



OFFICE OF RESEARCH ON WOMEN'S HEALTH

National Institutes of Health
U.S. Department of Health and Human Services

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BACKGROUND

The Office of Research on Women's Health (ORWH), established in September 1990 within the Office of the Director, NIH, **(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. 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.

ORWH benefits from two important committees: the **Advisory Committee on Research on Women's Health (ACRWH)** and the **Coordinating Committee on Research on Women's Health (CCRWH)**. ACRWH provides leadership to ORWH by advising the ORWH Director on appropriate research activities on women's health. ACRWH members are chosen from among physicians, practitioners, scientists, and other health professionals who are not federal employees. Committee members are actively involved in reviewing research priorities, the women's health research portfolio for NIH, career development, and the inclusion of women and minorities in clinical research. The CCRWH is composed of NIH institute and center (IC) directors or their designees as a direct liaison for ORWH with the NIH ICs. Both ACRWH and CCRWH are involved in the activities of the ORWH and women's health research and careers at the NIH.



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Advisory Committee on Research on Women's Health Membership Roster February 2007-2008

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Joyce Rudick, *Executive Secretary*
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F.A.A.N., NIAMS
Cora Lee Wetherington, Ph.D., NIDA

Denise Wiesch, Ph.D., M.P.H., CSR

RESEARCH ON WOMEN'S HEALTH FOR THE 21ST CENTURY

ORWH, in collaboration with the NIH and the extramural scientific and public advocacy communities, published a report, *Agenda for Research on Women's Health for the 21st Century*, which provides a basic strategic plan for the ORWH. ORWH continues to enhance, stimulate, fund and co-fund meritorious research, sponsor research conferences on women's health, and develop new research initiatives through partnerships with the NIH ICs. The strategic plan is available on our Web site at <http://orwh.od.nih.gov/>.

OVERARCHING THEMES IMPORTANT FOR ADDRESSING NIH PRIORITIES FOR WOMEN'S HEALTH

Lifespan: Developmental, physiological, and psychological age affect the health of women and girls across the lifespan, from intrauterine life to the elderly years. Other factors, such as work, caring for children and the elderly, marital and reproductive status, and chronic illness, also contribute to the health of women. These variables need to be considered when designing women's health studies.

Sex/Gender Determinants: Women are characterized by both sex and gender as highlighted in the *Agenda for Research in Women's Health for the 21st Century* and the Institute of Medicine report, *Exploring the Biological Contributions to Human Health: Does Sex Matter?* In these contexts, "sex" refers to being male or female according to reproductive organs and functions assigned by chromosomal complement, and "gender" refers to socially defined and derived expectations and roles rooted in biology and shaped by environment and experience. Consideration of these variables is critical to the accurate interpretation and validation of research affecting women's health.

Health Disparities/Differences and Diversity: Many conditions and diseases disproportionately affect women in terms of incidence, diagnosis, course, and response to treatment. Further, factors such as biology, genes, culture, education, income, access to and quality of care, and access to opportunities for inclusion in clinical trials and studies can contribute to adverse health outcomes for many populations of women. In order to better document, describe, prevent, and treat disease in women and girls, research should take into account this diversity of experience and population-specific characteristics.

Interdisciplinary Research: As the inter-relatedness and complexity of human health and disease is better understood, science is shifting to an interdisciplinary approach. Such practice can integrate knowledge across specialties and disciplines and improve the ability to define complementary and synergistic pathologies underlying disease conditions. Women's health research, an already multi-disciplinary field, is uniquely suited to promote and advance such an approach.

The current research priorities listed below are not comprehensive, but reflect selected areas identified for new or expanded investigative efforts. (<http://orwh.od.nih.gov/research/priorities.html>)

CURRENT NIH PRIORITIES FOR WOMEN'S HEALTH RESEARCH

Areas of Research Interest—Basic, clinical, and translational research that address priority areas, including:

Diseases and Conditions that Affect Women

Investigate the pathogenesis and develop preventive and therapeutic interventions for acute and chronic diseases and disorders that affect women.

Methodological Advances

Develop clinical trials methodology, such as novel recruitment strategies and statistical analysis, that addresses ethical and study design issues specific to studies of women, and detects sex and gender differences.

Education and Career Development of Women in Science

Identify and explore factors affecting the selection and advancement of women's careers in biomedical sciences; implement novel education programs directed at girls and women; and promote unique programs for addressing impediments to the advancement and effective mentoring of women to senior positions in science.

Quality of Life

Elucidate the unique sex and gender factors affecting women's quality of life, and develop disease and wellness management approaches.

Research Collaboration and Partnerships

Foster public-private partnerships and collaborations in all areas of research and career development related to women's health.

Special Emphasis Areas

Prevention and Treatment

Research to identify and validate biomarkers and their applications to disease prevention, early detection and treatment, including the development of novel tools.

Studies of the impact of biological, behavioral, cultural, social, economic, and environmental factors on susceptibility to or protection from disease and response to treatment.

Biological and Behavioral Basis of Sex and Gender Differences

While there has been much research to identify the function of cellular pathways and genes, research on the effects of sex as a modifier of cellular and gene function is under-investigated. Systemic and cellular modeling of the influence of sex differences in biological pathways and systems is needed. For example, greater research will clarify the mechanism of sex effects on gene expression and cellular signaling pathways, including the impact of puberty, the menstrual cycle, pregnancy, and menopause.

ADVANCING NOVEL SCIENCE IN WOMEN'S HEALTH RESEARCH (ANSWHR)

ORWH has just published two program announcements (for an R21 and an R03) to stimulate new research in women's health and/or the study of sex/gender factors. For more details:

The R21

<http://grants.nih.gov/grants/guide/pa-files/PAS-07-381.html>

The R03

<http://grants.nih.gov/grants/guide/pa-files/PAS-07-382.html>

ORWH INTERDISCIPLINARY INITIATIVES

ORWH develops, implements and funds innovative interdisciplinary research centers and interdisciplinary research training programs. These programs benefit both women's and men's health through sex and gender research, interdisciplinary scientific collaboration, and support for young investigators in a mentored environment. Each Fall, scholars, investigators and students participate in the Annual Interdisciplinary Women's Health Research Symposium and as a result several collaborations between independent centers have developed to promote independent research. These interdisciplinary programs are:

- ***Specialized Centers of Research on Sex and Gender Factors Affecting Women's Health (SCORs)***

ORWH led the development and implementation of eleven SCORs with co-funding from six NIH institutes. The interdisciplinary nature of these centers provides innovative approaches to advancing research on the influence of sex and gender as it relates to health and disease. Primary research areas currently under study include pain, pregnancy, substance abuse, and urologic health. A second round of SCOR applications was funded in 2007.

- ***Building Interdisciplinary Research Careers in Women's Health (BIRCWH)***

ORWH developed and implemented an innovative K12 program to support the training of junior faculty researchers in an interdisciplinary mentored environment in women's health research by pairing junior researchers with senior investigators. This program bridges advanced training with research independence, in addition to combining scientific disciplines in an interdisciplinary nature. ORWH leads the BIRCWH initiative with several cosponsors, including NIH Institutes, the NIH Office of Dietary Supplements, and the Agency for Healthcare Research and Quality. After three rounds of awards, a total of 29 BIRCWH Centers have been established. A fourth round of BIRCWH applications was funded in 2007.

- ***Intramural Programs***

ORWH developed a trans-NIH interdisciplinary collaboration on women's health and sex/gender research through the establishment of the Intramural Program on Research on Women's Health (IPRWH). In 2006, ORWH and IPRWH announced the selection of the first recipients of the NIH Women's Health Fellowships in Intramural Women's Health Research. Both fellowships are supported by ORWH and the Office of Intramural Research (OIR) and are funded by the Foundation for the NIH, with donations from Batelle (Shared Postdoctoral Fellowship) and AstraZeneca (Clinical/Translational Fellowship).

- ***Chronic Fatigue Syndrome***

ORWH serves as the focal point for NIH research on Chronic Fatigue Syndrome (CFS). CFS initiatives for the NIH are coordinated by the ORWH in partnership with NIH ICs and other Federal agencies. In 2006, ORWH sponsored, through the NIH Working Group for Research on Chronic Fatigue Syndrome, funding for seven awards to investigators whose research projects will help understand the central mechanisms underlying the neuro-immune interactions in CFS.

NIH MANDATE FOR THE INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH

ORWH leads NIH efforts in monitoring adherence to the NIH policy on the inclusion of women and minorities in clinical research studies. The NIH policy for inclusion (Federal Register, March 1994) was strengthened in response to the NIH Revitalization Act of 1993 (Public Law 103-43) to ensure that women, and minorities and their subpopulations, are included in research involving human subjects in sufficient numbers to allow for subset analysis by sex (or race). ORWH convenes a trans-NIH committee that ensures that the implementation of the inclusion policy is uniform across NIH. Working in collaboration with this committee, ORWH coordinates data collection and reporting methodologies to track numbers of women, men, minorities and non-minority men in NIH-supported research studies. These data are generated electronically and detail the number of subjects included in all clinical research studies as well as those enrolled in Phase III clinical trials. The aggregate data are used to help document investigator compliance with the NIH Inclusion Policy. NIH has updated guidelines to clarify and strengthen the requirement that Phase III clinical studies be designed and carried out to allow for the valid analysis of differences between women and men (http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm). Analyses of NIH-wide demographic data on subjects enrolled in clinical research studies show that substantial numbers of women and minorities have been included as research subjects. For complete inclusion data, see: <http://orwh.od.nih.gov/inclusion.html>.

OTHER INITIATIVES

Science of Sex and Gender

In order to establish a standard, uniform method of instruction in how to address sex and gender differences, the NIH in partnership with the FDA designed an online course to create the permanent foundation for sex and gender accountability in medical research and treatment. The first module of this course was designed to offer participants a basic scientific understanding of the major physiological differences between the sexes, their influence on illness and health outcomes, and their implications for policy, medical research and health care. This course is free to the public and allows participants to earn 6 CME credits. See <http://sexandgendercourse.od.nih.gov>

CAREER DEVELOPMENT FOR WOMEN SCIENTISTS

ORWH develops and supports opportunities for recruitment, retention, re-entry, and advancement of women in biomedical careers. *Women in Biomedical Careers: Dynamics of Change; Strategies for the 21st Century*, a report from an ORWH-sponsored workshop, identifies barriers and successful ways to overcome obstacles to research careers. This report serves as the basis for ORWH activities to increase opportunities for women in biomedical careers.

- **Building Interdisciplinary Research Careers in Women's Health** – see Interdisciplinary Initiatives.
- **Women's Reproductive Health Research Career Development Centers:** ORWH joined NICHD to fund 20 institutional career awards for Women's Reproductive Health Research Career Development Centers to increase the number of obstetricians-gynecologists conducting research in women's health.
- **ORWH/Office of Intramural Training and Education Programs** include opportunities for intramural research fellows, the Summer Research Program for High School Students, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, and students from the Sackler Faculty of Medicine/Tel Aviv University who are paired with NIH mentors. Additional programs include career development workshops, Speaking and Writing Science communication courses, and Fellows Award for Research Excellence. See <http://www.training.nih.gov>
- **ORWH Re-entry Program**
The ORWH Re-entry Program, now supported by 23 NIH institutes, was developed in 1992 as a pilot program to help fully trained scientists (women and men) reestablish careers in biomedical or behavioral science after taking time off to care for children or parents, or to attend to other family responsibilities.

- **WISH-net**

ORWH supports this Web site on mentoring, which is designed for girls and women who are interested in careers in science, research, and health care. See <http://wish-net.od.nih.gov>

- **Achieving XXcellence in Science**

In conjunction with the National Academy of Sciences, ORWH sponsored AXXS 2002 to discuss the role that professional societies can play in the advancement of women's careers in science. AXXS Effective Principles continue to be presented at annual society meetings. See <http://www4.od.nih.gov/axxs>

- **ORWH/Office of Science Education Programs**

ORWH provides support to the Office of Science Education to develop educational resources for pre-college students and others who are interested in science and health careers, such as the *Women are Scientists* Video Series and *Women in Science* Poster Series.

OUTREACH AND SEMINARS

ORWH provides funding and leadership for the following:

The ORWH Women's Health Seminar Series features nationally recognized leaders in women's health research who present the latest information on topics important to women's health. In 2006 and 2007, seminars addressed *Sexually Transmitted Infections, Caregiving, Diabetes* and *Adolescent Health*. Seminars are free and open to the public. See <http://orwh.od.nih.gov/news/whss.html>

The Women's Health Special Interest Group (WHSIG) sponsors scientific lectures by NIH and university researchers and encourages scientific exchange, networking, multi-institute collaboration, and sharing of laboratory resources. See <http://orwh.od.nih.gov/news/whsig.html>

The annual **Anita B. Roberts Lecture Series** was developed by the NIH Women Scientist Advisors (WSA) Committee, with support from ORWH. The seminar series is dedicated to the memory of Dr. Roberts, and honors her role as an exceptional mentor and scientist.

ORWH began a series of **podcasts** "Pinn Point on Women's Health" featuring ORWH Director Dr. Vivian W. Pinn in conversation with other NIH scientists. Podcasts are available at: <http://orwh.od.nih.gov>

ORWH publications are available on line at: <http://orwh.od.nih.gov>

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