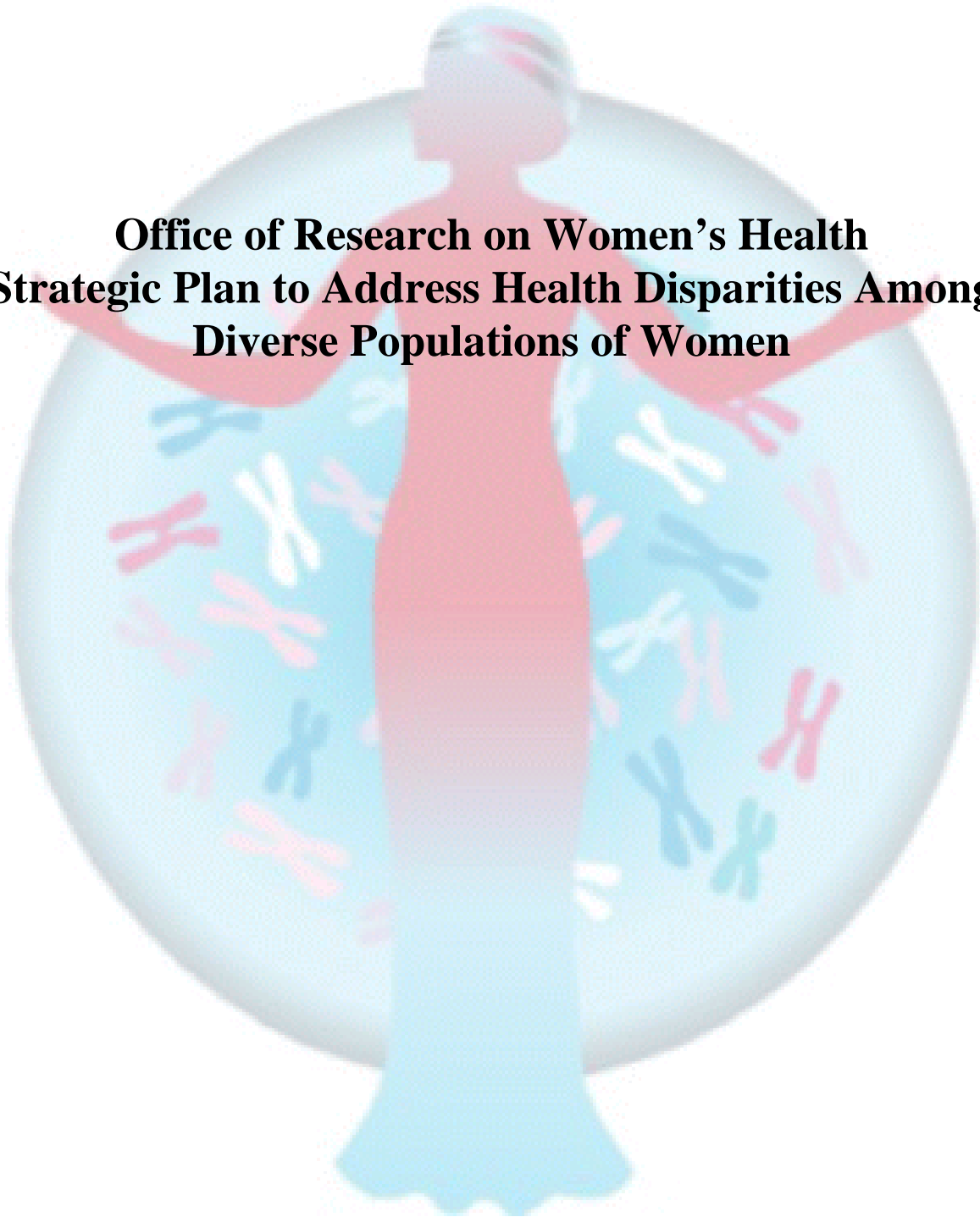


**Office of Research on Women's Health
Strategic Plan to Address Health Disparities Among
Diverse Populations of Women**



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The Office of Research on Women's Health (ORWH) at the National Institutes of Health (NIH), which was established in 1990 within the Office of the Director, NIH, is the catalyst and focal point for research related to women's health issues supported and conducted by the institutes and centers of the NIH. Because health status is the result of the complex interplay of genetic inheritance, lifestyle, and environmental factors, the ORWH, with the participation of the biomedical, public policy, and advocacy communities, developed a research agenda that addresses the ways in which biology, age, ethnic background, economic status, and other factors influence the health of women.

The ORWH (a) advises the NIH Director and staff on matters relating to research on women's health; (b) strengthens and enhances research related to diseases, disorders, and conditions that affect women; (c) ensures that research conducted and supported by NIH adequately addresses issues regarding women's health; (d) ensures that women are appropriately represented in biomedical and biobehavioral research studies supported by NIH; (e) develops opportunities for and supports recruitment, retention, re-entry, and advancement of women in biomedical careers; and (f) supports research on women's health issues. The ORWH works in partnership with the NIH institutes and centers to ensure that women's health research is part of the scientific framework at NIH and throughout the scientific community.

Recognizing that research is essential to providing the scientific basis for improvements in health care, the ORWH is dedicated to fostering and supporting efforts to improve the health of all Americans, especially those whose health concerns have not been adequately addressed by the biomedical research community in the past. This commitment to equity in health-related research is in accord with the President's Initiative for One America in the 21st Century and the Initiative to Eliminate Racial and Ethnic Disparities in Health of the Department of Health and Human Services (DHHS).

Basis for ORWH's Efforts to Improve Women's Health and Address Health Disparities

In 1985, a report issued by the Department of Health and Human Services' Secretary's Task Force on Black and Minority Health¹ documented disparate disease prevalence, progression, and health outcomes for many diseases -- such as cancer, diabetes, and cardiovascular disease -- and excessive mortality for members of minority groups. Although questions remain as to why these disparities exist, access to diagnostic, preventive, and curative health services certainly contributes to disparities in health status and health outcomes. Less obvious, but of equal importance, is the need to expand the science base that underpins medicine by increasing the medical community's understanding of sex and gender differences and the interplay of race and

culture, poverty and other factors in health and illness. If the disparities in health status and health outcomes for diverse populations of women are to be eradicated, knowledge about why these disparities exist is essential. To obtain that knowledge and have it affect health care delivery and public policy, clinical research studies must include adequate numbers of women and minority members as participants. If the results of research are to be generalized to women and minorities, they must be afforded the opportunity to participate in clinical research. Women and minorities should also be provided the chance to accept or reject this opportunity, based upon adequate information about the benefits and risks which might be incurred by their participation in the study being considered.

With the passage of the NIH Revitalization Act of 1993,² the ORWH was established in law, and given a responsible role in ensuring that the expanded guidelines mandating the inclusion of women and minority members in all NIH-supported research were implemented uniformly by all the NIH institutes and centers. The Revitalization Act essentially reinforced the then-existing NIH policies that required the inclusion of women and minorities in clinical research, but with four major differences:

- that NIH ensure that women and minorities and their subpopulations be included in all human subject research;
- that women and minorities and their subpopulations be included in Phase III clinical trials in numbers adequate to allow for valid analyses of differences in intervention effect;
- that cost is not allowed as an acceptable reason for excluding these groups; and,
- that NIH initiate programs and support for outreach efforts to recruit and retain women and minorities and their subpopulations as volunteers in clinical studies.

The current guidelines, which went into effect in Fiscal Year 1995, were established to elicit information about individuals of both sexes and diverse racial and ethnic groups such that research can better determine whether interventions affect women or men or members of minority groups and their subpopulations differently. They apply across the biomedical and behavioral research spectrum and provide the opportunity to gather information on women and minorities when hypotheses are being formulated and when Phase III clinical trials are being designed. The ORWH makes available to the scientific community the *Outreach Notebook for the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research*,³ which contains practical guidance and a list of resources for investigators as they seek to comply with the new NIH inclusion guidelines. The implementation of these guidelines is a partnership between the ORWH and components of the NIH and the broader scientific community.

The ORWH recognizes that cultural sensitivity on the part of researchers; the participation of clinicians within communities and community groups in the planning and implementation of such research; and having researchers who are themselves from the communities they seek to

include in studies are important factors in overcoming barriers that limit women's participation in research. The ORWH also recognizes that to succeed in recruiting and retaining diverse populations of women in clinical trials, it is necessary to enlist the help of community-based individuals and organizations and health professionals who are on the front lines of health care delivery.

The Need for Science-based Knowledge of the Health of Diverse Populations of Women

For certain diseases, such as HIV/AIDS, breast cancer, and diabetes, the burden of morbidity and mortality falls disproportionately on the poor and medically underserved, especially members of minority groups, the elderly, those dwelling in sparsely populated rural and densely populated inner-city communities, and all those who do not have access to or the ability to avail themselves of modern medical expertise and biomedical and technological advances. The need to understand more fully the disparities in health and health outcomes among diverse groups of Americans is an important issue for both researchers and those setting public health and health care policy. Lack of information about how specific diseases affect members of diverse groups differently also contributes to the health care community's inability to provide optimum care for many Americans. The findings of biomedical and behavioral research provide the scientific basis for improving standards of care, formulating public health policy, changing individuals' health-related behaviors and expectations of their health, modifying health care delivery systems, and creating strategies for overcoming cultural and economic barriers to health care.⁴

The ORWH is addressing issues to increase the participation of diverse populations of women and minorities in clinical research through monitoring the implementation of the NIH inclusion guidelines, as well as through efforts to help investigators recruit and retain diverse populations in their clinical studies. The ORWH sponsored a workshop and published a report of the meeting, *Retention and Recruitment of Women in Clinical Studies*, in which it is noted that "There are multiple barriers to recruiting and retaining poor women and women of color to clinical studies. The barriers are economic, cultural, social, and psychological."⁵ Addressing and creating strategies to eradicate those barriers figured prominently in the ORWH's review and revision of the agenda for women's health research undertaken by the ORWH in 1996 and 1997, as well as setting priorities to learn more about the hormonal, biological, environmental, and genetic factors that contribute to the health status of diverse populations of women.

Future Research on Women's Health Issues

To meet the challenges of the twenty-first century and build upon scientific achievements of the past decade, the ORWH convened a series of national scientific workshops and public hearings to review and revise its initial agenda on women's health research. Basic, clinical, and social scientists, health care providers, educators, and individuals from professional societies and community organizations and advocacy groups reviewed the NIH's initial agenda for research and formulated recommendations about areas of continuing or emerging scientific interest in need of further research and strategies to take advantage of these opportunities for new or

expanded research. The resulting report, *Agenda for Research on Women's Health for the 21st Century*,⁶ was published in 1999 and reflects the contributions and participation of more than 1,500 participants in this process. This report provides an impetus for rethinking women's health research and categorizes research opportunities by periods of the life span (such as adolescence and menopause) and by scientific fields (such as cardiovascular, digestive, and health outcomes research). The published research agenda delineates the need for biomedical as well as behavioral and psychosocial research on women's health issues in order to address the plurality of factors that contribute to health status and outcomes.

Critical issues addressed in the revised research agenda for the 21st century include the importance of delineating factors that contribute to disparities in health status and health outcomes among diverse populations of women. These include biological, genetic, racial, cultural and ethnic, psychosocial and behavioral factors, educational influences, traditional and alternative health practices, environmental influences, poverty and socioeconomic status, access to health care and occupational issues. The scientific sessions also resulted in recommendations for research that consider health issues of women who are challenged by physical or other disabilities and of lesbians.

Strategies to Address Disparities in Health Among Diverse Populations of Women

The published report of the agenda, and particularly recommendations to address health disparities among diverse populations of women,⁷ provide the basis for the ORWH's strategic plan to address and eradicate disparities in health among diverse populations of women. Recommendations and strategies address the a wide spectrum of issues, ranging from research design and methodology to career development of minority and women investigators. At the final meeting convened to review and revise the research agenda on women's health, held in Bethesda, Maryland, in November 1997, participants in the working group on Racial, Ethnic, and Cultural Diversity formulated many recommendations designed to benefit diverse communities of women in research projects. Their recommendations have been published in volume 2 of the new NIH women's health research agenda.⁸

IV A. Research - 1 b & d - Environment, Socioeconomic Status, and Risk Factors

Goal 1: Encourage investigators to include in their studies, populations of women who have previously been excluded from clinical trials.

- Examine the cultural and financial barriers to the participation of low-income populations in research
- Foster the design of more studies to include two groups of women who are now usually excluded from clinical studies: women with physical disabilities and lesbians.
- Encourage researchers to reach out to those minority women who never enter the

health care system or who do so only at a time of crisis

- Urge researchers to collaborate with churches on research in minority communities where appropriate.
- Promote the inclusion of the participants= families when the participants belong to minority groups where family is of great importance.

Goal 2: Encourage investigators to study diseases and conditions within particular populations of women who are at high risk for the specific disease or condition.

- Foster the design of more studies that are homogeneous in terms of ethnic and racial groups in order to find out more about a particular group.
- Encourage investigators to collaborate on research projects with researchers who have access to other populations, using the same variables.
- Encourage the study of substance abuse and violence in the general population, not only in low-income populations.
- Foster collaborative research with minority institutions, states, and communities

IV A. Research - 2 & 3 New Approaches for detecting, preventing, and/or diagnosing disease

Goal 1: In collaboration with the NIH institutes and centers, foster innovative approaches and methodologies to study health problems, risk factors, and protective factors among diverse populations of women in order to ensure that health disparities among women of racial and ethnic minority groups are addressed.

- Encourage a more comprehensive approach to the study of health problems of minority women than the traditional medical model allows.
- Encourage the development of research models that study population assets and strengths that prevent disease and promote survival.
- Encourage the development of culturally appropriate instrumentation and outcome measures.
- Foster the use of a qualitative rather than quantitative model of health care so that researchers can understand the health care needs of the community and how well they are meeting those needs.

Goal 2: Encourage investigators to involve the communities and populations whom they seek to recruit into clinical studies in the planning and design of studies by:

- Determining what participants themselves want to achieve through participation in the study.
- Examining barriers to health care from the participant-s point of view, which may differ radically from the researcher-s preconceptions as to what the barriers are.
- Asking women within the community to collaborate on projects by helping to identify the problem to be studied, suggesting appropriate recruitment strategies and methods of data collection, and participating in the analysis and interpretation of study results.
- Collaborating with community church groups in planning, conducting, and evaluating research.
- Establishing community-based centers for research, much like the community centers that have been established for HIV and drug abuse.
- Finding ways to give back to the community through providing health care, education and training, and employment.
- Including the participants- families in the planning of studies in populations where family is of great importance.

IV A. Research -5- Peer Review and Diversity

Goal 1: Create greater awareness among those who review grant applications of the need for investigators to involve diverse populations of women in their studies.

- Give peer review groups strict criteria to follow in reviewing grant applications and proposals, specifying requirements as to sex, race, and ethnicity of study participants.
- Diversify peer review groups, ensuring that they include women and minorities

Fostering Women-s Participation and Advancement in Biomedical Research

With expanding horizons in biotechnology and science, there is a need for greater participation by women in investigations that will open new frontiers of knowledge about health, disease, and

scientific technology. While exact figures are not available for those who are pursuing careers in biomedical research, the ORWH recognizes that there is a need to increase not only the numbers of women who are biomedical and behavioral investigators, but also the numbers of women who are in policy making positions that can influence or determine the direction of research initiatives and well as those who participate in the conduct of that research.

In addition to fostering research related to on women's health and promoting women's and minority members' inclusion in research studies, the ORWH has undertaken activities to increase opportunities for women, including minority women, in biomedical careers. In 1992, the ORWH convened a public hearing and workshop on women in biomedical careers to identify obstacles to women's participation in research careers and to formulate strategies and programs for overcoming such barriers. Nine broad areas were identified as presenting obstacles to women in the biomedical professions, regardless of racial, ethnic, cultural, or specialty backgrounds:

- Recruiting women to biomedical sciences
- Visibility, role models and mentors
- Career paths and equity in rewards
- Re-entry into a biomedical career
- Family responsibilities
- Sexual discrimination and sexual harassment
- Research initiatives on women's health
- Sensitizing men about special career concerns of women
- Special issues for minority women and racial discrimination.

A report from this effort, *Women in Biomedical Careers: Dynamics of Change; Strategies for the 21st Century*,⁹ continues to serve as the basis for ORWH activities to fulfill its mandate to foster women's participation and advancement in biomedical careers. The ORWH has developed strategies and programs to implement the recommendations made at this workshop and to address career issues, barriers, and concerns of women and minorities in science. Programs developed by the ORWH to foster women's participation and advancement in biomedical research careers include the following:

- The ORWH developed a pilot program to encourage fully trained women and men to reenter research careers after taking time off to attend to family needs. The success of this pilot program led to the expansion of the program across the NIH. The ORWH Reentry Scientist Program is currently supported by 17 ICS. ORWH is conducting an assessment of re-entry scientists' success in obtaining grants from the NIH and other institutions. Minority scientists are encouraged to apply under this program.

- The ORWH is inviting applications for the Transitional Career Development Award in Women's Health Research RFA in which minorities and women are encouraged to apply. This career development program gives investigators the opportunity to develop solid clinical research skills during two years of study and research within the environment of the NIH Intramural Research Programs (IRP). The award will also include a follow-on two-year period of salary and research support at an academic institution of the candidate's choice. Salary support

for the intramural phase of the program will be provided by Pfizer, Inc. through a grant to the Foundation for the National Institutes of Health.

- The ORWH co-sponsors a program that provides career development for interdisciplinary research in women's health. The Building Interdisciplinary Research Careers in Women's Health (BIRCWH) RFA supports junior faculty members who have recently completed clinical training or postdoctoral fellowships, and who are beginning basic, translational, clinical, and/or health services research related to women's health. Minorities and women have been encouraged to apply and investigators have been encouraged to include minorities as mentors as well as nominating minority scientists for the scholar positions.

- Women's Reproductive Health Research Career Development Centers - Undertaken with the National Institute of Child Health and Human Development, this initiative promotes the performance of research on women's reproductive health and the clinical transfer findings that will benefit the health of women. The Centers will accomplish this by combining clinical training with independent research, thereby increasing the number and skills of obstetrician-gynecologist investigators through a mentored research experience. A focus on the inclusion of minorities is paramount in this program.

- Career Development for Women in Science through Professional Societies - The ORWH sponsored a workshop with the American Society for Cell Biology on promoting women's careers in science and the role of professional societies can play in promoting women's career advancement. Participants shared strategies, success stories, and failures in promoting the careers of women in biomedical research. Special issues facing minority scientists were included in all aspects of the programs. A core group of scientists including several minority scientists has been formed to take the next steps in defining the role of professional societies.

In addition to these, the ORWH supports ongoing projects and has initiated specific training projects that include opportunities for high school students, with a special focus on the needs of minority students, to obtain research experience or exposure to current scientific concepts through the NIH. The ORWH has also developed and supported a number of programs for the advancement of girls and women in science through collaboration with the NIH Office of Science Education, including a video featuring minority women surgeons and an on-line curriculum designed to spark interest in biomedical sciences among middle-school and high-school students with a emphasis on the health needs of minority students. With the Office of Education, NIH, ORWH supports high school students from Montgomery county through the Howard Hughes Medical Institute, to provide summer research experiences in the NIH intramural labs. To date, over half of the students have been minority.

Strategies to Foster Women's and Minority Members' Participation in Biomedical Careers

At the meeting held in Santa Fe, New Mexico in July 1997 to revise the women's research agenda, a working group addressed Career Issues for Special Populations of Women Scientists. The working group concentrated on identifying specific strategies to address the barriers faced by

minority and other women in the biomedical professions. These include: Collecting, Monitoring, and Disseminating Data; Monitoring Education, Training, and Professional Development; Improving Institutional Accountability; Enriching Communication and Networking Skills; Securing Leadership Opportunities; Enhancing Cultural Acceptance; Attaining Mentoring Competency; Developing Disability and Access Initiatives. Many of these recommendations, which have been published in volume 6 of the agenda report, are currently being implemented by the ORWH and include Leadership and Policy; Cultural Framework; Mentoring; Disability and Access. Goals and strategies derived from recommendations pertaining to research infrastructure and the need to foster women's and minorities' participation in research careers include the following:

IV. B. Research Infrastructure -1- Research Training and Career Development

Goal 1. Foster education, training, and professional development of women and minorities in biomedical careers.

- Continue and expand the ORWH Reentry Program.
- Develop and expand scientific programs to support special populations of women at the pre-college level.
- Continue and expand the WHI Minority Investigator Career Development Award to other research areas.
- Increase the number of supplemental awards to minority students.
- Develop novel programs that will assure more grants to minority women investigators.

Goal 2: Facilitate mentoring of women and minority scientists.

- Develop mentoring programs and training materials related to mentoring.
- Work with professional societies and other agencies in defining, generating, and publicizing successful models of mentoring.
- Emphasize importance of clarifying roles and expectations of both mentor and mentee before the relationship begins with special focus on the needs of minorities.
- Provide special training, rewards, and recognition for mentors of special populations of women scientists.
- Develop a website that will serve as a clearinghouse for minority women scientists.

IV. B. Research Infrastructure -2- Institutional Resources

1. Goal: Encourage institutions to develop programs and mechanisms that allow women and minority scientists to pursue careers in biomedical science and to advance in their careers without sacrificing familial and community responsibilities.

- Develop programs that address the participation and advancement of women, especially women of racial and ethnic minority groups, in biomedical careers.
- Facilitate mechanisms that enable special populations of women scientists to meet family, work, and community responsibilities, (e.g., flexible time schedules and more flexible, Atenure clock@).
- Collect outcome data that demonstrate the effectiveness of programs targeted to special populations of women scientists.
- Establish a database of senior special populations of women scientists available for study sections, advisory boards, and recruitment efforts.
- Facilitate dissemination and publication of data about special populations of women scientists.

Goal 2: Encourage professional societies and organizations to develop programs, models, and other mechanisms to foster the advancement of women and minorities in science-based professions.

- Support workshops and provide funding to stimulate appropriate professional societies to develop management and leadership training programs.
- Expand collaboration and partnerships with underserved community organizations and scientific/professional societies, especially those focused on special populations of female scientists at all levels of the career pipeline.
- Facilitate ways to formalize networking opportunities for special populations of women scientists.
- Improve mechanisms for disseminating information on new and existing funding support for grants and training programs.

IV. B. Research Infrastructure -3- Contributions and Needs of Minorities and Women in Science

Goal 1: Foster a better understanding in the biomedical community of the contributions and needs of women and minorities in science.

- Celebrate the uniqueness and promote the acceptance of special populations of women

scientists in all areas of the scientific community.

- Develop and support programs that encourage diversity and heightened cultural sensitivity in all facets of the academic and medical environment.
- Collaborate with other organizations to ensure that the environmental and physical access needs of disabled women are met at conferences and meetings.
- Ensure that disabled conference participants receive housing at the geographically closest hotel; avoid making a disabled attendee part of a lottery system for housing.
- Provide a secure location near the conference site for overnight storage of mobility devices such as wheelchairs and scooters.
- Delegate one person to troubleshoot unexpected obstacles, including knowing the location of the elevators and ensuring that they work at all times.
- Prearrange complimentary shuttle service for transporting disabled attendees between conference sites, individualize a transportation plan prior to the meeting, and include this complementary service as part of the usual registration fee.

Public Information and Outreach/Education

In addition to sponsoring an on-line curriculum about science and health for middle-school and high-school students, the ORWH reaches out to the public and the biomedical community with information about women's health, current research on topics related to women's health, women in biomedical careers, and the health of minority women through a number of venues. The ORWH's web site (www4.nih.gov/od/orwh/) contains information on policies, programs, and activities related to women's health sponsored by the NIH and by other Federal agencies. The site also contains an annotated list of on-line resources (with links to other web sites) for information on diseases that affect the health of women, as well as links of interest to women in biomedical careers. Copies of NIH and ORWH publications can be downloaded and/or ordered from the web site, including English and Spanish versions of an ORWH-supported publication, the *Women of Color Health Data Book*.

The ORWH encourages the sharing of information on women's health through its Seminar Series on Women's Health, which brings to the NIH campus researchers and clinicians who address topics pertinent to the health of women, including HIV/AIDS in women, breast cancer, exercise and physical fitness for women, depression and other mood disorders in women, and a wide array of other topics. The seminars, which are open to the public, can be viewed by those outside the Washington, D.C., area via the ORWH web site.

The ORWH provided funding for the development of the first museum exhibition on women's health, *The Changing Face of Women's Health*. The exhibition, which opened in Baltimore in

1999, will travel to 10 sites across the United States and is designed to reach the general public with information on what women can do to prevent and detect diseases, including breast cancer and cardiovascular disease. The exhibition is augmented by a study guide for teachers who want to incorporate information on women's health into their curricula. Special efforts will be extended to reach minority communities and for minority participation in the exhibit.

The ORWH is always searching for innovative ways to reach the public and the scientific community with information on women's health and the importance of research to improved health care for all. At the meetings convened in Santa Fe, New Mexico, and Bethesda, Maryland in July and November 1997, participants made a number of recommendations for strategies to improve the dissemination of information and research results related to women's health. Their recommendations have been published in volumes 2 and 6 of the revised research agenda report. Using the revised agenda, the ORWH has identified the following goals and strategies related to the dissemination of information from research involving minority women:

IV. C. The Dissemination of Research Results Related to Diverse Populations of Women-1-3

Goal 1: Encourage the publication of research data and results related to the role of race, ethnicity, culture, socioeconomic background, and sexual preference in health and health outcomes.

- Meet with journal editors to encourage them to require that clinical studies report data classified by race and ethnicity.
- Encourage researchers to publish their experiences, successful and unsuccessful, in working with minority populations.
- Establish a clearinghouse for the publication of research experiences with minority populations.
- Encourage researchers to report data by gender and racial and ethnic categories.
- Encourage researchers to analyze the data for their previously published studies by gender, race, and ethnicity, and publish an addendum to the studies.
- Encourage researchers to report experiences, successful and unsuccessful, in working with participants from diverse racial, ethnic, and cultural groups.

Summary

The Office of Research on Women's Health at the NIH seeks to redress inequities in prevention, detection, and treatment of illness among women of all races, cultures, and socioeconomic back-

grounds through biomedical and biobehavioral research. In its policies and programs, the ORWH emphasizes the need for clinical research designs to consider not only sex and gender and the biologic and social bases for the differences between men and women in health and disease, but also other variables that affect the health of women, including, economic status, the environment, access to and use of health care services, and education. The ORWH will continue to work with ICs to ensure that NIH is in compliance with the guidelines on the inclusion of women and minority participants in clinical research. In concert with the institutes and centers of the NIH, the ORWH is supporting research and initiating programs to implement the recommendations of the *Agenda for Research on Women's Health for the 21st Century*. Through implementation of the research agenda, in collaboration with the NIH institutes and centers, and through programs and activities designed to foster women's participation in biomedical research as study volunteers and as investigators, the ORWH will continue to support and encourage efforts to improve the basic foundation of biomedical and behavioral knowledge that can and will improve the disparities health status and health outcomes of diverse populations of women and men.

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