Department:	**UAMS Institutional Review Board**
Policy Number:	**14.1**
Section:	**Recruitment Practices**
Effective Date:	**July 31, 2002**
Revision Date:	**June 24, 2004; February 15, 2016; July 21, 2020; October 15, 2024**

Subject: Subject Selection

POLICY

The Belmont Report principle of justice requires the equitable distribution of the benefits and burdens of human subject research. This principle aims to ensure one group does not bear the majority of research burdens while another bears the benefit of research. Subject selection must be equitable, and must take into account the purposes of the research and the setting in which it will be conducted. The history of human subject research contains many examples where subject populations were targeted for reasons unrelated to a study's scientific needs, and were instead based on potential participant availability and/or ability to be manipulated regarding the decision of whether to join a research study. Determining the target population and designing recruitment and consent methods are all factors in ensuring subject selection is equitable.

PROCEDURE

A. PIs and the IRB shall be mindful of subject selection considerations. Investigators and the IRB must consider factors such as whether the potential subjects are being systematically selected for reasons such as easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Examples include:
   1. Institutionalized individuals may not feel they have the autonomy to make their own decisions about participating.
   2. Students and employees of the individuals/institutions carrying out or otherwise involved in the research may feel their academic or employment standing will be affected by their decisions.
   3. The patient of a treating physician who is also a research may feel compelled to participate out a desire to please the physician or fear that failure to do so will result in hostility or abandonment.
   4. Patients dependent upon a particular facility for care may fear being treated less well or with less favor if they decline research participation.

B. The concept of vulnerability can be divided into two categories
   1. Categorical vulnerability, in which certain groups or populations are routinely considered vulnerable.
      a. Regulations describe some groups as vulnerable, e.g, children, prisoners, or people with impaired decision-making capacity, or economically or educationally disadvantaged individuals.
      b. This approach has been described as appropriate when all group members are disadvantaged for the same reason.
   2. Contextual vulnerability, in which individuals' vulnerability stems from their situations rather than from their personal characteristics.
   3. The IRB should be mindful of which type of vulnerability may be applicable to studies under review.

C. Keeping these considerations in mind, investigators and the IRB shall be careful to not overprotect vulnerable populations such that they are excluded from participating in research in which they wish to participate, or from which they or their community may benefit. Examples include:
   1. Patients with a serious or poorly understood condition may want to participate frequently in research designed to provide a better understanding of their condition.
   2. Racial and ethnic minorities, whose communities may have been inappropriately targeted for research participation in the past, should not be excluded from research that may benefit them or others similarly situated.

3. The National Institutes of Health requires its research grantees to include minorities and women in the study population "so that the research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study." If a proposed study includes a study population in which women and minorities are not appropriately represented, the investigator must provide "a clear, compelling rationale for their exclusion or inadequate representation".

D. Specific considerations for investigators and the IRB regarding equitable selection of subjects:
   1. Will the burdens of participating in the research fall on those most likely to benefit from the research?
   2. Will the solicitation of subjects avoid placing a disproportionate share of the burdens of research on any single group?
   3. Does the nature of the research require or justify using the proposed subject population?
   4. Are there any groups of people who might be more susceptible to the risks presented by the study and who therefore ought to be excluded from the research? Are the procedures for identifying such individuals adequate?
   5. To the extent that benefits to the subjects are anticipated, are they distributed fairly? Do other groups of potential subjects have a greater need to receive any of the anticipated benefits?
   6. To the extent that participation in the study is burdensome, are these burdens distributed fairly? Is the proposed subject population already so burdened that it would be unfair to ask them to accept an extra burden?
   7. Will any special physiological, psychological, or social characteristics of the subject group pose special risks for them?
   8. Would it be possible to conduct the study with other, less vulnerable subjects? What additional expense or inconvenience would that entail? Does the convenience of the researcher or possible improvement in the quality of the research justify the involvement of subjects who may either be susceptible to pressure or who are already burdened?
   9. Has the selection process *overprotected* potential subjects who are considered vulnerable (*e.g.*, children, cognitively impaired, economically or educationally disadvantaged persons, patients of researchers, seriously ill persons) so that they are denied opportunities to participate in research?
   10. If the subjects are susceptible to pressures, are there mechanisms that might be used to reduce the pressures or minimize their impact?
   11. Is the reimbursement provided equitable to subject or would it potentially unduly influence a decision about research participation?

E. Investigators may wish to keep a prospective screening and enrollment log to document subject selection.
   1. Many clinical trials require the use of screening and enrollment logs, and such logs may be a best practice in other types of research as well.
   2. The ICH guidelines list screening and enrollment logs as essential documents.

REFERENCES

The Belmont Report
45 CFR 46.111(a)(3)
21 CFR 46.111(a)(3)
NIH Policy and Guidelines on The Inclusion of Women and Minorities as Subjects in Clinical Research
Gordon, B.G. *Vulnerability in Research. Basic Ethical Concepts and Approaches to Review.* Oschner J., 2020 Spring; 20(1): 34–38.
ICH GCP 8.3.20 and 8.3.22
AAHRPP Elements II.3.C and III.1.E