



NIH Office of Research on Women's Health

DIVERSITY IN CLINICAL TRIALS PRODUCES BETTER SCIENCE, MORE EQUITY

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**March 29, 2021 – National Academies of Science, Engineering, and
Medicine “Overcoming Barriers to Diversifying Clinical Trials: Workshop”**



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#ResearchForWomen

ORWH Mission



Enhance and expand women's health research



Include women and minority groups in clinical research



Promote career advancement for women in biomedical careers

NIH Vision



Sex and gender integrated into biomedical research



Every woman receives evidence-based care



Women in science careers reach their full potential



National Institutes of Health
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NIH Policy on

Consideration of Sex as a Biological Variable (SABV) in NIH-funded Research

“NIH expects that [SABV] will be factored into research designs, analyses, and reporting in vertebrate animal and human studies. Strong justification from the scientific literature, preliminary data, or other relevant considerations must be provided for applications proposing to study only one sex.”



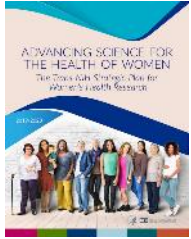
Effective 01/25/2016

Inclusion – It's in ORWH's DNA



- Seeks distribution of participants by sex/gender, race, ethnicity, and age needed to meet study goals
- Beginning in the 1980s, NIH and later Congress established, formalized, and expanded inclusion to include women and racial and ethnic minorities
- **21st Century Cures Act** expanded inclusion
 - Added **individuals of all ages** and eventually **pregnant and lactating women**
 - Requires NIH-defined applicable phase III CTs to report results **disaggregated by sex/gender, race, and ethnicity** into ClinicalTrials.gov

¹ Bernard MA, Clayton JA and Lauer MS. 2018. *JAMA* 320(15):1535-1536. doi:10.1001/jama.2018.12368



Bringing rigor to the study of sex effects

- Expand and develop advanced approaches for study design, data collection, and analysis
- Develop measures that evaluate conditions or diseases relevant to women
- **Expand and refine methodologies to improve the recruitment and retention of women underrepresented in clinical research**

FDA

FDA's OWH and ORWH have partnered on the
DIVERSE WOMEN IN CLINICAL TRIALS

<https://www.fda.gov/consumers/womens-health-topics/women-clinical-trials>



Strategic Goal 2

Methods

Develop methods and leverage data sources to consider sex and gender influences that enhance research for the health of women.

RADx-Underserved Populations (RADx-UP) - \$500M

Interlinked community-engaged projects focused on implementation strategies to enable and enhance testing of COVID-19 in underserved and/or vulnerable populations

Overarching Goals

- Enhance COVID-19 testing among **underserved and vulnerable populations** across US
- Develop/create a **consortium of community-engaged research projects** designed to rapidly implement testing interventions
- **Strengthen the available data** on disparities in infection rates, disease progression and outcomes, and **identify strategies to reduce these disparities** in COVID-19 diagnostics



Target populations



- African Americans/Blacks
- American Indians/Alaska Natives
- Nursing Homes/Assisted Living Facilities
- Correctional Facilities
- Congregate Housing/Shelters
- Underserved Rural/Urban Areas
- Pregnant Women

Specific activities included

- Establish research sites across U.S. to evaluate testing methods in specific populations, settings, etc.
- Collaboration between research sites and community partners to identify and address unique community needs – tribal health centers, faith-based orgs., homeless shelters, corrections systems
- Develop testing strategies to apply technological advances emerging from RADx efforts in real-world settings

NIH Community Engagement Alliance (CEAL) Against COVID-19 Disparities leads outreach/engagement efforts in underserved communities

VISION

Become the most trusted partner in community engagement efforts addressing the scientific response to the COVID-19 pandemic and related disparities



Establish Partnerships within the Community



Address Misinformation within Communities of Color



Grow an Understanding and Trust in Science



Accelerate the Uptake of Beneficial Treatments

Objective 1

Conduct urgent community-engaged **research and outreach** focused on COVID-19 awareness and education to address widespread misinformation and distrust and promote an evidence-based response

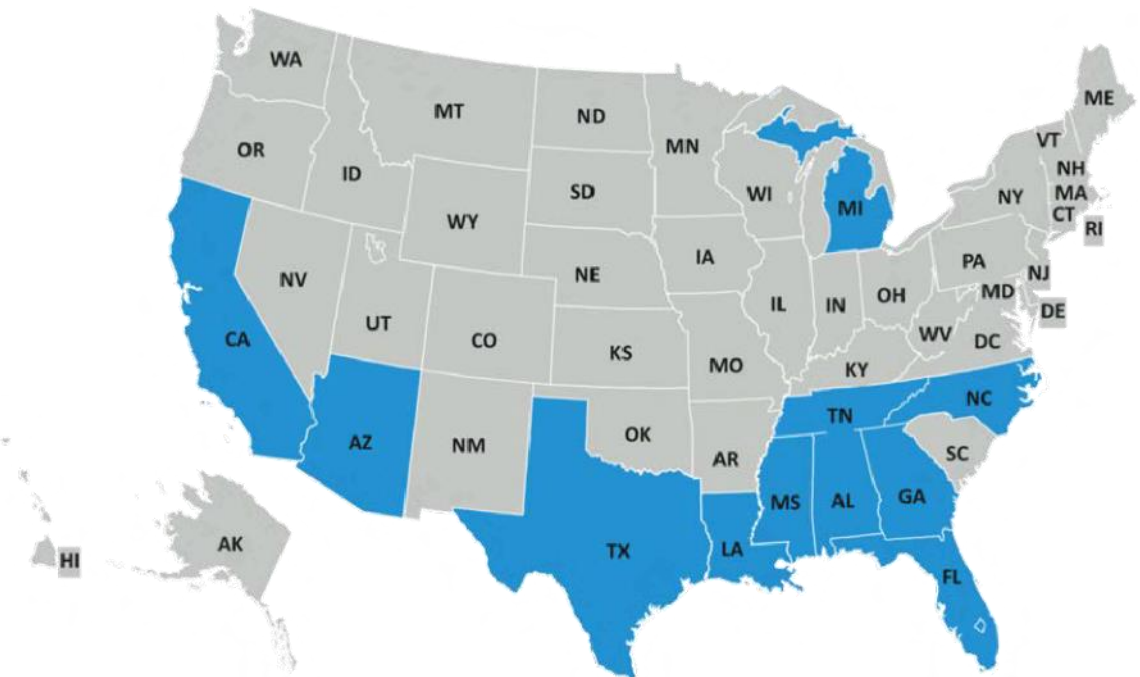
Objective 2

Promote and facilitate **inclusion of diverse racial and ethnic populations** in CTs (prevention, vaccine, therapeutics) representative of populations disproportionately affected



Addressing COVID-19 Vaccine Hesitancy: NIH Community Engagement Alliance Against COVID-19 Disparities

NIH-wide initiative leading outreach, engagement and inclusive participation efforts in ethnic and racial minority communities disproportionately affected by the COVID-19 pandemic



11 CEAL state teams partnering with national & local organizations



Academic Partners



Community-Based Organizations



Healthcare Centers & Providers



Faith-Based Organizations



State & Local Government Agencies



Pharmacy Networks



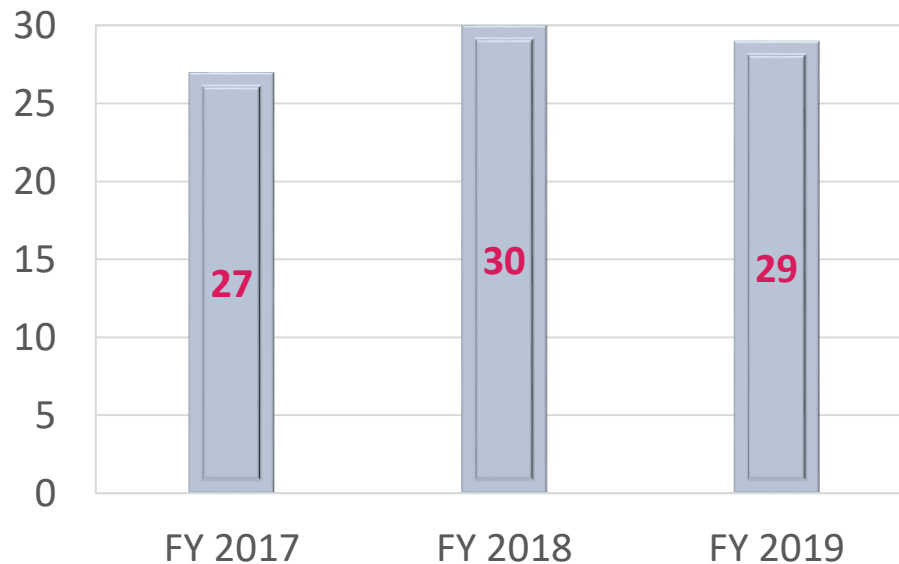
Research on the Health of Women of Understudied, Underrepresented and Underreported Populations

Historical Data

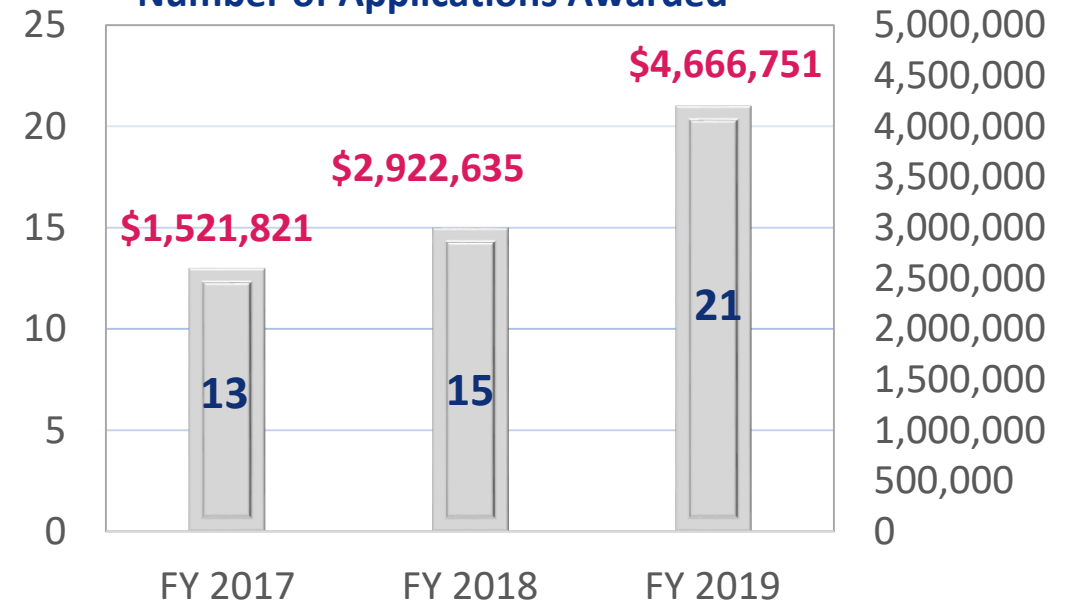
- FY20 10 applications were funded
- Broadly, the projects focused on maternal/child health, reproductive health, cancer and substance use



Number of U3 Applications Received



Number of Applications Awarded



Outreach efforts must meet women where they are



Facebook ads recruited at-risk women for an HIV prevention clinical trials better than traditional outreach methods (Jones et al., 2017)

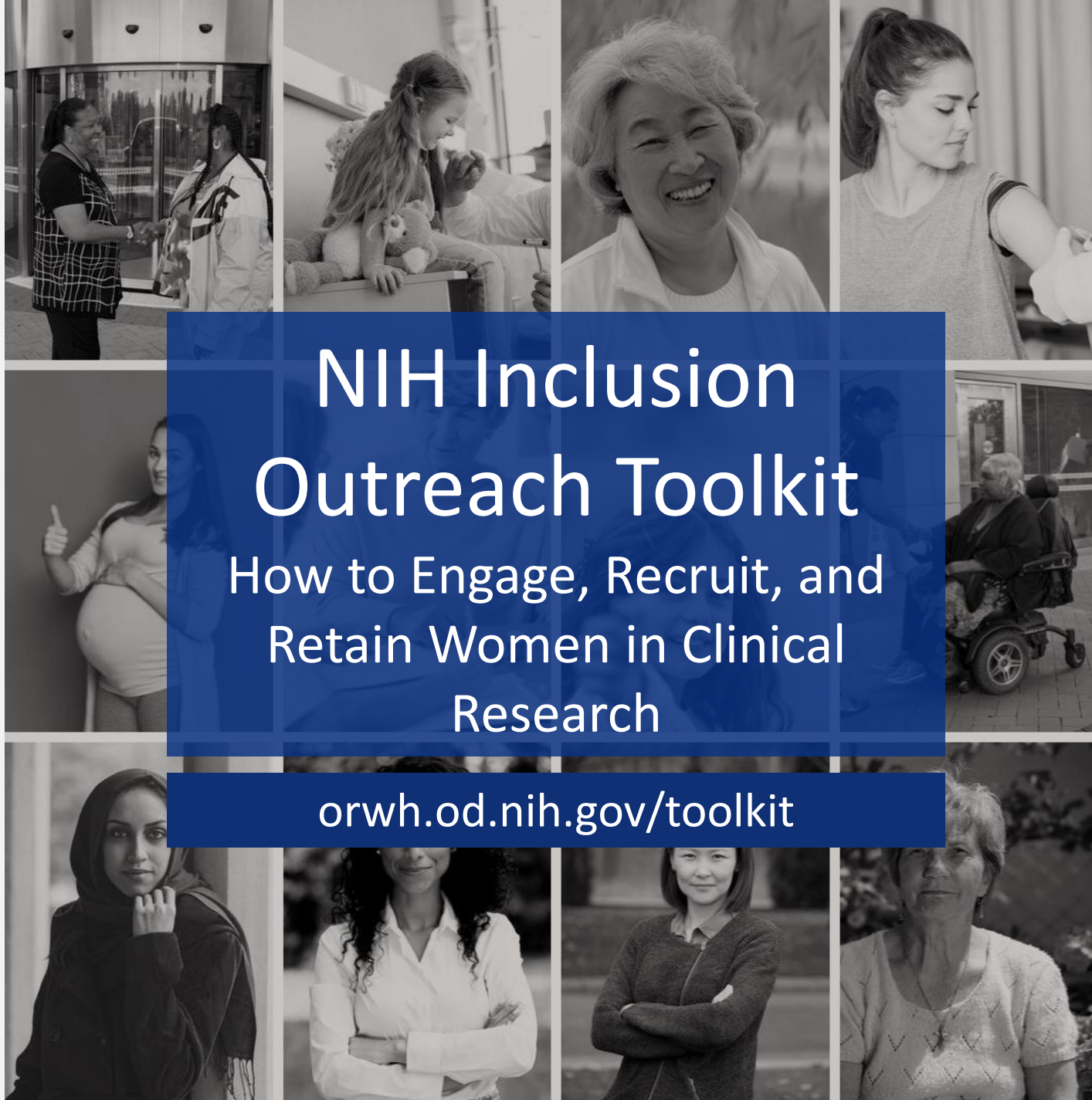
Mailings and phone calls effectively reached women aged 40-62 for trials to treat menopause symptoms (Freeman et al., 2011)



Project HEED used existing community groups to educate women, mostly minorities, who were at risk for diabetes (Parikh et al., 2010)

Researchers built connections to community for years, disseminated educational resources, before trials on a cervical cancer therapy began





NIH Inclusion Outreach Toolkit

How to Engage, Recruit, and
Retain Women in Clinical
Research

orwh.od.nih.gov/toolkit



NIH Clinical Center
Introductory
Principles of
Clinical
Research
Course*

Module Two

Persistent challenges foil truly representative studies

- Less research of diseases affecting women and lower funding levels
 - [Gender Disparity in the Funding of Diseases by the U.S. National Institutes of Health.](#)
Mirin AA. *J Women's Health*. 2020 Nov 27.
- Male-patterned inclusion criteria and sex-biased outcome measures persist
- Is underrepresentation baked in? Early mouse models for drug discovery use almost exclusively male mice
- Dependent care and time commitment impede participation
- Criteria limiting participation for those with complex needs/multiple chronic conditions
 - Women and certain racial and ethnic groups have higher prevalence of such comorbidities notwithstanding willingness to participate (comparable to Whites')



NIH Inclusion Across the Lifespan II

<https://grants.nih.gov/sites/default/files/IAL-II-Workshop-Report.pdf>



NIH National Institutes of Health
Office of Research on Women's Health

Fifth Annual Vivian W. Pinn Symposium

Integrating Sex and Gender Into Biomedical Research as a Path for Better Science and Innovation



Honoring the first full-time director of ORWH, Vivian W. Pinn Symposium is held annually during National Women's Health Week

May 11-12, 2021 | Virtual Meeting

Illustrate the scientific, societal, and economic opportunities of integrating sex and gender into biomedical research and the power of synergistically working together

- Create bridges and capacity across the scientific enterprise to build a broad-based network of government, non-profit, academic, and business organizations
- Develop strategies to integrate sex and gender considerations into research enterprise
- Apply multidimensional perspective to women's health to advance the integration of sex and gender considerations via trans-disciplinary approaches and partnerships



Vivian W. Pinn, M.D.

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30TH ANNIVERSARY ISSUES

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bit.ly/ORWHInFocus



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