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**Title of Initiative:** Innovations for Addressing Research Gaps and Promoting the Health of Women Experiencing Health Disparities

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**Objectives:** The goals of this initiative include: 1) Supporting entrepreneurial research and the development of innovative products that alleviate barriers in health research (e.g., participant engagement, data, clinical trials, and workforce) and interventions (e.g., services, prevention, devices, and digital health), focusing on promoting the health of women experiencing health disparities throughout the life course.

2) Leading across NIH Institutes and Centers (ICs) in creating a pathway for developing commercialized solutions addressing health equity and reducing the burden of health disparities in women.

### **Background:**

“Women’s health” was once synonymous with reproductive health. Women's health research has expanded to account for sex and gender influences on health, including within research study design. In addition, research shows diseases and conditions that affect only women (e.g., severe maternal morbidity and mortality, menopause, and endometriosis), are more prevalent in women (e.g., autoimmune diseases, intimate partner violence), or present differently in women (e.g., cardiovascular disease), deserve special considerations and require collaborations across NIH Institutes or Centers (ICs). As defined by the NIH Office of Research on Women’s Health (ORWH), these areas of health can influence a woman’s life course from pre-pregnancy, in utero, childhood/adolescence, to adulthood, and old age.

Two recent policy initiatives, the [White House Women's Health Research Initiative](#) and the U.S. Department of Health and Human Services ([HHS](#)) [Blueprint for Addressing the Maternal Health Crisis](#), provide striking evidence of women’s health disparities and guide federal policy in creating health equity for women’s health and research. These initiatives align with NIMHD’s research priorities and the [21<sup>st</sup> Century Cures Act](#) passed in 2016 to reduce the burden of health disparities. However, there are gaps in implementing successful interventions; for example, while safety bundles have shown large-scale improvements in pregnancy-related outcomes, they remain unimplemented in many hospitals. Furthermore, women within populations experiencing health disparities often suffer adverse health outcomes due to biological and social factors (e.g., adverse social determinants of health, skewed clinical research, socioeconomic status, and race and ethnicity). These disparities are further exacerbated in women living with poor health care access, economic barriers, lack of knowledge or cultural competency about products and services, insufficient infrastructure, and adverse environmental factors. For example, despite similar rates of HPV vaccination and cervical cancer screening, Black and African American women experience higher

incidence and mortality than Caucasian women due to delays in diagnosis after screening. This delay leads to an advanced stage at diagnosis, resulting in lower rates of receiving guidelines adherent to care. Additionally, there are racial and ethnic disparities in other chronic debilitating conditions for women, such as heart disease, diabetes, and autoimmune diseases, among others.

While NIH's policy on [Inclusion of Women and Minorities as Subjects in Clinical Research has improved the representation of women in clinical trials, substantial underrepresentation of women's enrollment in clinical trials persists in several essential disease categories, including human immunodeficiency virus \(HIV\), acquired immunodeficiency syndrome \(AIDS\), chronic kidney disease, and cardiovascular diseases—moreover, fewer than one-third of phase III clinical trials supported by NIH disaggregate results by sex. Also, clinical research on female-specific and relevant conditions, disorders, and diseases remains limited.](#)

The SBIR/STTR program is a mandatory spending set-aside program based on a portion of every NIH IC's extramural budget. The program serves as a vehicle for supporting small businesses and entrepreneurs in developing innovative solutions to support and further the NIH's mission. The program can also help influence an economic market's focus, such as providing federal research priorities and funding for technology, products, and service interventions to reduce barriers to care and research throughout a woman's life. In 2019 and 2023, out of 333,382 NIH SBIR/STTR-funded projects, only 150 focused on women's health, and 17 were funded by NIMHD. Topics included poverty, violence, maternal, aging diseases, neurology, obesity, cancers, bladder and pelvic areas, and chronic diseases.

This SBIR/STTR concept could provide Federal research direction and funding priorities to entrepreneurs for reducing the burden of health disparities throughout a woman's life course, including increasing access to health services, improving workforce training, strengthening research infrastructure, promoting maternal and child health, and improving access to and utility of prevention resources. A successful example of how supporting entrepreneurship can promote women's health includes the [Harvard Apple Study](#). In addition, according to a [2023 McKinsey and Co. report](#), private entities could dedicate an estimated \$1 trillion of investment in women's health to support a robust female entrepreneurship community working on women's health equity. Additionally, a 2023 report by the [Innovation Equity Forum](#), co-sponsored by NIH, on the [Women Health Innovation Opportunity Map](#), presents the case for women's health innovation investments and how they can generate transformative benefits across the research and development ecosystem and promote health equity and economic well-being for women. This SBIR/STTR concept can leverage small businesses, entrepreneurs, and research institutions to create technologies, services, and products that draw upon multiple levels and domains of the NIMHD research framework for reducing the burden of health disparities in women by race and ethnicity and socioeconomic status as well as the intersectionality with other identities (sexual and gender minorities, underserved rural residents, and persons living with disability).

## Description of Initiative:

In partnership with ORWH and other NIH institutes, this concept will utilize NIMHD research priorities, the pillars of health disparities research, and the research framework for supporting women-centric and community-centered evidence-based solutions to overcome barriers to women's health in populations experiencing health disparities. This concept will also allow other NIH IC's SBIR/STTR programs to utilize it to support entrepreneurs in their products and services to meet their research and health care needs for women experiencing health disparities. This concept aims to engage small businesses, entrepreneurs, and institutions from diverse backgrounds such as human services, health and clinical research, data and technology, allied health, engineering, science, and business in developing technologies, services, and products for women's health innovations among populations experiencing health disparities.

As shown above, this concept will help bridge gaps in women's health-related research through specific digital health, devices, product development, and services that can address economic, health care access, workforce, and health literacy and cultural competency barriers. These focused interventions will help reduce racial and ethnic, geographic, disability, and socioeconomic status disparities in women's health and promote women's health equity in populations experiencing health disparities. Leveraging the NIMHD and NIH's SBIR/STTR program will encourage commercialized solutions to develop innovative and culturally responsive solutions to further the understanding of women's health across the lifespan and address inequities of research, prevention, and treatment in women experiencing health disparities.

## Research Priorities:

Projects leading to commercializing affordable, accessible, and culturally acceptable technologies, services, and products and focusing on reducing women's health disparities by race and ethnicity, geographic location, disability status and socioeconomic status are encouraged. Proposals are encouraged to utilize the [NIMHD Research Framework and the ORWH multidimensional framework](#). The NIMHD Research Framework identifies diverse factors within socio-ecological domains and levels that, individually and synergistically, are known to influence the distribution of disparate health outcomes among racial and ethnic minority populations and other populations who experience health disparities. The ORWH multidimensional framework highlights that the health of women is affected by many biological, behavioral, social, structural, and environmental factors that affect women across their life course. These factors include biological systems, processes, and traits (e.g., sex, gender, age, hormonal, and reproductive phases). Other factors can include life context and the environment. A complex intersection of many internal and external factors affects a woman's health status, disease presentation, treatment response, and the effects of diseases

and conditions on a woman's quality of life. Thus, considering these dynamic factors is necessary for a more comprehensive understanding of women's health.

This concept will focus on the following:

- Support multidisciplinary research that focuses on evidence-based and patient-centered technology, services, and products for early diagnosis, surveillance, and treatment for addressing women's unmet health needs, including approaches that address disparities in maternal mortality and morbidity, cervical cancer, and other chronic debilitating diseases in women;
- Develop targeted solutions-based approaches to address the continuum of a woman's health throughout her life course - Pre-pregnancy, In Utero, Childhood and Adolescence, Adulthood, and Old Age; and
- Utilize implementation science and community-engaged methods to ensure women's equitable inclusion in research, address women's health disparities by race and ethnicity and socio-economic status and promote the implementation of evidence-based interventions that improve women's quality of and access to care and address social determinants of health.