

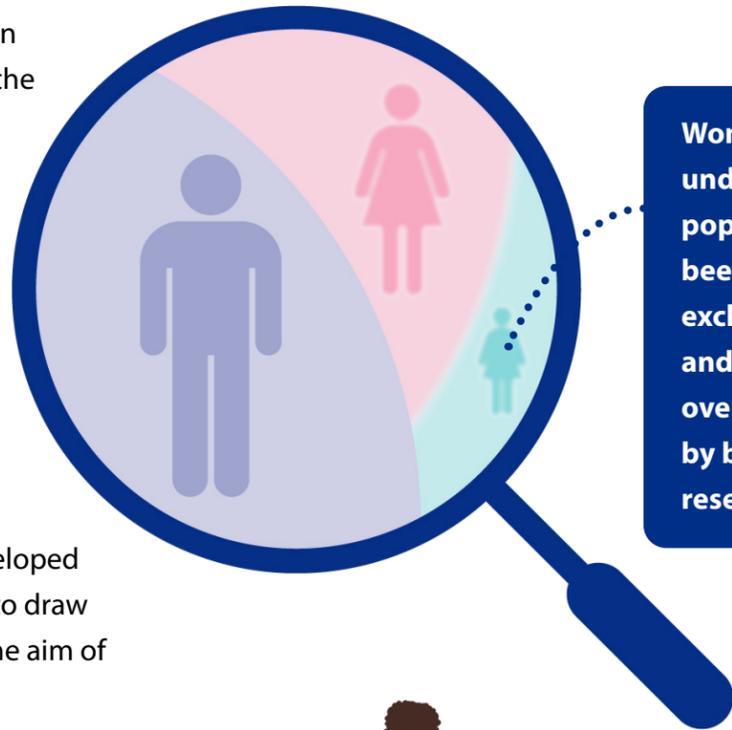


# U3 Interdisciplinary Research

*Bringing Women of Understudied, Underrepresented, and Underreported Populations into Focus*

The United States ranks lower than other high-income countries in terms of health and health care equity.<sup>1</sup> Health care inequities in the U.S. are particularly evident in the disproportionate burden of disease and adverse health outcomes experienced by women of underrepresented racial and ethnic communities, women in economically disadvantaged groups, women who live in rural areas, and women of sexual and gender minority groups. Despite the need for research to understand and reduce these inequities, women of these and other populations remain largely **U**nderstudied, **U**nderrepresented, and **U**nderreported in biomedical research.

The U3 framework and administrative supplement program, developed by the NIH Office of Research on Women's Health (ORWH), seeks to draw attention to and support research that addresses this gap, with the aim of advancing health equity.



**Women of underrepresented populations have been historically excluded from and remain often overlooked by biomedical research.**

## UNDERSTUDIED

Although a growing body of research has demonstrated that women of underserved populations are at greater risk for and experience worse outcomes with certain diseases, few research studies specifically focus on these populations. As a result, much is unknown about the complex drivers and mechanisms that give rise to and sustain these disparities.<sup>2,3</sup>



◀ **Women and people of color are undertreated for pain and cardiovascular symptoms.**<sup>4</sup>



▲ **From 2011 to 2015, rates of maternal deaths were threefold higher for NH Black women compared with NH White women and more than twofold higher for American Indian/Alaska Native women.**<sup>5</sup>



◀ **Despite lower incidence rates, death rates for uterine corpus and breast cancers are 98% and 41% higher, respectively, for non-Hispanic (NH) Black women compared with NH White women.**<sup>6</sup>



◀ **Across many health and care access indicators, rural women face greater health-related quality-of-life challenges.**<sup>7</sup>

## UNDERREPRESENTED

Women and people of color are consistently underrepresented in and are not always included in clinical study populations, contributing to concerns about the safety and effectiveness of treatments as they are applied to the general population. In addition, very few studies specify *both* a participant's sex and gender, *as well as* their race and/or ethnicity, making it difficult to look at data for women of a specific population unless the study specifically focuses on women of these populations.

Although just over 50% of the U.S. population is female, in an analysis of clinical trials for cancer drug approvals between 2008 and 2018, women represented only

**40%** of clinical trial participants.<sup>8</sup>



Although people who are African American or Black (AA/B) and people who are Hispanic or Latino (H/L) represent 13.4% and 18.5% of the U.S. population, respectively, an analysis of therapeutic clinical cancer trials in the U.S. from 2003 to 2016 found that across several different cancer types, only 5.9% of participants were African American or Black, and only 2.6% were Hispanic.<sup>9</sup>

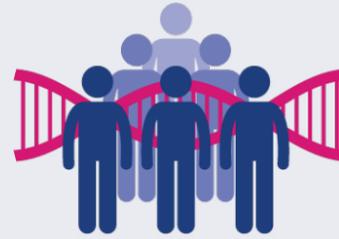
General Population



Cancer Trial Populations



**36%** of the clinical trial participants for novel cardiometabolic drug approvals between 2008 and 2017 were women.<sup>10</sup>



**19%** of samples in genome-wide association studies were of non-European ancestry, according to a 2016 analysis of 2,511 studies.<sup>11</sup>

## UNDERREPORTED

Even when studies include women and participants from many racial and ethnic groups, researchers rarely report their results with separate analysis based on sex and race or ethnicity. Without these analyses and data, advances in scientific knowledge of these populations are limited, and crucial insights may be overlooked.<sup>12</sup>

**26%** of studies reported results by sex separately.



**74%** of studies did not report outcomes by sex, and even fewer did so by race.



A 2018 analysis of NIH-funded clinical trials in 2015 found that only 26% reported at least one outcome by sex or clearly considered sex during analysis; even fewer reported outcomes by race or ethnicity.<sup>12</sup>



## ORWH U3 Research Supplement

ORWH's U3 Administrative Supplement Program provides support for scientists from across different disciplines who are conducting preclinical, clinical, behavioral, or translational research addressing health disparities among women from one or more NIH-designated health disparity populations.

**U3 Populations** (NIH-designated health disparity populations)

- Black or African American
- Hispanic or Latina
- American Indian or Alaska Native
- Asian
- Native Hawaiian/other Pacific Islander
- Socioeconomically disadvantaged
- Underserved rural
- Sexual and gender minority

1. Hero et al., 2017. PMID: [28583961](#); Woolf & Aron (Eds.), 2013. <https://www.ncbi.nlm.nih.gov/books/NBK154469>

2. Lathrop, 2020. PMID: [31911097](#).

3. Geller et al., 2018. PMID: [29053489](#).

4. Lee et al., 2019. PMID: [31186154](#); Hoffman et al., 2016. PMID: [27044069](#); Aggarwal et al., 2018. PMID: [29449443](#); Zhang et al., 2021. PMID: [33684539](#).

5. Petersen et al., 2019. PMID: [31071074](#).

6. DeSantis et al., 2019. PMID: [30762872](#).

7. James et al., 2017. PMID: [29145359](#).

8. Mendis et al., 2020. PMID: [32960478](#); <https://www.census.gov/quickfacts/fact/table/US/PST045219>

9. Duma et al., 2018. PMID: [29099678](#).

10. Khan et al., 2020. PMID: [32427023](#).

11. Popejoy & Fullerton, 2016. PMID: [27734877](#).

12. Geller et al., 2018. PMID: [29053489](#).

