

MOVING INTO THE FUTURE WITH NEW DIMENSIONS AND STRATEGIES:

**A VISION FOR 2020 FOR
WOMEN'S HEALTH RESEARCH**

OFFICE OF RESEARCH ON WOMEN'S HEALTH
NATIONAL INSTITUTES OF HEALTH
U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES

STRATEGIC PLAN

The Honorable Barbara Mikulski, U.S. Senator, Maryland

August 16, 2010

“Fighting for women’s health has been one of my life-long priorities. For far too long, women’s health was ignored. When I first came to the Senate, women’s health wasn’t a national priority. Remember the famous study, take an aspirin a day to keep the heart attack away? That study was done on 10,000 men. Not one woman was included. In a study of the aging process, they told me women weren’t included because there wasn’t a ladies room available for study participants. Yet the results of these studies were being applied to men and women. I vowed to fix that.

I helped establish the Office of Research on Women’s Health at the National Institutes of Health to make sure women were no longer being neglected. Through this office we have been able to increase women’s inclusion in clinical drug trials and to increase funding for breast cancer research by 700 percent since 1992. We now know that men and women have different symptoms before a heart attack. And there are many more biological differences that must still be studied and understood. I will continue to fight to make sure women’s health remains a priority in the federal checkbook and that women are not left behind when it comes to their health and survival.”

The Honorable John Lewis, Congressman, Fifth District, Georgia

Regional Strategic Planning Meeting—Emory University • February 17, 2010

“Do something about the health needs of women. That is a must. That is our mission and it is our goal....In the area of health, we must do what we can to bring about a revolution of values, a revolution of ideas....We must have the capacity to stand up, to speak up and out, to organize and mobilize.”

The Honorable Connie Morella, Member, U.S. House of Representatives, 1987-2003

August 17, 2010

“The legislation that established the Office of Research on Women’s Health represented not only a victory for women, but an important contribution to science. By specifically studying women’s health issues the entire realm of scientific inquiry is enriched and expanded, and science is made more relevant. But, the challenge continues. The work is not finished. Our legacy for future generations, and to ensure that new and important advances continue, requires us to dedicate our continued energy, enthusiasm, and resources for women’s health research.”

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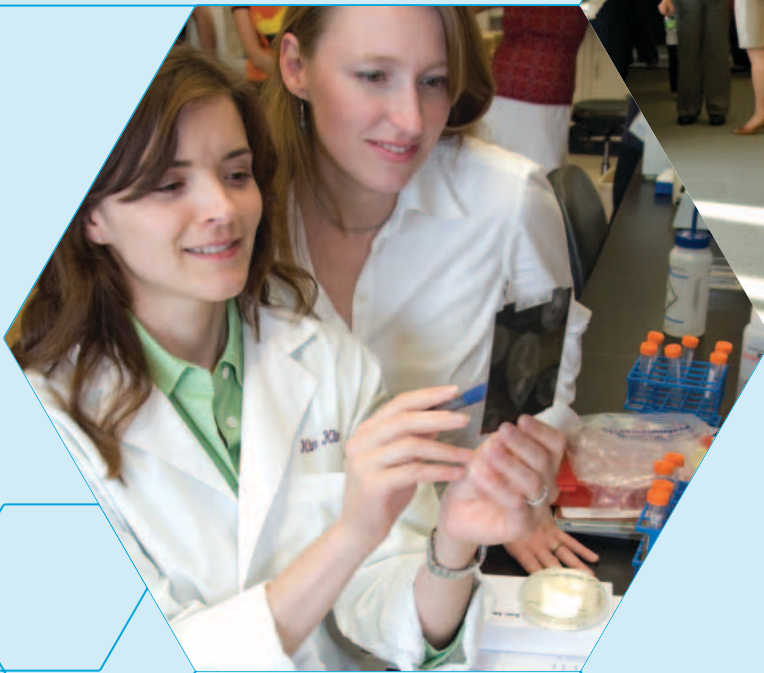


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Vivian W. Pinn, M.D.

MESSAGE FROM THE ASSOCIATE DIRECTOR FOR RESEARCH ON WOMEN'S HEALTH

The Office of Research on Women's Health (ORWH) was established in September 1990 in response to congressional, scientific, and advocacy concerns that a lack of systemic and consistent inclusion of women in NIH-supported clinical research could result in clinical decisions being made about health care for women based solely on findings from studies of men—without any evidence that they were applicable to women. The establishment of the Office heralded earnest efforts by NIH to develop a research agenda addressing gaps in scientific knowledge about women's health across the lifespan and to increase the number of scientists pursuing investigations with a scientific design that would reveal sex differences in outcomes. These aims were articulated in the first ORWH agenda-setting report, *Report of the National Institutes of Health: Opportunities for Research on Women's Health* (commonly referred to as the Hunt Valley report). In 1997, ORWH undertook a second systematic program of collaborative planning and convened a series of public hearings and scientific workshops that culminated in the publication of the *Agenda for Research on Women's Health for the 21st Century*. That agenda expanded the vision for NIH, going “beyond Hunt Valley” to highlight the importance of promoting interdisciplinary, collaborative research; studying and

addressing the health differences and needs of all populations of women; and increasing the diversity of the biomedical workforce.

ACCOMPLISHMENTS

Twenty years after the establishment of ORWH, significant progress has been achieved in four benchmark areas: (1) policies have been developed and implemented to ensure the inclusion of women in NIH clinical research; (2) women's health and sex differences research has increased; (3) new programs have been implemented to prepare researchers to conduct women's health research; and (4) there has been new focus on interdisciplinary career development and sex differences research across the research continuum. Consequently, reports on sex and gender-related factors in health and disease and analysis of clinical trials by sex of participants have steadily increased in the scientific literature. Over the years, the biennial reports of the Advisory Committee on Research on Women's Health, in collaboration with the NIH Coordinating Committee on Research on Women's Health, attest to the attention and greater appreciation that has developed for women's health and sex differences research in the design of studies and the translation of findings into clinical practice. The growth of NIH-funded women's health

research addressing the expanded concept of women's health across the lifespan—including more than just the reproductive years while continuing to explore understudied areas of reproductive health and the menopausal transition—has been impressive. Additionally, increasing numbers of investigator-initiated women's health research in areas such as cardiovascular disease and stroke, musculoskeletal and immune disorders, and mental health and substance abuse, among many others, reflect enormous progress.

As a result of the increased attention to women's health research funded by the NIH institutes and centers, women's health scientists, providers, and advocates have gained a strong sense of their capacity to effect change. Research on women's health has become a tangible reality. Furthermore, women's health, sex differences, and interdisciplinary women's health research have become distinct research career paths in multiple fields, a testament to the success of two ORWH signature programs: Building Interdisciplinary Research Careers in Women's Health (BIRCWH), established in 1999, and the interdisciplinary Specialized Centers of Research (SCORs) on Sex and Gender Factors Affecting Women's Health, established in 2002. As of 2010, the BIRCWH program has supported the career development of almost 400 early-stage research scientists at major research institutions throughout the United States. The SCORs on Sex and Gender Factors Affecting Women's Health support interdisciplinary research, from basic to translational to clinical investigations, by accomplished scientists; while a third program, Advancing Novel Science in Women's Health Research (ANSWHR), established in 2007, further

supports interdisciplinary research. In 2010, these three ORWH-initiated programs are flourishing and enjoy continuing cosponsorship from many of the NIH institutes, centers, and offices.

THE FUTURE

To build on past successes and determine future directions for the next generation of women's health and sex/gender research, ORWH has once more updated the NIH women's health research agenda in a third report, *A Vision for 2020 for Women's Health Research: Moving Into the Future With New Dimensions and Strategies*. The report is the culmination of a 2-year strategic planning process, involving more than 1,500 leading scientists, women's health advocates, public policy experts, health care providers, Federal, State, and local elected officials, and the general public in 5 regional scientific meetings. This Strategic Plan not only articulates new priorities, but also strongly reinforces existing areas, such as interdisciplinary and sex differences research. Unlike earlier reports, the current Plan is not disease specific. It encompasses disease-specific research in a broader vision of women's health that can benefit both women and men by increasing our understanding of the role of sex/gender factors in differential disease risk, vulnerability, progression, and outcome, as well as the effects of being female on health.

Over the past 20 years, research has revealed that from single cells to multiple biological systems and mechanisms, sex differences exist—and these differences are not just hormone based. Sex differences research is needed not only in fields such as endocrinology and immunology, but

also in rapidly evolving science areas such as epigenetics, systems biology, and neuroscience; and new technology-enabled fields such as genomics, proteomics, and metabolomics.

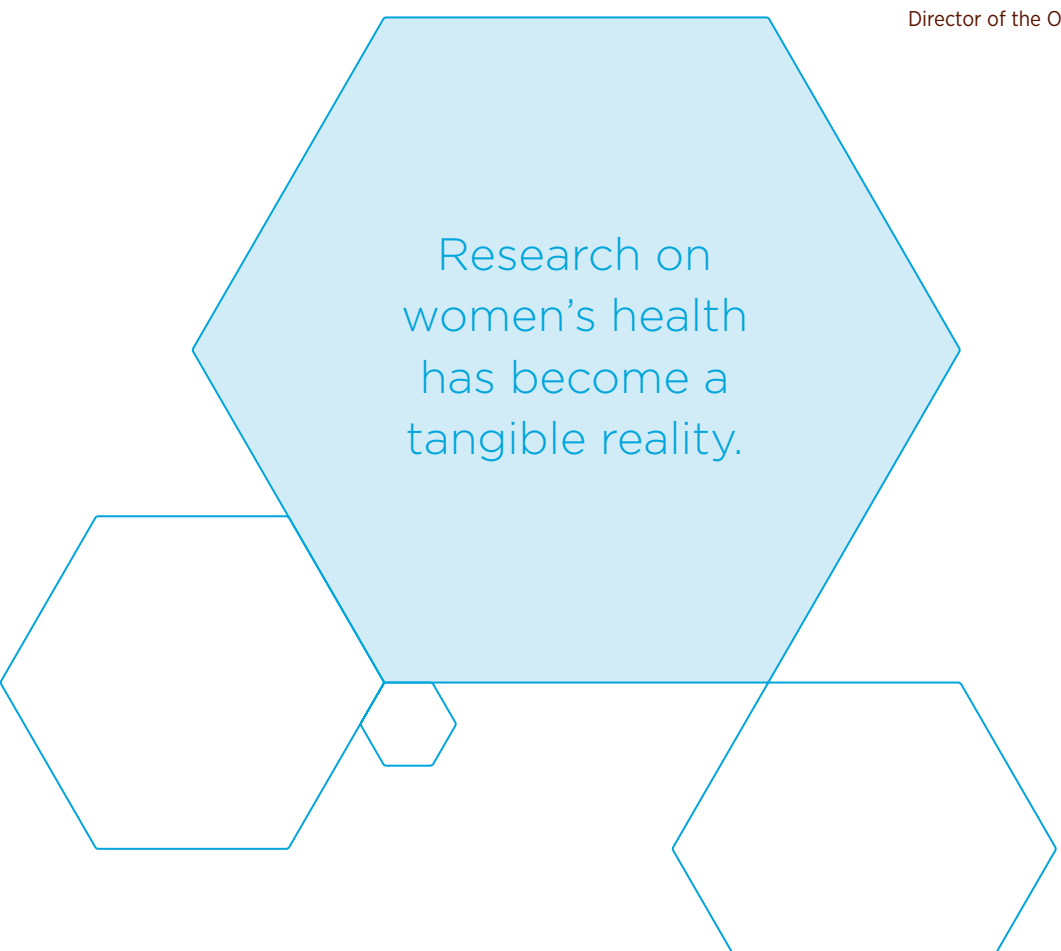
The health of women has a direct bearing on the health of their families and communities, and ultimately, the health of societies. In an increasingly interconnected world, the health of an individual or a community can, in some way, affect the health of all. Women's health research must encompass global considerations and continue to seek ways to address the pressing health needs of women worldwide.

Moving into the Future with New Dimensions and Strategies: A Vision for 2020 for Women's Health Research reflects ORWH's commitment to fostering innovations in women's health research from bench to bedside, and from laboratories to communities. Our strategy for the NIH pledges us and our many partners to address opportunities, challenges, and health needs of future generations of girls and women. We continue to look to our many partners among scientific groups, the public, advocacy groups, and policy leaders, who played such a defining role in creating ORWH, to continue to extol women's health research and to help us realize our shared vision.



Vivian W. Pinn, M.D.

Associate Director for Research on Women's Health
Director of the Office of Research on Women's Health



Research on
women's health
has become a
tangible reality.



I

MISSION AND HISTORICAL OVERVIEW

The Office of Research on Women's Health (ORWH) was the first Public Health Service office dedicated specifically to women's health. The office was established at the National Institutes of Health (NIH) on September 10, 1990. The office was reaffirmed by statute in congressional legislation by the NIH Revitalization Act of 1993 to serve as the focal point for women's health research at the NIH, reporting directly to the NIH Director, and working in a collaborative partnership with the institutes, centers, and offices. Congress assigned a far-reaching leadership role to the ORWH Director by mandating that the Director be responsible for the following:

- 1** Advise the NIH Director and staff on matters relating to research on women's health.
- 2** Strengthen and enhance research related to diseases, disorders, and conditions that affect women.
- 3** Ensure that research conducted and supported by NIH adequately addresses issues regarding women's health.
- 4** Ensure that women are appropriately represented in biomedical and biobehavioral research studies supported by the NIH.
- 5** Develop opportunities and support for recruitment, retention, reentry, and advancement of women in biomedical careers.
- 6** Support research on women's health issues.

Throughout its 20-year history, ORWH has worked in concert with the NIH institutes, centers, and offices and the biomedical, behavioral, health care, and advocacy communities to foster understanding in support of a comprehensive approach to women's health research. During this interval, the office initiated two research agenda-setting initiatives in 1991 and again in 1997. Each of these efforts included public hearings and scientific workshops in formulating the research agenda. The first initiative led to the publication of the *Report of the National Institutes of Health: Opportunities for Research on Women's Health*, commonly known as the Hunt Valley report. The second report, *Agenda for Research on Women's Health for the 21st Century*, was issued in 1998.

In October 2008, ORWH embarked on a 2-year process to plan the NIH women's health research agenda for the next decade. The current Strategic Plan is the product of a collaborative planning process informed by five regional scientific workshops and public hearings anchored in leading academic and research institutions in St. Louis, San Francisco, Providence, Chicago, and Atlanta. Central to the approach of these meetings was a decision to seek the opinions of a wide range of individuals from both within the NIH and from external scientific and lay communities regarding the research agenda for the future of women's health. As a result, the format of each of the regional scientific workshops was designed to promote an interactive discussion involving leading scientists and researchers from across the nation, women's health advocates, public policy experts, healthcare providers and the general public in a mutually informative and collaborative strategic planning process.

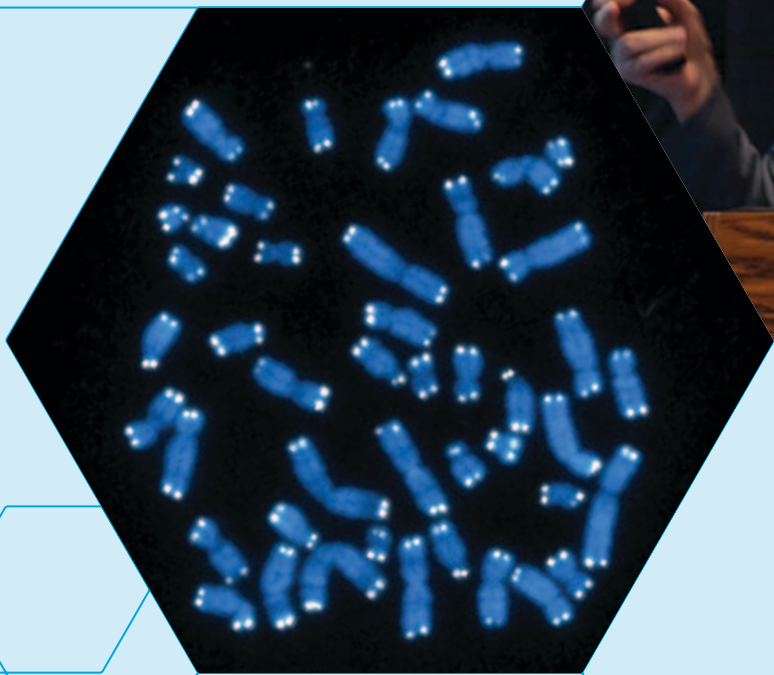
Participating in this process were more than 1,500 individuals, representing the full spectrum of academic institutions, professional associations, advocacy organizations, health care facilities, and science policy analysts interested in research on women's health and sex/gender factors in health and disease. Thirty-seven scientific and career development working groups were cochaired by leading external and NIH scientists, representing 44 academic institutions and 19 NIH institutes, centers, and the Office of the Director. Participants in the meetings came from 33 states, Great Britain, and Australia. Nearly 400 recommendations emerged during the course of 5 regional meetings. Public and written testimony was received from 141 advocacy and academic organizations, as well as from individuals presenting their personal health stories. The concerns and issues highlighted by the public testimony brought to the forefront remaining gaps in knowledge and unmet needs in women's health care, and served to underscore the ultimate goal of the research agenda, to improve the health of women.

In finalizing this document, the review process involved three different levels: (1) a review by the Advisory Committee on Research on Women's Health; (2) a Strategic Plan review group consisting of external scientists, some of whom also served as cochairs of various working groups at the regional meetings; and, finally, (3) an internal NIH review. The entire process is presented in three printed volumes and is also available to the public on the ORWH homepage <http://orwh.od.nih.gov>.

The benefit and purpose of the Strategic Plan are to identify a forward vision

that can further stimulate and continue scientific endeavor across and within all NIH institutes, centers, and offices and with an appreciation and understanding of the importance of conducting women's health and sex differences research. Such research will ensure that science continues to be vigorous and dynamic and public health is well served. The Strategic Plan is also a tool for energizing partnerships across NIH, academia, the advocacy communities, and the world of public policy, leading to a better understanding of women's health research and improving its benefits for human health worldwide.





Elizabeth H. Blackburn, Ph.D.
2009 Nobel Laureate

II

VISION, GOALS, AND OBJECTIVES

A CHANGING VISION OF WOMEN'S HEALTH

The mission of NIH is to seek fundamental knowledge about the nature and behavior of living systems and to apply that knowledge to enhance health, lengthen life, and reduce the burdens of illness and disability. ORWH works in partnership with the NIH institutes, centers, and offices to ensure that women's health research is part of the scientific framework. Since the establishment of ORWH in September 1990, the field of women's health research has greatly expanded in scope from a primary focus on reproductive health to a multifaceted area

of research. Health outcomes are influenced by biological sex, gender identity, as well as developmental, cultural, environmental, and socioeconomic factors. The scope of women's health research not only encompasses clinical studies, but a full spectrum of scientific investigations, such as molecular and genetic, other basic and laboratory studies, healthy lifestyle and behavior, risk reduction and disease prevention. It also includes studies to design clinical interventions and newly confirmed hypotheses to improve public health. There are striking sex/gender differences in prevalence, progression, and outcome of numerous conditions, including diabetes, obesity, cardiovascular diseases, substance abuse disorders, depression and brain disorders, infectious diseases, lupus and other autoimmune diseases, and cancer.

NIH has greatly expanded its portfolio of women's health and sex/gender differences research. Because of the continuum of women's lifespan transitions and roles, research on puberty, childbirth, and menopause are required considerations in the NIH women's health research agenda. For the last decade, four overarching themes have guided NIH research on women's health:

lifespan, sex/gender distinctions, health disparities/differences and diversity, and interdisciplinary research.

MAJOR CROSS-CUTTING THEMES, GOALS, AND OBJECTIVES

The current Strategic Plan encompasses disease-specific research in a broader vision of women's health, with the goal of increasing understanding of the major diseases and conditions that disproportionately affect women's overall quality of life. It is important to note that the research priorities identified in this Plan will benefit not only women, but men, by increasing our understanding of the role of sex/gender factors in disease risk, vulnerability, progression and outcomes. The Plan envisions how women's health research can enrich the biomedical landscape. The following key research themes provide additional context for the goals and objectives in this plan.

ADVANCING UNDERSTANDING OF BIOLOGICAL SEX DIFFERENCES IN HEALTH AND DISEASE

Over the next decade, the exploration of biological sex differences at multiple levels, from genes to hormones to complex systems, will be greatly accelerated. Research will fall far short of its promise to usher in an era of personalized medicine unless the contribution of biological sex to the diversity of health outcomes is better understood and this knowledge applied in the development of the next generation of interventions and medical technologies.

EMERGING NEW SCIENTIFIC FIELDS AND TECHNOLOGIES CAN PROVIDE UNIQUE OPPORTUNITIES TO MAXIMIZE RESEARCH

The emergence of new fields of interdisciplinary science and the application of new technologies and analytic methodologies (e.g., high-throughput screening, modeling, bioinformatics) to fundamental and translational research can provide unprecedented future opportunities for understanding biological sources of variance in human health and disease. Advances in science and technology hold the promise of identifying causative disease susceptibility genes and disease biomarkers, understanding the totality of physiological systems, and providing targeted and personalized sex appropriate therapeutics.

In an age emphasizing analytic strategies (e.g., mapping, data mining, meta-analysis), new enabling technologies will be able to take full advantage of information in data repositories, population datasets, observational studies, and clinical trials.

**FOSTERING PARTNERSHIPS TO IMPROVE
THE TRANSLATION AND DISSEMINATION
OF HEALTH INFORMATION**

Biomedical research ultimately serves human health by contributing to improved health care, reduction of morbidity and mortality, and enhanced health-related quality of life. In the next decade, NIH and ORWH will continue to provide leadership in forging links to further research along the translational spectrum toward community health and health services. By including academic partners from fields such as economics and ethnography as well as public and private partners, interdisciplinary research can also have significant impact on community health, health care delivery, and public policy.

The Plan identifies six major goals to advance women's health research and represents a synthesis of almost 400 recommendations that emerged from five regional planning meetings.



INCREASE SEX DIFFERENCES RESEARCH IN BASIC SCIENCE STUDIES

Over the past two decades that ORWH has promoted women's health research, most studies of sex differences have been in clinical research. Looking forward, and ensuring that scientific knowledge continues to advance, an expanded conceptual framework is needed that explores variations due to sex as an integral part of the search for knowledge across the entire research spectrum, beginning at the most basic laboratory level. This should encompass research in diverse fields, including genetics, immunology, endocrinology, developmental biology, cell biology, epidemiology, microbiology, biochemistry, and toxicology, as well as in behavioral and social sciences. Advances in these fields will be further strengthened by emerging technologies such as high-throughput sequencing, data acquisition, bioengineering, and bioinformatics, and on new modeling and data analytic techniques. This convergence of information presents an opportune time to expand what is known about the effects of biological sex on normal development and the structure and function of cells, tissues, and organs. Therefore, the identification of sex of origin of cells, tissues, and animal model systems, as appropriate, can lead to improved clinical diagnosis and health care based on accurate, sex-specific data.

OBJECTIVES

- 1.1** Encourage genetic and epigenetic studies to identify sex differences in gene expression.
- 1.2** Explore sex differences in the structure and function of male and female cells (including stem cells), tissues, organs, and physiological systems.
- 1.3** Study sex differences using a systems biology-based approach. This will include research based on new technology platforms such as microbiomics, genomics, phenomics, proteomics, and metabolomics.
- 1.4** Include sex parameters in the design of experiments using animal models.
- 1.5** Promote neuroscience research to study sex/gender differences in vulnerability to and clinical course of neurological, psychiatric, and substance abuse disorders.
- 1.6** Increase basic and translational research on sex/gender differences in the pathobiology, prevention, and treatment of diseases including HIV/AIDS, urinary tract and sexually transmitted infections.
- 1.7** Investigate the actions of steroid hormones and hormone-mimicking environmental agents on gene expression, cells, tissues, and organs. Apply this knowledge to sex differences in disease prevalence, symptoms, management and outcomes, in conditions such as lupus and cardiovascular diseases and to predominantly sex-specific diseases such as breast cancer and uterine fibroids.
- 1.8** Further understanding of sex/gender differences in fundamental mechanisms and patterns of behavioral and social functioning relevant to health and well-being.
- 1.9** Incorporate sex/gender considerations into discussions in scientific conferences and meetings.



INCORPORATE FINDINGS OF SEX/GENDER DIFFERENCES IN THE DESIGN AND APPLICATION OF NEW TECHNOLOGIES, MEDICAL DEVICES, AND THERAPEUTIC DRUGS

Improvements in research methodology, instrumentation, and technology have dramatically accelerated progress in the biomedical sciences. As a result of new technologies in the last decade, human DNA can now be sequenced in a matter of hours versus years, therapeutic small molecules can be accurately synthesized by robots under highly controlled conditions, and brain functions can be noninvasively imaged. In clinical medicine, the availability of new medical devices as well as advances in bioimaging, genetics, and biochemistry have revolutionized models of disease diagnosis and management.

In developing and utilizing new research technologies and clinical applications, it is important that sex/gender differences be part of their design and utilization. Some currently used technologies are not as applicable to women as to men because their development and standardization have been based primarily on study of males. Sex differences in biological response to drugs remain an underexplored area.

OBJECTIVES

- 2.1** Encourage the development of technologies that will address sex-based differences at all scales of detail, from the nanometer to the whole person.
- 2.2** Develop novel animal, in vitro, and computational (virtual) models to study sex differences in diseases and conditions.
- 2.3** Develop the information systems needed for collecting, sharing, and comparing clinical data for diseases and conditions of women and girls.
- 2.4** Develop computational models that will utilize multiple levels of analyses to address both qualitative and quantitative outcomes of clinical research related to women.
- 2.5** Work toward devising minimally invasive technologies for rapid and accurate screening, diagnosis, and treatment of diseases and conditions of women and girls.
- 2.6** Exploit high-resolution bioimaging technologies to provide structural and functional imaging of sex differences in a variety of areas such as pain, brain activity, metabolism, infectious diseases, inflammation, and drug delivery.
- 2.7** Design drugs, biologics, and devices to diagnose, prevent, and treat diseases and conditions affecting women and girls.
- 2.8** Consider the sex and age of the patient in the development of engineered medical products, cell-based therapeutics, and regenerative procedures.
- 2.9** Encourage collaborative interactions among clinicians, bioethicists, and technologists regarding accessibility of new technologies, drugs, and other interventions relevant to women's health.



ACTUALIZE PERSONALIZED PREVENTION, DIAGNOSTICS, AND THERAPEUTICS FOR GIRLS AND WOMEN

A major goal of biomedical research is to create knowledge that will lead to more accurate strategies for diagnosis, and preventive and therapeutic interventions, thereby ushering in a new era of personalized medicine. Personalized medicine considers individual differences in genetics, morphology, behavior, and health history. A comprehensive approach to personalized medicine must take into account biological sex, age, and factors such as social and cultural influences.

NIH research has provided a wealth of biomedical scientific knowledge about women's health across the lifespan, placing strong emphasis in recent years on the importance of speeding the translation of basic research into clinical applications. But efforts to translate clinical knowledge into interventions, services, and policies with measurable public health impact have had mixed success. To truly affect women's health, translational research must go beyond "bench to bedside" by pursuing opportunities for dissemination and community uptake and involvement,

Sex differences research can increasingly make major contributions to the goals of individualized medicine and improved public health.

including advocacy and policy development. Achieving this goal will require interdisciplinary collaboration and communication between basic science researchers, clinical researchers, behavioral scientists, public health researchers, clinicians, the community, and policymakers.

OBJECTIVES

3.1 Conduct developmental and developmentally framed research to understand the role of hormones, hormonal changes, and reproductive transitions on conditions affecting women and girls throughout the life span.

3.2 Study sex/gender differences in embryonic development, including epigenetic changes.

3.3 Encourage research on safe and effective interventions for conditions affecting pregnant women.

3.4 Expand research on pregnancy related conditions, such as preeclampsia, diabetes, and hypertension on the subsequent health of women and their offspring.

3.5 Identify and validate sex-specific biomarkers for disease risk and prognosis across the lifespan.

3.6 Study sex/gender differences in the aging process.

3.7 Explore differences in response to therapeutic interventions among samples of elderly women, including those with comorbid conditions.

3.8 Conduct research on aging women with emphasis on prevention of frailty, promotion of healthy lifestyles, maintenance of independent living, self-management of symptoms, preservation of cognitive functions, and health-related quality of life.

3.9 Examine health disparities among women stemming from differences in such factors as race and ethnicity, socioeconomic status, gender identity, and urban-rural living, as they influence health, health behaviors, and access to screening and therapeutic interventions.



CREATE STRATEGIC ALLIANCES AND PARTNERSHIPS TO MAXIMIZE THE DOMESTIC AND GLOBAL IMPACT OF WOMEN'S HEALTH RESEARCH

Strategic alliances and partnerships with women's health stakeholders, including NIH institutes, centers, and offices; other Federal agencies; academia; advocacy groups; foundations; and industry are imperative to furthering women's health research. Collaborations resulting from these alliances can help advance improvements in women's health, leverage resources among public and private entities, help advance public health, and enhance public knowledge. Effective partnerships will also promote increased attention to women's health research issues and ORWH's role as a national and global leader in this arena.

In an increasingly interconnected world, the health of an individual or a community can, in some way, affect the health of all. Women's health research must encompass global considerations and continue to seek ways to address the pressing health needs of women worldwide.

OBJECTIVES

- 4.1** Convene futuristic thinkers from many fields of science, engineering, business, and the humanities to assist in devising implementation strategies for women's health research.
- 4.2** Establish new ventures and initiatives with a wide cross-section of partners, including NIH institutes, centers, and offices; academia; other Federal agencies; international organizations; private foundations; and industry.
- 4.3** Promote an environment which uses multiple avenues and technologies to facilitate continuing input from partners committed to improving women's health and promoting research.
- 4.4** Create solid partnerships by engaging in scientific briefings and ad hoc meetings with policymakers, elected officials, and advocacy groups.
- 4.5** Partner with professional societies to include women's health research issues in national scientific meetings and conferences, including issues involving career training and development.
- 4.6** Expand global strategic alliances and partnerships aimed at improving the health of women and girls throughout the world, particularly in developing countries.



DEVELOP AND IMPLEMENT NEW COMMUNICATION AND SOCIAL NETWORKING TECHNOLOGIES TO INCREASE UNDERSTANDING AND APPRECIATION OF WOMEN'S HEALTH AND WELLNESS RESEARCH

Advances in all areas of science must be shared with diverse audiences. Effective communication can improve health outcomes for women and girls, both for their own sake and because women throughout the world play a central role in the health of their families and communities. Communications, policy development, and implementation science must be linked effectively to achieve these outcomes. Moreover, because of cultural and racial/ethnic diversity in national and international societies and communities, information about women's health research and related issues must be disseminated in culturally appropriate ways. Multiple media strategies, along with the latest communication technologies, should be considered in communications research to determine how to best reach diverse audiences.

The NLM-ORWH Web portal, Women's Health Resources (<http://womenshealthresources.nlm.nih.gov>), provides information about the latest NIH-funded research in a centralized location for consumers, health providers, and researchers. The portal provides research literature, videocasts of NIH presentations, podcasts, videos, fact sheets, and other formats with health information. The portal also uses social media to connect with the public for awareness campaigns.

OBJECTIVES

5.1 Serve as a key informational resource for Federal and State agencies, elected representatives, the media, health and advocacy organizations, and the public on women's health research issues.

5.2 Expand collaboration with other NIH institutes and centers and Federal agencies in outreach activities on issues related to women's health.

5.3 Expand strategic alliances and partnerships with key national and international organizations to maximize the communication and impact of women's health research.

5.4 Convene leaders in communication sciences to explore and identify optimum messages and messaging to benefit women's health research.

5.5 Support research to explore and evaluate the ability of women and men of different ages to access, process, and act on health-related information.

5.6 Build a central portal of information for women's health research findings suitable for the specific needs of researchers, health care practitioners, patients, and their families.



EMPLOY INNOVATIVE STRATEGIES TO BUILD A WELL-TRAINED, DIVERSE, AND VIGOROUS WOMEN'S HEALTH RESEARCH WORKFORCE

The research workforce serves as the foundation for scientific progress and must reflect the brightest talent equipped with essential scientific knowledge and exceptional training. Although women are well represented in early career phases of the life sciences, there is a well-recognized underrepresentation or absence of women in senior research leadership positions. It is therefore essential to learn from and expand upon successful efforts and develop and implement innovative programs and policies that will attract, retain, and advance women throughout their scientific careers. ORWH assumes a large-scale view of these challenges and extends career outreach efforts to include a focus on girls in secondary education settings, particularly among underserved populations. To advance women's health research, it is also critical to prepare researchers with the interdisciplinary training and knowledge to evaluate and improve all aspects of women's health.

OBJECTIVES

- 6.1** Connect and empower scientists across career stages by developing a central career advice/development resource that includes contact with knowledge-rich people at the NIH.
- 6.2** Lead the way in encouraging institutions to recognize mentoring as an essential component of building career success in their training programs; encourage evaluation of mentoring practices.
- 6.3** Address the organizational, institutional, and systemic factors that impede recruitment, retention, and advancement of women in science, and modify practices that impede the careers of biomedical scientists.
- 6.4** Evaluate the challenges and successes of part-time research careers and explore strategies to allow part-time faculty to remain involved in their fields of science.
- 6.5** Promote recognition and understanding of women's health among future health professionals and scientists by informing the design of curricula with up-to-date research findings for use in educational materials for medical, dental, nursing, and other professional training.

Jeffrey Henderson, M.D., Ph.D.

Instructor of Medicine,
Washington University School of Medicine

"This program [BIRCWH] has helped me tremendously as I begin the transition from mentored research toward an independent research career. Through this, I have obtained protected time to establish a research track record and have established a helpful mentoring relationship with several successful and established researchers. It has also helped me to better understand women's health and the outstanding questions in this area."

Valerie Flaherman, M.D., M.P.H.

UCSF

"My relationship with my BIRCWH mentors and advisors has allowed me to move forward much more rapidly on the path to independent clinical research."

Clay Semenkovich, M.D.

Professor, Washington University

"....the [BIRCWH] program provides salary support for the Scholars that enables each Scholar to devote a majority of their efforts to developing their own independent research program. This support comes at a pivotal time in the development of the Scholar and is essential for fostering their careers as biomedical researchers in the area of women's health."

Joan Riley, Ph.D.

Instructor, Washington University

"I hope that one day I can help shape the career of young scientists the way that....the members of my BIRCWH advisory committee have shaped mine."

III

MAJOR ORWH PROGRAMS

INTERDISCIPLINARY PROGRAMS

Because many factors influence women's health, a comprehensive and interdisciplinary approach to conducting research in this area is fundamental. Interdisciplinary research facilitates the integration and synergy of basic science, clinical, translational, population, behavioral, social, and outcomes research. Women's health research is best served by integrating this extensive variety of disciplines and fields. With increasing understanding of the interrelatedness and complexity of disease, the nature of scientific investigations has increasingly shifted to an interdisciplinary, collaborative approach. Interdisciplinary research provides an opportunity not just for medical specialists but also for researchers in dentistry, pharmacy, nursing, biotechnology, social sciences, anthropology, genetics, and other disciplines representing different perspectives and areas of expertise to work together in a mutually beneficial collaboration. Broadening this approach to encourage collaboration among research scientists in academia, private industry, and Federal settings provides expanded access to the latest scientific tools and technologies.

ORWH, with the support of 23 NIH institutes, centers, and offices, the Agency for Healthcare Research and Quality (AHRQ),

and the Food and Drug Administration (FDA) developed the following programs, beginning in 1999, to enhance collaboration and encourage interdisciplinary research. It was a prescient undertaking. The concept has not only been critical to the development of women's health research at the NIH, but it also served as a template for what could be accomplished through interdisciplinary approaches throughout the NIH.

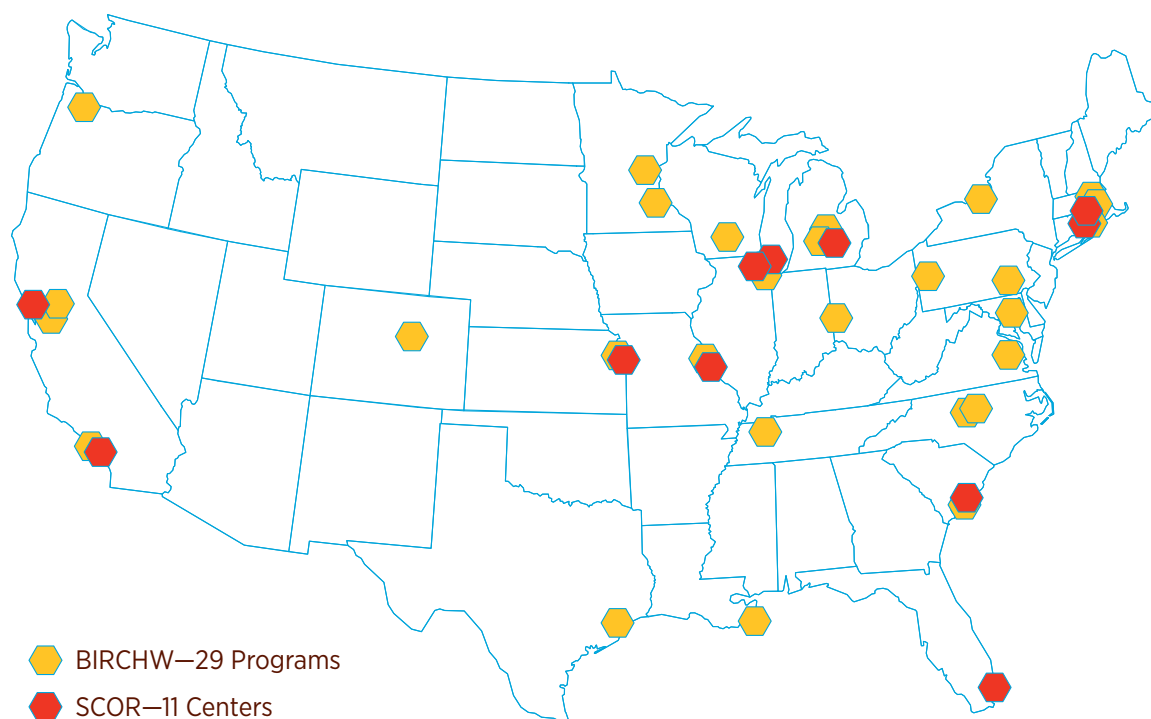
BUILDING INTERDISCIPLINARY RESEARCH CAREERS IN WOMEN'S HEALTH

The Building Interdisciplinary Research Careers in Women's Health (BIRCWH) program is a novel, NIH-mentored research career development program (K12) for men and women junior faculty that is based upon three components: (1) career development, (2) strong mentoring, and (3) interdisciplinary research. BIRCWH supports the training of junior faculty in an interdisciplinary mentored environment by pairing junior researchers with senior investigators in women's health. Mentors are established researchers in their respective fields. Each scholar has an interdisciplinary mentoring team comprising of at least two mentors from different disciplines. The BIRCWH program is a bridge to research independence as scholars learn not only research techniques, but also the

skills to become independent investigators and mentors. A key goal of BIRCWH is to promote sustained independent research careers. Scholar research areas cover a variety of topics including mental health, diabetes, cardiovascular health, neurological disorders, trauma, health disparities, reproductive health, menopausal hormone therapy, substance abuse, cancer, and arthritis/musculoskeletal health.

The success of the program is impressive. Since its inception in 1999, 63 BIRCWH career development programs have been established at 41 institutions, with 27 programs currently active. To date almost 400 individuals have participated in the program as BIRCWH scholars, of which 80% have been women. These scholars will further advance and support the interdisciplinary team approach to science and health care, providing valuable knowledge in overcoming the fragmentation of women's health care delivery. Support for the BIRCWH program comes from ORWH; multiple institutes, centers, and offices at the NIH; and AHRQ.

ORWH INTERDISCIPLINARY RESEARCH AND CAREER DEVELOPMENT PROGRAMS



SPECIALIZED CENTERS OF RESEARCH ON SEX AND GENDER FACTORS AFFECTING WOMEN'S HEALTH

The Specialized Centers of Research (SCOR) on Sex and Gender Factors Affecting Women's Health program consists of 11 currently funded P50 centers that conduct interdisciplinary research focused on major medical problems affecting women and examine the influence of sex/gender on health and disease. A SCOR consists of at least three individual but interrelated research projects, each with high scientific merit and clear research objectives and, in the aggregate, devoted to a specific major health area. Basic, translational, and clinical research must be included. Each center has an administrative core to coordinate the research program, providing intellectual leadership as well as basic management functions. Many programs include one or more core resources, defined as a resource shared by multiple investigators that enhances research productivity and increases the functional capacity of the SCOR. Collaboration and sharing of scarce resources among institutions is encouraged within any given SCOR.

The currently funded SCOR programs are interdepartmental, intercollegiate, and interinstitutional, covering research on depression, pain, urinary tract health, reproductive issues, substance abuse, and osteoporosis. With a focus on sex/gender research, the SCOR program hopes to improve the lives of girls and women through research that examines how health or disease may differ between women and men, as well as how such differences affect diagnosis, progression, and treatment of diseases

across the lifespan. By integrating sex differences research into broad experimental methodologies and scientific approaches, SCORs ensure that new therapies and diagnostic tools will be developed that will ultimately improve the future practice of health care.

Support for the SCOR program comes from ORWH; multiple institutes, centers, and offices at the NIH; and the FDA.

ADVANCING NOVEL SCIENCE IN WOMEN'S HEALTH RESEARCH

Established in 2007, the Advancing Novel Science in Women's Health Research (ANSWHR) program is aimed at stimulating new approaches to women's health research using a 2-year R21 grant mechanism. The program solicits investigator-initiated, innovative, interdisciplinary research that will advance new concepts in women's health research and the study of sex/gender differences. Since its inception, the ANSWHR program has partnered with most of the institutes and centers at the NIH to support research in multiple areas of science, including cancer, human genetics, drug and alcohol abuse, heart diseases, immune disorders, lupus, infectious diseases, mental health, pain, obesity, pulmonary dysfunction, pregnancy, ovarian dysfunction, and stress. Prevention research is one of the areas of special emphasis for the ANSWHR program. Such 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. The program is highly competitive and between 80 and 165 applications are received annually.

RESEARCH ENHANCEMENT AWARDS PROGRAM

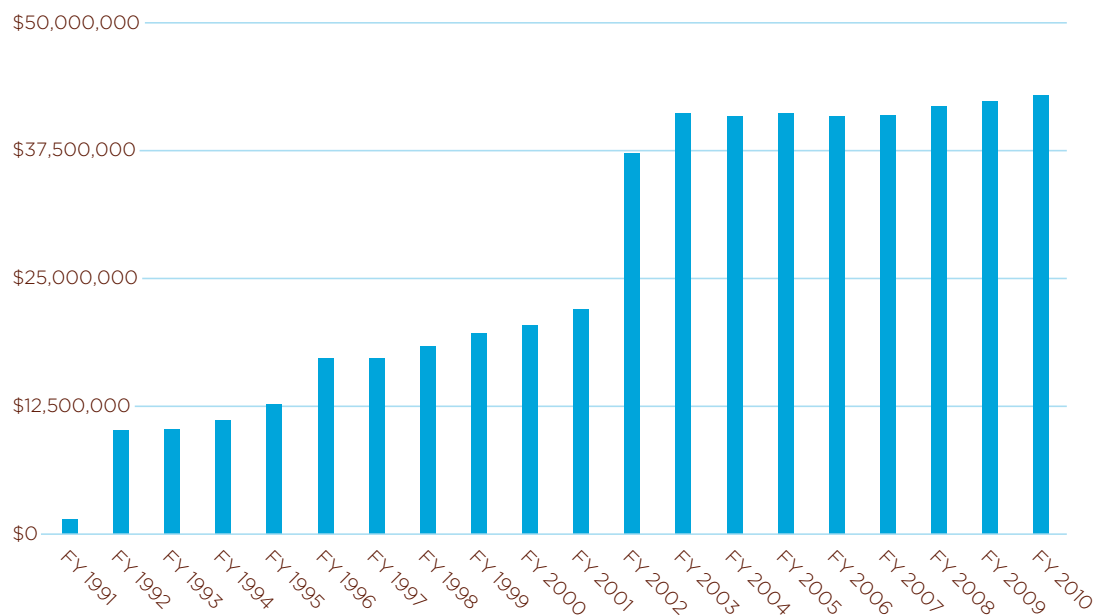
ORWH developed a trans-NIH Research Enhancement Awards Program (REAP) in the mid-1990s as a mechanism to facilitate co-funding of NIH institute and center peer reviewed research that might otherwise not be funded. The REAP program spans basic, clinical, behavioral, and translational research. The program offers 1-year of support for meritorious research in women's health that has just missed the payline for funding by an institute or center at the NIH. The "out year" funds are provided by the primary NIH institute or center. This program was developed to increase the number of new research studies of women's health and the study of sex/gender factors by collaborating with the NIH institutes, centers, and offices,

to identify and cofund meritorious research grants. The REAP program broadens and enhances the NIH women's health research portfolio by supporting a wide range of scientific areas.

ORWH BUDGET

The ORWH was established in 1990 with a budget that covered staff requirements and minor programmatic activities. As increases took place, ORWH developed the programmatic initiatives that would have a major influence on women's health and career development and training. Early planning in 1999, coupled with increases in the budget between 2001 and 2002, led to the development and implementation of the BIRCWH and SCOR programs. An additional increase in the 2007 budget facilitated the development of the ANSWHR program. The following graphic shows the budget history of ORWH since its founding.

ORWH FUNDING HISTORY



APPENDIX A: HOSTS AND WORKING GROUP COCHAIRS OF THE REGIONAL SCIENTIFIC MEETINGS

WASHINGTON UNIVERSITY IN ST. LOUIS SCHOOL OF MEDICINE

ST. LOUIS, MISSOURI • MARCH 4–6, 2009

HOST: Scott Hultgren, Ph.D., Helen L. Stoevers Professor in Molecular Microbiology
and Director, Center for Women's Infectious Disease Research

BLADDER AND PELVIC FLOOR DISORDERS

Jeanette Brown, M.D.
Professor of Obstetrics, Gynecology, and
Reproductive Sciences; Epidemiology and
Biostatistics; and Urology
Director, Women's Continence Center
University of California, San Francisco
San Francisco, California

Kimberly S. Kenton, M.D., M.S., FACOG
Associate Professor, Department
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Department of Urology
Director, Female Pelvic and
Reconstructive Surgery
Fellowship Program
Loyola University Medical Center
Maywood, Illinois

Chris Mullins, Ph.D.
Director of Basic Cell Biology Programs in
Urologic and Kidney Disease
National Institute of Diabetes and
Digestive and Kidney Diseases
National Institutes of Health
Bethesda, Maryland

Estella Parrott, M.D., M.P.H.
Medical Officer
Eunice Kennedy Shriver National Institute
of Child Health and Human Development
National Institutes of Health
Bethesda, Maryland

BRAIN AND PSYCHIATRIC DISORDERS

Nancy L. Desmond, Ph.D.
Associate Division Director
Division of Neurosciences and Basic
Behavioral Science
National Institute of Mental Health
National Institutes of Health
Bethesda, Maryland

Jill M. Goldstein, Ph.D.
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Director of Research for Women's Health
Brigham and Women's Hospital
Harvard Medical School
Boston, Massachusetts

Rajita Sinha, Ph.D.
Professor of Psychiatry
Director, Yale Stress Center
Yale University
New Haven, Connecticut

CHRONIC PAIN SYNDROMES

Leslie J. Crofford, M.D.
Professor of Internal Medicine
Chief, Division of Rheumatology
University of Kentucky
Lexington, Kentucky

Emeran A. Mayer, M.D.
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of Stress
University of California, Los Angeles
Los Angeles, California

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Director of Basic Cell Biology Programs in
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National Institute of Diabetes and
Digestive and Kidney Diseases
National Institutes of Health
Bethesda, Maryland

Linda I. Porter, Ph.D.
Program Director, Extramural Research
Program
National Institute of Neurological
Disorders and Stroke
National Institutes of Health
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EATING DISORDERS

Mark Chavez, Ph.D.
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National Institute of Mental Health
National Institutes of Health
Bethesda, Maryland

B. Timothy Walsh, M.D.
Professor of Psychiatry
College of Physicians and Surgeons
Columbia University
New York, New York

Denise E. Wilfley, Ph.D.
Professor
Departments of Psychiatry, Medicine,
Pediatrics, and Psychology
Washington University in St. Louis School
of Medicine
St. Louis, Missouri

GENETICS AND MICROBIAL COMMUNITIES (METAGENOMICS/ MICROBIOME)

Larry Forney, Ph.D.
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National Institute of Allergy and
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Jacques Ravel, Ph.D.
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Institute for Genome Sciences
University of Maryland School of Medicine
Baltimore, Maryland

INFECTIOUS DISEASES OF THE URINARY AND REPRODUCTIVE TRACTS

Carolyn Deal, Ph.D.
Branch Chief
Sexually Transmitted Disease Branch
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National Institutes of Health
Bethesda, Maryland

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Executive Director, Global Alliance to
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OBESITY

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National Heart, Lung, and Blood Institute
National Institutes of Health
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WOMEN IN

BIOMEDICAL CAREERS

Phoebe S. Leboy, Ph.D.

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Professor Emerita of Biochemistry
University of Pennsylvania School of
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Narberth, Pennsylvania

Walter Schaffer, Ph.D.

Senior Scientific Advisor for
Extramural Research
Office of Extramural Research
National Institutes of Health
Bethesda, Maryland

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO (UCSF)

SAN FRANCISCO, CALIFORNIA • MAY 27-29, 2009

HOSTS: Linda C. Giudice, M.D., Ph.D., M.Sc., Robert B. Jaffe MD Endowed Professor and Chair
UCSF Obstetrics, Gynecology & Reproductive Sciences • **Nancy Milliken, M.D.,** Vice Dean of the UCSF
School of Medicine & Director of the UCSF National Center of Excellence in Women's Health

GLOBAL WOMEN'S HEALTH

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WOMEN'S HEALTH & THE ENVIRONMENT

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HIV/AIDS AND WOMEN

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 Centers for Disease Control and Prevention
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 National Library of Medicine
 National Institutes of Health
 Bethesda, Maryland

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 Bethesda, Maryland

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 Harvard Medical School
 Boston, Massachusetts

Joan P. Schwartz, Ph.D.

Assistant Director
 Office of Intramural Research
 Office of the Director
 National Institutes of Health
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**THE WARREN ALPERT MEDICAL SCHOOL OF BROWN UNIVERSITY
 AND WOMEN & INFANTS HOSPITAL OF RHODE ISLAND**

PROVIDENCE, RHODE ISLAND • SEPTEMBER 21-23, 2009

HOSTS: Joanna M. Cain, M.D., Chace/Joukowsky, Professor and Chair, Obstetrics and Gynecology
 Assistant Dean for Women's Health • **Constance A. Howes, J.D.,** President, Women & Infants Hospital

PRENATAL, INFANCY, AND CHILDHOOD YEARS

Gilman Grave, M.D.

Endocrinology, Nutrition, and Growth Branch
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 Atlanta, Georgia

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 Brigham and Women's Hospital
 Boston, Massachusetts

ADOLESCENT YEARS

Christine A. Bachrach, Ph.D.

Acting Director
 Office of Behavioral and Social Sciences Research
 National Institutes of Health
 Bethesda, Maryland

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Vice Chair, OB/GYN & Director
OHSU Center of Excellence in
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Oregon Health & Science University
Portland, Oregon

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Center for Reproduction and Infertility
Director of the Division of Reproductive
Endocrinology and Infertility
Women & Infants Hospital of
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The Warren Alpert Medical School of
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Providence, Rhode Island

REPRODUCTIVE AND MIDDLE YEARS

Robert Barbieri, M.D.
Chairperson, Obstetrics and Gynecology
Brigham and Women's Hospital
Harvard Medical School
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Alan DeCherney, M.D.
Program Head
Eunice Kennedy Shriver National Institute
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New Haven, Connecticut

Katharine Wenstrom, M.D.
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Providence, Rhode Island

MENOPAUSAL TRANSITION

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Oncology Group
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Reproductive Medicine
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Jacques E. Rossouw, M.D.
Branch Chief
Women's Health Initiative
National Heart, Lung, and Blood Institute
National Institutes of Health
Bethesda, Maryland

Marcia L. Stefanick, Ph.D.
Professor of Medicine and Professor
of OB/GYN
Stanford Prevention Research Center
Stanford University
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ELDERLY, FRAIL ELDERLY, AND HEALTHY AGING

Richard Besdine, M.D.
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Director of the Center for Gerontology
and Health Care Research at
Brown University
Director of the Division of Geriatrics in
the Department of Medicine
Chief of Geriatrics for Lifespan
Greer Professor of Geriatric Medicine
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Providence, Rhode Island

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FACP, AGSF
Clinical Director, Quality Partners
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Bernadette Tyree, Ph.D.
Health Scientist Administrator
National Institute of Arthritis and
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National Institutes of Health
Bethesda, Maryland

ORAL HEALTH AND SYSTEMIC CONDITIONS

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Raul Garcia, D.M.D., M.M.Sc.
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Henry M. Goldman School of
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Brenda Heaton, M.P.H.
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Michelle M. Henshaw, D.D.S.
Assistant Dean
Henry M. Goldman School of Dental
Medicine
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**CAREERS IN DENTISTRY,
BIOENGINEERING, AND OTHER
NON-M.D. DISCIPLINES**

Paula K. Friedman, D.D.S., M.S.D., M.P.H.
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Henry M. Goldman School of
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Belinda Seto, Ph.D.
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National Institute of Biomedical Imaging
and Bioengineering
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Valerie Wilson, Ph.D.
Associate Provost and Director of
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Brown University
Providence, Rhode Island

**NORTHWESTERN UNIVERSITY FEINBERG SCHOOL OF MEDICINE,
NORTHWESTERN MEMORIAL HOSPITAL**

CHICAGO, ILLINOIS • OCTOBER 14–16, 2009

HOST: Andrea Dunaif, M.D., Charles F. Kettering, Professor of Medicine Chief,
Division of Endocrinology, Metabolism, and Molecular Medicine

**UNDERSTUDIED AND
UNDERREPRESENTED
POPULATIONS**

Vickie M. Mays, Ph.D., M.S.P.H.
Department of Health Services
University of California, Los Angeles
School of Public Health
Los Angeles, California

Gloria Sarto, M.D., Ph.D.
Professor, Department of
Obstetrics & Gynecology
Co-Director, Center for Women's
Health Research
University of Wisconsin–Madison
Madison, Wisconsin

**UNDERSTUDIED AND
UNDERREPRESENTED
POPULATIONS SUBGROUP 1:
MINORITIES, URBAN, RURAL,
AND ISSUES OF POVERTY**

Pamela K. Brown, M.P.A.
Associate Director, Mary Babb Randolph
Cancer Center
Past Chair, Intercultural Cancer Council
Morgantown, West Virginia

Rebecca L. Clark, Ph.D.
Extramural Program Staff
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Celia J. Maxwell, M.D.
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Howard University Hospital
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Derrick Tabor, Ph.D.
Centers of Excellence Program, Office of
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National Center on Minority Health and
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National Institutes of Health
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**UNDERSTUDIED AND
UNDERREPRESENTED
POPULATIONS SUBGROUP
2: LESBIAN, BISEXUAL,
TRANSGENDER, AND INTERSEX
ISSUES**

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Alicia Matthews, Ph.D.
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Health Systems Science
University of Illinois at Chicago
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Diane Abbe Sabin, D.C.
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Lesbian Health & Research Center
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CLINICAL AND TRANSLATIONAL RESEARCH

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Department of Health Policy
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NEW TECHNOLOGIES/ BIOENGINEERING/IMAGING

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Professor of Biochemistry, Molecular
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IN ELDERLY AND FRAIL
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MANAGEMENT AND RESEARCH**

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APPLICATION OF NEW
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