

Wayne State University Human Investigation Committee	
SUBJECT	The Inclusion of Women and Minorities in Clinical Research
Section	
Form Date	
Approvals	10/27/97 Steering Committee, 11/97 All IRB Committees, 4/25/98 Administrative

Background

Based on federal regulations described in the Civil Rights Act of 1964, it is illegal to discriminate against individuals on the basis of sex or race. By extension, the *automatic* exclusion of women or minorities from research protocols is discriminatory.

Sections of the Code of Federal Regulations (45 CFR 46.111) as well as recent FDA and NIH guidelines, also address the inclusion of women and minorities in research. The inclusion of these groups is meant to ensure that they receive an equal share of the benefits of research and that they do not bear a disproportionate burden. For the purposes of generalizability, investigators must include the widest possible range of populations as well as both genders.

NIH guidelines encourage investigators to actively recruit women and minorities into their trials in order to assure that adequate numbers are included in clinical research. These groups must be included in such a way that valid analyses of differences can be accomplished, especially in Phase III clinical trials. Outreach programs are recommended, and cost is not an acceptable reason to exclude underrepresented groups.

Inclusion requirements do not apply if they are inappropriate with respect to the subjects' health or the purpose of the research, or other circumstances as designated by federal agencies. They do not apply if there is substantial evidence that there are no differences in the study variables or treatment effects.

Clinical research includes any biomedical or behavioral research in human subjects. A *minority group* is a readily identifiable subset of the U.S. population that is distinguished by racial, ethnic, and/or cultural heritage. The Office of Management and Budget Directive No. 15 defines the minimum standard of categories as follows: American Indian or Alaskan Native, Asian or Pacific Islander, Black, not of Hispanic origin, and Hispanic.

HIC Policy

Inclusion of women: The HIC requires that clinical research protocols include adequate representation of women. Specifically, there should be approximately equal numbers of both sexes in populations at risk unless different proportions are appropriate because of *known* prevalence, incidence, morbidity, mortality rates, or expected intervention effect.

Such exceptions should be described in the protocol as part of the justification for any apparent gender inequity. The rationale must be scientifically based.

Inclusion of minorities: The HIC requires that clinical research protocols include adequate representation of minorities, including their sub-populations. The inclusion of minorities must be considered in all stages of research design. Researchers should collect data on groups of whom knowledge gaps exist, or in whom the disease or condition is disproportionately prevalent. Therefore, investigators should be aware of concurrent research that addresses specific minority populations, as well as areas where it would be appropriate to study a single minority group.

From a practical perspective, there is some theoretical limit on the number of such subgroups that can realistically be studied in detail in any given protocol. Therefore, the investigator should clearly address the rationale for inclusion or exclusion of minorities and their subgroups in terms of the purpose of the research. Scientific justifications must be presented. Emphasis should be placed upon inclusion of those sub-populations in which there is little information, or in which the disease or condition of interest manifests itself disproportionately, or in which the intervention operates in an appreciably different way.

In geographic locations where limited numbers of racial/ethnic populations are available, the investigator must address the issue of terms of the purpose of the research and such factors as the size of the study; the relevance of the disease or condition; and the feasibility of collaborating to include minority groups. Outreach programs are recommended.

Women and minorities are to be included in such a way that valid analysis of gender or populations differences can be accomplished if appropriate particularly in Phase III clinical trials.

HIC Policy for IRB Review of Protocols

Each protocol must be reviewed individually to determine whether the plans for inclusion of minorities in that particular study are appropriate and/or adequate. The automatic exclusion of women or minorities (i.e. without a stated rationale) is not acceptable. Reviewers should ask the investigator for an explanation of the rationale for inclusion or exclusion if it is not given or it is not clear. The rationale must be scientifically justifiable.

The NIH has recently provided a "Decision Tree for Inclusion of Women and Minorities in Clinical Research". Reviewers are encouraged to use this as a guideline for reviewing individual protocols.