DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
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Proponents: Office of Science
Application: Domestic and International Locations
Applicable Staff: All CDC Employees

INCLUSION OF WOMEN AND RACIAL ETHNIC MINORITIES IN RESEARCH

Sections:

1. PURPOSE AND SCOPE

It is the intent of the Centers for Disease Control and Prevention (CDC)[2] to ensure that research conducted with CDC funds addresses health problems that affect women and minority populations to the extent practicable and relevant to the proposed research. This policy updates the guidelines on the inclusion of women and minorities and their subpopulations in research involving human subjects which is supported or conducted by CDC. The guidelines are to ensure that men and women, and members of racial and ethnic minority groups be included in CDC studies involving human subjects whenever feasible and appropriate.

This policy applies to (a) all **extramural** research projects submitted after the effective date of this policy (includes initial applications and proposals) when the extramural research involves human subjects, and (b) all **intramural** research projects that involve human subjects. It supersedes the previous version of CDC-GA-1996-01 (Inclusion of Women and Racial and Ethnic Minorities in Research) and Federal Register Notice: Vol. 60, No. 179, 9/15/95 (CDC/ATSDR Policy on the Inclusion of Women and Racial and Ethnic Minorities in Externally Awarded Research).

This policy is consistent with CDC-SA-2010-01 (Human Research Protections) and CDC-SA-2010-02 (Distinguishing Public Health Research and Public Health Nonresearch).

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[1] Updated to conform to current policy standards and updated CDC/ATSDR guidance.
[2] References to CDC also apply to the Agency for Toxic Substances and Disease Registry (ATSDR).

This policy applies to all CDC employees[3] and non-employees[4], consistent with their underlying agreement with CDC, at all locations, domestic and international, and to all CDC's Centers, Institute, and Offices (CIOs) and Business Services Offices (BSOs), which are hereafter called "CDC Components"[5] unless otherwise noted.

2. BACKGROUND

This policy addresses CDC's commitment to protecting the health of all people regardless of their age, sex, race, ethnicity, national origin, religion, sexual orientation, socioeconomic status, or other characteristics. It also addresses Healthy People 2020, the nation's health agenda, and its overarching goals which are: (1) to help individuals of all ages increase life expectancy and improve their quality of life, and (2) to eliminate health disparities among different segments of the population.[6]

A. Women's Health

It is widely recognized that 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. These differences are largely related to biological and environmental factors. 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.[7]

While some differences are well documented, much is still unknown, and continued research is needed to effectively address women's health needs. For example, more research is needed to understand how behavioral and sociocultural factors interact with biological factors to affect the health of women over their life stages. Additional examples include the need for research on workplace hazards that affect women's health, the special health concerns of minority women and all women across the life course, and diseases that affect women differently from men.[8,9,10]

CDC's requirement to include women in research when appropriate and feasible addresses these concerns and facilitates collection of data that can be used to improve the health of women.

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[3] For the purposes of this policy, "employees" consists of members of the civil service, Commissioned Corps officers, and locally employed staff. For more information on these categories, refer to "Employee Categories (Updated July 2018).

[4] For the purposes of this policy, "non-employees" are individuals who provide consistent services to CDC, maintain a regular presence on a CDC facility, or have been issued a physical or logical access credential and are funded by CDC-managed appropriations. As used in this policy, non-employees includes groups of individuals such as guest researchers, contractors, Intergovernmental Personnel Act (IPA) personnel, or students. For more information on these categories, refer to "Non-Employee Categories (Updated March 2017).

[5] More information on CDC organizational nomenclature is available at: https://sbi.cdc.gov/DOA/pdf/orgnom.pdf.

[6] Healthy People 2020. Retrieved from: http://www.healthypeople.gov/hp2020. Accessed September 23, 2010.

[7] Wizemann M and Pardu ML (eds). Exploring the biological contributions to human health: does sex matter? Institute of Medicine, Committee on Understanding the Biology of Sex and Gender Differences; 2001. Washington, DC; National Academy Press.

[8] Beech B, and Goodman M (eds). Race and research: perspectives on minority participation in health studies. Washington, DC: APHA; 2004.

[9] Sex and Gender. Online Course. National Institutes of Health. Retrieved from: http://sexandgendercourse.od.nih.gov. Accessed November 5, 2010.

[10] Wizemann M and Pardu ML (eds). Exploring the biological contributions to human health: does sex matter? Institute of Medicine, Committee on Understanding the Biology of Sex and Gender Differences; 2001. Washington, DC; National Academy Press.

B. Racial and Ethnic Minority Health

Health disparities between the white majority and some racial and ethnic minority groups are also well documented. However, whites do not always have better outcomes when compared to other racial minorities. It is commonly accepted that increased participation of minorities in health research will yield additional data which can be used to better understand and improve the health status of minorities.[11] For the purpose of this policy, minority populations include African American, Hispanic, Asian/Hawaiian/Pacific Islander, American Indians and Alaska Natives.

In its 2005 National Health Disparity Report, the Agency for Healthcare Quality and Research states that disparities related to race, ethnicity, and socioeconomic status are observed in almost all aspects of health and health care.[12] Health disparities between majority and minority populations account for dramatically shorter life expectancy, higher morbidity rates, and inadequate access to quality health care. A notable problem is that these disparities persist over time, despite significant advances in the prevention, treatment, and diagnosis of disease over the past 50 years, and in many cases the gap has grown.[13,14,15]

There is a continued need for greater representation and participation of racial and ethnic minorities in research in order to: (a) better understand and address health problems for their subpopulations; (b) inform policies, practices, and research aimed at improving health outcomes; and (c) track and evaluate progress toward the goal of eliminating health disparities. Especially lacking is practical knowledge on determinants of health that influence multiple risk factors and multiple disease outcomes, and community level knowledge that is "locally relevant and culturally appropriate."[16,17,18]

CDC's policy to ensure the inclusion of racial and ethnic minorities in research is but one way to address the need for new knowledge to reduce health disparities. The challenges associated with collecting meaningful data will vary according to the research focus, the sample size, and study design. The guidelines in this policy are intended to help researchers make decisions that ensure appropriate levels of inclusion.

3. POLICY

It is the policy of CDC that women and racial and ethnic minorities must be sufficiently represented in human subjects research that is conducted or supported by CDC, unless there are scientific and ethical reasons that justify under-representation. Given the volunteer nature of subject participation in research, direct efforts should be made to actively recruit and enroll women and minorities in all funded research. This policy applies to all CDC-conducted or CDC-

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[11] Beech and Goodman. (See Note 3).

[12] Agency for Healthcare Quality and Research. National Health Disparities Report, AHQR 2005. Available at: http://www.ahrq.gov/qual/nhdr05/fullreport/Index.htm . Accessed September 23, 2010.

[13] Beech and Goodman. (See note 3).

[14] CDC Office of Minority Health. (See note 2).

[15] Griffith D, Moy E, Reischl T, and Dayton E. National data for monitoring and evaluating racial and ethnic health inequities: where do we go from here? J Health Education and Behavior. 2006:470-487.

[16] Beech and Goodman. (See Note 3).

[17] CDC Office of Minority Health. (See note 2).

[18] Report of the Secretary's Task Force on Black & Minority Health. U.S. Department of Health and Human Services. August 1985. Retrieved from: http://www.omhrc.gov/assets/pdf/checked/ANDERSON.pdf. Accessed September 23, 2010.

supported research involving human subjects, including research that is otherwise exempt in accordance with Sections 101(b) of Title 45, Code of Federal Regulations (C.F.R.) Part 46, HHS Policy for the Protection of Human Subjects. Therefore, proposals for research involving human subjects must include a description of plans for including women and minorities as participants. If women and minorities will not be adequately represented in the research, the application or proposal must present an acceptable justification for the under-representation.[19,20]

It is the policy of CDC that women of childbearing potential should not be routinely or arbitrarily excluded from participation. However, ethical issues must be considered for inclusion and exclusion. HHS regulations at 45 C.F.R. Part 46 Subpart B extend additional protections for pregnant women, human fetuses and neonates involved in research. These regulations must be considered when research may involve pregnant women.[21] Information conveying adverse differences in outcome or risk profiles for pregnant women and fetuses is a valid reason for exclusion.

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 the investigation of outbreaks that do not involve women or racial/ethnic minorities).

This policy will be reviewed by the Office of the Associate Director for Science with the goal of improving procedures, clarifying responsibilities, and optimizing the intent and impact of the policy. This review will occur, at a minimum, every three (3) years.

4. RESPONSIBILITIES

This policy applies to (a) all extramural research projects submitted for receipt dates after the effective date of this policy (includes initial applications and proposals), and (b) all intramural research projects, when the extramural or intramural research involves human subjects. Certain individuals and groups have special roles and responsibilities with regard to the adoption and implementation of these guidelines.

A. Investigators

- **Recruitment Outreach**

  Investigators and their staff(s) shall 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

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[19] NIH. Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research. DHHS. Available at: http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

[20] Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research: As Reported in FY07 and FY08. Available at: http://orwh.od.nih.gov/inclusion/2009AnnualTrackingInclusionComprehensiveRpt.pdf

[21] Public Welfare; Protection of Human Subjects. 45 CFR pt. 46 Subpart B (through 6/23/05). Retrieved from: http://ecfr.gpoaccess.gov .

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.

- **Dissemination of Research Results**

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

  Dissemination and translation strategies include, but go beyond, scientific publications and presentations. In order to adequately reach communities and key stakeholders, dissemination efforts will need to apply innovative and relevant approaches such as social media, community networks or changes in policy.

B. Centers, Institutes and Offices (CIOs)

CIOs are responsible for ensuring that CDC-conducted and CDC-supported studies involving human subjects meet the requirements of these guidelines. CIO Directors will inform investigators and other appropriate staff concerning this policy and monitor its implementation during the development, review, award, and conduct of research.

C. CDC Project Officers and Program Officials

CDC Project Officers and Program Officials shall design their Funding Opportunity Announcements (FOAs) in compliance with this policy. CIO Directors shall ensure this policy is fully considered and implemented prior to the release of the FOA to the CDC Procurement and Grants Office. CDC funding components will not award any grant, cooperative agreement or contract for external research projects announced on or after which does not comply with this policy beginning with the date of its implementation.

D. 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 minorities with relevant professional backgrounds and experience and will do the following:

- Evaluate the proposed protocol for appropriate inclusion of both sexes and minority populations

- Evaluate the appropriateness of the proposed justification when women and racial/ethnic minorities are under-represented or absent from the study population

- Determine whether the design of the study is adequate to measure differences between women and men and racial/ethnic minorities and non-minorities when warranted

- Evaluate the plans for recruitment and outreach for study participants. Include these criteria as part of the technical assessment

Requirements pertaining to Federal Advisory Committee Act (FACA) panel composition are administered by the CDC Management Analysis and Services Office (MASO); Federal Advisory Committee Management Branch.[22]

E. Institutional Review Boards (IRBs)

CDC IRBs are expected to consider whether investigators have appropriately addressed the inclusion of women and minorities in research protocols that require CDC IRB review.

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[22] Federal Advisory Committee Act (FACA); General Services Administration. Available at: http://gsa.gov/portal/category/21242

5. REFERENCES

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E. Centers for Disease Control and Prevention. Office of Women's Health Internet site; Retrieved from: http://www.cdc.gov/women/. Accessed September 23, 2010.

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M. Office of Management and Budget. Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity. Executive Office of the President, Office of Management and Budget, Office of Information and Regulatory Affairs. Federal Register Notice, October 30.

6. ACRONYMS AND ABBREVIATIONS

APHA — American Public Health Association
CDC — Centers for Disease Control and Prevention
CFR — Code of Federal Regulations
CIO — Center, Institute, Office
FACA — Federal Advisory Committee Act
FOA — Funding Opportunity Announcement
HHS — Department of Health and Human Services

IRB — Institutional Review Board
OMB — Office of Management and Budget

7. DEFINITIONS

Minority Populations — For the purpose of this policy, the term “racial and ethnic minority,” refers to American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, and Native Hawaiian or Other Pacific Islander populations as defined in the revision to Office of Management and Budget (OMB) Directive No. 15, “Standards for the Classification of Federal Data on Race and Ethnicity.” Data collection and reporting activities pertinent to this policy should be in compliance with this OMB Notice of Decision, which defines the minimum categories for data on race and ethnicity for Federal statistics, program administrative reporting, and civil rights compliance reporting. Retrieved from:

http://www.whitehouse.gov/sites/default/files/omb/assets/information_and_regulatory_affairs/re_guidance2000update.pdf

Research — The definition “research,” which applies to this policy is in Title 45 CFR 46.102(d), the Department of Health and Human Services regulations for the protection of human subjects: “Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.”

Human Subjects — The definition of “human subjects” which applies to this policy is drawn from Title 45 of the U.S. Code of Federal Regulations, Part 46, 102(f): “Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.”

Intramural Research — Research conducted by CDC staff (employees, contractors, visiting scientists, fellows, agents, and students) in its own facilities or its components (research programs and research studies) and scientific investigations and developmental efforts supported by CDC through contracts and performed by other organizations. Research programs are typically the mission related research agenda or portfolio for the CIO. Research studies include projects undertaken by CDC scientists that involve research findings intended for dissemination and that are not funded through assistance (grant or cooperative agreement) or acquisition (contract).

Extramural Research — Research activities funded through a grant or cooperative agreement instrument (assistance relationship)