

 JOHNS HOPKINS BLOOMBERG SCHOOL of PUBLIC HEALTH	Human Research Protection Program Policies & Procedures	
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Title: Recruiting Research Subjects	Date Effective 5/25/04	Supercedes P&P dated

Minorities and Women

Background

Investigators and IRBs are responsible for ensuring the equitable selection of subjects in research. The Belmont report emphasizes the importance of including men, women and minorities in research so they can share equally in its benefits and do not bear a disproportionate share of its burdens. It also stressed that investigators should include the widest range of population groups in their research so their results can be generalized as widely as possible.¹

In 1994, NIH established guidelines on the inclusion of women and minorities of all ages in all biomedical and behavioral research that it supports. These stated that:

“. . .women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that exclusion is appropriate with respect to the health of the subjects or the purpose of the research.”²

This policy specifically prohibits the exclusion of women of child-bearing age from research without a reasonable scientific justification. It furthers states that cost is not an acceptable reason for excluding a particular group or subgroup.

Although DHHS previously stipulated that paternal consent was required for a pregnant woman to participate in clinical research, this is no longer the case. A pregnant woman is now the sole decision-maker about whether or not to participate in the research.³ There are, however, exceptions to this rule (see CHR Policy and Procedure on Pregnant Women, Fetuses and Neonates).

Proposals for NIH-supported research, including exempt research, must include details on the selection of research subjects, including characteristics of the subject population, anticipated numbers, age range and health status. The gender and racial/ethnic composition of the subject population must also be described, as well as the rationale for including or excluding any specific subpopulation(s).

JHSPH POLICY AND PROCEDURES

CHR applies the NIH requirements to all JHSPH research, regardless of the funding source, unless adequate justification for exclusion of specific subgroups is provided with the CHR application. When applying these requirements CHR will consider:

- the sex, race, ethnicity and age of the targeted study population,
- the characteristics of the larger population from which study subjects will be recruited,
- whether the study population is appropriate for the purpose of the research,
- whether any group or individual is excluded from the research without a good scientific reason, and
- the rationale for inclusion/exclusion criteria.

At the time of continuing review, investigators must provide specific information on the population and subpopulations enrolled. The Committee may, based on the information provided, require investigators to explain why a specific subpopulation has not been enrolled or is under-represented.