

# UNDERSTANDING SEX DIFFERENCES IN MEDICAL RESEARCH

Sex differences research investigates how being biologically male or female can affect health, disease, and treatment outcomes. **Men and women can differ in how their cells, hormones, and bodies function—and these differences can impact how diseases start, progress, and respond to treatments.**

For many years, most clinical studies were conducted primarily in men, and preclinical animal models over-utilized male subjects. Because of this, there wasn't enough information about how diseases and treatments might uniquely or differently affect women.

Over recent decades, researchers and advocates worked to address this problem, and, in 2016 the **National Institutes of Health (NIH)** introduced a policy requiring researchers to consider **sex as a biological variable (SABV)** in studies that utilize vertebrate and human subjects. This policy has helped the health care ecosystem better understand how certain conditions and treatments affect men and women differently.

For example, Alzheimer's disease and autoimmune disorders are more common in women, whereas pancreatic cancer and Parkinson's disease are more common in men. In a condition like psoriatic arthritis that occurs equally in men and women, **the same medications interact differently between the sexes**, which is why research that incorporates SABV is so important.

## Real-Life Examples of Health Differences Between Men and Women

 **Bone Health:** Hormones like estrogen help build and protect bones. After menopause, women lose estrogen, which puts them at higher risk for bone loss and fractures compared to men.

 **Heart Disease:** Men and women tend to present with different symptoms of heart disease. Women's symptoms have been studied less, resulting in more delays in getting diagnosed or treated.

 **Drug Metabolism:** Due to differences in body fat, hormones, and how the body breaks down medicine, men and women can respond to the same drugs in different ways.



By studying these differences, scientists can develop better ways to prevent disease, make earlier diagnoses, and create more individualized, effective treatments, so everyone gets the care they need to live a healthier life.



# SIGNIFICANT STEPS TOWARD INCORPORATING SEX DIFFERENCES IN RESEARCH

**1986**

NIH releases a policy that encourages the inclusion of women in clinical research

**1990**

NIH establishes the Office of Research on Women's Health (ORWH)

**1991**

U.S. Department of Health and Human Services (HHS) creates the Office on Women's Health

**1993**

NIH Revitalization Act mandates the inclusion of women and underrepresented minority populations in clinical research and codifies the ORWH

**1994**

Food and Drug Administration (FDA) establishes its Office of Women's Health

**2010**

The Patient Protection and Affordable Care Act includes the Women's Health Office Act (WFOA), which codified the offices of women's health across the Centers for Disease Control and Prevention (CDC), FDA, NIH, and other HHS agencies

**2012**

Congress passes the FDA Safety and Innovation Act, requiring FDA to provide special reports and accounts of clinical trials by sex, race, and ethnicity

**2016**

NIH establishes SABV Policy

**What role will you play in advancing sex differences in research and improving health outcomes for all?**

**Want to learn more?** These organizations provide research, resources, and further information on the role of biological sex in biomedical research and health outcomes:

- [American Medical Women's Association Sex & Gender Health Collaborative](#)
- [Endocrine Society](#)
- [FDA Office of Women's Health](#)
- [HHS Office on Women's Health](#)
- [NIH Office of Research on Women's Health](#)
- [Organization for the Study of Sex Differences](#)
- [Society for Women's Health Research](#)