IRB will require investigators to justify protocols that call for homogeneous study populations. The UAMS IRB will be aware of the implications of various recruiting strategies, and be prepared to suggest alternative recruitment methods so as to ensure an appropriately diverse or focused subject population.

In addition to ensuring adequate appropriate representation of minorities in study populations (and guarding against inappropriate overburdening of minorities), the UAMS IRB must ensure that any special vulnerabilities of subjects are accounted for and handled appropriately. To the extent that prospective minority study populations are also economically or educationally disadvantaged, the UAMS IRB will safeguard their rights and welfare by making sure that any possible coercion or undue influence is eliminated (*e.g*., compensation that is not commensurate with the risk, discomfort, or inconvenience involved, or recruiting in institutional settings where voluntary participation might be compromised).

The UAMS IRB will also safeguard the consent process (and, indeed, the entire research relationship) to ensure open and free communication between the researcher and the

prospective subject. Consent documents must be written in language easily understandable to subjects; the possibility of illiteracy should be accounted for, as should the need for communicating in foreign languages. The informed consent documents should be available in English and other languages as appropriate to the subject population(s). Foreign language consent documents should be developed using quality control procedures. Translation from English to the other language and then back to English, to ensure that the information is correctly conveyed, is encouraged. The UAMS IRB will require a letter from the translator certifying that the foreign language consent is a faithful rendition of the approved English consent form. The role of cultural norms of subjects should also be addressed. The involvement of representatives from the target population(s) may also be pertinent to IRB review.