

FY 2006 NIH Research Priorities for Women's Health

The mission of the Office of Research on Women's Health (ORWH) is to stimulate and encourage meritorious research on women's health, including the role of sex and gender in health and disease. Each year, the *ad hoc* Subcommittee of the *Coordinating Committee on Research on Women's Health* (CCRWH), composed of representatives from the NIH institutes and centers, considers the continuing gaps in knowledge, and emerging scientific opportunities for current research priorities in women's health. The Subcommittee recommendations are reviewed and approved by the entire CCRWH and the members of the *NIH Advisory Committee on Research on Women's Health* (ACRWH).

Research opportunities are described in terms of overarching themes, areas of research interest, and special emphasis areas. The priorities signify approaches and areas for which there is a need to stimulate and encourage research on women's health, or sex/gender factors, and the advancement of women in biomedical research careers. These research priorities are not an exclusive list of research areas important to women's health; therefore other innovative or significant research areas should also be considered.

I. OVERARCHING THEMES

The following four overarching themes are important for addressing research on women's health: Lifespan, Sex/Gender Determinants, Health Disparities/Differences and Diversity, and Interdisciplinary Research.

Lifespan: The health of girls and women is affected by developmental, physiological, and psychological age. Women's lives are marked by a continuum from intrauterine life to the elderly years: infancy, childhood and adolescence, menarche, reproductive life, the menopausal transition, postmenopausal years, the elderly, and frail elderly. Many women's lives and health status are influenced by factors such as work inside and outside the home, care-giving such as childcare and elder care responsibilities, reproductive status, marital status, and chronic illness. Each of these may influence health, disease, treatment choices, and response to therapy. Researchers should consider these variables in designing studies related to women's health.

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, entitled *Exploring the Biological Contributions to Human Health: Does Sex Matter?* In this context, the term sex refers to being male or female according to reproductive organs and functions assigned by chromosomal complement. Sex factors that contribute to the biological differences include chromosomes, reproduction, and hormones. Gender refers to socially defined and derived expectations and roles rooted in biology and shaped by environment and experience. Gender and sex are important considerations in most areas of research, including psychological, social, and behavioral studies. Consideration of these variables is critical to the accurate interpretation and validation of research affecting women's health. Moreover, these variables determine how similar or different health or disease processes may be among women or between men and women.

Health Disparities/Differences and Diversity: Women are disproportionately affected by some conditions and diseases in terms of incidence, diagnosis, course, and response to treatment. Some populations of women may be at higher risk for adverse disease outcomes because of factors such as: biology, genes, culture, education, access to care, quality of care, and access to

opportunities for inclusion as research subjects in clinical trials and studies. Thus, clinical research should include, but not be limited to, population-specific characteristics such as cultural diversity, race/ethnicity, immigrant status, rural or inner city residency status, effects of poverty or low socioeconomic status, sexual orientation, and physical or mental disabilities.

Interdisciplinary Research: With increasing understanding of the inter-relatedness and complexity of disease, the nature of scientific investigation is shifting to an interdisciplinary collaborative approach. Advances in women's health can be better achieved by promoting partnerships across disciplines. Interdisciplinary approaches can integrate knowledge from multiple specialties, thus defining underlying common pathologic processes. Collaborations among researchers in academia, private industry, and federal settings, could provide access to the latest scientific tools and technologies for women's health research.

II. AREAS OF RESEARCH INTEREST

Basic, clinical and translational research should be considered in addressing priority areas in women's health research. Some examples may include, but are not limited to:

- **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 including, but not limited to, metabolic, inflammatory, endocrine, autoimmune, gastrointestinal, liver, urologic, ophthalmic, oral, reproductive, musculoskeletal, neurological, psychiatric, and cardiovascular diseases.
- **Methodological Advances.** Develop clinical trial methodology, including novel recruitment strategies and statistical analysis methodology that addresses ethical and study design issues specific to studies of women. Develop new methodologies for animal model studies of diseases and normal development of women, including use of female animals. Methodological studies related to the conceptualization, distinction and detection of sex and gender differences in basic and clinical biomedical research.
- **Education and Career Development of Women in Science.** Identify and explore factors that affect 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. Develop approaches to management of disease and promotion of wellness that are directed at women and their unique issues.
- **Trans NIH Collaboration.** Foster special trans-NIH research partnerships and collaborations in all areas of research and career development related to women's health.

III. SPECIAL EMPHASIS AREAS

The NIH is especially interested in fostering research in women's health in the high priority areas of prevention and treatment, and the biological and behavioral basis of sex and gender differences.

Prevention and Treatment

Increased investigation into methods to prevent conditions and diseases, or to better treat them, can result in significant improvements in the quality and length of women's lives. Prevention research spans the continuum from the most basic biological studies to understanding the basis and effects of risk behaviors across the lifespan and the interventions to change them, including a focus on wellness and healthy behaviors. Examples of needed prevention and treatment research studies in women's health include, but are not limited to:

- Research to identify and validate biomarkers, including genetic polymorphisms, of disease risk, pathogenesis, progression, and their applications to disease prevention, early detection and treatment, including the development of novel tools
- Studies of the impact on health of diet, nutrition, hormones, exercise, weight patterns, toxin exposures, obesity, eating disorders, sex practices, tobacco, alcohol and drug use or abuse, occupation, violence or trauma
- Studies of the factors that are involved in disease initiation and progression, both biologic and behavioral, in order to develop effective preventive and treatment strategies
- Development, testing, and validation of preventive, early detection, and treatment strategies for conditions and diseases including, but not limited to: sexually transmitted diseases, cancer, coronary artery disease, stroke, obesity, diabetes, musculoskeletal disorders, pain syndromes, addictions, and chronic multi-systemic diseases
- Studies of the effect 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, including, but not limited to:

- Determination of sex differences that may modify the role of known cellular pathways and gene defects in disease
- Sex and gender differences in prevention, pathogenesis, course, response to treatment, and prevention, using basic, translational, behavioral, and clinical research approaches
- Mechanism of sex effects on gene expression and cellular and signaling pathways in healthy women, including the impact of puberty, the menstrual cycle, pregnancy, and menopause
- Genetic, molecular and cellular basis of action of pharmacologic agents in women, including differential effects between males and females
- Development of novel methods of analysis to assist in discerning impact of sex in mechanisms of disease initiation, course, and response to treatment or other interventions
- Effect of biologic and behavioral sex and gender difference on quality of life and quality of care

**FY 2006 *ad hoc* Research Subcommittee of the NIH Coordinating Committee
on Research on Women's Health**

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