

# Role of the Office of Research on Women's Health

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## INTRODUCTION

This conference brought together an impressive confluence of behavioral, psychosocial, and biomedical expertise to address drug addiction and the health of women. The Office of Research on Women's Health (ORWH) serves as the focal point for biomedical and behavioral research related to sex and gender differences and gender issues across the National Institutes of Health (NIH). The Office is in a unique position to promote a multidisciplinary approach to the study of all women's health issues. In fact, the multidisciplinary approach that characterized this conference is also central to the research agenda of ORWH.

## MANDATE OF THE OFFICE OF RESEARCH ON WOMEN'S HEALTH

When this Office was established in 1990, with Dr. Ruth Kirschstein serving as its acting director, it was given a threefold congressional mandate:

1. To strengthen, develop, and increase research into diseases, disorders, and conditions that affect women; determine gaps in knowledge about such conditions and diseases; and establish a research agenda for NIH for future directions in women's health research
2. To ensure that women are appropriately represented in biomedical and biobehavioral research studies, especially clinical trials, that are supported by NIH
3. To create direct initiatives to increase the number of women in biomedical careers and to facilitate their advancement and promotion

Thus, ORWH's mandate directs it to stimulate research on conditions that affect both men and women, which previously were studied

primarily in men and for which there is a need to understand more fully sex and gender issues in prevention and treatment. That mandate, and Dr. Kirschstein's early leadership of the Office, laid the groundwork for the ORWH comprehensive research agenda on women's health. The foundation for that agenda, which was published in 1992 as *Opportunities for Research on Women's Health* (Office of Research on Women's Health 1992, p. 89), has been continually modified and expanded in response to new scientific data and women's emerging health needs.

The research agenda is based on an expanded definition of women's health, a definition encompassing health issues that go far beyond women's reproductive capacity and cutting across scientific disciplines, medical specialties, psychosocial and behavioral factors, and environmental determinants.

Some sex- and gender-specific issues that must be better understood are normative changes in males and females at different ages, gender differences in physiological or psychosocial processes, the effects of female hormones, and data pertaining to the possibly different effects on men and women of drugs that have been tested primarily in men. As stated by Bennett in the *New England Journal of Medicine*, "Only by formulating scientifically meaningful questions and then testing them in rigorous studies can we expect to learn how women and men respond to therapy and how best to prevent and treat diseases" (Bennett 1993, p. 291).

ORWH's agenda, which calls for a multidisciplinary and collaborative approach to research, also encompasses the lifespan of women, from birth through adolescence, adult life, the menopausal years, and the more advanced, or elderly, years. In addition, it stresses the need for inclusion, not exclusion, of all populations of women who are part of society, including ethnic minorities, women of varied socioeconomic status, lesbians, and women from rural as well as inner-city locations.

The ORWH mandate, *Opportunities for Research on Women's Health*, noted, "The distinction between behavior and biology is artificial" (Office of Research on Women's Health 1992, p. 89). It further stated, "All future research efforts should aim at merging these two areas whenever it is appropriate." The agenda recommends that studies be undertaken to explore the link between high-risk behavior patterns—like substance abuse and dependence—and neurobiologic abnormalities.

It identifies the need for more research to understand the interactions among biological, psychological, and social factors that lead to harmful behaviors among women, such as early and unprotected sexual activity and use of harmful substances, including alcohol and other drugs. The agenda also states,

Research is needed to clarify the patterns and mechanisms of substance use by adolescent females—specifically, nonuse, experimentation, heavy use, and addiction. The influence of gender roles and relationships with male partners should receive special attention in these studies (Office of Research on Women's Health 1992, p. 88).

The multidisciplinary approach embodied in the research agenda has been strengthened through the integration of behavioral science, basic science, and clinical investigation made possible by the recent reintegration of the National Institute on Drug Abuse (NIDA), National Institute of Mental Health, and National Institute on Alcohol Abuse and Alcoholism into NIH. The reintegration created new opportunities for collaborative, multidisciplinary studies and allowed more specific focus on certain areas where it is known that gaps in knowledge about women's health issues exist.

## **FOCUS AREAS**

Each year, ORWH prioritizes areas so that NIH can stimulate additional or new research or expand current investigations on women. Among the 10 areas considered most important for stimulating and targeting research has been the study of the behavioral and cultural factors related to women and disease risk or intervention, such as alcohol and other drug use and abuse, sexual behavior, domestic violence, and elder abuse.

In keeping with this research target, ORWH provides supplemental support to several of NIH's Institutes to address this goal. For example, ORWH provides supplemental support through NIDA to recruit women into a methadone maintenance program that addresses lifetime and current risk behaviors, posttraumatic stress disorder (PTSD), and correlations between treatment efficacy and the severity of comorbid

depression and PTSD. Another supplemental grant provided by the Office through NIDA has allowed researchers to test the hypothesis that carbamazepine might be more effective in treating cocaine-dependent women who suffer from PTSD than those who do not. The supplemental funding also has allowed investigators to extend patients' followup visits by 9 months.

In addition, ORWH has supported a NIDA-sponsored study of gender differences in the pattern of cocaine and alcohol abuse and cocaine metabolism in women. The study sought to determine gender differences in the distribution of key cocaine metabolites after coadministration of alcohol and cocaine and the tissue distribution of cocaine esterases and ethyl ester transferases in women. Studies of cocaine abuse are particularly important because there was an increase in the number of cocaine-related emergency room episodes involving women between 1990 and 1992, reversing a pattern of overall decline in such episodes between 1988 and 1990. In fact, the number of such episodes involving African-American women is at an all-time high, with women between the ages of 26 and 34 accounting for almost half of such episodes involving African-American women (Centers for Disease Control and Prevention 1994, p. 162).

For a prevention study sponsored by NIDA, ORWH has provided supplemental support to expand data collection and analysis to identify risk factors for tobacco, alcohol, and other drug abuse among African-American and Hispanic adult and adolescent women. The study also has looked at the effectiveness of life skills training in preventing substance abuse among adolescent women in housing projects, schools, and homeless shelters.

Because patterns of behavior chosen and established during adolescence are so important in determining an individual's health in later life, ORWH also has cosponsored a study of adolescent health with the National Institute of Child Health and Human Development. The study, called ADD HEALTH, has examined the causes of health-endangering behaviors to provide a better understanding of the forces that shape the health of young men and women as well as strategies for improving their health.

These ORWH-supported projects illustrate the utmost importance of efforts to reach the goal of this meeting—to develop a better definition of research on women's health and drug addiction.

## ENSURING PARTICIPATION OF WOMEN IN STUDY POPULATIONS

Ensuring the inclusion of adequate numbers of women in clinical studies was the focal issue in the establishment of the Office of Research on Women's Health. Although inclusion is clearly measurable in terms of numbers and percentages, it is far less clear from both an ethical and a practical standpoint. There have been several new developments related to the inclusion of women in clinical research studies to define gender differences.

In response to concerns about the inclusion or exclusion of women of childbearing age, NIH awarded a contract to the Institute of Medicine (IOM), an independent advisory body, to address the legal and ethical implications of including more women in clinical studies. The report from this study was released in February 1994 and contains many recommendations for NIH, the Federal Government, and investigators to consider (Institute of Medicine 1994). Above all, IOM's report emphasizes the importance of inclusion rather than exclusion of women from clinical studies. It also stresses the need to address the gaps in medical knowledge of how best to manage disease and illness in pregnant women or women with childbearing potential. It recommends that women of childbearing age not be excluded from clinical trials because of the risk that *some* will get pregnant and that there is a need to study diseases of pregnant women. Obviously, ORWH and investigators will need to carefully consider the counsel of the IOM panel in promoting the inclusion of women of all ages in clinical research studies.

Although NIH has strengthened and revitalized its policy on the inclusion of women and minorities in study populations and has taken steps to ensure that these new policies are followed—including setting up a computerized tracking system to monitor women's inclusion as study subjects—the inclusion of women in all NIH-supported research was given the force of law through the NIH Revitalization Act (Public Law 103-43), which was signed by President Clinton in June 1993. A section of this legislation, "Women and Minorities as Subjects in Clinical Research," requires that NIH:

- Ensure that women and minorities and their subpopulations are included in all human subject research

- Include women and minorities and their subpopulations in phase III clinical trials so that valid analyses of differences in intervention effect can be accomplished
- Not allow cost as an acceptable reason for excluding these groups
- Initiate programs and support for outreach efforts to recruit and retain these groups as volunteers in clinical studies

Although the legislation is explicit in many of its provisions, there has been much for NIH to interpret since these guidelines went into effect in fiscal year 1995. The NIH guidelines were published in the *Federal Register* on March 28, 1994, and allowed for an extended period of public comment for changes (U.S. Department of Health and Human Services 1994). These provisions ensure that women and minorities are included in human subject research, thereby strengthening and expanding through public law what already had been NIH policy.

## CONCLUSION

The exclusion of women from clinical trials has often occurred for good reasons, that is, because of concerns about the health risks and consequent legal and ethical implications of using women participants, especially women of childbearing potential. Now, with changes in policies and law requiring the inclusion of women, a balance must be found between policies that protect women as research subjects and policies of inclusion.

Addressing the complex behavioral and social factors—including drug dependence, high-risk sexual practices, domestic violence, sexual abuse, and homelessness—that endanger the health of women in this country will require the talents, energies, and expertise of men and women from a wide variety of disciplines. Conference participants can help expand, refine, and carry out the agenda to improve women's health today and into the next century. ORWH looks forward to working with conference attendees to reduce drug abuse and dependence among women, thereby improving the health of women, the health of their children, and the health of communities nationwide.

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