INNOVATIONS in Women's Health

Spring 2023

VOLUME 21, ISSUE 1

A QUARTERLY PUBLICATION of Women's Health Research at Yale

25 Years of Women's Health Research at Yale

Making every year count

Google came online the same year Women's Health Research at Yale (WHRY) was created. Each, as it turned out, would fill a void in the search for information.

It was 1998, soon after the National Institutes of Health issued a grant requirement that women be included as participants in clinical research. Without this requirement, the existing gap in what was known about the health of women would continue. This directive also meant that the largest single funder of biomedical research in the world was changing the ground rules about who was studied and calling for data on the health of women beyond the existing focus of reproductive health.

And so, the search for information began.

Through our Pilot Project Program, WHRY began generating studies on the causes, mechanisms, and interventions for the health conditions that affect women and broadening the scope of what was considered women's health. These studies also allowed Yale faculty to collect the necessary feasibility data required to secure new NIH grants for further study on the wide span of critical women's health topics.

With one of the first pilot project grants, Bruce Haffty, MD, Professor

Continued on page 3...

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Women's Health Research at Yale is tremendously grateful to the members of our Legacy Society, who have included WHRY in their estate plans or have made planned gifts through a will or trust.

Sally Brotton and Mark L. Barra
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Women's Health Research at Yale was founded in 1998 with initial funding from The Patrick and Catherine Weldon Donaghue Medical Research Foundation. Women's Health Research at Yale is a center within Yale School of Medicine. Yale University is a 501(c)(3) nonprofit organization.

25 Years of Women's Health Research at Yale (Continued from front cover)

of Therapeutic Radiology, found, in a rare 15-year follow-up study of women with breast cancer, that women with BRCA1 or BRCA2 mutations were more likely to develop **breast cancer recurrence** in either breast than women without this genetic risk factor. These findings became crucially important to women weighing treatment options at the time of diagnosis and developing plans for follow-up.

Dr. Haffty's study was one of many that demonstrated rapid benefit derived from our pilot studies. Another offered girls with **autism spectrum disorder** (ASD) a new treatment option. Traditionally, girls with ASD have been under-represented in research. Pamela Ventola, PhD, Associate Professor in the Child Study Center, demonstrated that Pivotal Response Therapy (PRT), a social-behavioral treatment could help girls, along with boys, with ASD. Dr. Ventola showed that girls benefited from PRT and made larger net gains than did boys, resulting in its therapeutic use today in both girls and boys.

Similar to an internet search, some research studies can provide swift answers, while others require longer investigation. Here's an example of research that requires a longer-term commitment.

Previous studies have shown women have a higher risk for parathyroid disorders, such as **hypoparathyroidism** in which insufficient parathyroid hormone is secreted. Women are also more likely to develop thyroid cancer requiring surgical treatment, which often comes with the unintended consequence of damage to the parathyroid glands. In either case, lifelong hypoparathyroidism can result. This means that parathyroid hormone is not available to maintain needed calcium levels in the blood. Without proper calcium levels, patients are at risk for painful muscle spasms, seizures, and brain fog when the condition is mild and can develop a life-threatening calcium deficiency when it is severe. Treating hypoparathyroidism with calcium supplements, which is the standard of care, is often ineffective for maintaining the proper calcium balance, in addition to causing unwanted side effects. As the Associate Director of Yale's Stem Cell Center, Diane Krause, MD, PhD, Anthony N. Brady Professor of Laboratory Medicine, has taken on the intensive work of turning patients' stem cells into parathyroid cells to give patients the capacity to produce parathyroid hormone on their own. The round-the-clock effort is a multi-year process involving five stages of development. Dr. Krause and her team established a protocol to orchestrate the molecular cues that mimic the natural development process of turning stem cells into parathyroid cells. This protocol, which will provide a revolutionary new treatment option, has been validated in collaborating laboratories, and is now being fine-tuned to improve the efficiency of parathyroid cell differentiation.

Dr. Krause's work is the result of believing that the current standard of treatment can be improved. She is among the many researchers who have used WHRY's Pilot Project Program seed grants to explore novel ideas and shape the future of health care.

Samit Shah, MD, PhD, Assistant Professor of Medicine (Cardiology) focused his grant on creating a new approach to improve the diagnosis of **heart disease** in women. Most

Bruce Haffty, MD

Pamela Ventola, PhD

Diane Krause, MD, PhD

heart attacks in women and men are due to blockage of major cardiac arteries, thus preventing blood flow to the heart. However, chest pain and heart attacks can also be caused by constriction or spasm of the small vessels that feed the heart. Known as microvascular disease, this cause is more common in women and it is not detected by routine diagnostic protocols that are designed to detect major blockages. Consequently, women are more likely to be left without a diagnosis or appropriate treatment. Dr. Shah's research focuses on this physiological difference between women and men and, if a cholesterol blockage is not found during cardiac catheterization, he uses specialized techniques to determine whether there is another cause of reduced blood flow, such as microvascular disease. In women without blockages, nearly 90 percent of women who underwent testing were found to have a cause of reduced blood flow to the heart, despite having no significant plaque blockage in the large blood vessels. This advanced testing helps patients find an accurate diagnosis and allows providers to develop precision treatment plans.

Other novel advances in treating a particular disease have now turned out to be useful for other disorders. For example, the innovative approach used in two different pilot studies by Akiko Iwasaki, PhD, Sterling Professor of Immunobiology, to treat **herpes infections** is now being applied to the fight against Covid-19. In her first WHRY study, Dr. Iwasaki focused her research on the role of mucous membranes in understanding why women are more susceptible than men to viral genital herpes infections. Her second study expanded upon that knowledge and created a treatment strategy dubbed "prime and pull" that would prime the immune system to create a memory response to the herpes simplex virus and then pull those immune memory cells to the site of infection to stop the virus. In a third WHRY study at the start of the **COVID-19** pandemic, Dr. Iwasaki showed sex differences in immune response to the novel SARS-CoV-2 virus and is now using her combined expertise on this virus and viral transmission to develop an intranasal vaccine to create mucosal immunity that would stop the virus at the site of infection – the nasal muscosa.

The importance of ingenuity in scientific discovery is also evident in the **ovarian and breast cancer** research by Peter Glazer, MD, PhD, Robert E. Hunter Professor of Therapeutic Radiology. Dr. Glazer, along with James Hansen, MD, began investigating a nontoxic lupus antibody that can penetrate cancer cells for its potential as a mechanism for cancer treatment. In his WHRY study, he found that this specific lupus antibody could be used to inhibit the DNA repair component of the cancer cell in a manner that stops the cancer cell from sustaining itself. Further research showed efficacy in the antibody destroying specifically those cancer cells associated with mutations in the tumor suppressing BRCA1/2 genes. As mutations in these BRCA genes lead to higher rates of breast and ovarian cancer, this research is of great value for BRCA-related cancers that affect many women around the world. The antibody has now been developed into a therapy to fight these cancers and clinical trials are planned for later this year.

Women's Health Research at Yale's search for information began 25 years ago to address the scarcity of information on women's health. It has led to knowledge on a myriad of conditions and uncovered vital sex and gender differences that influence the health of all people.

As this sampling of WHRY funded studies show, there is much to learn that can advance the health of women and men. And so, the search continues. ◀

Samit Shah, MD, PhD

Akiko Iwasaki, PhD

Peter Glazer, MD

Applying Scientific Research to Our Lives

New medical research findings are published every day, and the results are frequently picked up by mainstream media sources. Some of these reports focus on studies of people who have health concerns similar to you or may point to health findings that are of interest to you. However, before you apply the results of any given study to your daily life, you should consider if the research findings are relevant to you. Here are three questions that may help.

Who participated in the study?

Consider whether you fit the profile of the people who were studied. Compare your own demographics – such as sex and gender, age, race, and ethnicity – and your health history to those who were studied. Then, even if you share the characteristics of those studied, consider whether you have additional risk or protective factors that may alter how these findings apply to you.

How can I understand how studies are designed to collect health data?

There are many ways to investigate a scientific question. The two main approaches to collecting health data are through observational and experimental studies.

Observational Studies

In an observational study, health behaviors are not controlled nor is a specific intervention tested. Researchers watch and chart health conditions and related behaviors over time as these naturally occur in a broad sample of people and measure the health outcomes. An example of a well-known observational study is the Framingham Heart Study, which has followed three generations of participants to identify common cardiovascular disease characteristics and risk factors.

Experimental Studies

In an experimental study, participants are chosen who share similar demographics, health history, and have the same health condition under investigation. Participants are then typically randomly divided into two groups with one group receiving, for example, a new medication, and the other group receiving the current usual treatment. This allows researchers to see if there is a difference in health outcome due specifically to the new medication. An example of a large, ongoing experimental study is comparing a new three-medication regimen with treatment as usual for women with small vessel heart disease who are at risk for heart attack.

Both types of studies provide value, however experimental studies are considered a "gold standard" because key factors affecting outcome are held constant between the two groups.

How can I have confidence in the information I get from mainstream media sources?

It is a good idea to double-check what you have read with another source. Reliable sources include academic medical centers, federal agencies, such as the National Institutes of Health, and health-based non-profit organizations, such as the American Heart Association.

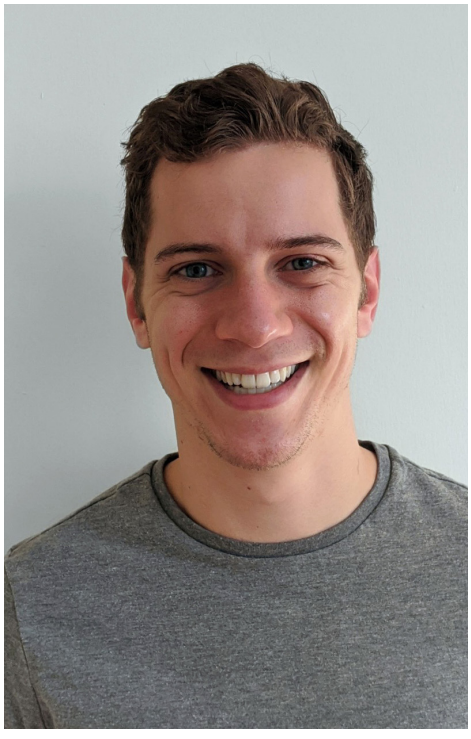
The best individual health decisions, however, are made when informed consumers consider study results in collaboration with trusted health care providers.

Want a resource you know you can rely on?

Scan the QR code below to visit our website and read the latest news from Women's Health Research at Yale. If you want to stay up to date with women's health research and new medical findings, be sure to click the red button on the right side of our homepage that says, "Keep Me Informed! Subscribe to Receive Our Latest News." ◂

Our WHRY Undergraduate Fellows: Where are They Now?

Our commitment to education includes mentoring undergraduate students interested in women's health and the influence of sex and gender on health. This fellowship is designed to enrich students' studies by learning about timely health questions and the most contemporary approaches to the science of women's health. Here is a look at what two of our former fellows are doing now.



Benjamin Fait, '17

Upon graduation, Ben was awarded a Fulbright Fellowship to study the brain biology of hunger in a world-renowned lab specializing in this work at Pompeu Fabra University in Barcelona, Spain.

Returning to the United States, Ben began doctoral studies in neuroscience at Rockefeller University in New York City, and is currently working in a laboratory devoted to Amyotrophic Lateral Sclerosis (ALS) research. In this context, he is studying the connectivity of corticospinal circuits, which transport signals from the brain, down the spinal column, and to muscles allowing skilled movements. As in his past research, his focus is on increased understanding of how brain processes affect bodily and behavioral functioning. "My work at WHRY has made me a scientist who considers sex as a biological variable automatically when designing experiments and reviewing data," he said. "It is easy to forget these everyday decisions can percolate over time into major health disparities and scientific blind spots."

As a WHRY fellow, Ben worked with Dr. Mazure and WHRY's Communication Officer to develop his interest in health policy and scientific communications. In particular, he played a major role in producing a series of videos in which "the person on the street" was asked health literacy questions regarding women's health. The questions and answers successfully sparked conversations about women's health, and the videos of these encounters have subsequently been used to call attention to the value of studying the health of women as well as men. During his fellowship, Ben also published in the widely read political newspaper, *The Hill*, in which he discussed the importance of funding biomedical research and supporting careers in science.

He continues to advocate for health policy, authoring a perspective during the Covid-19 pandemic on the need to address the public's distrust of scientists and the disregard for scientific advice. It was featured in *Science & Diplomacy*, a publication of the American Association for the Advancement of Science (AAAS), which is the world's largest multi-disciplinary scientific society.

"I'm grateful to WHRY for instilling in me the value of thinking about the impact of sex and gender as an issue affecting both the practice of science and the health of women. I know these are lessons I will carry with me throughout my career," he said.

Rose Davis, '18

After graduation from Yale, Rose chose a position in London advising personalized healthtech startups. She subsequently was recruited by an emerging health care company to oversee their business and operation strategy. This role provided Rose with a first-hand look at entrepreneurship, the health care industry in the UK and Europe, and the role of technology in access to health care services.

To further inform her interest in biotech, Rose then earned a

master's degree from Imperial College London in Applied Biosciences and Biotechnology. She then joined a venture capital firm where she now focuses on funding start-up technology companies. Her main focus is healthtech with an emphasis on companies that work to improve the health of women.

"My job is to meet with entrepreneurs in the early stages of building," she said. "They pitch ideas, I ask questions, try to understand the opportunity, and then build a case as to why it would make a good investment."

As a WHRY undergraduate fellow, Rose worked with Dr. Lisa Freed, director of Yale New Haven Hospital's Women's Heart and Vascular Program, shadowing her at the clinic and helping to formulate clinical research questions as Dr. Freed collaborated with WHRY on integrating health research into clinical practice.

"My time at WHRY informed a lot of how I think about health and health care," she said. "I am proud that my company is backing cutting-edge health companies that can improve the health and well-being of women."

She particularly embraces the opportunity to continue learning in "a job that doesn't feel like a job."

"I met with 10 founders today, all doing something different from one another, all entrenched in their specific expertise," she said. "I am constantly talking to brilliant people who are passionate and want to make a difference in this world." ◄

Advancing Medical Education

WHRY's ongoing work to integrate data on the health of women and sex and gender into the Yale Medical school pre clinical curriculum is now receiving global attention. An article authored by WHRY Associate Director for Medical Education in Women's Health Kelsey Martin, MD and Carolyn Mazure, PhD and has been accepted for publication in *The Lancet Haematology*. As a practicing oncologist, hematologist, Dr. Martin has experienced, first hand, the value of considering sex as a biological variable when evaluating and treating patients. In the article, Drs. Mazure and Martin demonstrate their model for integrating data on sex, gender, and health into a medical school curriculum. ◄

Meet Sara Rolon

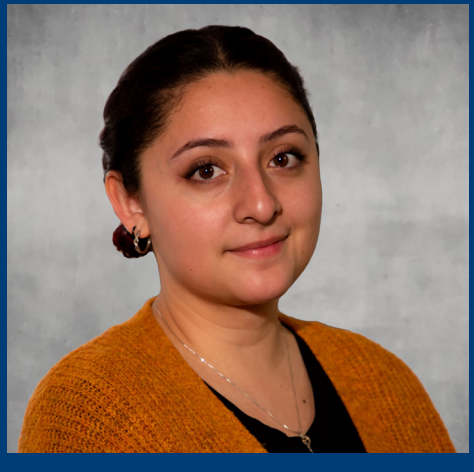
WHRY is pleased to introduce Sara Rolon, our new Senior Administrative Assistant.

Sara comes to WHRY with years of administrative experience, fluency in multiple languages, background in graphic design, and world-class organizational skills. She reports feeling "at home in the office environment" – having worked in several administrative positions and different industries, including insurance and affordable housing.

Sara reports having agreat appreciation for the WHRY mission. She offers that it is easy to see the need for studies on many areas of women's health, and it is WHRY's track record in funding studies on conditions that affect women that drew her to this position.

She quickly adds that WHRY's commitment to sharing the news about our research findings was also a great draw for her as she can see how this helps the community.

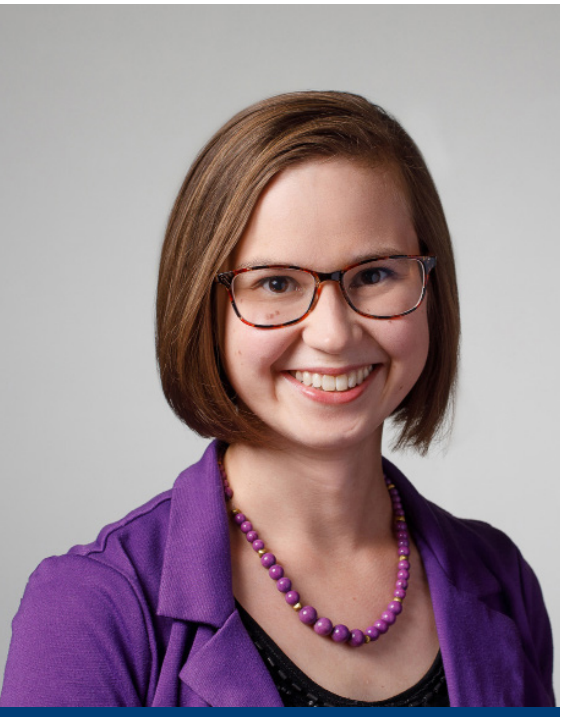
"I feel it's exciting to be here, like I am part of an important purpose. I look forward to contributing to the



work of WHRY," Sara said. "I want to help make a difference in the lives of other women," she says. "I feel like there's no better place than WHRY to do that." ◄

There's No Better Source than the Scientist

By Amanda Steffen



One of the very first lessons in journalism is recognizing the importance of an interview. It is often referred to as the mainstay of the profession. An article or even a video report is rarely published without some sort of quote or first-hand account.

There is a good reason for this. Seeking out primary sources and accounts from those who were part of an event adds credibility to reporting. It allows the journalist to clarify facts and offer a perspective and a context that would otherwise be missing. Moreover, it ensures that when reporting is printed, posted, or aired, it is as accurate as possible.

In this regard, journalism is not unlike scientific research. Investigators and journalists both ask questions and seek answers. In journalism, the questions and answers revolve around who, what, where, when, why, and how? In science, reports focus on who and what is studied, when and how the outcome came to be, and why it may be of value.

My goal as WHRY's communications officer is to ensure the public knows about the emerging developments in women's health and the role sex and gender play in health outcomes. It is why I consistently rely on the mainstay of journalism – the interview.

There is no better source for information on scientific research than the scientist who planned and conducted the experiment, analyzed the data, and explained the findings. Recently, I have been sitting down with several WHRY-funded investigators to learn more about their work so that I can report it as accurately as possible.

From neurologist Carolyn Fredericks, MD, I was reminded that two-thirds of those in our nation who suffer from Alzheimer's disease (AD) are women. Dr. Fredericks is working to understand if sex differences in brain connectivity can explain this. For example, her research has shown that women rely on certain brain connections differently than men and at an earlier age. The repeated use of these connections over a life span cause "wear and tear," which could potentially make women more vulnerable to AD.

In my conversation with psychologist Sarah Lichenstein, PhD, she drew my attention to that fact that women are the biggest users of cannabidiol (CBD) and since anxiety is more common in women than men, it is no surprise many women are using CBD to ease anxiety symptoms. Although, the effect of CBD on brain functioning has begun to be studied in men, it has not been studied in women. Dr. Lichenstein is, for the first time, investigating how CBD affects anxiety in women, whether it has benefit and, if so, how it should be used.

Each conversation was enlightening and offered me the chance to ask follow-up questions – the kind of questions you might ask. As a result of these interviews, the articles are enhanced by first-hand knowledge from the scientist responsible for the work. When the scientist is the source, readers get a perspective like no other. ◄

News You Need to Know

The FDA has approved a new treatment for Alzheimer's Disease (AD) through the Accelerated Approval Pathway – offered for serious conditions where there is an unmet need.

Dr. Christopher Van Dyck at Yale, the lead author on the trial publication, commented that "Based on the data from this trial, lecanemab appears to slow disease progression in the early stages of AD. It targets amyloid beta protein in the brain – a hallmark feature of AD."

The long-term clinical benefit of the drug, marketed as Leqembi, is not yet known. However, a trial is already underway to determine whether administration of the drug to asymptomatic individuals with elevated brain amyloid might slow decline even more.

Marking an Anniversary While Focusing on the Future

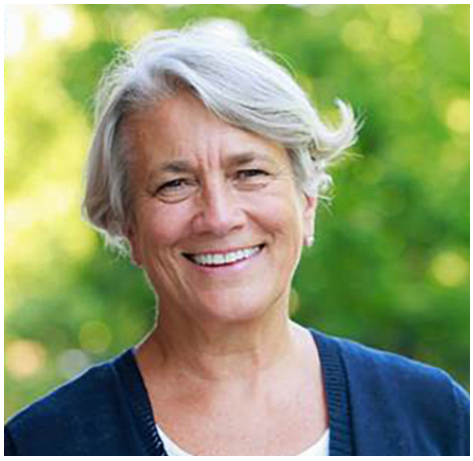
This year Women's Health Research at Yale celebrates its 25th anniversary. But the center has never been about looking back. WHRY has always looked toward the future, challenging science to explore women's health, to consider the differences between and among women and men, and to acknowledge the intersection of social and biological variables when it comes to health.

The words, "better science, better lives" underlining WHRY's name, are more than a slogan. They point to a mission, one that addresses health challenges and seeks to help everyone lead healthier lives.

For example, WHRY studies took on the complicated but critical area of addictions. First focusing on smoking, the greatest preventable cause of mortality in the U.S., our early work determined the biological and psychological reasons why women and men smoke, and how science-based approaches must be different for women and men to increase success when quitting smoking. As use of social media grew, WHRY supported research designed to understand why women are more likely to become addicted to internet platforms and to help shape thoughtful public policy. Now, as the use of CBD grows preferentially among women, WHRY is funding a study to understand how this unregulated substance affects mood and brain functioning in women.

An ongoing WHRY study is investigating the concurrent relationship of pain and opioid effects on the brain. The opioid crisis claims more than a 100 thousand lives a year and leads to an estimated $35 billion in health care costs – placing enormous strain on families, economies, and health systems. The primary way women are introduced to opioids is in seeking care for pain; further, women are more likely than men with pain to receive these agents. This study is unique in investigating how the sensations of pain and pain relief relate to opioid misuse.

At the same time, a study on the effect of medications other than opioids for the control of pain is also in progress. In particular, the use of high-potency steroids for control of pain after caesarean section is being studied with women who are recovering from opioid dependence. This work seeks to reduce exposure to



opioids for both these mothers and their infants and to provide an alternative in pain management for all women.

When the nation has faced concerns over addiction or many other health problems, WHRY has been there to initiate the research necessary to shape interventions that improve health. This all started twenty-five years ago with a grant from The Patrick and Catherine Weldon Donaghue Medical Research Foundation. With your support, WHRY will continue our mission well into the future. ◂

With appreciation,

Barbara

Barbara M. Riley

Philanthropy Chair

▸ Better science, better lives ▸ ▸

(Left to right) Raymond Andrews and Sheila Rostow, trustees of the Donahue foundation, Dr. David Kessler, Dean of Yale Medical School, Dr. Richard Levin, President of Yale University, and Linda Lorimer, Vice President of Yale University, at the 1998 announcement of Women's Health Research at Yale.

Women's Health Research at Yale: The Prologue

We came from academic centers all over the country and assembled for the first time on September 4, 1991, at the Hunt Valley Conference Center in Maryland. It was a historic event convened by the National Institutes of Health's Office of Research on Women's Health (ORWH), which had been established one year earlier in 1990.

Researchers devoted to studying the health of women were invited to set a research agenda to address the dramatic gaps in scientific information on the health of women. This included conducting research on conditions unique to, more prevalent among, or more serious in women, or for which different interventions for women and men were needed.

Dr. Bernadine Healy, the first and only woman to be appointed as a director of the NIH, spoke to us. She called our experience together an "awakening."

Increasing calls for research attention on the health of women during the 1980s within the Department of Health and Human Services, of which the NIH is a part, were spurred by a 1990 government report showing that NIH-funded research was not including women as study participants.

The ORWH was now charged with ensuring that women were appropriately represented and studied in research supported by the NIH, which as the greatest single funder of biomedical research in the U.S. had great influence over the direction of scientific inquiry.

Although some of us at the Hunt Valley Conference had been working within professional societies to establish the importance of studying women, most of us were largely on our own at our home institutions. We were elated to find colleagues who shared our scientific interests and personal commitment in recognizing the health needs of women. We were exhilarated by what we thought would be the impending change that would soon occur in science conducted across the nation.

It was not too long before we realized that what we were expecting would take time and lots more effort. In fact, it would be three years before the NIH began requiring that their funded research must include women, four years until guidelines for inclusion were official, and 10 years until investigations designed to study women were reflected in the scientific literature.

From 1990 until 1998, I was privileged to work with the ORWH, professional groups, and great colleagues in advancing the message that the health of women had to be studied.

And, for me, the sea change for which I had hoped came in 1998 with support from Yale Medical School, a grant from The Patrick and Catherine Weldon Donaghue Foundation, and the inception of Women's Health Research at Yale. The work of building a research center that could also form relationships with the community, educate the next generation, and have a national voice in improving health then began, and continues to be a joy. Looking forward, I see even more opportunity to advance this work and the initiatives of our center. ◀

Sincerely,

Carolyn M. Mazure, Ph.D.
Norma Weinberg Spungen and Joan Lebson Bildner Professor in Women's Health Research

Reflections on a Quarter of Century of Women's Health Research

"Women's Health Research at Yale has been a pioneering program for the past quarter of a century. Under founding director Dr. Carolyn Mazure's visionary direction, the program has helped launch careers of many investigators, and made substantial contributions to the health of women and girls across the globe."

- Dr. Marc Potenza, Women and Addictions Core Director

"I have been so grateful for the opportunities WHRY has offered me to engage with fellow researchers interested in sex and gender differences in health outcomes and with the larger community."

- Dr. Carolyn Fredericks, Neurology

"My time with WHRY has been foundational for my training as a scientist. It's an experience I try to pass on as I continue my career. To this day, WHRY's work informs my training and research."

- Ben Fait '17 & WHRY Undergraduate Fellow

25 YEARS OF

Women's Health Research at Yale

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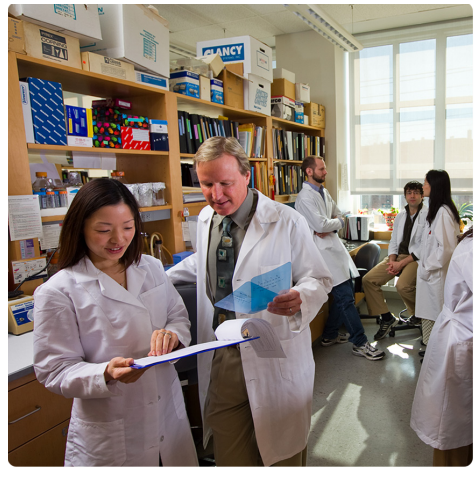
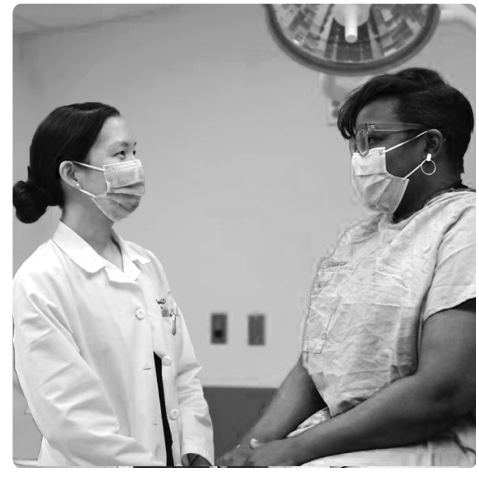
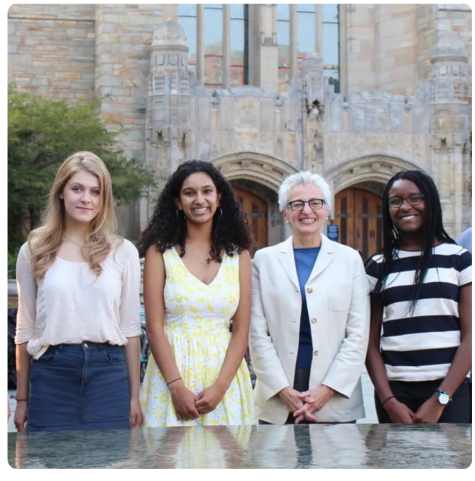
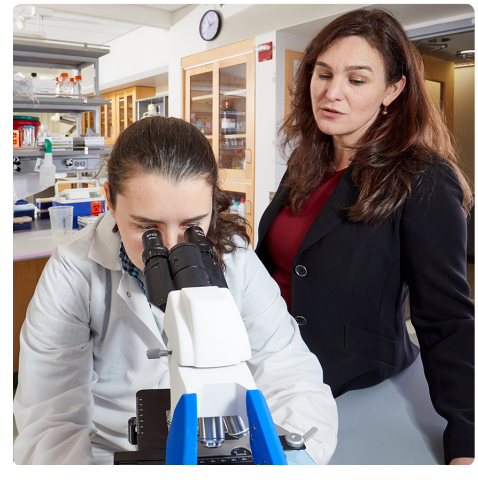




(Top Photo) Dr. Carolyn Mazure and Mona Gregg during the launch of WHRY. (Bottom photo) Dr. Ryan Jensen explores BRCA gene cancer risk



(Top Photo) Dr. Mark Mamula and his team investigate autoimmune disorders. (Bottom photo) Dr. Carolyn Mazure & WHRY Undergraduate Fellows



(Top Photo) Dr. Christine Ko speaks with a patient. (Bottom photo) Dr. Claire Flannery in the lab with medical student

Women's Health Research at Yale

▸ Better science, better lives ▸ ▸

Women's Health Research at Yale is changing the landscape of medical research and practice by ensuring the study of women and examining health differences between and among women and men to improve the lives of everyone.

Women's Health Research at Yale
135 College Street, Suite 220
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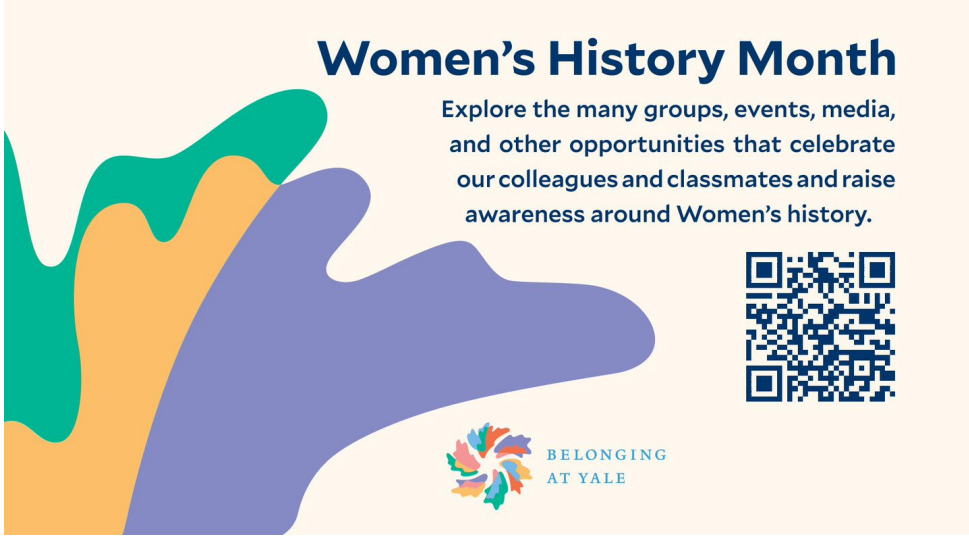

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