



## OFFICE OF RESEARCH ON WOMEN'S HEALTH

Office of the Director, National Institutes of Health  
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.

### 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 is used to establish research priorities for each year. ORWH continues to enhance, stimulate, fund and co-fund meritorious research, sponsor research planning conferences on women's health, and recommend and develop new research initiatives through partnerships with the NIH institutes and centers.

### Overarching Themes for Women's Health Research 2004

The following are overarching themes important for addressing research on women's health:

- **Sex/Gender Differences** in health and disease and therapeutic interventions at genetic, molecular, cellular and functional levels. Sex factors that contribute to the biological differences include chromosomes, reproduction, and hormones
- **Lifespan Issues** and the continuum from intrauterine life and infancy, through menopausal transition into elderly years, and factors such as care-giving roles
- **Health Disparities/Differences and Diversity** among different populations or subpopulations of women, including cultural diversity, racial/ethnic minorities, lesbians, rural/inner city residency status, effects of poverty, and disabilities
- **Interdisciplinary Research** with comprehensive collaboration and integration of knowledge from disparate disciplines and multiple areas of scientific expertise.

The following FY2004 research priorities are not comprehensive, but reflect selected areas identified for new or expanded investigative efforts. (<http://www4.od.nih.gov/orwh>)

### 2004 Priorities for Women's Health Research

- ◆ Studies of chromosomal, genetic, gonadal and phenotypic sex *in vitro* or in animal models
- ◆ Etiologic mechanisms to elucidate sex differences in cellular, tissue/organ, physiological and/or immune responses to environmental and/or infectious agents
- ◆ Mechanism of action and effects of complementary and alternative medicines and dietary supplements
- ◆ Pathogenesis of diseases that differentially affect women, including those affecting behavioral pathways
- ◆ Systemic and cellular modeling of biological pathways and systems related to women's health
- ◆ Clinical trial methodology, including ethical issues and study designs specific to women
- ◆ Mental health issues, including addictive and behavioral aspects
- ◆ Studies on new agents for management of menopausal symptoms
- ◆ Prevalence and validation of sex differences in diagnosis/therapy of disorders/diseases differentially affecting men and women
- ◆ Treatments and other interventions for specific diseases that have enhanced clinical presentation in women
- ◆ Special trans-NIH research collaborations in areas such as Chronic Fatigue Syndrome, uterine fibroids and menopause.

#### Special Emphasis Areas

- ◆ Prevention and Treatment: from basic biological factors to effects of risk behaviors/interventions
- ◆ Genetics/Pharmacogenomics: genetic, molecular, and cellular basis for action of pharmacologic agents known to have different effects in females than in males.

### ORWH Interdisciplinary Initiatives

ORWH developed, implemented and funded new and 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 to become independent investigators doing research in women's health.

- *Specialized Centers of Research on Sex and Gender Factors Affecting Women's Health (SCORS)* – Eleven SCORs on Sex and Gender Factors Affecting Women's Health were established by ORWH. ORWH led the development and implementation of this major new research initiative. The multidisciplinary nature of these centers provides innovative approaches to advancing research on the role of sex and gender related health effects. Primary research areas currently under study include pain, pregnancy, substance abuse, and urologic health. The centers are co-funded by six NIH institutes and the Food and Drug Administration.

- *Building Interdisciplinary Research Careers in Women's Health (BIRCWH)* – ORWH developed and implemented an innovative K-12 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 will bridge advanced training with research independence, as well as bridge scientific disciplines or areas of interest. ORWH leads the BIRCWH initiative and several NIH Institutes, the NIH Office of Dietary Supplements, and the Agency for Healthcare Research and Quality co-sponsor this program. To date, there are 24 BIRCWH Centers.

IPRWH – ORWH recently began a new trans-NIH interdisciplinary collaboration on women's health and sex/gender comparison research through the establishment of the Intramural Program on Research on Women's Health (IPRWH). The Women's Health Special Interest Group (WHSIG) sponsors monthly lectures by NIH and university researchers. The WHSIG also encourages scientific exchange and multi-institute collaboration, sharing of laboratory resources and equipment, and a network to allow brainstorming of ideas for collaboration. (<http://videocast.nih.gov/PastEvents.asp?c=11>)

### 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, 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, and minorities in NIH-supported research studies. These data are generated through a computerized system that provides aggregate data to document adherence to the policy and the number of women, minorities and non-minority men included in all clinical research studies as well as those enrolled in Phase III clinical trials. In response to the General Accounting Office (GAO) report of 2000, NIH has issued updated guidelines to clarify and strengthen the requirement that Phase III clinical trials 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](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 both women and minorities have been included as research subjects. In 2003, approximately 60.7 percent of human subjects enrolled in all extramural clinical research were women as were 55.8 percent of those in Phase III clinical trials. For complete inclusion data, see: [www4.od.nih.gov/orwh/inclusion](http://www4.od.nih.gov/orwh/inclusion).

### Career Development for Women Scientists

One of the major mandates of ORWH is to develop and support opportunities for recruitment, retention, re-entry, and advancement of women in biomedical careers. A report, *Women in Biomedical Careers: Dynamics of Change, Strategies for the 21st Century*, from an ORWH sponsored workshop to identify successful ways to overcome obstacles to research careers,

continues to serve as the basis for ORWH activities to increase opportunities for women in biomedical careers, including the following:

- *Building Interdisciplinary Research Careers in Women's Health* – see Interdisciplinary Initiatives.
- *Women's Reproductive Health Research Career Development Centers* – ORWH joined NICHD to fund institutional career awards for Women's Reproductive Health Research Career Development Centers to increase the number of ob-gyns doing research in women's health. To date, ORWH provides support for 28 centers.
- *ORWH/OIR Programs* include the Summer Research Program for High School Students, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, and the Sackler Faculty of Medicine/Tel Aviv University Students who are paired with NIH mentors.
- *ORWH Re-entry Program* – The ORWH Re-entry Program 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. This program is now supported by all NIH institutes.
- *WISH-net* – ORWH supports this website on mentoring, which is designed for girls and women who are interested in careers in science, research, and health care (<http://wish-net.od.nih.gov/>).
- *AXXS* – ORWH, with the American Society of Cell Biology and NIEHS, sponsored AXXS (Achieving Xcellence in Science) to explore the roles of basic scientific societies in building the careers of women, including action items that societies could consider, a bibliography of career resources, and exchange of information on strengths and weaknesses of existing programs (<http://www4.od.nih.gov/axxs>).

In conjunction with the National Academy of Sciences, ORWH sponsored AXXS 2002 to discuss the role that clinical societies can play in the advancement of women's careers in science and to build upon previous recommendations. A report is available at <http://books.nap.edu/catalog/10964.html>

### ORWH Initiatives with the Office of Science Education and the Office of Intramural Training and Education

ORWH provides support to the Office of Science Education and the Office of Intramural Training and Education to develop programs that enhance opportunities for students and intramural research fellows. Programs include video and poster series aimed at middle school and college students, career development workshops, science communication courses, and Fellows Award for Research Excellence (FARE). (See ORWH website for details.)

### ORWH Women's Health Seminar Series

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. Seminars are free and open to the public. Recent topics included heart disease, complementary and alternative medicine, and obesity. (<http://videocast.nih.gov/PastEvents.asp?c=11>)

ORWH and related publications can be found at <http://www4.od.nih.gov/orwh>