MANUAL GUIDE - GENERAL ADMINISTRATION CDC-80
REFERENCE POINTS
CDC Associate Director for Science
CIO Associate Directors for Science
ATSDR Associate Administrator for Science
TRANSMITTAL NOTICE 96.2, 2/16/96

INCLUSION OF WOMEN AND RACIAL AND ETHNIC MINORITIES IN RESEARCH

Sections

I. PURPOSE

The Centers for Disease Control and Prevention (CDC)[1] is committed to protecting the health of *all* people regardless of their sex, race, ethnicity, national origin, religion, sexual orientation, socioeconomic status, or other characteristics. To the extent that participation in research offers direct benefits to the participants, underrepresentation of certain population subgroups denies them the opportunity to benefit. Moreover, for purposes of generalizing study results, investigators must include the widest possible range of population groups.

This Guide sets forth CDC policy on the inclusion of women and members of racial and ethnic minority groups in intramural research[2] conducted by CDC staff. The guidelines are intended to ensure that individuals of both sexes, regardless of sexual orientation, and the various racial and ethnic groups will be included in CDC studies involving human subjects, whenever feasible and appropriate. Furthermore, it is the intent of CDC to proactively identify significant gaps in knowledge about health problems that affect women and racial and ethnic minority populations and to encourage research which addresses these problems.

II. BACKGROUND

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[1] References to CDC also apply to ATSDR.

[2] A "Policy on the Inclusion of Women and Racial and Ethnic Minorities for Externally Awarded Research" was published in the Federal Register, September 15, 1995 and is applicable for all CDC externally awarded research projects submitted in response to CDC Program Announcements (i.e., Requests for Assistance) and solicitations (i.e., Requests for Proposals) announced on or after October 1, 1995.

The health conditions and health care needs of women differ from those of men in a variety of ways. Some health conditions are unique to women and others are more prevalent in women. For some illnesses, there are marked distinctions, not only in onset and progression of disease, but also in the approaches necessary to combat them in women. Furthermore, initial entry into the health care system may be different for some subgroups of women, such as low-income and uninsured women. Lesbians may also enter the health care system differently because they may be less likely to access prevention services, like cancer screening because they may not utilize family planning services. The Public Health Service Task Force on Women's Health Issues published a report in 1987 stating that it is becoming more important to note the environmental, economic, social, and demographic characteristics that influence a woman's health status. The Task Force focused on the direct and indirect effects these factors could have on the status of a woman's health and noted that when a woman is "outside the normal range of societal expectations," that is, when she is of a racial, ethnic or cultural minority or if she is physically or mentally disabled, her health status is potentially at greater risk. These observations should be recognized and reflected in study protocols and proposals.

The disparity in health outcomes between majority and some racial and ethnic minority groups is now well documented. Although some minority populations (e.g., some Asian groups) have better overall health status than non-Hispanic whites, other minority populations have dramatically shorter life expectancy, higher morbidity rates, and inadequate access to quality health care. The Secretary for the Department of Health and Human Services' Task Force on Black and Minority Health issued a report in 1985 noting the underrepresentation of racial and ethnic minorities in research. This underrepresentation has resulted in significant gaps in knowledge about the health of racial and ethnic minority populations and their responses to interventions.

Recently, Congress has legislated that special attention be given to the inclusion of women and racial and ethnic minority groups in all clinical research conducted or supported by the National Institutes of Health. Although this legislation does not apply to CDC, the agency is committed to the appropriate inclusion of women and racial and ethnic minority groups in its research activities.

III. EFFECTIVE DATE

This policy applies to all intramural research projects at CDC that are implemented on or after April 1, 1996. (For guidance regarding externally awarded research, CDC project officers should refer to Federal Register, Vol. 60, No. 179, September 15, 1995, pgs. 47947-47951, Notice

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"Policy on the Inclusion of Women and Racial and Ethnic Minorities for Externally Awarded Research.")

IV. DEFINITIONS

A. Human Subjects

As defined in Department of Health and Human Services regulations for the protection of human subjects (Title 45 CFR Part 46), human subject means "a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information."

B. Research

As defined in Department of Health and Human Services regulations for the protection of human subjects (Title 45 CFR Part 46), research means "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

C. Racial and Ethnic Categories

1. Minority Groups

This policy shall comply with the Office of Management and Budget (OMB) Directive No. 15, and any subsequent revisions to the Directive. OMB Directive No. 15 defines the minimum standard of basic racial and ethnic categories. Despite significant limitations, (as outlined in the Public Health Reports "Papers from the CDC/ATSDR Workshop on the Use of Race and Ethnicity in Public Health Surveillance"), these categories remain useful because they allow comparisons among many national data bases, especially Bureau of the Census and national health data bases. Therefore, the racial and ethnic categories described below should be used as basic minimum guidance, cognizant of their limitations.

American Indian or Alaskan Native: A person having origins in any of the original people of North America, and who maintains cultural identification through tribal affiliation or community recognition.

Asian or Pacific Islander: A person having origins in any of the original peoples of East Asia, Southeast Asia, the Indian subcontinent, or the Pacific Islands. This area includes, for example, China, India, Japan, Korea, the Philippine Islands, and Samoa.

Black, not of Hispanic Origin: A person having origins in any of the black racial groups of Africa.

Hispanic: A person of Mexican, Puerto Rican, Cuban, Central or South American or other Spanish culture or origin, regardless of race.

2. Majority Group

White, not of Hispanic Origin: A person having origins in any of the original peoples of Europe, North Africa, or the Middle East.

While investigators should focus primary attention on the above categories, CDC recognizes the diversity of the population. For example, Blacks describe themselves in several different ways, including African-American and Caribbean (e.g., Haitian, Jamaican, West Indian, Trinidadian, etc.) Native Hawaiians have expressed the desire to be considered a separate racial/ethnic category exclusive of the current Asian/Pacific Islander designation. Therefore, investigators are encouraged to investigate national or geographic origin or other cultural factors (e.g., customs, beliefs, religious practices) in studies of race and ethnicity, and their relationship to health problems. Furthermore, since race, ethnicity, and cultural heritage may serve as surrogate markers for other more important characteristics or conditions associated with a health problem or outcome, investigators should actively seek to identify these other characteristics or conditions.

V. POLICY ON RESEARCH INVOLVING HUMAN SUBJECTS

CDC Centers/Institute/Offices (CIO) must ensure that women and racial and ethnic minority populations are appropriately represented in their research protocols. Women and members of racial and ethnic minority groups should be adequately represented in all CDC research involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the CIO Director that inclusion is inappropriate or clearly not feasible. Although this policy does not apply to studies when the investigator cannot control the race, ethnicity, and sex of subjects, women and racial and ethnic minority populations must not be routinely and/or arbitrarily excluded from such investigations.

In addition, women of childbearing potential should also not be routinely and/or arbitrarily excluded from participation even though there are ethical/risk issues to consider for inclusion and exclusion. Information on differences in adverse outcomes or risk profiles for pregnant women

may be reason for exclusion. Therefore, pregnancy status may need to be determined prior to enrollment for some studies and, if necessary, during an intervention to safeguard the participants' health.

All proposed research involving human subjects and conducted by CDC staff will be evaluated for compliance with this policy, including those projects that are exempt from Institutional Review Board (IRB) review (as specified in Title 45 CFR Part 46). *However, nothing in this policy is intended to require IRB review of protocols which otherwise would be exempt from such review.* This policy applies to all CDC intramural research. This policy does not apply to those projects in which the investigator has no control over the composition of the study population (e.g., cohort studies in which the population has been previously selected, or research to follow-up outbreak investigations).

VI. GUIDANCE FOR COMPLIANCE

A. General

In determining whether special efforts should be made to set specific enrollment goals for women and members of racial and ethnic minority groups, or whether to design special studies to specifically address health problems in such populations, principal investigators should consider the following points:

- Is the disease or condition under study unique to, or is it relatively rare in men, women or one or more racial and/or ethnic minority populations?

- What are the characteristics of the population to which the protocol results will be applied? Does it include both men and women? Does it include specific racial and ethnic minority populations?

- Are there scientific reasons to anticipate significant differences between men and women and among racial and ethnic minority populations with regard to the hypothesis under investigation?

- Are there study design or recruitment limitations in the protocol that could result, unnecessarily, in underrepresentation of one sex or certain racial and ethnic minority populations?

- Could such underrepresentation cause an adverse impact on the generalizability and application of results?

- Is the underrepresentation correctable?

- Does racial and ethnic characterization of study subjects serve a bona fide purpose or might it serve only to stigmatize a group?

Inclusion of women and/or racial and ethnic minority groups in research can be addressed either by including all appropriate groups in one single study or by conducting multiple studies. In general, protocols and proposals for support of studies involving human subjects should employ a design with sex and/or minority representation appropriate to the scientific objectives. It is not a requirement that the study design provide sufficient statistical power to answer the questions posed for men and women and racial and ethnic groups separately; however, whenever there are scientific reasons to anticipate differences between men and women and/or racial and ethnic groups with regard to the hypothesis under investigation, investigators should include an evaluation of these sex and minority group differences in the study proposal. If adequate inclusion of one sex and/or minority group is impossible or inappropriate with respect to the purpose of the proposed study, the rationale for the study population must be well explained and justified. Similarly, if in the only study population available, there is a disproportionate representation of one sex or minority/majority group, the rationale for the study population must be well explained and justified. The cost of inclusion of women and/or racial and ethnic minority groups shall not be a permissible consideration for exclusion from a given study unless data regarding women and/or racial and ethnic minority groups have been or will be obtained through other means that provide data of comparable quality. Acceptable reasons for exclusion are as follows:

- Inclusion is inappropriate with respect to the health of the subjects.

- Inclusion is inappropriate with respect to the purpose of the study.

- Substantial scientific evidence indicates there is no significant difference between the effects that the variables to be studied have on women and/or racial and ethnic minority groups.

- Substantial scientific data already exist on the effects that variables have on the excluded population.

- Inclusion is inappropriate under other circumstances as determined by the CIO Director or Inclusion Review Committee (see Section VIII).

Each protocol or research proposal should include an explicit discussion of the sex and racial and ethnic composition of the proposed study population. A separate section is not required, but including one in the protocol may be a practical way to discuss the inclusion of women and racial and ethnic minorities as study subjects, or be helpful in directing a reader to parts of the document where the pertinent references to that subject might be found. If the CDC policy on the inclusion of women and racial and ethnic minorities does not apply to this research (i.e., the investigator has no control over the composition of the study population), the discussion should offer details explaining why certain groups were excluded, and the protocol should include:

- the rationale for selecting the study population; and
- the consideration of sex and racial and ethnic issues addressed in developing the research design and sample size appropriate for the scientific objectives of the study.

If the CDC policy on the inclusion of women and racial and ethnic minorities applies, the discussion or appropriately referenced sites in the protocol should include:

- research plans that describe outreach programs, if any, for recruiting women and racial and ethnic minorities as participants;
- the cultural differences and variety of languages inherent in the population to be enrolled; and
- the possibility of non-proficiency in English or illiteracy of a potential research participant and, consistent with this possibility, assurances that adequate provision has been made for appropriate translation of the consent document or the availability of translators to ensure an adequate understanding of the research project.

B. Studies of Public Health Interventions

Investigators must consider the following when planning an intervention trial or a clinical trial:

- If the data from prior studies strongly indicate the existence of significant differences of clinical or public health importance in intervention effect between the sexes or among racial and ethnic populations, the primary question(s) to be addressed by the

scientific investigation and the design of that study must specifically accommodate the difference(s). For example, if men, women, and racial and ethnic minority groups are thought to respond differently to an intervention, then the study should be designed to answer separate primary questions that apply to men, women, and/or specific racial and ethnic groups with adequate sample size for each.

- If the data from prior studies strongly support no significant differences of clinical or public health importance in intervention effect between subgroups, then sex and race and ethnicity are not required as subject selection criteria; however, the inclusion of sex and racial and ethnic subgroups is still strongly encouraged.

- If the data from prior studies neither support nor negate the existence of significant differences of clinical or public health importance in intervention effect, then the study should include sufficient and appropriate male and female and racial and ethnic minority populations so that valid analysis of the intervention effect in each subgroup can be performed.

- If women of childbearing potential are to be included and if there is reason to suspect that adverse events may occur in pregnant women, pregnancy status should be determined prior to enrollment.

VII. ROLES AND RESPONSIBILITIES

Certain individuals and groups have special roles and responsibilities with regard to the implementation of these guidelines.

A. Investigators

Investigators should assess the theoretical and/or scientific linkages between sex, race and ethnicity and their topic of study. Following this assessment, the principal investigator will address the policy in each protocol, providing the required information on inclusion of women and racial and ethnic minorities and any required justifications for exclusions of any groups. Investigators are also responsible for monitoring implementation of this policy during the conduct of the study.

1. Recruitment Outreach by Intramural Investigators

Investigators and their staff(s) are urged to develop appropriate and culturally sensitive outreach programs and activities commensurate with the goals of the research. The purpose should

be to establish a relationship between the investigator(s), populations, and community(ies) of interest so that mutual benefit is derived by all groups participating in the study. Investigators should document the process for establishing a partnership with the community(ies) and the mutual benefits of the study and ensure that any factors (e.g., educational level, non-proficiency in English, low socioeconomic status) are accounted for and handled appropriately. In addition, investigator(s) and staff should ensure that ethical concerns are clearly noted and enforced, e.g., minimizing the possibility of coercion or undue influence in the incentives or rewards offered in recruiting into or retaining participants in scientific studies.

2. Dissemination of Research Results

Investigators and program managers are urged to make special efforts to disseminate relevant research results to the communities who participated in the studies and to the affected populations, especially racial and ethnic minority populations that may have cultural, language, and socioeconomic barriers to the easy receipt of such information.

B. Centers/Institute/Office Directors (CIO)

CIO Directors are responsible for ensuring that studies involving human subjects conducted by their CIO meet the requirements of these guidelines. CIO Directors will inform investigators and other appropriate staff concerning this policy.

C. Technical/Peer Review Groups

If applicable, in conducting technical/peer review of protocols, technical/peer review groups, to the extent possible, will include women and racial and ethnic minorities and will do the following:[3]

- Evaluate the proposed protocol for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.

- Evaluate the appropriateness of the proposed justification when representation is limited or absent.

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[3] CIO Directors may waive this requirement if it is clearly inappropriate or clearly not feasible.

- Determine whether the design of the study is adequate to measure differences when warranted.

- Evaluate the plans for recruitment and outreach for study participants.

- Include these criteria as part of the technical assessment and assign a score.

D. Institutional Review Boards (IRBs)

CDC IRBs are expected to consider whether investigators have addressed the inclusion of women and racial and ethnic minorities in research protocols that require CDC IRB review, as an additional criterion for IRB approval.

VIII. EVALUATION

A. Inclusion Review Committee

1. Membership

An Inclusion Review Committee (IRC) will be formed with representatives from the Office of the Associate Director for Science, the Office of the Associate Director for Minority Health, and the Office of the Associate Director for Women's Health.

2. Responsibility

The IRC will review any questions, issues, or comments pertaining to this policy and recommend necessary changes or modifications to the Director, CDC. This committee will meet regularly to review compliance with this policy and evaluate the impact of this policy on research activities at CDC. The IRC may periodically conduct random audits of research protocols to assess compliance with this policy.

B. Annual Reports

Investigators and project officers are responsible for providing data to assess the extent to which women and racial and ethnic minorities are being included in protocols. For studies covered by this policy, investigators and project officers will report annually to the IRC, through CIO Directors, on enrollment of women and men and racial and ethnic minorities.