NATIONAL INSTITUTES OF HEALTH

## Report of the Advisory <br> Committee on Research on Women's Health: Fiscal Years 2021-2022

Office of Research on Women's Health and NIH Support for Research on the Health of Women

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## Report of the Advisory Committee on Research on Women's Health: Fiscal Years 2021-2022

Office of Research on Women's Health and
NIH Support for Research on Women's Health


NIHNational Institutes of Health Office of Research on Women's Health

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## Letter from the ORWH Director

The National Institutes of Health (NIH) Office of Research on Women's Health (ORWH) has published the Report of the Advisory Committee on Research on Women's Health: Office of Research on Women's Health and NIH Support for Research on Women's Health (biennial report) every two years since 2007 to detail NIH's activities related to the health of women. Required by the NIH Revitalization Act of 1993, this eighth biennial report on NIH's women's health research, covers fiscal years (FYs) 2021 and 2022. NIH's Advisory Committee on Research on Women's Health (ACRWH) reports serve as an important resource for Congress, the scientific community, and the public.

As an NIH-wide collaboration, this biennial report highlights valuable contributions from NIH's 27 Institutes and Centers, and many of its Offices, for which I am thankful. I am also grateful to the members of ACRWH for their contributions to the work we do for the health of women.

This biennial report describes important changes requested by NIH leadership. In response, ORWH:
" Streamlined the composition process, and reduced the length of the report
" Leveraged more digital content on the activities of NIH Institutes, Centers, and Offices (ICOs)
" Utilized the Office of Evaluation, Performance, and Reporting's Strategic Plan Tracking and Reporting Tool (START) module to collect data from ICOs

For additional information, please refer to the following resources: ORWH's expanded and improved website and the report: Perspectives on Advancing NIH Research to Inform and Improve the Health of Women (March 2022). The Perspectives report was informed by the Advancing NIH Research on the Health of Women: A 2021 Conference, an event requested by Congress and co-hosted by ORWH and ACRWH.

Additional noteworthy developments are featured below:
Inclusion. In FY 2021 and FY 2022, NIH produced important advances in its decades-long efforts to ensure that women and diverse populations are appropriately represented in NIH-funded clinical research. Continued implementation of previously reported NIH policies and laws, including the NIH Revitalization Act of 1993 (inclusion of women and underrepresented racial and ethnic populations) and the 21st Century Cures Act (inclusion of people of all ages).

With the release of the previous ACRWH biennial report in December 2021, NIH addressed the Government Accountability Office's (GAO) final five recommendations originally included in the October 2015 report, Better Oversight Needed to Help Ensure Continued Progress Including Women in Health Research (GAO-16-13). GAO has officially closed its recommendations.

In 2022, NIH launched the Researching COVID to Enhance Recovery (RECOVER) initiative, a major research project that includes women and pregnant people in an intentional manner. RECOVER seeks to understand how people recover from a SARS-CoV-2 infection and why some people do not fully recover and develop post-acute sequelae of COVID-19 (PASC), otherwise known as "long COVID." Importantly, RECOVER includes women who had COVID-19 during or immediately after pregnancy, such as a diverse group of 3,895 people who delivered at 35 different hospitals across the country.

Research on sex and gender. In April 2022, ORWH and 11 ICs reissued The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional). Initially issued in FY 2019, this funding opportunity was NIH's first investigator-initiated, disease-agnostic R01 on sex and gender that supported research investigating sex- and gender-related factors and their intersection in health and disease.

Also in 2022, ORWH and 11 other ICOs introduced the Galvanizing Health Equity Through Novel and Diverse Educational Resources (GENDER) research education program, ORWH's first (R25), which focused on improving sex- and gender-specific training in science, medicine, and other health fields relevant to biomedical research through course and curricula development.

Maternal morbidity and mortality (MMM). Since NIH launched the Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) initiative in 2019-co-led by ORWH—support for research on ways to prevent maternal deaths and improve health before, during, and after delivery has significantly increased. In FY 2022, President Joe Biden's budget included $\$ 30$ million to expand IMPROVE, and create the Maternal Health Research Centers of Excellence.

As the country's maternal health crisis worsens, researchers have found that over half of maternal deaths and severe pregnancy-related complications occur postpartum between one day and one year after delivery. Most of these deaths are preventable.

To better understand, address, and prevent the risk factors, ORWH collaborated with other ICOs to co-sponsor a workshop led by the Office of Disease Prevention's "Pathways to Prevention" program at the end of 2022.

ORWH's partnership with the National Institute of General Medical Sciences expanded women's health research capacity in 18 states with low levels of NIH funding—and with some of the highest maternal and infant mortality rates. Four Institutional Development Award (IDeA) initiatives, including three notices of special interest (NOSI) with administrative supplements and a NOSI creating a Center of Biomedical Research Excellence in Women's Health, fund women's health research across the lifespan with a special interest in maternal and infant morbidity and mortality. Of the 34 administrative supplements awarded (totaling $\$ 9$ million), ORWH co-funded 10 and six of these awards focus on maternal health.

Careers. The second and third years of the COVID-19 pandemic produced more challenges for women and disproportionately on women scientists who experienced increased caregiving duties, and more family and household responsibilities. This impact included reduced research hours and declines in women authorship in scientific fields. These changes are impeding the biomedical careers of many women scientists and may alter the demographics of the biomedical workforce for years to come.

Closer to home, ORWH was instrumental in shaping the conversation about women in biomedical careers:
" In 2022, I co-authored an article in Nature Communications about NIH's leadership in instituting "inclusive excellence," a new strategy for fostering a diverse scientific ecosystem and the full inclusion of women in the scientific workforce.

In 2021, ORWH partnered with Office of the Director (OD) and the NIH Working Group on Women in Biomedical Careers to select 10 institutions to receive the NIH Prize for Enhancing Faculty Gender Diversity in Biomedical and Behavioral Science. The \$50,000 awards recognized institutions that had acted to effect systemic change to address gender diversity and equity among faculty members.
» The National Institute of Arthritis and Musculoskeletal and Skin Diseases and ORWH announced in late FY 2022 an exciting new pilot program designed to create a more robust cadre of women's health research leaders. With $\$ 2.5$ million in ORWH funding, the Team Science Leadership Scholars Program will help researchers acquire and hone team science leadership and mentoring skills.

As women's health research begins its third decade as a formally recognized focus of NIH research through signage of the NIH Revitalization Act of 1993, the path forward offers the promise of greater gains in scientific knowledge, improvements in clinical practices and outcomes, and advances in women's biomedical careers. Regarding the latter, the number of women IC directors increased from 10 to 12 in FY 2021-FY 2022. Additionally, the National Cancer Institute welcomed its first woman director, Dr. Monica Bertagnolli, in late 2022. Dr. Bertagnolli became the NIH director in FY 2024.

In closing, I extend my deepest appreciation to the many people who have supported ORWH and its mission. This includes countless administrators and scientists who work for or are supported by NIH's 27 ICOs. Thank you to the thousands of women who have participated in clinical trials and the research teams that have supported them-all in an effort to advance science for women. I appreciate the concerned stakeholder groups and the community at large who work tirelessly to improve the health of women. Collaborative efforts such as these will ultimately make it possible for all women to receive evidence-based care tailored to their personal needs, circumstances, and goals.

## With Gratitude,

Janine A. Clayton, M.D., FARVO
Associate Director for Research on Women's Health
Director, Office of Research on Women's Health
National Institutes of Health
December 2023

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## Preface

The Report of the Advisory Committee on Research on Women's Health: Fiscal Years 2021-2022 describes the programs and initiatives undertaken by NIH and its Office of Research on Women's Health (ORWH). As outlined in the NIH Revitalization Act of 1993 (Public Law 103-43, Section 486B), ORWH's mission is to:
» Advise the NIH Director on matters relating to research on women's health;
» Strengthen and enhance research related to diseases, disorders, and conditions that affect women;
» Ensure that research conducted and supported by NIH adequately addresses issues regarding women's health;
" Ensure that women are appropriately represented in biomedical and biobehavioral research studies supported by NIH;
" Develop opportunities for and support recruitment, retention, reentry, and advancement of women in biomedical careers; and
" Support and advance rigorous research that is relevant to the health of women.

Members of the Advisory Committee on Research on Women's Health (ACRWH) are pleased to submit this report to the NIH Director through the Director of ORWH, who is also the NIH Associate Director for Research on Women's Health. They have reviewed the report and found that it illustrates the breadth and depth of the research, programs, and activities undertaken by ORWH and the NIH institutes, centers, and offices (ICOs) to achieve the above mission and support implementation of the 2019-2023 Trans-NIH Strategic Plan for Women's Health Research during fiscal years (FY) 2021 and 2022, including:

NIH-supported research on the health of women and the influence of sex and gender on health and disease;

NIH budget allocations for research on the health of women, submitted by the U.S. Department of Health and Human Services Office of the Assistant Secretary for Financial Resources;

Efforts to advance implementation of the NIH Policy on Sex as a Biological Variable (SABV) across the biomedical research community through the NIH-Wide SABV Working Group and development of e-learning courses, including Bench to Bedside: Integrating Sex and Gender to Improve Human Health;

Programs to drive exploratory research on sex and gender differences to improve science, such as related administrative supplements; the reissuance of NIH's first investigator-initiated, disease-agnostic R01 on sex and gender; and continuation of the Specialized Centers of Research Excellence on Sex Differences (SCORE) cooperative agreement program;

Conferences and events to promote interdisciplinary exploration of women's health research priorities, including "Advancing NIH Research on the Health of Women: A 2021 Conference"-which focused on rising rates of maternal morbidity and mortality, the current status of chronic debilitating conditions in women, and the stagnant cervical cancer survival rate-and two Vivian W. Pinn Symposia, which included discussions on the dearth of education regarding the impact of sex and gender on health and disease, and the impact of the COVID-19 pandemic on the careers of women scientists, held during National Women's Health Week in 2021 and 2022;

Programs and funding opportunities that have expanded inclusion in women's health research, such as the administrative supplement to support inclusion of women in understudied, underrepresented, and underreported (U3) populations in biomedical research and recurring meetings of the NIH Inclusion Governance Committee (IGC); and
" Communications and outreach related to women's health research advancements and priorities, conducted through the ORWH website, email, Twitter, Linkedln, and Facebook, as well as ORWH's monthly e-newsletter, The Pulse, and quarterly periodical, Women's Health in Focus at NIH.

Additionally, during FYs 2021 and 2022, ORWH continued to advance equity and career mobility for women in science, technology, engineering, mathematics, and medicine (STEMM) through:
» Continuing the Building Interdisciplinary Research Careers in Women's Health (BIRCWH) mentored career-development program, which now includes 19 active sites;
» Leading the NIH Working Group on Women in Biomedical Careers (WgWBC) and hosting the "NIH Partnership Summit: Reimagining Women in the Bioengineering, Technology, and Data Science Ecosystem"; and
» Offering research supplements to promote reentry and retention of women in the biomedical workforce, including the administrative supplements to promote research continuity and retention of NIH mentored career development $(\mathrm{K})$ award recipients and scholars, and funding opportunities to meet the contemporary needs of a diverse biomedical workforce.

Those are a sample of the activities conducted across NIH to improve the health of women during the past 2 years-and indeed there is more work to be done. ACRWH would like to express gratitude for the focused attention of NIH leadership and ICO leaders, who have conducted tireless work on behalf of women's health, sex and gender issues, and women in biomedical careers. ACRWH also acknowledges the accomplishments of the NIH Coordinating Committee on Research on Women's Health, the NIH-Wide SABV Working Group, the NIH IGC, the WgWBC, and the Sex and Gender in Health and Disease scientific interest group. Although progress has been made, continued work on these efforts will remain necessary for years to come.

## NIH Advisory Committee on Research on Women's Health (ACRWH)

## Fiscal Year 2021-2022 Membership

Janine A. Clayton, M.D., FARVO, Chairperson

Associate Director for Research on Women's Health
Director, Office of Research on Women's Health National Institutes of Health

Samia Noursi, Ph.D., Executive Secretary
Associate Director for Science Policy, Planning, and Analysis
Office of Research on Women's Health
National Institutes of Health
Garnet L. Anderson, Ph.D.
Senior Vice President
Director, Public Health Sciences Division
Fred Hutch 40th Anniversary Endowed Chair
Fred Hutchinson Cancer Center
Irene O. Aninye, Ph.D.
Chief Science Officer
Society for Women's Health Research
Wendy R. Brewster, M.D., Ph.D.
Professor, Division of Gynecologic Oncology
Department of Obstetrics and Gynecology University of North Carolina School of Medicine

Amanda BruegI, M.D.
Assistant Professor of Obstetrics and Gynecology, School of Medicine
Oregon Health \& Science University
Roger B. Fillingim, Ph.D.
Distinguished Professor, College of Dentistry
Director, Pain Research and Intervention Center of Excellence (PRICE)
University of Florida
Stacie E. Geller, Ph.D.
G. William Arends Professor of Obstetrics \& Gynecology
Professor of Medicine, Division of Academic Internal Medicine
Director, Center for Research on Women and Gender
University of Illinois College of Medicine

Stephen T. Higgins, Ph.D.
Director, Vermont Center on Behavior and Health
Director, Behavioral Pharmacology of Drug
Dependence Training Program
Vice Chair and Professor, Department of Psychiatry
The University of Vermont

## Scott J. Hultgren, Ph.D.

Helen L. Stoever Professor of Molecular Microbiology
Director, Center for Women's Infectious Disease Research
Washington University School of Medicine in St. Louis

Reshma Jagsi M.D., D.Phil.
Chair, Department of Radiation Oncology
Winship Cancer Institute
Emory University
Hendrée Jones, Ph.D.
Executive Director, Horizons Program
Professor, Department of Obstetrics and Gynecology
University of North Carolina at Chapel Hill
Sabra L. Klein, Ph.D.
Professor, Department of Molecular Microbiology and Immunology
Professor, Department of Biochemistry and Molecular Biology
Johns Hopkins Bloomberg School of Public Health
Ana Langer, M.D.
Director, Maternal Health Task Force
Women and Health Initiative
Department of Global Health and Population
Harvard T.H. Chan School of Public Health
Margaret M. McCarthy, Ph.D.
Professor and Chair, Department of Pharmacology University of Maryland School of Medicine

Louise D. McCullough, M.D., Ph.D.
Professor and Chair, Department of Neurology
Chief of Neurology, Memorial Hermann-Texas Medical Center
McGovern Medical School
University of Texas Health Science Center at Houston

## Alyson J. McGregor, M.D.

Associate Dean of Faculty Affairs and Development
University of South Carolina School of Medicine Greenville

Amy S. Paller, M.D.
Professor and Chair, Department of Dermatology
Feinberg School of Medicine
Northwestern University
Judith G. Regensteiner, Ph.D.
Judith and Joseph Wagner Chair in Women's Health Research
Distinguished Professor, Divisions of Internal Medicine and Cardiology
Director, Ludeman Family Center for Women's Health Research
University of Colorado Anschutz Medical Campus
Elena V. Rios, M.D., M.S.P.H.
President \& CEO
National Hispanic Medical Association
Michelle Robinson, D.M.D.
Interim Dean
University of Alabama School of Dentistry
Yoel Sadovsky, M.D.
Executive Director, Magee-Womens Research Institute \& Foundation
Elsie Hilliard Hillman Chair of Women's Health Research
Distinguished Professor of OB-GYN and Microbiology and Molecular Genetics
Associate Dean for Women's Health Research and Reproductive Sciences
University of Pittsburgh School of Medicine

Neel Shah, M.D., M.P.P.
Assistant Professor of Obstetrics, Gynecology, and Reproductive Biology
Harvard Medical School
Director, Delivery Decisions Initiative
Ariadne Labs
Phyllis Sharps, Ph.D., M.S.N., RN
Professor Emerita
Associate Dean for Community Programs and Initiatives
Elsie M. Lawler Chair
Johns Hopkins School of Nursing
Melissa A. Simon, M.D., M.P.H.
Vice Chair for Research, Department of Obstetrics and Gynecology
Director, Center for Health Equity Transformation
George H. Gardner, M.D., Professor of Clinical Gynecology
Professor of Obstetrics and Gynecology (General Obstetrics and Gynecology)/Preventive Medicine and Medical Social Sciences
Feinberg School of Medicine
Northwestern University
Kimberly J. Templeton, M.D.
Professor and Vice Chair, Department of Orthopedic Surgery and Sports Medicine
Director, Orthopedic Surgery Residency Program
Associate Dean for Continuing Medical Education
University of Kansas Medical Center
Past-President, American Medical Women's Association

Susan F. Wood, Ph.D.
Research Professor, Department of Health Policy and Management
Research Professor, Department of Environmental and Occupational Health
Director, Jacobs Institute of Women's Health
Milken Institute School of Public Health
George Washington University


## Introduction: Research Mission

The National Institutes of Health (NIH) Office of Research on Women's Health (ORWH) is dedicated to putting science to work for the health of women. Having completed 32 years of service, ORWH affirms its commitment to advancing research on the health of women within and beyond the NIH scientific community and regularly reevaluates how to effectively fulfill its mission. To that end, ORWH has adopted a whole-health paradigm to encompass the many factors that affect a woman's health, which frequently do so in tandem and with cumulative impact across the life course. This means that each stage of a woman's life, from infancy to menopause and beyond, is affected by the stages that precede it. It also acknowledges that in addition to being affected by sex and gender, health is situated within external and societal contexts, including structural elements that can affect a woman's access to and receipt of high-quality health care, such as race and ethnicity.

Employing a whole-health paradigm also conveys the vital need to integrate information and approaches across relevant scientific disciplines; to incorporate research that explores what constitutes
healthy lifestyles and behaviors, research that explores resilience factors and risk reduction, and research that examines disease prevention and the maintenance of wellness; and to generate data-driven paths to diagnosis and treatment, especially of chronic conditions, that are centered on the needs of women. Such an endeavor calls for a comprehensive approach to women's health research and identification of gaps in knowledge and compelling current research needs, along with innovative ways to assess and act on input and information gathered in the process.

The NIH Revitalization Act (Public Law 103-143) was signed into law on June 10, 1993, formally establishing ORWH along with the Advisory Committee on Research on Women's Health (ACRWH) and the Coordinating Committee on Research on Women's Health (CCRWH) to catalyze the advancement of the then nascent field of women's health research. ACRWH, composed of external experts, provides critical perspectives to NIH on the full range of diseases that affect the health of women of all ages, as well as the influences of sex and gender on
disease presentation, treatment, and study, with attention to women's health conditions requiring interdisciplinary approaches. CCRWH—which comprises the directors of the NIH institutes, centers, and offices (ICOs) or their senior-level designees-has been an effective tool for building connections and bridging gaps in women's health research across NIH, promoting research, and disseminating women's health research initiatives. As ORWH expands its definition of women's health, it is building upon its rich history, partnerships, and scientific advances to bring critical topics to the forefront, forge innovative paths to collaboration, and create novel opportunities for "synergistic science" to accelerate improvement of the whole health of women. More recently, the $21^{\text {st }}$ Century Cures Act (Public Law 114-255) has encouraged female-focused research initiatives and annual consultation between NIH institute and center (IC) leadership and ORWH leadership to coordinate the ICOs' pursuits relevant to the health of women. The act requires the incorporation of women's health priorities into ICs' strategic plans. It also requires that applicable Phase III clinical trials report results of valid analyses by sex and/or gender and by race and ethnicity in ClinicalTrials.gov and has led to NIH expanding its inclusion policies to incorporate individuals of all ages in applications and solicitations submitted on or after January 25, 2019. Implementation of the $21^{\text {st }}$ Century Cures Act's requirements represents an important milestone in women's health, ensuring that women, people of all ages, and people of all racial and ethnic backgrounds are appropriately represented in clinical research and that the results of this research are available to the public and health care providers.

## Driving the NIH Women's Health Research Agenda

A whole-health paradigm lends itself to a conceptualization of women's health that encompasses the importance of biopsychosocial integration, consideration of each life stage (such as the menopausal transition), and expanding the understanding of how sex- and gender-related factors influence patterns of health and disease. As we learn more about chronic debilitating conditions, the interaction of multimorbidity, and the influence
of hormones on health and disease, ORWH is devoted to supporting more science that ultimately paves the way for more effective clinical treatments for women.

ORWH fulfills this commitment by partnering with ICOs to fund research that will address gaps or topics specific to women's health. Successful ORWH research initiatives include:
" The Specialized Centers of Research Excellence on Sex Differences (SCORE) program
" The Building Interdisciplinary Research Careers in Women's Health (BIRCWH) program
" The U3 Administrative Supplement Program, which supports interdisciplinary research on populations of women that are understudied, underrepresented, and underreported (U3) in biomedical research
» The R01 funding opportunity to explore how sex and gender influence health and disease
» The newest ORWH program-the Galvanizing Health Equity Through Novel and Diverse Educational Resources research education program (GENDER R25), which supports the development of sex- and gender-focused courses, curricula, and methods

ORWH has increased outreach avenues to educate the public and scientific communities on new research findings that are critical to women's health and care. In addition to creating research initiatives in collaboration with ICOs, ORWH develops and disseminates a wide variety of resources highlighting specific topics in women's health. Also, ORWH promotes inclusion in clinical trials to deepen our understanding of sex and gender influences in disease and care and promotes the advancement of women in populations that remain underrepresented in most scientific disciplines and at multiple career stages in biomedicine, especially at leadership levels. ORWH is proud to be at the forefront of putting research evidence into practice for women and looks forward to forging ahead with new partnerships and pathways to galvanize progress for a future in which every woman receives evidence-based prevention, diagnostics,
and treatment based on her own circumstances, goals, and needs. Imagine that world!

# Increasing Consideration of Sex as a Biological Variable in Preclinical Research 

Women now account for roughly half of participants in NIH-supported clinical research, which is subject to the NIH Policy on Inclusion of Women and Minorities as Subjects in Clinical Research.
Preclinical research studies, however, have traditionally relied heavily on male animals and/or omitted the sex of animal subjects in their reporting; this has been particularly problematic because preclinical studies are intended to increase our understanding of diseases and conditions affecting people of all sexes and genders.

In 2014, NIH leadership and the ORWH Director stated an intention to develop and implement policies requiring applicants to consider sex as a biological variable in the design and analysis of NIH-funded research involving animals and cells. ${ }^{1}$ Subsequently, in 2015, the NIH Office of Extramural Research released two notices in the NIH Guide for Grants and Contracts clarifying NIH's expectations regarding rigor and transparency (NOT-OD-15-103) and consideration of sex as a biological variable (NOT-OD-15-102). These notices announced updates to application instructions and review criteria. The latter notice, known as the NIH Policy on Sex as a Biological Variable (SABV), 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.

The SABV policy complements and extends NIH's long-standing requirement, established in the NIH Revitalization Act of 1993, to appropriately include women and underrepresented racial and ethnic groups in clinical studies and is responsive to the $21^{\text {st }}$ Century Cures Act. Section 2039 of that act, on "enhancing the rigor and reproducibility of scientific research," requires the development of recommendations for applications requesting NIH funding support about including, among
other items, the analysis of SABV in preclinical experimental design.

With this mandate, ORWH and the NIH-Wide SABV Working Group, under the leadership of ORWH Director Janine A. Clayton, M.D., FARVO, have diligently pursued a three-pronged approach to integrating SABV in an end-to-end manner, from basic and preclinical investigations to translational and clinical research to improved health care delivery throughout the biomedical research enterprise. First, ORWH has provided educational and training resources for the NIH intramural community and the larger extramural biomedical community. Sex as a Biological Variable: A Primer, which includes the SABV Primer Supplement video series, and SABV Primer: Train the Trainer, which includes the SABV Primer Instructor Guide, are among ORWH's e-learning courses on the rationale for considering SABV and how to craft applications that incorporate sex and gender into designs and analyses. The NIH Sex and Gender in Health and Disease scientific interest group hosts webinars that allow for topical dialogue on sex and gender and intersectionality to expand the understanding of intramural and extramural scientists about the range of ways that SABV applies across scientific disciplines.

ORWH-led funding opportunities are leading to disease-agnostic investigations into the influences that sex and gender have on human healthwith support from NIH institutes and centers and other NIH offices-e.g., studies resulting from the Specialized Centers of Research Excellence on Sex Differences, administrative supplements for research on sex and/or gender influences, and The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional). ORWH, in conjunction with the NIH-Wide SABV Working Group, is undertaking an assessment of the uptake of the SABV policy among NIH applicants and awardees-and in peer review, extramural programming, and NIH business practices-to develop data-driven enhancements to the policy for the biomedical community. The publication "Sex as a Biological Variable: A 5-Year Progress Report and Call to Action" highlights progress made but calls for more work to be done by the scientific publishing industry to set higher expectations for the consideration of
sex and gender when conducting and reporting biomedical research. ORWH continues to work on implementation, dissemination, education, and training-now with a focus on the application of SABV to the science-to build a more complete
knowledge base and provide a system-based understanding of the influences of sex and gender on health and disease that will inform sex- and gender-informed diagnosis and treatment.

# ORWH Programs to Advance Women's Health Research \& Understand the Influence of Sex \& Gender on Health \& Disease 


#### Abstract

Specialized Centers of Research Excellence on Sex Differences The Specialized Centers of Research Excellence on Sex Differences (SCORE) program is a signature program of ORWH. It supports diseaseagnostic research on sex differences, with a special focus on interdisciplinary and translational projects, supported by a cooperative agreement (U54 grant mechanism). The program began in 2002 as a P50 initiative. These centers have conducted cuttingedge basic, clinical, and translational research that has made seminal contributions to our knowledge about sex differences related to women's health. They also serve as vital hubs for research on sex and gender that also provide pilot funding, training, and education. These contributions can assist in understanding the diversity of health outcomes, and this knowledge can be applied to the development of the next generation of interventions and medical treatments leading to improvements in women's health. ORWH advances sex differences research across the centers and coordinates cross-SCORE interactions by working in partnership with ICOs to implement and fund this program.


The current U54 SCORE program supports 33 unique research projects at 11 centers across the U.S. and is co-funded by five NIH institutes (the National Institute on Aging [NIA]), the National Institute on Alcohol Abuse and Alcoholism [NIAAA], the National Institute on Drug Abuse [NIDA], the

National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK], and the National Institute of Mental Health [NIMH]), with a total investment of $\$ 18$ million per year for 5 years. In FY 2022, ORWH and eight NIH institutes reissued the funding opportunity announcement (RFA-OD-22-014), with participation from eight NIH institutes (the National Heart, Lung, and Blood Institute; NIA; NIAAA; the National Institute of Arthritis and Musculoskeletal and Skin Diseases; NIDA; NIDDK; the National Institute of Environmental Health Sciences; and NIMH). It expires August 16, 2024.

## Sex and Gender (SAGE) Administrative Supplement Program for Research on Sex and/or Gender Influences

In 2013, ORWH initiated an NIH-wide program to catalyze exploratory research on the influences of sex and/or gender (SAGE) and provided administrative supplements to ongoing peerreviewed grants. This initiative advanced research on the influences of sex and/or gender that predated the NIH Policy on Sex as a Biological Variable, which was published in June 2015.

Consideration of sex- and/or gender-related variables and comparisons of males and females can be critical to the accurate interpretation, validation, and generalization of research findings.


These influences may also determine how health and disease processes differ among women or between women and men and may inform the development and testing of sex- and genderaware preventive and therapeutic interventions. The funded supplemental projects span a wide array of scientific disciplines and perform basic, preclinical, clinical, translational, implementation, and behavioral research.

In FY 2021, 12 administrative supplement applications were supported, for a total cost of \$2,580,670 (54.5\% success rate). In FY 2022, 15 applications were supported, for a total cost of $\$ 3,002,631$ ( $48.39 \%$ success rate). Since the program's inception, ORWH has invested about $\$ 16.34$ million providing supplemental funds to peer-reviewed NIH grantees from 18 ICOs, with an overall success rate of $56.58 \%$.

Research on the Health of Women in Understudied, Underrepresented, and Underreported (U3) Populations
ORWH has supported the U3 Administrative Supplement Program since 2017. The U3 framework was developed by ORWH to draw attention to the intersectional experiences of women, exploring the ways in which socially determined categories overlap and interact to create differences in health outcomes. The program supports interdisciplinary research to improve understanding of the etiologies of health and health care inequities, improve understanding of the mechanisms by which social determinants of health contribute to them, and identify effective community-engaged and multilevel interventions to reduce disparities.

Proposed research is expected to be responsive to goal 1, 2, or 3 of the 2019-2023 Trans-NIH Strategic Plan for Women's Health Research.

From 2017 to the end of FY 2022, 71 U3 awards were made, and the total investment was $\$ 13.33$ million. Four U3 investigators were featured in ORWH's "Diverse Voices: Intersectionality and the Health of Women" virtual lecture series in FY 2022.

> ORWH Program to Advance Research on the Health of Women and Understand the Influence of Sex and Gender on Health and Disease

The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) is an ORWH funding opportunity supporting research to understand the role of sex and gender in
disease manifestation, progression, treatment, and outcomes. Applications submitted in response to the funding opportunity are required to address sexand gender-related factors and their intersection. Additionally, proposals must be relevant to one of the five objectives from goal 1 of the 2019-2023 Trans-NIH Strategic Plan for Women's Health Research. Awards made under the first funding opportunity were administered by 11 scientific partnering ICs using funds made available through ORWH. The Sexual \& Gender Minority Research Office (SGMRO) may co-fund applications assigned to those Institutes/Centers. The program has an overall success rate (applicants receiving awards) of $18.57 \%$. New and early-stage investigators (NIs/ ESIs) have a $34.6 \%$ success rate, which surpasses the overall NIH success rate for $\mathrm{NIs} / \mathrm{ESIs}$ of $18 \%$. The funding opportunity was reissued in 2022, with 10 ICs and SGMRO as co-sponsors. Three receipt dates are scheduled between FY 2022 and FY 2024.

# ORWH Co-funding With the ICs in Targeted Research Activities 

## COVID-19

According to the World Health Organization (WHO), on December 31, 2019, China reported a cluster of cases of viral pneumonia in the city of Wuhan, which is the capital of the central Hubei province. Soon afterward, similar cases were reported in other nations, and the spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) was declared a pandemic on March 11, 2020.

Sex and gender affect COVID-19 outcomes, ${ }^{2}$ and the NIH Policy on Sex as a Biological Variable (SABV) can guide the process of how to appropriately evaluate risk, disease progression, and outcomes for COVID-19 patients in a way that will inform development of further treatments and vaccines. Researchers identified sex differences in susceptibility and outcomes to prior pathogenic human coronaviruses, including the severe acute respiratory syndrome coronavirus (SARS-CoV)
responsible for the SARS epidemic in 2002 and 2003. ${ }^{3}$ Similar observations have been made with COVID-19, with generally worse outcomes in men than in women. ${ }^{4}$

The causes of sex differences in disease severity and mortality are complex and include differences in host cell vulnerability; interactions with steroid hormones; incidence of comorbidities (with men disproportionately affected by cardiovascular disease, hypertension, and diabetes); immunity; ${ }^{5}$ disorders of the brain and heart; ${ }^{6}$ sex hormones; ${ }^{7}$ and other factors. ${ }^{8}$ Sex differences are also apparent in adaptive immune responses and can inform further vaccine development. ${ }^{9}$ Additionally, gender differences have been observed in vaccine hesitancy in the U.S. ${ }^{10}$ These findings make clear that incorporating sex and gender into research on COVID-19 is essential to understanding the disease and developing effective interventions. ${ }^{11}$

The COVID-19 pandemic has had a profound impact on communities of color. The cumulative data show that the pandemic has disproportionately affected marginalized communities, with Black, Hispanic, American Indian/Alaska Native, and Native Hawaiian/other Pacific Islander populations experiencing the highest rates of SARS-CoV-2related infection, hospitalization, and mortality. ${ }^{12}$

The COVID-19 pandemic has caused upheavals in nearly all aspects of life, and it has taken a toll on biomedical research, as well. These disruptions have emphasized the importance of ORWH's mission, of NIH's policies on SABV and inclusion, and of equitable representation in STEMM fields and health policy management. ORWH has served its mission with several critical efforts, including:

1. Participating in NIH-wide initiatives, committees, and working groups to provide scientific expertise relevant to women's health.
a. Created a strategic approach to COVID-19 response by emphasizing short- and longterm strategies to successfully navigate the COVID-19 public health emergency.
b. Launched the Women, Science, and the Impact of COVID-19 webpage, disseminating useful resources and information.
c. Developed the COVID-19 and Maternal Health webpage, as pregnant women are at higher risk of COVID-19 because of physical, psychological, and immunological alterations.
d. Collaborated with the NIH Office of Extramural Research in efforts to mitigate the adverse effects of the pandemic on the career trajectories of the workforce, particularly those in their early careers.
e. Helped to identify common data elements for the full spectrum of post-acute sequelae of COVID-19 (PASC), aka long COVID, in pregnant individuals and lactating individuals; pregnancy and postpartum function; infant care practices; childcare and education; attribution of symptoms; intimate partner violence; access to care; COVID-19 vaccination history; vaccine attitudes; and family planning.
f. Continuing efforts by the NIH can be found at: Coronavirus Disease 2019 (COVID-19): Information for NIH Applicants and Recipients of NIH Funding.
2. Presenting and obtaining approval for a new funding opportunity concept, "COVID-19 and the Health of Women," during the April 2021 ACRWH meeting.
3. Performing activities under the umbrella of the CCRWH COVID-19 Working Group. The charge of the working group is to identify and address gaps related to sex and gender differences and women's health in NIH-funded research. For example, the working group has performed a portfolio analysis of the research funded by NIH from the start of the pandemic in March 2020 through June 2022.
a. The working group issued Request for Information (RFI): Inviting comments to inform the National Institutes of Health (NIH) on the intersection of the SARS-CoV-2/COVID-19 pandemic and the health of women (NOT-OD-22-092). The RFI data showed that $13 \%$ of the responses were related to long COVID/PASC.
4. Providing co-funding to many initiatives and grant applications, including:
a. The National Academies of Sciences, Engineering, and Medicine's project "Policies and Practices for Supporting Family Caregivers Working in Science. Engineering, and Medicine."
b. Notice of Special Interest (NOSI): Administrative Supplements and Urgent Competitive Revisions for NIH Grants to Add or Expand Research Focused on Maternal Health, Structural Racism and Discrimination, and COVID-19 (NOT-OD-21-071). ORWH co-funded four applications focused on this question in the NOSI: "What is the effect of post-acute sequelae of COVID-19 (PASC) on the health, well-being, functioning and quality of life for pregnant and postpartum persons?"
c. Notice of Special Interest (NOSI): Administrative Supplements for Research on Sex and/or Gender Influences (Admin Supp Clinical Trial Optional) (NOT-OD-22-030). ORWH funded two applications related to COVID-19.
d. U3 Populations (Admin Supp Clinical Trial Optional) (NOT-OD-22-031 and NOT-OD-20-048). ORWH supported a total of five applications related to COVID-19, including two applications to study long COVID.
e. The Women's Health Awareness program of the National Institute of Environmental Health Sciences. Since 2015, more than 3,000 women in U3 populations have participated in this intervention and provided a wealth of data. ORWH co-funding in this initiative will allow the current and future analyses of associations among environmental factors, social factors, and long-term health outcomes related to the exposure to and impacts of SARS-CoV-2 and COVID-19.
5. Conducting outreach to the community:
a. Published articles in peer-reviewed journals on pregnancy and SARS-CoV-2/COVID-19. ${ }^{13}$
b. Initiated a webinar series, "Diverse Voices: Intersectionality and the Health of Women," to disseminate key findings relevant to a multidimensional sex-and-gender focus.
c. Invited experts to discuss long COVID during CCRWH meetings' Science Spotlight speaker sessions:
i. "Long Covid, Neuroscience Advances, and Women's Health"-Dr. Walter J. Koroshetz, Director, National Institute of Neurological Disorders and Stroke
ii. "An Overview of PASC Activities"Dr. Michelle Olive; Deputy Chief, Atherothrombosis and Coronary Artery Disease Branch; National Heart, Lung, and Blood Institute
6. Making staff members available for interviews with news agencies. For example:

- ORWH Director Janine A. Clayton, M.D., FARVO, was interviewed for an online article by ABC News' Good Morning America ("COVID-19 puts spotlight on disparities in research on women's health").
- ORWH Associate Director for Basic and Translational Research Chyren Hunter, Ph.D., was interviewed by Stat ("Men and women may respond differently to vaccines. Research needs to account for that").
- ORWH Associate Director for Careers Xenia Tigno, Ph.D., was interviewed by Pharmacy Times ("The Impact of the Pandemic on the Careers of Women Researchers in Biomedicine").

7. Writing blog entries and posting on social media. ORWH has posted COVID-19-related content on various social media platforms, including Facebook (total of 13) and Twitter (total of 45).

## ORWH-Supported Pain Research

 ActivitiesDuring FYs 2021 and 2022, ORWH engaged in several important NIH pain research initiatives. ORWH is a member of and continues to support the NIH Pain Consortium. This is a collaboration of 25 ICOs that create, coordinate, and support pain research initiatives and activities. The consortium funds the Centers of Excellence in Pain Education. Each center acts as a hub for the development, evaluation, and distribution of resources for pain management curricula for medical, dental, nursing, pharmacy, and other types of schools.

The National Center for Complementary and Integrative Health (NCCIH) leads an interagency partnership, known as the NIH-DOD-VA Pain Management Collaboratory, which was funded in the fall of 2017. It includes ORWH, the National Institute of Neurological Disorders and Stroke, the National Institute on Alcohol Abuse and Alcoholism, the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), the National Institute on Drug Abuse, the National Institute of Nursing Research, the U.S. Department of Defense, and the U.S. Department
of Veterans Affairs. This initiative prioritizes realworld research on nonpharmacological approaches to pain management and related conditions by organizations that deliver health care to service members and veterans. Almost two-thirds of veterans say they are in pain, and nearly $10 \%$ say the pain is severe.

ORWH joined several NIH funding opportunity announcements related to the Helping to End Addiction Long-term (HEAL) Initiative to support research on chronic pain, from basic research on the molecular, genetic, and biobehavioral basis of chronic pain to large-scale clinical studies of treatments. In FY 2021-2022, ORWH contributed $\$ 850,000$ to support the HEALthy Brain and Child Development Study, which is establishing a large cohort of pregnant women from regions of the country significantly affected by the opioid crisis, with plans to study them and their children for at least 10 years. Additionally in FY 2021-2022, ORWH contributed \$100,000 to support the Adolescent Brain Cognitive Development (ABCD) Study, a longitudinal NIH-supported study of 10,000 children conducted at 21 sites across the U.S. This study aims to increase understanding of environmental, social, and biological factors (such as genetic factors) that affect the brain and cognitive development. Finally, also as part of the HEAL Initiative, ORWH participated in the National Institute of Diabetes and Digestive and Kidney Diseases-led Hemodialysis Opioid Prescription Effort (HOPE) consortium to reduce hemodialysis pain without an overreliance on opioids. ORWH continued to serve on the Data and Safety Monitoring Board and offer guidance on the development of clinical research protocols used in this trial.

Additionally, ORWH staff members David Thomas, Ph.D., and Jamie White, M.S., co-authored a paper (with Hannah Bruckheim of the National Heart, Lung, and Blood Institute) in the Journal of Women's Health titled "The Need to Consider Pregnancy As a Biological Variable to Reduce Preventable Suffering Related to Pregnancy." This paper discussed the need to consider sex as a biological variable in pain research, furthered the argument that pain differs during pregnancy, and underscored the need to study pain and other
conditions during pregnancy. Dr. Thomas-along with Richard L. Nahin, Ph.D., of NCCIH—published another paper in 2022 in the Journal of Women's Health, which demonstrated that pain is reduced during pregnancy in White and Hispanic people but not Black people.

## Maternal Morbidity and Mortality

In alignment with the White House Blueprint for Addressing the Maternal Health Crisis (released by the Biden administration on June 24, 2022), ORWH—along with the other ICOs-strengthened its focus on maternal health research, continuing the emphasis on severe maternal morbidity and maternal mortality (SMM/MM), associated health disparities, and methods to improve health outcomes for those from understudied, underrepresented, and underreported populations through administrative supplements, initiatives, research challenges, and programs.

In 2021, ORWH initiated an unbiased, evidencebased process called the Pathways to Prevention (P2P) program to understand the current state of the science; identify research gaps in maternal and postpartum health care that result in poor health, disease, and death; and suggest an action plan. The P2P program, led by the NIH Office of Disease Prevention, includes experts from the sponsoring ICOs: ORWH; the National Heart, Lung, and Blood Institute; the National Institute on Minority Health and Health Disparities; and NICHD.

The NIH-wide Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) initiative-supported by more than two dozen ICOs since its inception in 2019 and led by NICHD, ORWH, and the NIH Office of the Director-continued to build its foundation for future work. More than $\$ 13$ million was awarded in FY 2021 to support 22 projects in response to NOT-OD-21-071, focused on the interplay among the COVID-19 pandemic, structural racism and discrimination, and maternal health outcomes. Most notably, in FY 2022, two challenges, the Decoding Maternal Morbidity Data Challenge and the NIH Technology Accelerator Challenge for Maternal Health, awarded cash prizes for innovative methods for identifying complication

risks in first-time pregnancies and innovative diagnostic technologies to help improve maternal health by diagnosing conditions related to maternal morbidity and mortality, respectively. The strategy for FY 2022 focused on the areas of community engagement, through NOT-HL-22-054; implementation and dissemination research, through NOT-HD-22-043; foundational work to enable use of electronic health records and surveillance systems, through the Rapid Acceleration of Diagnostics Technology (RADx Tech) for Maternal Health Challenge and NOT-EB-21-001; and continued support for principal investigator-initiated work to build the base of fundamental knowledge to reduce

SMM/MM. Collaboration between ORWH and the National Institute of General Medical Sciences (NIGMS) supported the study of maternal and infant morbidity and mortality in the Institutional Development Award (IDeA) program, through NOT-GM-21-018 and NOT-GM-22-005. The IDeA women's health program supports research in States with historically low levels of NIH funding; many of these predominately rural States have higher levels of maternal and infant mortality than the U.S. as a whole. In FY 2021, this NIGMS-ORWH IDeA program support provided a combined $\$ 4.3$ million to 15 applications, with a goal of fostering collaborations among researchers working in different disciplines in the biological, medical, social, and behavioral sciences. Housed on the ORWH website, the NIH Maternal Morbidity \& Mortality Web Portal highlights the NIH-wide funding for maternal health research and other efforts from the ICOs and HHS.

## Research Dissemination and Engagement

## ORWH Publications

Through its publications, ORWH consistently provides in-depth insights and timely updates to internal and external stakeholders, researchers, clinicians, and the public. ORWH publications include:

## Women's Health in Focus at NIH

Written with input from biomedical professionals across and outside of NIH, this quarterly periodical shares salient information through feature stories, journal article summaries, profiles of prominent women in science, resources on the health of women, ORWH funding opportunities, and more. Recent feature stories have discussed research on menopause, transgender women's health, chronic debilitating conditions in women, maternal morbidity and mortality (MMM). At FY 2022's close, FY 2021-2022 In Focus issues had garnered 31,671 unique views.

## The Pulse

This brief monthly e-newsletter offers news on women's health and health research, relevant updates from other Federal agencies, grant opportunities, and upcoming ORWH events, and it often includes an ORWH Director's message. By the end of FY 2022, there were 55,965 subscribers to The Pulse, an increase of $128 \%$ compared with the beginning of the fiscal year.

## Funding Fridays

In May 2022, ORWH sent its first biweekly email on funding opportunity announcements relevant to women's health research to 19,179 subscribers. At the end of FY 2022, subscribers totaled 24,046, an increase of $25 \%$.

## Effective Approaches to Fostering Faculty Gender Diversity, Equity, and Inclusion: Celebrating Progress

This executive summary was published in June 2022 and captures insights shared at the ORWH virtual forum honoring the winners and honorable mentions of the NIH Prize for Enhancing Faculty Gender Diversity in Biomedical and Behavioral Science. ORWH held the forum in partnership with the American Association for the Advancement of Science's STEMM Equity Achievement (SEA) Change initiative and in collaboration with the National Academies of Sciences, Engineering, and Medicine. By the end of FY 2022, the webpage housing the summary had been viewed 527 times.

## Guiding Principles: Sex and gender influences in COVID-19 and the health of women

Complementing the NIH-Wide Strategic Plan for COVID-19 Research, the principles promote rigorous research, advance health equity, and enhance the Nation's response to the COVID-19 pandemic by laying out a systematic approach to incorporating sex and gender into research to improve the health of women. By the end of FY 2022, the webpage housing the document had been viewed 1,406 times.

## Maternal Morbidity and Mortality: What Do We Know? How Are We Addressing It?

This one-page fact sheet provides an overview of MMM, definitions of commonly used terms, statistics, and factors influencing MMM, as well as NIH investment and work to address maternal health. At the end of FY 2022, the webpage housing the document had been viewed 2,491 times.

## Perspectives on Advancing NIH Research to Inform and Improve the Health of Women

A product of the 2021 conference held at Congress's request, the full report and executive summary provide background on the public
health needs related to MMM, chronic debilitating conditions in women, and cervical cancer; current NIH activities in women's health research; women's health research gaps; and women's health research opportunities at NIH. The report was published in August 2022, and at the end of FY 2022, the webpage housing it had been viewed 5,654 times.

## The ORWH Website—Putting Science to Work for the Health of Women

In FYs 2021 and 2022, ORWH developed and published several additions to its website, including a page called Women, Science, and the Impact of COVID-19 and pages for the NIH Prize for Enhancing Faculty Gender Diversity in Biomedical and Behavioral Science, "Advancing NIH Research on the Health of Women: A 2021 Conference," and the U3 Administrative Supplement Program. ORWH continually updated the website with information about events, media coverage, monthly and quarterly publications, journal articles authored by staff members, Director's messages, opportunities for career development and interprofessional education, news about ORWH and NIH as a whole, and other resources. Additionally, ORWH regularly published In the Spotlight articles on its website, highlighting key efforts to improve the health of women and advance the careers of women in the biomedical fields. In FYs 2021 and 2022, the ORWH website had nearly 54,000 unique visitors.

## E-Learning Programs

During FY 2021-2022, 1,191 learners registered for e-learning on the ORWH course dashboard, which includes Bench to Bedside, the primer on sex as a biological variable (SABV), and Introduction: Sexand Gender-Related Differences in Health

## Bench to Bedside

Bench to Bedside: Integrating Sex and Gender to Improve Human Health was developed by ORWH in partnership with the Food and Drug Administration Office of Women's Health. This course explores sex- and gender-related differences in six disease areas: immunology, cardiovascular disease, pulmonary disease,
neurology, endocrinology, and mental health. The course provides biomedical researchers, clinicians, and students in the health professions with knowledge they can apply when designing and conducting research and/or interpreting evidence for clinical practice. In FY 2021-2022, 563 learners completed a module of Bench to Bedside. Through the joint providership of the Johns Hopkins University School of Medicine and NIH, the Accreditation Council for Continuing Medical Education has designated Bench to Bedside: Integrating Sex and Gender to Improve Human Health for a maximum of six American Medical Association Physician's Recognition Award (AMA PRA) Category 1 Credits.

## SABV Primer

Available to the public since 2019, Sex as a Biological Variable: A Primer is a four-module e-learning course developed by ORWH in partnership with the National Institute of General Medical Sciences and the NIH Office of the Director. The four independent modules are "SABV and the Health of Women and Men," "SABV and Experimental Design," "SABV and Analyses," and "SABV and Research Reporting." The course helps investigators and applicants for NIH funding understand the rationale for including SABV in research and apply the NIH Policy on Sex as a Biological Variable in the design, analyses, and reporting of research studies in basic, preclinical, clinical, and population health studies. The SABV Primer Instructor Guide is a companion to the e-learning course. It is a resource for guided discussions of course content to enhance learning and appreciation of key concepts underlying the SABV policy and the application of SABV in science. The SABV Primer Supplement is a video series, narrated by world-class investigators from different scientific disciplines, on SABV and scientific investigation. In FY 2022, 733 learners accessed the SABV primer, with an overall $77 \%$ completion rate for the course.

## Introduction: Sex- and Gender-Related Differences in Health

Introduction: Sex- and Gender-Related Differences in Health is a self-paced introductory training course for researchers, clinicians, and
policymakers. It includes a downloadable slide deck, which can be incorporated into other presentations, and the Facilitator's Guide, which helps individuals and teams initiate dialogue about how-and why-to incorporate a sex-and-gender lens into research and clinical care. In FY 2022, the training was revised and updated to include expanded discussion of sex, gender, and intersectionality.

## Educational Resources

ORWH maintains a curated list of educational resources, with the goal of amplifying trainings of relevance to the health of women. Resources include materials developed by ORWH, NIH-wide resources, materials developed by other agencies in the U.S. Department of Health and Human Services, and non-Federal resources.

## Meetings, Conferences, and Workshops

ORWH-sponsored events provide a forum for educating researchers on the association between women's health and specific research topics. Additionally, ORWH often collaborates with other NIH institutes, centers, and offices on meetings, conferences, and workshops, where scientific experts and other stakeholders in women's health discuss current and emerging clinical and research developments. These efforts help to strengthen research relevant to the health of women, ensure that women are appropriately represented in biomedical and biobehavioral research supported by NIH , and develop opportunities for the professional advancement of women in biomedical careers.

## Nonrecurring Events

To foster awareness, discussion, and discovery in women's health, ORWH hosted, co-hosted, and convened seven nonrecurring events during the reporting period, including:

[^1]" The "Effective Approaches to Fostering Faculty Gender Diversity, Equity, and Inclusion: Celebrating Progress" forum, October 5, 2021, held in partnership with the American Association for the Advancement of Science's STEMM Equity Achievement (SEA) Change initiative and in collaboration with the National Academies of Sciences, Engineering, and Medicine's Committee on Women in Science, Engineering, and Medicine; and
» Other topics explored and promoted by ORWH include diagnostic technologies to improve maternal health, cardiovascular risk and polycystic ovary syndrome, and overcoming barriers to diversifying clinical trials. To see all the events from FY 2021-2022, please visit the ORWH Events webpage.

## Recurring Events

ORWH hosted 20 recurring events during the reporting period, including ACRWH meetings, Vivian W. Pinn Symposia, Building Interdisciplinary Research Careers in Women's Health (BIRCWH) Annual Meetings, Specialized Centers of Research Excellence on Sex Differences (SCORE) Annual Meetings, and webinars related to the health of women in understudied, underrepresented, and underreported (U3) populations.

## ACRWH Meetings

The NIH Revitalization Act of 1993 established ACRWH, a Federal Advisory Committee Act committee, to give advice and make recommendations on priority issues affecting women's health and sex differences research. During FY 2021-2022, ORWH called to order six ACRWH meetings. During these meetings, presentations were provided by several IC Directors on cross-cutting topics and included the following:
" A presentation by the Director of the National Center for Complementary and Integrative Health (NCCIH) on Whole Person Health (Oct 2020);
» A presentation by the Director of the National Institute of Mental Health (NIMH) on COVID-19 and Mental Health (April 2021);
" A presentation by the Director of the National Cancer Institute ( NCI ) on NCl's Role in Promoting Research in Women's Health (October 2021); and
" A presentation by the Director of the National Health Lung and Blood Institute (NHLBI) on Advancing Shared Priorities for Eliminating Health Inequities and Improving Women's Health (April 2022).

## Vivian W. Pinn Symposia

The annual Vivian W. Pinn Symposium is an opportunity for the scientific community to discuss and share research dedicated to promoting the health of women. The symposium is named after and honors the inaugural full-time Director of ORWH, Vivian W. Pinn, M.D., and is hosted every year during National Women's Health Week. The FY 2021 and 2022 events have collectively received more than 1,100 live and videocast views.
" 6th Annual Vivian W. Pinn Symposium: "The Impact of the COVID-19 Pandemic on the Careers of Women Scientists," May 12, 2022
» 5th Annual Vivian W. Pinn Symposium: "Integrating Sex and Gender into Biomedical Research as a Path for Better Science and Innovation," presented by ORWH in collaboration with the Foundation for the NIH, May 11-12, 2021

## BIRCWH Annual Meetings

Created by ORWH, BIRCWH is a mentored careerdevelopment program designed to connect junior faculty, known as BIRCWH Scholars, to senior faculty with shared interest in women's health and sex differences research. The annual meeting gives junior investigators a chance to network with senior investigators and allows BIRCWH Scholars to present their research findings related to the influences of sex and gender on health and disease. Additionally, ORWH selects distinguished leaders from academia to deliver lectures. The keynote lecture for the BIRCWH Annual Meetings, the Ruth L. Kirschstein Memorial Lectureship, was created to honor Dr. Kirschstein's life and achievements at NIH, especially her mentoring skills of young researchers and her commitment to advancing the careers of those in underrepresented populations. The speakers
are asked to recount key aspects of their own career development, as well as scientific and mentoring highlights. Nearly 500 people attended the program's meetings in FYs 2021 and 2022, and the videocasts of the meetings have received over 400 views.
" BIRCWH Annual Meeting, December 13, 2021

- Ruth L. Kirschstein Memorial Lectureship keynote speaker: Molly L. Carnes, M.D., M.S. Lecture title: Bias Is a Habit We Must All Work Hard to Break
" BIRCWH Annual Meeting, December 14, 2020
- Ruth L. Kirschstein Memorial Lectureship keynote speaker: Patricia E. Molina, M.D., Ph.D. Lecture title: Importance Of, and Improvements Made In, Mentoring Young Investigators


## SCORE Annual Meetings

The SCORE program is the only NIH cooperative agreement program supporting disease-agnostic research on sex differences. Each center serves as a national resource for translational research to identify the role of biological sex differences in the health of women. The annual meeting's keynote address is the only portion of the meeting open to the public. In FY 2021-2022, the keynote addresses collectively had 574 viewers.
" SCORE keynote address by Tracy L. Bale. Ph.D., of the University of Maryland School of Medicine: "Extracellular Vesicles as Stress Signals: Identifying Novel Biomarkers in Maternal and Fetal Health," December 14, 2021
" SCORE keynote address by Jocalyn Clark. Ph.D., Executive Editor of The Lancet: "Sex Differences Research and the Health of Women: An Editor's Perspective," December 16, 2020

## Webinars on U3 Women's Health

Through the "Diverse Voices: Intersectionality and the Health of Women" lecture series, ORWH focuses on research on populations of women that are understudied, underrepresented, and underreported (U3) in biomedical research. The series highlights the work of investigators supported through the U3 Administrative Supplement Program and aims
to increase awareness of health disparities and to foster greater interest in this critical research area. In FY 2022, ORWH combined its U3 Women's Health Lecture Series and its "Diverse Voices" lecture series (which previously dealt exclusively with research related to COVID-19) and kept the "Diverse Voices" name. During FYs 2021 and 2022, these webinars were viewed almost 3,000 times.

## U3 Women's Health Lecture Series

" Gender-Based Violence Prevention and Intervention Programs: Dissemination of Tools and Resources to Support Survivors, November 17, 2021
» Targeted Strategies to Address Gender Disparities in Care Utilization for HIV as a Chronic Condition, August 19, 2021

## Diverse Voices: Intersectionality and the Health of Women

" Violence and Women: Trauma and Addiction Impacts on Pregnant/Postpartum Women, September 29, 2022
" COVID-19 and Women, July 28, 2022
" Environmental Exposures and Disparities in Pregnancy, March 31, 2022
» Cancer in Women, January 27, 2022
" Analysis and Action: Applications of Intersectionality in COVID-19, June 24, 2021
" Sex and Gender Disparities in the COVID-19 Pandemic, January 27, 2021

## Advancing NIH Research on the Health of Women: A 2021

 ConferenceIn FY 2021, the House and Senate Appropriations committees requested that NIH convene a conference to evaluate research currently underway related to women's health and identify priority areas for additional women's health research. Three key topics were identified for focused review: (1) rising rates of maternal morbidity and mortality; (2) rising rates of chronic debilitating conditions in women; and (3) stagnant cervical cancer survival rates. The topics
designated by Congress represent significant public health crises in the U.S. Rates of maternal mortality are considerably higher in the U.S. than peer countries and continue rising, and there are profound racial disparities in the rates. ${ }^{14}$ Women in the U.S. are more likely to have a diagnosis of a chronic debilitating condition and multimorbidity than men in the U.S., and rates continue to rise. ${ }^{15}$ And despite the widespread availability of effective screening for cervical cancer and vaccines for human papillomavirus (HPV), which is the main cause of cervical cancer, the disease's mortality rates have remained stable. ${ }^{16}$

ORWH, in response to Congress, obtained input on the three priority areas from experts in women's health; members of the public; representatives from NIH institutes, centers, and offices; and members of the Advisory Committee on Research on Women's Health (ACRWH). A working group formed by ACRWH reviewed and discussed data on current NIH activities, planned the conference, and prepared a report. On October 20, 2021, ORWH and ACRWH co-hosted the convening, titled "Advancing NIH Research on the Health of Women: A 2021 Conference." The activities leading up to this conference and the conference itself revealed that though exciting advances in women's health research have taken place, gaps in research and knowledge related to critical areas of women's health remain.

Opportunities to advance research on women's health identified through conference activities included a need for implementation research specific to the needs of women; research that addresses persistent inequities in care for women from populations that are understudied, underrepresented, and underreported in biomedical research; and research that is intentionally designed to address the health of women. A final report details the recommendations from ACRWH.

## Diverse Voices

In January 2022, ORWH rebranded its "Diverse Voices" virtual lecture series. No longer solely about COVID-19-related research, the quarterly series, now titled "Diverse Voices: Intersectionality and the Health of Women," disseminates research findings that are relevant to diverse groups of women, incorporating a multidimensional focus on sex and gender. "Diverse Voices" serves to increase public awareness of,

understanding of, and engagement with research relevant to intersectionality and highlights work by investigators receiving ORWH funding. Events in FY 2022 attracted approximately 2,000 registrants:
» September 29, 2022: "Violence and Women: Trauma and Addiction Impacts on Pregnant/ Postpartum Women," featuring a presentation from Dr. Natacha De Genna of the University of Pittsburgh School of Medicine
» July 28, 2022: "COVID-19 and Women" featuring a presentation from Dr. Heather ShattuckHeidorn of the University of Southern Maine
» March 31, 2022: "Environmental Exposures and Disparities in Pregnancy," featuring a talk by Dr. Tamarra James-Todd of the Harvard T.H. Chan School of Public Health
" January 27, 2022: "Cancer in Women," featuring a presentation from Dr. Katie O'Brien of the National Institute of Environmental Health Sciences

## ORWH Biomedical Career Development

The mission of ORWH's Careers program is to work collaboratively within ORWH and across ICOs to promote a well-trained, diverse, and robust research workforce that advances science for the health of women. The program is also poised to address the underrepresentation of women in biomedical careers and help fulfill the vision that women in scientific careers reach their full potential. Several ongoing ORWH-led and NIH-wide collaborative activities and programs accelerate the translation of research findings into improved health care for women.
" Building Interdisciplinary Research Careers in Women's Health (BIRCWH). The BIRCWH program was established by ORWH and its ICO partners in 2000. Currently, BIRCWH has 19 sites across the U.S., and it has graduated more than 750 BIRCWH Scholars (junior faculty members matched with several
research mentors) throughout the years. The vast majority of the Scholars have proceeded to achieve productive careers in women's health and sex differences research, have impactful publications, and receive at least one NIH research grant.
» Women's Reproductive Health Research (WRHR) Program. The WRHR Program was established in 1998 by the Eunice Kennedy Shriver National Institute of Child Health and Human Development, with support from ORWH, to provide junior obstetrician-gynecologists (OB-GYNs) with an opportunity to obtain intensive mentored research training in basic, translational, and/or clinical research on women's reproductive health. There are 15 WRHR sites in OB-GYN departments throughout the Nation to provide junior faculty members with state-of-the-art training in women's reproductive health research in an academic setting and to increase the research capacity of OB-GYN departments. More than 235 OB-GYN junior faculty members have been appointed to the WRHR Program since its inception.

Working Group on Women in Biomedical Careers (WgWBC). In collaboration with ICOs, the WgWBC develops innovative strategies and concrete actions to promote the entry, recruitment, retention, and sustained advancement of women in biomedical research careers, both within NIH and throughout the extramural community. The WgWBC developed concepts such as the NIH Prize for Enhancing Faculty Gender Diversity in Biomedical and Behavioral Science, the continuity and retention supplements, and the Advancing Gender Inclusive Excellence (AGIE) Coordinating Center (discussed below). There are four committees of the working group-the Committee on the NIH Intramural Research Program, the Committee on the NIH Extramural Research Program, the Committee on Women of Color in Biomedical Careers, and the Partnerships Committee-each of which is developing programs to address current issues that prevent women scientists from achieving their full potential.
" Re-entry Supplements and Re-integration programs. These programs provide mentored research training experience for scientists and were expanded to allow them re-entry or reintegration into active research careers after interruptions caused by family responsibilities or having been adversely affected by unsafe or discriminatory environments. From FY 2012 to FY 2021, the majority ( $80 \%$ ) of the applicants were women, and the most cited reason for a hiatus was child-rearing.

Notice of Special Interest: Administrative Supplements to Promote Research Continuity and Retention of NIH Mentored Career Development (K) Award Recipients and Scholars and Notice of Special Interest (NOSI): Administrative Supplement for Continuity of Biomedical and Behavioral Research Among First-Time Recipients of NIH Research Project Grant Awards. The administrative supplement programs for $K$ and research project grant awardees aim to retain investigators facing critical life events such as childbirth, adoption, or having primary caregiving responsibilities for an ailing immediate family member as they transition from career development grants to research independence or transition to the first renewal of their first independent research project grant award or to a second research project grant award. In the first two years (FY 2020-2021) of these two NOSIs, the success rate for both programs combined was around $65 \%$, the majority of the awardees were women, the most frequently cited critical life event was childbirth, and funds were used to hire additional personnel to keep the research going.

AGIE Coordinating Center. The funding opportunity announcement (FOA) establishing this U54 cooperative agreement was published in 2021. The goal is to support a coordinating center that will serve as an online central repository for sharing resources, tools, technologies, expertise, and strategies that address challenges in overcoming systemic gender-based inequities affecting the biosciences' academic and research workforce. No award was made during the reporting period, so the FOA was reissued in the fall of 2022, and applications were due in the spring of 2023.
» Women of Color Research Network (WOCRN). The WOCRN was created to provide women of color and supporters of their advancement in the biomedical sciences with information about the NIH grants process, advice on career development, and a forum for networking and sharing information. As of June 7, 2023, the Linkedln page had more than 2,600 members.

## Accelerating Medicines Partnership®

 Autoimmune and Immune-Mediated Diseases (AMP® AIM). The AMP AIM program, managed by the Foundation for the NIH, is a public-private partnership among NIH, the Food and Drug Administration, and multiple nonprofit and industry partners. AMP AIM was launched in 2021 by the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the National Institute of Allergy and Infectious Diseases, the National Institute of Dental and Craniofacial Research, the National Eye Institute, and ORWH to advance the understanding of the cellular and molecular interactions that lead to inflammation and autoimmune diseases and advance the development of new research tools in four primary diseases-rheumatoid arthritis, systemic lupus erythematosus, psoriasis/ psoriatic arthritis, and Sjögren's syndrome. The ORWH-NIAMS Team Science Leadership Scholars Program was recently launched to train research scholars to lead transdisciplinary, cross-sectoral collaborative projects.Notice of Special Interest (NOSI): Interventions Designed to Change the Culture to Mitigate or Eliminate Sexual Harassment in the Biomedical Research Enterprise. This NOSI was published in 2021 to support research on evidence-based, generalizable, and reproducible interventions that will diminish or eliminate sexual harassment, along with its attendant costs and harm to individuals' health and careers, in the biomedical research environment by producing a change in the institutional culture where harassment is tolerated. Two awards were issued in the first year.

Office of Intramural Training \& Education (OITE). ORWH collaborates with OITE to
support trainees working on all NIH campuses. ORWH supports two important diversity programs: (1) the High School Scientific Training and Enrichment Program (HiSTEP and HiSTEP 2.0), which supports students from disadvantaged backgrounds, and (2) the Postbac Enrichment Program (OITEPEP), a program to bring a diverse cadre of postbaccalaureate students to NIH for training before graduate or professional school. ORWH also supports OITE's diversity certificate program, Becoming a Resilient Scientist Series, mentor training, Mental Health \& Well-Being of Biomedical Researchers Series, and leadership programs, some of which are open to trainees and staff members in the intramural and extramural communities. Over $50 \%$ of trainees who attend OITE programs identify as female.

Committee on Women in Science, Engineering and Medicine. This committee of the National Academies of Sciences, Engineering, and Medicine has been contracted to conduct a comprehensive study to explore promising and innovative policies and practices for supporting caregivers working in STEMM. The findings of the report (to be released in 2024) are expected to provide leaders in academia and government with evidence-based strategies that will not only raise awareness of the inequities in this space but also promote culture change resulting in the retention and advancement of STEMM professionals with caregiving responsibilities. Two public symposia will be held in 2023.

Launching Future Leaders in Global Health (LAUNCH) Research Training Program. This Fogarty International Center research training program, supported by ORWH, fosters the next generation of global health scientists by providing a 1 -year mentored research training experience in global health for early-career trainees from the U.S. and low- and middleincome countries.

NIH/National Medical Association (NMA) Travel Award. Led by the National Institute of Diabetes and Digestive and Kidney Diseases, these travel awards are given to senior residents, fellows, and junior faculty members who are

# interested in pursuing careers in academic medicine or biomedical research. ORWH participates in the program, and ORWH Director Janine A. Clayton, M.D., FARVO, addressed the 2021 and 2022 NMA Annual Convention and Scientific Assembly. 

1. Clayton, J. A., \& Collins, F. S. (2014). Policy: NIH to balance sex in cell and animal studies. Nature, 509(7500), 282-283. https://doi. org/10.1038/509282a
2. Alwani, M., Yassin, A., Al-Zoubi, R. M., et al. (2021). Sex-based differences in severity and mortality in COVID-19. Reviews in Medical Virology, 31(6), e2223. https://doi.org/10.1002/rmv. 2223
Gebhard, C., Regitz-Zagrosek, V., Neuhauser, H. K., et al. (202). Impact of sex and gender on COVID-19 outcomes in Europe. Biology of Sex Differences, 11(1):29. https://doi.org/10.1186/s13293-020-00304-9

Spagnolo, P. A., Manson, J. E., \& Joffe, H. (2020). Sex and gender differences in health: What the COVID-19 pandemic can teach us. Annals of Internal Medicine, 73(5), 385-386. https://doi.org/10.7326/M20-1941
3. Channappanavar, R., Fett, C., Mack, M., et al. (2017). Sex-based differences in susceptibility to severe acute respiratory syndrome coronavirus infection. Journal of Immunology, 198(10), 4046-4053. https://doi.org/10.4049/ iimmunol. 1601896
4. Alwani, M., Yassin, A., Al-Zoubi, R. M., et al. (2021). Sex-based differences in severity and mortality in COVID-19. Reviews in Medical Virology, 31(6), e2223. https://doi.org/10.1002/rmv. 2223
Takahashi, T., Ellingson, M. K., Wong, P., et al. (2020). Sex differences in immune responses that underlie COVID-19 disease outcomes. Nature, 588(7837), 315-320. https://doi.org/10.1038/s41586-020-2700-3
5. Scully, E. P., Haverfield, J., Ursin, R. L., et al. (2020). Considering how biological sex impacts immune responses and COVID-19 outcomes. Nature reviews. Immunology, 20(7), 442-447. https://doi.org/10.1038/s41577-020-0348-8
6. Goldstein, J. M., Langer, A., \& Lesser, J. A. (2021). Sex differences in disorders of the brain and heart-a global crisis of multimorbidity and novel opportunity. JAMA Psychiatry, 78(1), 7-8. https://doi.org/10.1001/ jamapsychiatry.2020.1944
7. Mohamed, M. S., Moulin, T. C., \& Schiöth, H. B. (2021). Sex differences in COVID-19: The role of androgens in disease severity and progression. Endocrine, 71(1), 3-8. https://doi.org/10.1007/s12020-020-02536-6
8. Takahashi, T., Ellingson, M. K., Wong, P., et al. (2020). Sex differences in immune responses that underlie COVID-19 disease outcomes. Nature, 588(7837), 315-320. https://doi.org/10.1038/s41586-020-2700-3
9. Fink, A. L., Engle, K., Ursin, R. L., et al. (2018). Biological sex affects vaccine efficacy and protection against influenza in mice. Proceedings of the National Academy of Sciences of the United States of America, 115(49), 12477-12482. https://doi.org/10.1073/pnas.1805268115
10. Yasmin, F., Najeeb, H., Moeed, A., et al. (2021). COVID-19 vaccine hesitancy in the United States: A systematic review. Frontiers in Public Health, 9, 770985. https://doi.org/10.3389/fpubh.2021.770985
11. Klein, S. L., Dhakal, S., Ursin, R. L., et al. (2020). Biological sex impacts COVID-19 outcomes. PLoS Pathogens, 16(6), e1008570. https://doi. org/10.1371/iournal.ppat. 1008570
12. Centers for Disease Control and Prevention. Demographic trends of COVID-19 cases and deaths in the US reported to CDC. U.S. Department of Health and Human Services. https://covid.cdc.gov/covid-datatracker/\#demographics

Ndugga, N. (2022, November 17). COVID-19 cases and deaths, vaccinations, and treatments by race/ethnicity as of fall 2022. KFF. https://www.kff.org/ racial-equity-and-health-policy/issue-brief/covid-19-cases-and-deaths-vaccinations-and-treatments-by-race-ethnicity-as-of-fall-2022/

Tromberg, B. J., Schwetz, T. A., Pérez-Stable, E. J., et al. (2020). Rapid scaling up of covid-19 diagnostic testing in the United States - The NIH RADx Initiative. The New England Journal of Medicine, 383(11), 1071-1077. https://doi.org/10.1056/NEJMsr2022263
13. Barr, E., Whitaker, D., \& Stratton, P. (2022). Pregnancy and SARS-CoV-2: an opportunity to systematically study the complexity of maternal health. The Lancet. Digital Health, 4(2), e76-e77. https://doi.org/10.1016/S2589-7500(21)00277-6
Stratton, P., Gorodetsky, E., \& Clayton, J. (2021). Pregnant in the United States in the COVID-19 pandemic: A collision of crises we cannot ignore. Journal of the National Medical Association, 113(5), 499-503. https://doi. org/10.1016/j.jnma.2021.03.008
14. Hoyert, D. L. (2022, February). Maternal mortality rates in the United States, 2020. Health E Stats. https://www.cdc.gov/nchs/data/hestat/maternal-mor-tality/2020/e-stat-maternal-mortality-rates-2022.pdf
Kassebaum, N. J., Barber, R. M., Bhutta, Z. A., et al. (2016). Global, regional, and national levels of maternal mortality, 1990-2015: A systematic analysis for the Global Burden of Disease Study 2015. The Lancet, 388(10053), 1775-1812. https://doi.org/10.1016/S0140-6736(16)31470-2
15. King, D. E., Xiang, J., \& Pilkerton, C. S. (2018). Multimorbidity trends in United States adults, 1988-2014. Journal of the American Board of Family Medicine, 31(4), 503-513. https://doi.org/10.3122/jabfm.2018.04.180008
16. Cronin, K. A., Scott, S., Firth, A. U., et al. (2022). Annual report to the nation on the status of cancer, part 1: National cancer statistics. Cancer, 128(24), 4251-4284. https://doi.org/10.1002/encr. 34479

## NIH Workforce Demographic Composition

This section includes information about the sex, race, and ethnicity breakdown of the NIH workforce, building on the data presented in the Report of the Advisory Committee on Research on Women's Health for fiscal years (FYs) 2019-2020. Data presented include the composition of the NIH workforce overall, as well as the proportions within different workforce and program types, and across group membership by supervisory status, pay plan or grade, sex, race, and ethnicity.

Data, analysis, and definitions are provided as of the fourth quarter (Q4) of FY 2022 by the NIH Office of Equity, Diversity, and Inclusion's Data Analytics Branch, unless otherwise noted, and compared to historical data. Appendix B provides definitions for terms used in this section and additional details on items discussed in this section.

The research questions answered in this section include:

## What was the composition of the NIH workforce for FY 2022?

" Overall by sex, race, and ethnicity
» Engaged in scientific occupations by program type, sex, race, and ethnicity
» With a supervisory status by sex, race, and ethnicity
» By pay plan or grade, sex, race, and ethnicity

## Composition of the NIH

## Workforce in Q4 FY 2022

As of September 30, 2022, NIH maintained a total workforce of 18,993 full-time and part-time, permanent, and temporary employees. Of the onboard staff, $59.7 \%$ were female and $40.3 \%$ were male (Figure 1). The majority (greater than 50.0\%) of the workforce self-identified as White (52.6\%), followed by Black or African American (20.5\%), Asian (20.3\%), and Hispanic or Latino
(4.7\%). Employees included in the two or more race group, American Indian or Alaska Native, or Native Hawaiian or Other Pacific Islander groups constituted a combined $2.0 \%$ of the workforce. None of these proportions were more than 1.0 percentage point different than the proportions recorded for Q4 of FY 2020, except Asian employees, which increased as a proportion of the overall NIH workforce by 1.2 percentage points, and White employees, which decreased by 2.2 percentage points.

By workforce type, individuals in Scientific occupations comprised 47.6\% of the NIH workforce, followed by those in Infrastructure occupations (41.6\%) and Health and Research occupations (10.8\%). As compared to the entire NIH workforce, females had higher than expected representation in Health and Research (81.7\%) and Infrastructure occupations (62.1\%), and less than expected representation in Scientific occupations (52.5\%). White employees constituted the majority of those in Scientific occupations (58.0\%), followed by Asian employees (29.6\%). Black or African American individuals comprised 6.8\% of employees in Scientific, 30.0\% in Health and Research, and 33.6\% in Infrastructure occupations.

Figure 1: NIH Total Workforce Demographics for Q4 of Fiscal Year 2022


FY 2022 Q4

Data for employees represented in this reporting are self-identified; those classified in the five racial groups and two or more race group are all non-Hispanic or Latino. Hispanic or Latino employees are included in that category regardless of their race selection(s).


Produced by the Office of Equity, Diversity, and Inclusion (EDI): Data Analytics Branch. Data are included for onboard employees classified as permanent or temporary full-time, and part-time or intermittent at the end of the fiscal year (09/30). Data for Contractors, Fellows, Trainees, Commissioned Corps (CC) and Advisory Council (EI) and ZZ pay plans are not included. To maintain confidentiality and protect individual identification from deductive disclosure risk, values of less than four are suppressed for reporting purposes and designated with an asterisk. Total calculations shown may not match that derived from detailed data presented due to rounding. Data source: nVision that includes 09/30/22 pay period; downloaded on 02/14/23.

## Scientific Occupations by Sex and Program Type in Q4 FY 2022

In FY 2022, within Scientific occupations, females represented the majority in the Extramural (61.1\%) program type, but less than half (46.6\%) of the Intramural program type (Figure 2). The remaining Scientific workforce classified as Other program type is not reported in this analysis. The Extramural proportion of females has increased by 2.6 percentage points since Q4 of FY 2020, while the Intramural program type proportion of females have differed by no more than 1.0 percentage points between the time periods.

Within Scientific occupations, White employees constituted the majority of the workforce (overall 58.0\%; Extramural: 59.6\%; Intramural: 56.3\%), followed by Asian (overall: 29.6\%; Extramural: 24.9\%; Intramural: 34.2\%), Black or African American (overall: 6.8\%; Extramural: 9.5\%; Intramural: 4.4\%), and Hispanic or Latino (overall: 4.3\%; Extramural: 4.9\%; Intramural: 4.0\%) employees. Individuals included in the two or more race group, American Indian or Alaska Native, or Native Hawaiian or Other Pacific Islander groups constituted a combined $1.3 \%$ of the Scientific occupations (Extramural: 1.1\%; Intramural: 1.1\%). Compared to Scientific occupations as of Q4 of

Figure 2: NIH Workforce by Workforce Category and by Sex and Ethnicity/Race: Q4 FY 2022


FY 2020, White employees in FY 2022 showed a decrease of more than 3.0 percentage points, and Asian employees an increase of 1.6 percentage points. No other groups had proportions with a more than 1.0 percentage points difference between the two time periods.

## Composition of NIH leadership and supervisory roles in Q4 FY 2022

As of September 30, 2022, $50.5 \%$ of NIH supervisory (including leadership) positions were held by females (Figure 3). While this was 9.2
percentage points less than the proportion of females in the overall NIH workforce in Q4 of FY 2022, it was an increase of 2.4 percentage points as compared to the end of Q4 of FY 2020.

In the Scientific occupations, 43.1\% of supervisory positions were held by females, 16.6 percentage points less than the proportion of females in the overall NIH workforce in Q4 of FY 2022. Also, among Scientific occupations, $53.7 \%$ of supervisory positions in the Extramural program, and 34.7\% in the Intramural program were held by females. The percentage of supervisory positions held by females in the Scientific occupations overall has increased by 2.3 percentage points overall since

Figure 3: Employees with Supervisory Status by Sex and Race/Ethnicity: Q4 FY 2022


Produced by the Office of Equity, Diversity, and Inclusion, Data Analytics Branch. Data are included for onboard employees classified as permanent or temporary fulltime, part-time, or intermittent, at the end of fiscal year 2022. Data for Contractors, Fellows, Trainees, Commissioned Corps, and Advisory Council (including El and ZZ pay plans) are not included. Not identified sex include missing values. Total calculations shown may not match that derived from detailed data presented due to rounding. Data source: $n$ Vision that includes pay period ending 09/30/22; downloaded on 02/14/23.

RACE \& ETHNICITY
FY 2022 Q4


|  | Hispanic or <br> Latino | White | Black or African <br> American | Asian | Native Hawaiian or <br> Other Pacific Islander | American Indian <br> or Alaska Native | Two or More <br> Race Group |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Supervisor | $3.8 \%$ | $67.2 \%$ | $13.3 \%$ | $14.0 \%$ | $0.1 \%$ | $0.5 \%$ | $1.1 \%$ |
| Non-Supervisor | $4.9 \%$ | $49.3 \%$ | $22.1 \%$ | $21.7 \%$ | $0.1 \%$ | $0.7 \%$ | $1.3 \%$ |

[^2]Q4 of FY 2020, with a 2.1 percentage points increase in Extramural and a 1.6 percentage points increase in Intramural.

Compared to the overall NIH workforce, all races or ethnicities had less than expected representation in supervisory positions except for White employees (with more-than-expected representation), and Native Hawaiian or Other Pacific Islander employees (who were at parity). As of September 30, 2022, White employees represented $67.2 \%$ of supervisory positions, followed by Asian (14.0\%), Black or African American (13.3\%), and Hispanic or Latino (3.8\%) employees. Native Hawaiian or Other Pacific Islander employees constituted $0.1 \%$ of the supervisory positions. Employees included in the two or more race group and American Indian or Alaska Native constituted a combined $1.6 \%$ of the supervisory positions. The racial and ethnic
composition of supervisory positions has changed by less than 1.0 percentage points across all groups since Q4 of FY 2020 except for White employees, which has decreased by 1.4 percentage points.

## NIH workforce by pay plan or grade in Q4 FY 2022

In addition to females comprising the majority of the supervisory NIH workforce in Q4 of FY 2022, they also made up the majority of all pay groups except for the Wage Grade pay group and the Title 42 and equivalent pay group (which includes Scientific executives) (Figure 4). Female employees made up the majority of the Senior Executive Service (SES) and equivalent pay group, but with less than expected representation compared to their representation in the NIH workforce.

Figure 4: Percentage of NIH Workforce Pay Group and Sex: Q4 of FY 2022


White employees were the majority of each of the pay groups at GS or equivalent 13 or above (including Title 42 and equivalent and SES and equivalent pay groups) as of September 30, 2022 (Figure 5). Black or African American employees had more-than-expected representation compared to their representation in the NIH workforce at GS or equivalent 13 and below pay groups.

## Conclusions

As of the end of Q4 of FY 2022, females constituted the majority of the NIH workforce. Overall, females represented a slight majority of supervisory positions. This was a different pattern as compared to Q4 of FY 2020, when males occupied the majority of the overall supervisory positions. When examining by program and
workforce type, males comprised the majority of the Intramural Scientific workforce, including supervisory positions, a pattern also observed in Q4 of FY 2020. For the Extramural Scientific workforce, females comprised the majority, including supervisory positions, a pattern also similar to Q4 of FY 2020. Females comprised the majority of almost all pay groups, including senior level, except Title 42 and equivalent positions. However, females still demonstrated less-than-expected representation in the highest pay plan and grade groups, as compared to their proportion of the overall NIH workforce. This pattern was similar to those observed in Q4 of FY 2020, with males comprising the majority of the Title 42 and equivalent pay groups and females representing the majority of the SES and equivalent pay groups.

Figure 5: Percentage of NIH Workforce Pay Group and Ethnicity/Race: Q4 of FY 2022


# NIH Grant Funding and Success Rates: Differences by Sex During Fiscal Years (FYs) 2016 to 2022 

This chapter presents data about the sex, race, and ethnicity of scientists designated as principal investigators (PIs) on NIH grants during FY 2016FY 2022 and builds on the data presented in Report of the Advisory Committee on Research on Women's Health: Fiscal Years 2019-2020. The data in this chapter include the number of awards, success and funding rates, and the average amount of funding for the grants. Details on sex, race, ethnicity, the types of grant mechanisms, the career stages of the PIs, and the types of applications are also discussed in this chapter, with more detailed data graphs presented in Appendix B. Appendix B also provides definitions for terms used in this section. The Division of Statistical Analysis and Reporting within the NIH Office of Extramural Research's Office of Research Reporting and Analysis compiled and analyzed the grant data presented in this section.

The research questions, addressing FY 20162022, answered in this section include:

1. How many supported PIs on NIH grants are male, and how many are female?
2. What are male and female supported Pls' application funding rates and success rates on NIH grants?
3. What are the average amounts of funding support for male and female supported PIs on NIH grants?
4. What percentage of individuals supported by NIH career development awards are female?

## NIH Grant Awards by Sex of the Supported Pls, FY 2016-2022

The number of female Pls supported on R01equivalent grants increased from 2,057 in FY 2016 to 3,444 in FY 2022, an average increase
of about 230 supported PIs per year (Figure 1). During the same period, the number of male Pls supported on R01-equivalent grants increased from 4,765 in FY 2016 to 6,050 in FY 2022, an average increase of about 214 supported PIs per year. The percentage of supported Pls who were female increased from 29.4\% in FY 2016 to $34.0 \%$ in FY 2022, increasing on average by about 0.8 percentage point per year. A similar trend occurred for all research project grants (RPGs), with female Pls supported on RPGs constituting $30.8 \%$ of supported PIs in FY 2016 and $36.2 \%$ in FY 2022, an average increase of 0.9 percentage point per year. Among female Pls supported on R01-equivalent grants, the percentage who were non-Hispanic White was 70.6\% in FY 2016 and $63.0 \%$ in FY 2022. This 7.6-percentagepoint decrease was accompanied by a 2.5 -point increase in the percentage of female supported Pls who were Asian and 1.5-1.9-point increases in the percentages of female supported Pls who were Hispanic and those who were Black, as well as those in the "other" racial category.

Among early-stage investigators, $46.7 \%$ and $47.2 \%$ of PIs supported on R01-equivalent grants were female in FY 2021 and FY 2022, respectively, which is 13-14 points higher than the percentages of overall Pls supported on R01-equivalent grants who were female. Consistently across the FY 2016-FY 2022 period, over 32\% of Pls supported on research career, other research, and RPG awards were female, while $31 \%$ or less of supported Pls were female for center grants, Small Business Innovation Research (SBIR), and Small Business Technology Transfer (STTR) awards. SBIR and STTR awards had the smallest increase in the percentage of female supported PIs; from FY 2016 to FY 2021, 19\%-22\% of SBIR and STTR awards supported female Pls, which increased to 24\% in FY 2022.

Figure 1: Number of Supported PIs on R01-Equivalent Grants by Sex and Fiscal Year


| Year | Female | Male | Unknown/withheld sex |
| :---: | :---: | :---: | :---: |
| 2016 | 2057 | 4765 | 93 |
| 2017 | 2097 | 4818 | 109 |
| 2018 | 2789 | 5913 | 189 |
| 2019 | 2825 | 5811 | 222 |
| 2020 | 3112 | 6007 | 288 |
| 2021 | 3180 | 6021 | 278 |
| 2022 | 3444 | 6050 | 313 |

Source: Data were drawn from the frozen Success Rate Demographic file on February 14, 2023. Data were produced by the Division of Statistical Analysis and Reporting within the NIH Office of Extramural Research's Office of Research Reporting and Analysis. Percentages do not add up to $100 \%$ because of rounding.
R01-equivalent grants are defined in Annex B. Data on sex profiles are maintained by the investigator in the NIH Electronic Research Administration (eRA) system and are subject to change. Data include direct budget authority only and include all competing applications.

## NIH Grant Application Funding and Success Rates by Sex and Fiscal Year

The funding and success rates of R01-equivalent grants for all sex categories of supported Pls were lower in FY 2021 than in FY 2020 and FY 2022. This coincided with over 1,700 more applications and 690 or more designated Pls in FY 2021 than in FY 2020 and FY 2022 (Figure 2). Funding and success rates associated with male Pls were comparable (within 0.2 percentage point) in FY 2022 and FY 2020 but were 1.0 (funding rate) to 1.2 (success rate) percentage points higher in FY

2022 than in FY 2020 for applications associated with female PIs.

Since FY 2018, applications supporting female Pls have had a higher success rate than applications supporting male or mixed-sex Pls, while funding rates were lower for female supported Pls than male supported PIs until FY 2022, when the funding rate was $30.1 \%$ for both male and female supported PIs. Trends are similar for all RPGs, although in FY 2022, applications supporting mixed-sex Pls had a success rate that was 0.3 percentage point higher than applications supporting male PIs.

Figure 2: NIH Total R01-Equivalent Funding Rates and Success Rates by Sex Category and Fiscal Year


| Year | Success rate: <br> Female(s) | Success rate: <br> Male(s) | Success rate: <br> Mixed Sex | Success rate: <br> Unknown/ <br> Withheld | Funding rate: <br> Female | Funding rate: <br> Male | Funding rate: <br> Unknown/ <br> Withheld |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2016 | $19.5 \%$ | $20.4 \%$ | $18.1 \%$ | $7.7 \%$ | $24.5 \%$ | $27.1 \%$ | $11.3 \%$ |
| 2017 | $19.2 \%$ | $20.1 \%$ | $17.2 \%$ | $7.7 \%$ | $23.7 \%$ | $26.6 \%$ | $11.5 \%$ |
| 2018 | $22.4 \%$ | $22.1 \%$ | $20.2 \%$ | $11.8 \%$ | $28.8 \%$ | $30.5 \%$ | $15.8 \%$ |
| 2019 | $22.4 \%$ | $21.2 \%$ | $18.7 \%$ | $12.0 \%$ | $28.1 \%$ | $29.4 \%$ | $15.6 \%$ |
| 2020 | $22.1 \%$ | $21.5 \%$ | $20.9 \%$ | $14.5 \%$ | $29.1 \%$ | $30.2 \%$ | $18.1 \%$ |
| 2021 | $21.3 \%$ | $20.2 \%$ | $18.9 \%$ | $12.5 \%$ | $27.8 \%$ | $29.2 \%$ | $15.2 \%$ |
| 2022 | $23.3 \%$ | $21.3 \%$ | $20.8 \%$ | $14.3 \%$ | $30.1 \%$ | $30.1 \%$ | $18.3 \%$ |

> Source: Data were drawn from the frozen Success Rate Demographic file on February 14,2023. Data were produced by the Division of Statistical Analysis and Reporting within the NIH Office of Extramural Research's Office of Research Reporting and Analysis.
> R01-equivalent grants are defined in Annex B. "Male(s)"and "Female(s)" include awards supporting a single PI and those supporting multiple PIs of the same sex. The "Mixed R01-Equivalent" category includes mixed-sex multi-PI (MPI) teams with unknown/withheld sex. This category only applies to MPI applications. Data on sex profiles are maintained by the investigator in the NIH eRA system and are subject to change. Data include direct budget authority only and include all competing applications.

Success rates for new R01-equivalent applications supporting female PIs (20\% in FY 2020; 19\% in FY 2021; 21\% in FY 2022) and male PIs (19\% in FY 2020; 18\% in FY 2021; $19 \%$ in FY 2022) had similar patterns to R01equivalent applications overall. Among both first-time contact PIs and established contact PIs, female supported PIs had higher funding rates than male supported PIs in FY 2021-FY 2022. Female first-time contact Pls had a $22.1 \%$ funding
rate in FY 2021 and a 26.0\% funding rate in FY 2022, representing the largest percentage-point increase in funding rates from FY 2021-FY 2022 across all the career stages. Female early-stage supported Pls saw an increase in their funding rate in FY 2022-from 27.0\% in FY 2020 and 27.7\% in FY 2021 to 30.6\% in FY 2022.

The difference in the funding rate for R01equivalent grants between those supporting nonHispanic White female PIs and those supporting

Figure 3: NIH Research Grants and R01-Equivalent Grants: Average Funding in Current Dollars by Sex of the Supported PI and Fiscal Year

|  | \$650 |  |  |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: |
|  | \$600 |  |  |  |  |
|  | \$550 |  |  |  |  |
|  | \$500 |  |  |  |  |
|  | \$450 |  |  |  |  |
|  | 2016 | 20172019 |  | 2020 | 20212022 |
| Fiscal Year |  |  |  |  |  |
| $\square \text { Research Grants: Female } \quad \square \text { Research Grants: Male }$ |  |  |  |  | rants: Male <br> nt Grants: Male |
|  |  | Year | Research Grants: Female | Research Grants: Male | R01 Equivalent Grants: Female | R01 Equivalent Grants: Male |
|  | 2016 | \$472,889 | \$547,136 | \$478,624 | \$450,130 |
|  | 2017 | \$496,360 | \$566,037 | \$505,649 | \$472,930 |
|  | 2018 | \$505,271 | \$579,673 | \$547,492 | \$528,776 |
|  | 2019 | \$530,694 | \$599,511 | \$564,094 | \$541,184 |
|  | 2020 | \$540,256 | \$610,479 | \$573,752 | \$552,810 |
|  | 2021 | \$560,238 | \$624,339 | \$586,746 | \$564,186 |
|  | 2022 | \$563,386 | \$636,889 | \$601,771 | \$577,139 |
| Source: NIH IMPAC, Pub File. Data were produced by the Division of Statistical Analysis and Reporting within the NIH Office of Extramural Research's Office of Research Reporting and Analysis and drawn on December 16, 2022. |  |  |  |  |  |
| Each data point reflects only current dollars and is not adjusted for inflation. |  |  |  |  |  |
| projects, SBIR/ STTR program grants, and other research grants. Research grants are defined by the following activity codes: R, P, M, S, K, U (excluding UC6), DP1, DP2, DP3, DP4, DP5, D42, and G12. |  |  |  |  |  |
| Analysis is restricted to Pls who reported their sex. Data on sex profiles are maintained by the investigator in the NIH eRA system and are subject to change. |  |  |  |  |  |

Black female Pls was 10.1 percentage points in FY 2016 and 10.9 percentage points in FY 2019. In FY 2022, this difference was 4.3 percentage points. In FY 2022, applications supporting nonHispanic White female Pls had a 30.8\% funding rate, while the funding rates were $30.7 \%$ for applications supporting female Pls of "other" races and ethnicities, $30.3 \%$ for applications supporting Hispanic female Pls, 28.5\% for applications supporting Asian female Pls, and $26.5 \%$ for applications supporting Black female Pls.

## Average Funding for NIH Research Grants by Sex of the Supported PI

Since FY 2018, the average funding amount of R01equivalent grants supporting female Pls has been about 1.04 times the average funding amount of R01-equivalent grants supporting male Pls (Figure 3; note that data are not adjusted for inflation). However, from FY 2018 through FY 2022, the average funding amount of RPGs supporting female

Pls was between 0.87 and 0.90 times the average funding amount of RPG awards supporting male Pls.

Since FY 2016, over 78\% of center awards, which typically have higher funding amounts than other RPGs, have supported male PIs.

From FY 2021-FY 2022, the average funding amount of RPG awards supporting female Pls increased by 0.6\%, the lowest year-on-year increase
in the FY 2016-FY 2022 period, while the average funding amount of RPG awards supporting male Pls increased by 2.0\% from FY 2021-FY 2022.

From FY 2021-FY 2022, the average funding amount of an R01-equivalent award increased by $2.6 \%$ for female supported PIs and by $2.3 \%$ for male supported PIs. Through the period from FY 2016FY 2022, RPGs supporting male Pls received, on average, more funding than R01-equivalent grants

Figure 4: NIH Research Career Development Awards and Kirschstein-NRSA: Percentage of Female Supported Recipients, Trainees, and Fellows by Fiscal Year

supporting male PIs. The opposite was true for female supported PIs, with R01-equivalent grants receiving more funding than RPGs.

## Females Supported as Investigators by Career Development Awards

Of the investigators supported by research career development awards during the FY 2016-FY 2022 period, $50 \%$ or more were female.

In FY 2021, each type of investigator supported on career development awards was over $50 \%$ female, and each type of investigator supported on Kirschstein National Research Service Award (Kirschstein-NRSA). (Figure 4).

In FY 2022, females constituted 55\% or more of supported investigators for each of the award types.

In FY 2021, females were 60\% of supported postdoctoral institutional trainees while they were $56 \%$ of supported postdoctoral institutional trainees in both FY 2020 and FY 2022. Female supported postdoctoral fellows increased from $50 \%$ of fellows in FY 2020 to 57\% of fellows in FY 2021 and then decreased to 55\% of fellows in FY 2022. Conversely, female supported predoctoral institutional trainees decreased from $58 \%$ of trainees in FY 2020 to 53\% of trainees in FY 2021 and then increased to $61 \%$ of trainees in FY 2022.

## Conclusions

The data presented in this chapter show that female supported PIs had the same funding rates as male supported PIs in FY 2022 and have constituted 50\% or more of the investigators supported on research career and training awards since FY 2016. Female supported Pls constituted $31 \%-34 \%$ of designated Pls applying for R01-equivalent applications during the period of FY 2016-FY 2022.

With lower numbers and lower to similar funding rates than males, female supported PIs have constituted between $29 \%$ and $34 \%$ of Pls supported on R01equivalent grants over the past six years. Although in FY 2022, female supported Pls were $48 \%$ of earlystage supported Pls on R01-equivalent grants.

Male supported Pls have had a higher overall average amount awarded across research grant projects than female supported PIs, and male supported PIs are more likely to be supported on some grant mechanisms, including center grants, than female supported Pls. While funding rates for female supported Pls of Hispanic ethnicity and nonWhite races have increased since FY 2016, and the gap between the percentage of supported nonHispanic White female PIs and the percentages of other female PIs has decreased since FY 2016, supported female PIs of Hispanic ethnicity and nonWhite races have lower funding rates than nonHispanic White female PIs.

# Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities as Participants in Clinical Research 

## Historical Perspective

The establishment of policies for the inclusion of women and members of underrepresented racial and ethnic populations in National Institutes of Health (NIH)-funded clinical research stemmed from the women's health movement. After the Public Health Service Task Force on Women's Health Issues published a special report in 1985, ${ }^{1}$ NIH established a policy urging the inclusion of women in clinical research. This policy was first published in the "NIH Guide for Grants and Contracts" in 1987. Later that year, NIH published a policy encouraging the inclusion of racial and ethnic minorities in clinical studies.

To ensure that NIH implemented the inclusion policies, Congress codified policy into public law through a section in the NIH Revitalization Act of 1993 (Public Law 103-43) titled, "Women and Minorities as Subjects in Clinical Research." In 1994, NIH revised its inclusion policies to comply with the statutory language. The NIH Revitalization Act essentially reinforced certain existing NIH policies, ensuring that:
» Women and minorities and their subpopulations are included in all clinical research

Women and minorities and their subpopulations are included in Phase III clinical trials in a way that allows for valid analysis

Cost is not allowed as an acceptable reason for excluding these groups
» NIH initiates programs and support for outreach efforts to recruit and retain women and minorities and their subpopulations as participants in clinical studies

## Government Accountability Office Report

In October 2015, the Government Accountability Office (GAO) released a report examining women's participation in NIH research titled, "Better Oversight Needed to Help Ensure Continued Progress Including Women in Health Research" (GAO-16-13). GAO examined (1) female enrollment and NIH efforts to monitor this enrollment in NIH-funded clinical research and (2) NIH efforts to ensure that NIH-funded clinical trials are designed and conducted to analyze potential sex differences when applicable. GAO recommended that NIH examine and report more detailed data on women's enrollment in NIH-funded studies and collect, examine, and report data on the extent to which these studies include analyses of potential differences between men and women. NIH agreed with the report and implemented all the GAO recommendations, and all five recommendations were closed by GAO.

## The 21st Century Cures Act and the Inclusion Across the Lifespan Policy

The 21st Century Cures Act (Public Law 114-255), enacted December 13, 2016, included several new reporting requirements for inclusion of sex or gender in clinical research. As a result, in 2017, NIH updated its policy on the inclusion of women and minorities as participants in clinical research to require studies that are both NIH-defined Phase III clinical trials and applicable clinical trials to report the results of analyses by sex or gender and race and ethnicity in ClinicalTrials.gov.

Additionally in 2017, NIH revised its Inclusion of Children in Clinical Research policy (NOT-OD-18-116). The revision, now called Inclusion Across the Lifespan, requires inclusion of individuals of all ages (including children and older adults) in clinical research unless there are scientific or ethical reasons not to do so. The policy also requires investigators conducting clinical research to submit individual-level data on the sex or gender, race, ethnicity, and age of participants at enrollment in annual progress reports. The policy applies to all applications submitted on or after January 25, 2019. Appendix C and Figure 14 exhibit data on the age of participants at enrollment in NIH clinical research during fiscal years (FYs) 2021 and 2022.

In response to the 21st Century Cures Act's requirements, and as recommended by the GAO report, NIH makes inclusion data by disease or condition category available on the NIH RePORTER website every three years. The NIH RCDC Inclusion Statistics Report allows users to view the number and proportion of participants in NIH clinical research by sex or gender and race or ethnicity for each category in the Research, Condition, and Disease Categorization (RCDC) system. Users can view these data for each NIH Institute and Centers (ICs) and use filters to exclude single-sex/single-gender, single-race, or single-ethnicity studies.

## Inclusion Monitoring Activities Communication and Outreach Efforts to the Scientific Community

NIH regularly updates application, contract proposal, and intramural project instructions and guidance to ensure that investigators address inclusion as required and report inclusion enrollment data at least annually. Policy documents, podcasts, answers to frequently asked questions, and other resources are available for investigators and NIH staff members on the Office of Research on Women's Health (ORWH) and Office of Extramural Research (OER) websites. Tools to help investigators understand the new policies and their implementation, including a decision tree and infographic, are available on the OER website. These resources are intended to help
the extramural research community understand and implement NIH requirements for monitoring inclusion in clinical research.

In FY 2022, NIH issued a notice (NOT-OD-22-008) to the extramural research community about reporting requirements for Research Performance Progress Reports (RPPRs) for Phase III clinical trials. This notice clarified that valid analyses for sex or gender, race, and ethnicity for Phase III clinical trials are required in the "Project Outcomes" section of the final RPPR, in addition to the existing reporting requirements for ClinicalTrials. gov. To assist investigators in complying with this requirement, OER enhanced its guidance on the Sample Project Outcomes webpage.

NIH staff members have authored several publications to communicate inclusion requirements to the scientific community and the public, including articles and blog posts published on the Extramural Nexus.

NIH also conducts outreach to the extramural community through educational sessions at scientific meetings and conferences. For example, OER discusses inclusion policies at the NIH Grants Conference and PreCon events.

The Center for Scientific Review (CSR) and OER provide training for reviewers and applicants for applicants. ${ }^{2}$ These training and outreach efforts improve understanding of the inclusion policies and help extramural and NIH intramural investigators appropriately address issues throughout the research funding process. Specifically, these tools help applicants understand how NIH monitors inclusion, reviews the importance of reporting the race and ethnicity of clinical research participants, and describes how grantees and applicants should report race and ethnicity.

## NIH Inclusion Outreach Toolkit

ORWH hosts the NIH Inclusion Outreach Toolkit to help researchers recruit and retain women participants in their clinical studies. The toolkit includes information on the history of inclusion at NIH, current policies, case studies and testimonials, regulations, checklists, seminars, and other resources. These resources are intended to assist investigators and their research teams
in fulfilling responsibilities for including women in clinical research and ensuring that the distribution of study participants by sex or gender, race, ethnicity, and age reflects the population needed to accomplish the scientific goals of the clinical study. The toolkit features case studies with researchers' experiences including women in their studies. Topics include recruiting young urban women into a clinical trial related to HIV prevention, recruiting females into clinical trials related to cervical cancer prevention, treatments for menopause symptoms, dental caries prevention in young children, and diabetes prevention.

## Peer Review Expectations

Scientific Review Groups (SRGs) are instructed to focus on scientific considerations when assessing inclusion for a proposed study described in an NIH grant application. The SRGs evaluate inclusion plans and will find them unacceptable if the applicant (1) fails to provide enough information about the planned sample, (2) does not adequately justify limited inclusion or lack of inclusion of women or minorities, or (3) does not realistically address recruitment.

Reviewers on NIH peer review panels are given specific guidance on reviewing inclusion based on sex or gender, race, ethnicity, and age when considering clinical research applications. For NIH-defined Phase III clinical trials, the SRGs also evaluate the descriptions of plans for valid analyses and whether investigators need to examine differences in the intervention effect by sex or gender, race or ethnicity. "Valid analyses" refers to stratified analyses that explore how well the intervention works among sex or gender and racial and ethnic groups. Although they may or may not have high statistical power, these trials provide essential information to inform future studies. Previous data suggesting that differences may exist could indicate a need to consider specific analyses.

Unacceptable inclusion plans are documented in the minutes of the review session. Initial review groups make recommendations on the acceptability of proposed study populations with respect to inclusion policies. If issues are raised during the
review, program staff members notify the principal investigators (Pls), who are required to address these issues prior to funding. Applications with unacceptable inclusion plans cannot receive funding and an award will not be issued until an acceptable resolution is received. NIH staff members must be assured that the revised plans meet inclusion policy requirements.

## Communication and Outreach Efforts Within NIH

The NIH Extramural Activities Working Group (EAWG), established by the NIH Director as a working group of the NIH Steering Committee, facilitates the governance for the policies, procedures, and utilization of resources for extramural research and research training. The Inclusion Governance Committee (IGC) was formed in 2011 as a subcommittee of the EAWG to oversee policy issues related to inclusion. During FY 2021, the IGC was co-chaired by the ORWH Director and the National Institute on Aging (NIA) Deputy Director. In FY 2022, the National Institute on Minority Health and Health Disparities (NIMHD) Deputy Director assumed the co-chair position in place of the NIA Deputy Director. Members of the IGC are primarily senior-level staff members from the NIH Office of the Director and various ICs; other participants represent business areas involved in the implementation of inclusion policy.

CSR handles approximately $70 \%$ of the grant applications that NIH receives and offers a robust resource page with trainings, resources, and updates for scientific review officers (SROs) and program officers. In addition, OER regularly provides trainings for institute program officials/ program directors, grants management staff members, and SROs on implementation of the NIH policies for the inclusion of women, racial and ethnic minorities, and individuals across the lifespan. In coordination with other NIH Institutes, Centers, and Offices (ICOs), OER provided several online trainings on NIH staff procedures for implementing inclusion policies in 2021. These trainings continue to be available to staff members on the NIH extramural intranet website.

## Monitoring Compliance and Inclusion Enrollment Outcomes

NIH staff monitor and document compliance with the inclusion policies and work with grantees to address any issues. Program officers and staff members provide technical assistance to investigators as they develop their applications and proposals. Program staff members monitor actual enrollment progress in annual progress reports and provide consultation when necessary.

In preparation for peer review meetings, SROs remind reviewers of the guidelines for evaluating investigators' plans for the inclusion of women and minorities in clinical research. Instructions and requirements for reviewing NIH-defined Phase III clinical trials, particularly how the proposed work considers plans for valid analyses of sex differences, are also discussed during these preparatory meetings. Program staff members note whether valid analyses of sex differences are required prior to awarding grants. When new and competing continuation applications that were selected for payment appear to be deficient in meeting inclusion policy requirements, NIH staff members are required to withhold funding until the PI has satisfactorily addressed the policy requirements. Grants management staff members ensure that appropriate terms and conditions of the awards are included in the Notice of Award and ensure that this information is appropriately documented in the official grant file. At the time of award and at the time of submission of progress reports, program officials monitor and verify that progress on inclusion of participants is appropriate for the scientific goals under study.

Inclusion enrollment data aggregated across the ICs are presented in this report in summary figures and aggregate data tables (Appendix C), providing documentation of inclusion monitoring with some analysis. Caution should be used in interpreting these figures. As such, conclusions that can be reasonably drawn from the data are provided.

When assessing inclusion data, NIH avoids directly comparing enrollment figures with national Census figures. The goal of the NIH policy is to ensure that the scientific knowledge acquired through NIH-defined clinical research ultimately will be
generalizable to the appropriate population(s), not to satisfy any proportional target based on Census data. The numbers of women, men, and representatives of racial and ethnic groups included in a study depend on the scientific question(s) being addressed and may consider several factors, such as the prevalence among women, men, or racial and ethnic groups of the disease, disorder, or condition under investigation; gaps in scientific knowledge; and disparities in health risks or outcomes. A key principle of the inclusion policies is that inclusion is integral to conducting good science. Inclusion should not be considered based on absolute numbers of individuals in the population groups; rather, the focus should be on whether a given study population is appropriate for its scientific goals and how sex or gender, race, and ethnicity may affect outcomes.

## NIH Human Subjects System

NIH has monitored aggregate inclusion data for study populations since FY 1994. All ICs have wellestablished practices for monitoring compliance with NIH's inclusion policies. NIH has used the Electronic Research Administration (eRA) Human Subjects System (HSS) to monitor inclusion data since June 9, 2018. This system consolidates study-level participant data and clinical trial information in one place. HSS facilitates data collection, allows submission of participant-level enrollment data in comma-separated values (CSV) format, and reduces the need for duplicate data entry in other systems, such as ClinicalTrials.gov. NIH staff members use HSS to manage participantrelated information associated with a grant, cooperative agreement, or contract, including plans for inclusion and inclusion enrollment data. HSS provides an electronic means of entering, storing, approving, monitoring, and reporting the planned and actual enrollment of research participants based on sex or gender, race, and ethnicity.

HSS promotes increased transparency by displaying the same information to grant recipients and NIH staff members. In 2019, NIH introduced an indicator to monitor requirements for valid analysis by sex or gender, race, and ethnicity for NIH-defined Phase III clinical trials. The use of this indicator allows NIH to more easily monitor and report
requirements for analysis by sex or gender, race, and ethnicity in NIH-defined Phase III clinical trials.

## Summary Report of NIH Inclusion Data for FYs 2021 and 2022

Reporting of sex or gender, racial, and ethnic categories is based on self-identification of participants, who have the option to not self-identify. Although inclusion is mandated for all clinical research projects conducted or supported by NIH, for this summary report, the primary focus of the racial and ethnic analyses is on studies involving populations in the U.S. Appendix C contains data tables describing inclusion data for all clinical research and NIH-defined Phase III clinical trials from FYs 2012-FY 2022.

## Important Considerations for Interpreting NIH Inclusion Data

Analysis of aggregate NIH inclusion data demonstrates that substantial numbers of women and men and individuals of different races and ethnicities have been included as research participants in NIH clinical research studies and NIH-defined Phase III clinical trials. In addition, multiyear data are provided to show inclusion trends over time. As explained in the section titled, "Monitoring Compliance and Inclusion Enrollment Outcomes," ORWH recommends using caution to avoid overinterpreting the figures and data tables provided in this chapter.
» Portfolio Composition: The NIH portfolio is diverse in terms of the types of clinical research studies it supports, the size of the studies, and the expectations for inclusion within them. The size of clinical research and clinical trial portfolios and the studies within those portfolios vary substantially across the ICOs, depending on such factors as budget and mission and the scientific goals of a given study. Some ICOs do not conduct NIH-defined Phase III clinical trials or support very few of them.
» Funding Life Cycle: It is crucial to consider the nature of the funding life cycle at NIH and how that can affect inclusion enrollment information. The average length of an NIH grant award
is four years. This means that every year, approximately $25 \%$ of the NIH funding portfolio turns over to newly funded awards or competing continuation awards. However, funding can be as short as one year or can last up to 10 years. The total amount of funding can vary from year to year, and at times, spikes or dips in appropriations may affect inclusion enrollment. Changes caused by the funding life cycle may create noticeable shifts in inclusion enrollment data, particularly for ICOs with small clinical research or clinical trial portfolios. This life cycle also affects the reported enrollment numbers. In any given year, some projects have just begun, so enrollment is low. Other projects have higher enrollment rates in later years. Furthermore, other projects have ended, so their data are no longer reported. These fluctuations across studies can also lead to notable shifts in enrollment numbers from year to year.

Coding Categories: The NIH-defined clinical research category includes not only NIH-defined Phase III clinical trials but also many other types of clinical studies, such as observational and epidemiological studies, exploratory studies, and other phases of clinical trials, all of which are monitored for compliance with the inclusion policies. The NIH-defined Phase III clinical trial category is a subset of all NIH-defined clinical research.
» Excluding An Outlier: In FY 2022, NIH supported a study with an extraordinary enrollment of more than 86 million participants. This large study is an NIH-defined Phase III clinical trial funded by NIA and involves a social media intervention for COVID-19 vaccination in 1,397 counties across the U.S. Because this trial has a total number of participants that is more than seven times the total enrollment of all NIH-funded research for FY 2022, it is considered an outlier and is not included in the summary of NIH aggregate inclusion data in Figures 1-13 or the data in Appendix C, Sections 1-5. By presenting the FY 2022 aggregate data in this way, we can ensure a more accurate interpretation of inclusion data trends across all ICOs.

## Summary of Key Trends

The following sections summarize data on the inclusion of women and racial and ethnic minorities in NIH-funded clinical research and NIH-defined Phase III clinical trials. Appendix C summarizes all available inclusion data from FY 2012-FY 2022, excluding the outlier described above. Key trends for NIH-funded clinical research, including research at U.S. sites and research at non-U.S. sites, based on the inclusion data summary are as follows:
" Investigators reported that in FY 2021 and FY 2022, 12,937,156 and 10,751,975 participants, respectively, enrolled in NIH-funded clinical research (Appendix C, Table 1A). If we exclude studies conducted outside the U.S., the enrollment counts were $9,957,714$ and $8,755,755$ in the corresponding years (Table 1B).
» Enrollment of women in all NIH-funded clinical research in FY 2021 was $58.5 \%$. This figure decreased to $55.8 \%$ in FY 2022 (Appendix C, Table 1A).
» Enrollment of clinical research participants from racial minority groups across all NIH research was $41.8 \%$ in FY 2021 and remained at a similar level (41.0\%) in FY 2022 (Appendix C, Table 2E). Participation of the Hispanic/Latino ethnicity slightly increased; it was approximately 10.2\% in FY 2021 and 12.4\% in FY 2022 (Appendix C, Table 2F).

NIH-defined Phase III clinical trials are a subset of NIH clinical research studies. In FY 2021, 61.2\% of participants in NIH-defined Phase III clinical trials were female, and $60.6 \%$ were female in FY 2022 (Appendix C, Table 1E). Similarly, female enrollment in Phase III trials at only U.S. sites was $62.6 \%$ and $60.4 \%$ in $F Y 2021$ and $F Y$ 2022, respectively (Appendix C, Table 1F).

Racial minority inclusion in NIH-defined Phase III clinical trials was $70.3 \%$ in FY 2021 and 38.3\% in FY 2022 (Appendix C, Table 3E). In FY 2021, approximately $31.2 \%$ of participants recruited to NIH-defined Phase III clinical trials were of Hispanic/Latino ethnicity. This figure decreased to 14.8\% in FY 2022 (Appendix C, Table 3F). We will provide more detail and explain these declining trends in the inclusion summaries below.

## Source of Inclusion Data

The following summary is based on inclusion data tabulated from participants in NIH-funded clinical research and NIH-defined Phase III clinical trials. NIH defines human clinical research as patientoriented, epidemiological, behavioral, outcomerelated, or health services-related research that includes human participants.
» Patient-oriented research is research conducted with human participants (or on material of human origin, such as tissues, specimens, and cognitive phenomena) in which an investigator directly interacts with human participants. Excluded from this definition are in vitro studies that use human tissues that cannot be linked to a living individual. Patientoriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical studies, and (d) development of new technologies. Studies falling under 45 CFR 46, Exemption 4 for human subject research are not considered clinical research by this definition. Exemption 4 applies to secondary research uses of identifiable private information or identifiable biospecimens that meet specific criteria outlined in 45 CFR 46.104(d)(4) of the revised Common Rule. Clinical trials are a subset of clinical research studies. They are research studies in which one or more participants are prospectively assigned to one or more interventions (which may include placebos or other controls) to evaluate their effects on health-related biomedical or behavioral outcomes. Clinical trials test treatment, prevention, and diagnostic strategies and include studies of drugs, devices, surgical techniques, health care delivery systems, and strategies to change health-related behavior, such as diet and therapy.

- NIH -defined Phase III clinical trials are a subset of clinical trials. NIH-defined Phase III clinical trials usually compare interventions with other standard or experimental interventions (biomedical or behavioral) in large groups of people, from several hundred to several thousand. Typically, these trials monitor adverse effects and collect information that will
allow the interventions to be used safely. NIH-defined Phase III clinical trials require valid analyses by sex or gender, race, and ethnicity. NIH program staff members monitor requirements for these analyses, and ICOs report the number of NIH-defined Phase III trials requiring valid analyses in their triennial inclusion reports.
- The 21st Century Cures Act requires reporting of valid analyses for studies that are both NIH-defined Phase III clinical trials and applicable clinical trials. "Applicable clinical trials" is the term used in Title VIII of the Food and Drug Administration Amendments Act (FDAAA) of 2007 (Public Law 110-85) to designate the scope of clinical trials that may be subject to the registration and results reporting requirements of the FDAAA.
- Clinical trials that are subject to the regulation are, in general, clinical trials of drug, biological, and device products regulated by the Food and Drug Administration (FDA). A pediatric postmarket surveillance study of a device product required by FDA is also subject to the regulation (NOT-OD-18-014).
- Applicable NIH-defined Phase III clinical trials require reporting of results of valid analyses in ClinicalTrials.gov.

The following summary of inclusion of women and underrepresented racial and ethnic populations in NIH research was derived from HSS data to facilitate the congressional report required biennially by statute (Public Health Service Act Section 492B, 42 U.S.C. Section 289a-2). The data are aggregated across all ICs. Each IC has reviewed and approved its inclusion data used in this report. Individual IC reports are made available triennially on the NIH RePORT website.

In FY 2021, investigators submitted 25,941 inclusion enrollment reports (IERs), with 14,621
IERs reporting enrollment of 12,937,156 participants. The remaining 11,320 IERs indicated that participants had not yet been enrolled.
» In FY 2022, investigators submitted 27,970 IERs, with 16,091 IERs reporting enrollment of 10,751,975 participants. The remaining 11,879 IERs for FY 2022 indicated that participants had not yet been enrolled.

## Inclusion Summaries

This report defines population subgroups by research participants' sex or gender, race, and ethnicity. The percentage of female participants in NIH-funded clinical research is the proportion of enrolled participants who selected "female" as their sex or gender. During FY 2021, 7,572,143 enrollees were female, accounting for $58.5 \%$ of NIH-defined clinical research participants. The FY 2021 enrollment count for males was $5,047,190$, constituting $39.0 \%$ of the study population. Similarly, for FY 2022, the female and male participant percentages were $55.8 \%$ and $41.4 \%$, respectively. The sex or gender of participants was unknown or not reported for $2.5 \%$ and $2.8 \%$ of participants in FY 2021 and FY 2022, respectively (Appendix C, Table 1A).

Figure 1: Enrollment for All NIH Clinical Research at U.S. Sites by Racial Categories, FY 2021 and FY 2022


Figure 1 displays the racial composition of participants enrolled in NIH-funded clinical research at U.S. sites for FY 2021 and FY 2022. The percentage of enrollment of White participants was $64.2 \%$ in FY 2021 and increased slightly, to $67.7 \%$, the following year. In both FY 2021 and FY 2022, enrollment of Black/African American participants was 13.0\%. The number of Asian individuals (FY 2021 was 5\% and FY 2021 was $3.4 \%$ ) and Native Hawaiian/Other Pacific Islander participants (FY 2021 was . $8 \%$ and FY 2022 was .3\%) decreased in clinical research participation from FY 2021 to FY 2022, while the percentage of American Indian/Alaska Native participants (FY 2021 was .9\% and FY 2022 was 1\%) and those individuals identifying as more than one race (FY 2021 was $2 \%$ and $F Y 2022$ was $2.5 \%$ ) marginally increased. Unknown or not reported percentages were 14\% in FY 2021 and 12.2\% in FY 2022.

Figure 2: Enrollment for All NIH Clincial Research at U.S. Sites by Ethnic Categories, FY 2021 and FY 2022


The ethnic breakdown of participants in Figure 2 indicates that the percentage of enrollment of nonHispanic participants increased slightly, from 77.7\% in FY 2021 to 78.3\% in FY 2022. While the percentage of enrollment of Hispanic/Latino participants increased from $10.5 \%$ to $12.1 \%$ during this interval, the percentages of participants of unknown/not reported ethnicity were substantial; these participants accounted for $11.8 \%$ and $9.6 \%$ of enrollment in FY 2021 and FY 2022, respectively.

## Inclusion Trends in NIH-Funded Clinical Research

Data regarding enrollment of women and underrepresented racial and ethnic populations for NIH-funded clinical research in FY 2021 and FY 2022 are presented in Figures 3 through 6. In each figure, the data are summarized for (a) all NIH clinical research, (b) all NIH clinical research at U.S. sites, (c) clinical research supported by the NIH Extramural Research Program conducted at U.S. sites, and (d) clinical research conducted through the NIH Intramural Research Program at U.S. sites. All clinical research at U.S. sites includes studies conducted through the Extramural Research Program and the Intramural Research Program.

The information in this report represents new data collected prospectively. Studies that analyzed retrospective data using extant data sets were excluded from the report. The exclusion of retrospective data prevents possible inflation of enrollment counts, which may have been analyzed and reported previously.

Figure 3: Percentage of Participants in NIH-Funded Clinical Research Who Are Female, FY 2021 and FY 2022


Figure 3 summarizes the percentages of enrollees who were women in NIH-funded clinical research during FY 2021 and FY 2022. Although all categories had a decrease in women's participation, women represented more than 50.0\% of enrollees, except for in NIH-funded intramural clinical research at U.S. sites in FY 2022. For all NIH-funded clinical research categories, women accounted for $58.5 \%$ of research participants in FY 2021 and $55.8 \%$ in $F Y$ 2022. When we exclude female-only studies from the enrollment counts, women accounted for $43.8 \%$ of participants in FY 2021 and $47.7 \%$ in FY 2022 (Appendix C, Table 1A). Continued comparison of female participation is as follows: all clinical research at U.S. sites was $58.4 \%$ in FY 2021 and $55.2 \%$ in FY 2022; clinical research at U.S. sites with the extramural program was 59.9\% in FY 2021 and 56.9\% in FY 2022; and clinical research at U.S. sites in the intramural program were 50.1\% in FY 2021 and 46.5\% in FY 2022.

Appendix C, Table 1B presents enrollment information for NIH-funded clinical research at U.S. sites from FY 2017 to FY 2022. It shows that enrollment of women has been $49.1 \%$ or higher, whereas for men, the recruitment rate since FY 2017 has been 39.2\% or higher. Across all years, women had a higher percentage of enrollment than men.


Figure 4 demonstrates the percentages of participants in NIH-funded clinical research who are members of racial and ethnic minority groups. Overall participation in NIH clinical research decreased slightly from FY 2021 at $41.8 \%$ to $41 \%$ in FY 2022. For all clinical studies conducted at U.S. sites, racial and ethnic minority participants accounted for $30.8 \%$ of enrollees in FY 2021, compared with $30.6 \%$ in FY 2022. The percentage of enrollment of racial and ethnic minority participants in U.S. site studies supported through the Extramural Research Program were larger than those in U.S. site studies supported through the Intramural Research Program in both FY 2021 (19.1\% for intramural, versus 32.9\% for extramural) and FY 2022 ( $18.2 \%$ for intramural, versus 32.9\% for extramural).

Figure 5: Percentage of Female Participants in NIH-Funded Clinical Research Who Are Members of a Racial and Ethnic Minority Group, FY 2021 and FY 2022


To illustrate a complete picture of racial and ethnic minority enrollment in clinical research, Figures 5 and 6 provide an enrollment summary for female and male minority participants. In terms of all NIH-funded clinical research, the percentage of racial and ethnic minority female participants was stable, 43.5\% in FY 2021 and 43.2\% in FY 2022. Similarly, there was a consistent percentage of enrollment of female minority participants in clinical research conducted at U.S. sites in FY 2021 (32.7\%) and FY 2022 (32.9\%). The percentage in the U.S. site Extramural Research Program category marginally increased, by 0.5 percentage points and marginally decreased in the Intramural Research Program from FY 2021 (23.3\%) to FY 2022 (22.5\%) (Figure 5).

Figure 6: Percentage of Male Participants in NIH-Funded Clinical Research Who Are Members of a Racial and Ethnic Minority Group, FY 2021 and FY 2022


Figure 6 demonstrates the participation of racial and ethnic minority males in clinical research. For all NIH clinical research, the percentage of enrollment marginally decreased from FY 2021 (40\%) to FY $2022(39.1 \%)$. Of clinical research conducted at U.S. sites, the percentage of enrollment of racial and ethnic minority males was about $29.0 \%$ in FY 2021-2022. The percentage of male minority participants in extramural research at U.S. sites was also stable, at about $32.5 \%$ in both years. The percentage of male minority participants in intramural research decreased from FY 2021 (15.5\%) to FY 2022 (14.9\%). Note that for both minority men and minority women, the percentages of intramural research participants slightly decreased between FY 2021 and FY 2022 (Figures 5 and 6).

Tables 4A-4D in Appendix C provide details on inclusion from FY 2017 to FY 2022 for male and female participants in clinical research who are members of racial and ethnic minority groups. Tables 4I-4L provide a detailed breakdown of enrolled participants by race and ethnicity of male and female enrollees for FY 2021 and FY 2022.


## Inclusion Trends in NIH-Defined Phase III Clinical Trials

NIH-defined Phase III clinical trials are a subset of NIH clinical research studies. Enrollments for Phase III clinical trials conducted at U.S. sites are shown in Figures 7 through 13.

Figure 7 illustrates the percentages of women enrolled in NIH-defined Phase III clinical trials at U.S. sites in FY 2021 and FY 2022, with a subset analysis for extramural and intramural research enrollments. The percentage of female participants in Phase III clinical trials at U.S. sites was 62.6\% in FY 2021 and 60.4\% in FY 2022. For extramural Phase III clinical trials, the percentage of female participants was $62.6 \%$ in FY 2021 and $60.2 \%$ in FY 2022. Enrollment of female participants in the intramural Phase III clinical trials rose from $60.6 \%$ in FY 2021 to $93.3 \%$ in FY 2022. This sharp increase was most likely caused by a combination of factors: (1) a decrease in male enrollment in intramural Phase III trials in FY 2022 and (2) an ongoing femaleonly Phase III clinical trial with high enrollment for both FY 2021 and FY 2022 (Table 1H).


Tables 3A-3D in Appendix C show minority enrollment in NIH-defined Phase III clinical trials from FY 2017 to FY 2022. Tables 3E-3L provide a detailed breakdown of NIH-defined Phase III clinical trials' enrollment by race and ethnicity from FY 2017 through FY 2022.

Figure 8 (above) and Tables 3C-3D in the appendix represent racial and ethnic minority participants' enrollment data in NIH-defined Phase III clinical trials. Of the Phase III clinical trials performed at U.S. sites, the racial and ethnic minority enrollment was noticeably higher, at $57.8 \%$ in FY 2021, but returned to a more typical percentage of $26.3 \%$ in FY 2022. Similarly, U.S. site Phase III clinical trials supported by the NIH Extramural Research Program had a noticeably higher percentage of racial and ethnic minority participants, $58.5 \%$, in FY 2021. This percentage decreased to $26.2 \%$ in FY 2022. The spike was most likely because of one large extramural Phase III clinical trial, a vaccine uptake-related study completed in FY 2021, that had a large percentage of Hispanic/Latino participants. U.S. site Phase III clinical trials supported by the NIH Intramural Research Program increased from FY 2021 (32.8\%) to FY 2022 (43.9\%).

Figure 9: Percentage of Female Participants in NIH-Defined Phase III Clinical Trials at U.S. Sites Who Are Members of a Racial and Ethnic Minority Group, FY 2021 and FY 2022


Figure 9 illustrates enrollment by sex or gender of minority participants at U.S. sites. The percentage of enrollment in all NIH-defined Phase III clinical trials for women who are members of racial and ethnic minority groups was remarkably high in FY 2021 at 57.5\% and decreased to 28\% in FY 2022. These percentages are similar to the percentages of minority women's participation in extramural Phase III clinical trials, which were also high in FY 2021 at $58.0 \%$ and also decreased in FY 2022 to $27.8 \%$. This was most likely because of the high number of Hispanic/Latino participants in the previously mentioned large Phase III clinical trial completed in FY 2021. Enrollment of female minority participants in intramural Phase III clinical trials increased from 38.3\% in FY 2021 to 42.4\% in FY 2022.

As with females, the participation of minority males in NIH-defined Phase III clinical trials was high in FY 2021 ( 58.9 \%) and it decreased to 26.3 \% in FY 2022 (Figure 10). For U.S. site trials supported by the Intramural Research Program in FY 2021, the enrollment rate for minority men was lower than that for minority women. In FY 2021, the difference was about 14.6 percentage points. However, in FY 2022, a greater percentage of minority men were enrolled than minority women, $64.9 \%$ compared with $42.4 \%$ (Figures 9 and 10).


Tables 4F through 4H in Appendix C provide details on inclusion from FY 2017 to FY 2022 for minority male and female participants in NIH-defined Phase III clinical trials at U.S. sites. Tables 4 N through 4P further break down enrolled participants by the race and ethnicity of male and female enrollees for FY 2021 and FY 2022.

Figure 10 shows that the percentage of males enrolled in intramural Phase III clinical trials who are members of racial and ethnic minority groups increased from $23.5 \%$ in FY 2021 to $64.9 \%$ in FY 2022. This was because of the completion of two studies with substantial numbers of White male participants in FY 2021 reflected in the breakdown of participants in intramural Phase III trials at U.S. sites by sex or gender and race and ethnicity (Appendix C, Table 4P). Participation in NIH-defined Phase III clinical trials in extramural programs decreased from 59.9\% in FY 2021 to $26.3 \%$ in FY 2022. Participation in all NIH-defined Phase III clinical trials in the U.S. decreased from 58.9\% in FY 2021 to 26.3\% in FY 2022.

Figure 11: Enrollment for AII NIH-Defined Phase III Clinical Trials at U.S. Sites by Racial Categories, FY 2021 and FY 2022


## Racial and Ethnic Breakdown of Participants Enrolled in NIH-Funded Phase III Clinical Trials at U.S. Sites

Figures 11 and 12 summarize enrollment data for self- reported race and ethnicity of research participants enrolled in NIH-defined Phase III clinical trials at U.S. sites. Figure 11 illustrates that in FY 2021 and FY 2022, White participants constituted $74.5 \%$ and $76.0 \%$ of enrollees in NIH-defined Phase III clinical trials, respectively. The participation of each racial minority group decreased in FY 2022. For example, the percentage of enrollment of Black/African American participants decreased from 14.2\% in FY 2021 to $11.4 \%$ in FY 2022. In addition, the percentage of enrollees who self-reported as being more than one race decreased by 2.3 percentage points. The magnitudes of change for Asian and Native Hawaiian/Other Pacific Islander individuals were less evident. Notably, the percentage of participants of unknown race increased from 4.7\% in FY 2021 to 8.6\% in FY 2022.

Figure 12. Enrollment for All NIH-Defined Phase III Clinical Trials at U.S. Sites by Ethnic Categories, FY 2021 and FY 2022


Figure 12 shows that Hispanic/Latino enrollment decreased from 39.5\% in FY 2021 to 12.0\% in FY 2022. This was most likely because of the aforementioned large extramural Phase III clinical trial, a vaccine uptake-related study completed in FY 2021 that enrolled many Hispanic/Latino participants. The percentage of enrollment of people of unknown Hispanic/Latino identity increased from 3.4\% in FY 2021 to $9.0 \%$ in FY 2022. Not Hispanic enrollment increased from FY 2021 (51\%) to FY 2022 (79\%).

## Valid Analysis Requirement for NIH-Defined Phase III Clinical Trials

Consistent with GAO's 2015 report titled, "Better Oversight Needed to Help Ensure Continued Progress Including Women in Health Research" (GAO-16-13), and its associated recommendations, NIH is committed to assessing the extent to which NIH-funded studies include analyses of potential differences between men and women. To this end, NIH added questions regarding required valid analysis for NIH-defined Phase III clinical trials beginning in FY 2016. Below is information on NIH-defined Phase III clinical trials requiring valid analysis plans by sex or gender and NIH-defined Phase III clinical trials requiring valid analysis plans by race and ethnicity.

Figure 13: Valid Analysis Requirements for Extramural NIH-Defined Phase III Clinical Trials, FY 2019 to FY 2022


Note: Plans for valid analysis methodologies specified in the project application are reported for all IERs, including IERs that have no reported actual enrollment at the time of reporting.

|  | FY 2019 | FY 2020 | FY 2021 | FY $\mathbf{2 0 2 2}$ |
| :--- | :---: | :---: | :---: | :---: |
| IERs Requiring Sex-Gender Valid Analysis | 625 | 800 | 900 | 1076 |
| \% IERs Requiring Sex-Gender Valid Analysis | $94.1 \%$ | $88.2 \%$ | $89.1 \%$ | $92.3 \%$ |
| IERs Requiring Race-Ethnicity Valid Analysis | 622 | 853 | 961 | 1138 |
| \% IERs Requiring Race-Ethnicity Valid Analysis | $93.7 \%$ | $94.0 \%$ | $95.1 \%$ | $97.6 \%$ |
| Total IERs | 664 | 907 | 1010 | 1166 |

Figure 13 (above) and Table 5 in Appendix C summarize valid analysis requirements for NIH-defined Phase III clinical trials between FY 2019 and FY 2022, focusing on studies supported by the Extramural Research Program. "Valid analyses" refers to stratified analyses by sex or gender and racial and ethnic groups. Valid analyses enable researchers to explore the intervention effects across these demographic categories. Over the course of four years, the total number of IERs for NIH-defined Phase III clinical trials increased from 622 to 1,138. Among those submitted IERs, 89.1\% and 92.3\% in FY 2021 and FY 2022, respectively, were required to justify a plan for sex-gender valid analysis, while $95.1 \%$ of IERs in FY 2021 and $97.6 \%$ in FY 2022 required a race-ethnicity valid analysis.

As stated above, the NIH Inclusion Across the Lifespan policy, implemented in response to the 21st Century Cures Act, requires individuals of all ages (including children and older adults) be included in NIH-supported clinical research unless there are compelling scientific or ethical reasons. Figure 14 (next page) and Table 6 in Appendix C illustrate the age distribution for all NIH-defined clinical research based on IERs for FY 2021 and FY 2022. Between FY 2021 and FY 2022, there was a decrease in the percentage of participants age 17 or younger, from $19.6 \%$ to $13.6 \%$, while the percentages of adults (ages 18-64) and older adults (age 65 or older) increased. The percentages of participants with unknown or unreported ages were low for both years.


## Summary

NIH uses several measures to address the inclusion of women and underrepresented racial and ethnic populations in clinical research. During the peer review process for grant applications, the inclusion plan for clinical research is examined. All NIH-funded clinical research studies are required to have inclusion plans to inform enrollment targets. Peer reviewers assess the inclusion plans, and prior to each advisory council meeting, program directors examine the reviewers' comments on "unacceptable" inclusion goals and resolve issues with the investigators in writing. Program directors determine whether the enrollment targets for inclusion are scientifically appropriate and they review actual enrollment data submitted in the annual progress reports.

In summary, the aggregate enrollment data for the reporting period provide an overview of NIH clinical research participation and demonstrate substantial inclusion of women and underrepresented racial and ethnic populations in clinical research projects and NIH-defined Phase III clinical trials.

NIH's HSS allows access to clinical inclusion records and cumulative reports and enables program staff members to monitor enrollment data. Overall trends in the data suggest a consistent pattern of $47.2 \%$ or greater enrollment of women in NIH-funded clinical research since 2012, with most of these years exceeding 52\% (Appendix C, Table 1A). Racial and ethnic minority enrollment for NIH-defined Phase III clinical trials at U.S. sites has consistently been $22 \%$ or greater since 2017 (Appendix C, Table 3B). The percentage of Hispanic/Latino participants in all clinical research increased during the reporting period (Appendix C, Tables 2 F and 2 H ), and one large extramural Phase III clinical trial completed in FY 2021 boosted the percentage of Hispanic/Latino participants well above the rates seen in other years during FY 2017-FY 2022 (Appendix C, Tables 3F, 3H, and 3J).

## NIH Budget for Women's Health Research

## I. Introduction

NIH funding of research that is focused on diseases and conditions relevant to women during fiscal years (FYs) 2020 to 2022 is presented in this budget summary. Budget totals for each year were calculated using NIH Research, Condition, and Disease Categorization (RCDC) data and the internal RCDC "Search and Visualize" intersect tool.
"Women's health conditions," as defined in section 141 of the NIH Revitalization Act of 1993 (Public Law 103-43), include all diseases, disorders, and conditions:

1. That are unique to, more serious in, or more prevalent in women
2. For which the factors of medical risk or types of medical intervention are different for women or for which it is unknown whether such factors or types are different for women
3. With respect to which there has been insufficient clinical research involving women as subjects or insufficient clinical data on women

Research on women's health conditions includes research on prevention and applies to women of all ages and racial and ethnic groups.

A variety of spending categories for diseases or disorders relevant to women are used for budgetary reporting on women's health research. For this report, ORWH presents the disease and budget information in three topic areas:

1. Diseases and conditions that are female-specific
2. Diseases and conditions that predominately affect women
3. Other selected diseases and conditions

Specifically, diseases and conditions in topic areas one and two were identified by NIH scientists from the RCDC list as being highly relevant to the health
of women. Topic area three contains ORWH-selected RCDC categories that affect both women and men, however with important implications for women.

## II. Reporting Methodology Data Source

In previous reporting cycles, NIH used the Moyer Women's Health Crosscutting Category report (known as the Moyer Report) to classify women's health research budgets by disease and health condition category. The U.S. Department of Health and Human Services (HHS) mandated that the Moyer Report have specific disease categories and budget allocation definitions. Prior to FY 2020, all HHS agencies, including NIH, were required to submit data annually for the Moyer Report. Although HHS made a few adjustments over time, the primary guidance generally remained the same.

Starting in FY 2020, NIH did not receive a request from HHS to complete the Moyer data collection. Therefore, we needed to identify alternative data sources and analytical methods for this report. ORWH determined that using the NIH RCDC data set and its internal "Search and Visualize" intersect tool to generate the budget estimate would be the most effective alternative and was consistent with the advice offered by the NIH Office of Extramural Research (OER) and the NIH Office of Budget (OB). This approach allowed ORWH to leverage official data thoroughly, validated by the proven RCDC process. This approach also allowed ORWH to access the advanced analytical tools necessary to reliably perform data manipulations to parse womenfocused research from the general pool of actual projects reported for relevant RCDC categories.

Reporting for the RCDC categories reflects an automated approach to identifying projects relevant to each topic according to specific criteria that characterize the disease, condition, and study areas determined by NIH scientific subject matter experts. Relevant research for each category can include
basic science, preclinical, clinical, health services, behavioral, social, translational, training, and policy assessment projects. Historically, clinical research projects were assigned to the RCDC Women's Health category based on data from the inclusion process. Prior to FY 2019, NIH Institutes, Centers, and Offices (ICOs) used a manual approach to identify relevant studies and assign cost allocations for qualified projects. In FY 2019, subject matter experts across ICOs achieved consensus that the allocation of women's health-related spending should be grounded in more rigorous definitions of scientific relevance and developed new prorating guidance accordingly. To ensure a robust reporting transition, starting with the FY 2019 actuals reporting cycle, ICOs applied new definitions only to the competing projects and retained previous prorating schemes for the noncompeting awards, which will gradually roll out in subsequent fiscal years to achieve improved consistency. As of FY 2022, NIH has developed 315 RCDC categories for public reporting and ORWH identified approximately 40 diseases and health conditions that are highly relevant to the health of women to be included in this report. Individual research projects can involve multiple scientific topics and the RCDC categorization is not mutually exclusive; therefore, the total spending amounts across the RCDC categories will not add up to $100 \%$.

## Analytical Approach

Although some spending categories are female-specific, many diseases and health conditions presented in this report affect males as well. For female-specific diseases and health conditions-such as Gynecological Cancers and Endometriosis-the RCDC research budgets are reported at $100 \%$. However, for health conditions that affect males and females, ORWH must estimate how much of the total RCDC investments were relevant to women's health. Following OER's and OB's guidance, ORWH used the internal RCDC "Search and Visualize" intersect tool to accomplish this goal. This approach allowed ORWH to leverage official data that was validated by the proven RCDC process and to access the advanced analytical tools necessary to reliably perform data manipulations to parse womenfocused research from the general pool of actual projects reported for relevant RCDC categories.

To determine the number of individuals participating in clinical research cross-cut with the RCDC categories, a query tool known as NIH RCDC Inclusion Statistics Report (RISR) is made publicly available. These numbers reflect the median proportion of clinical research participants for various demographic groups within each RCDC category. Because RCDC categories contain more than clinical research projects, financial calculations to allocate spending by sex/gender cannot be produced by using only the number of participants provided by RISR.

## III. Principles of Interpreting the Data Tables

As mentioned, HHS did not request a Moyer Report in FY 2020. Therefore, the FY 2019-2020 ACRWH biennial report did not present the FY 2020 research spending. In that reporting cycle, ORWH included the FY 2020 data to fill the information gap using the new analytical methods.

Table 1 summarizes the overall research expenditures for specific diseases and health conditions from FY 2020 to FY 2022. The columns are split into "Women" and "Total." Each RCDC category parameter is developed independently based on criteria contributed by NIH-wide subject matter experts. The parameters are applied to determine funded projects relevant to each topic area. (For example, projects that match key terms in the "breast cancer" topic definition would have costs counted to the Breast Cancer category.) When intersecting the Women's Health category with any other RCDC category, this can affect how the financials are included in the cross-cut "Total" column. Projects that do not meet the Women's Health parameters may include research on males; research spanning multiple genders, i.e., both men and women, and/or sexes; or research with deidentified data. For Table 1, the "Total" column is the annual NIH-wide amount displayed for a given fiscal year for each topic on the NIH RePORT page that lists categorical spending. The "Women" column amounts are limited to the sum value of projects listed in the cross-cut category. NIH does not currently calculate or report annual funding associated with projects dedicated solely to men's health or projects benefiting men and women.

Table 2 presents the over-time percentage change in spending on the disease and health condition categories. However, because of changes in methodology, comparing the analytical results in this reporting cycle with the previous ACRWH biennial reports would not be appropriate.

## IV. Summary of Key Findings Total Women's Health Research Budget in NIH

As shown in Table 1 and Table 2, NIH invested $\$ 4.47$ billion in women's health research in FY 2020. Between FY 2020 and FY 2021, the total spending increased by $3.2 \%$. However, the research expenditure in FY 2022 was $\$ 4.59$ billion, indicating a $0.4 \%$ decrease from FY 2021 to FY 2022. Overall, NIH increased its support for women's health research by $2.8 \%$ over the course of 3 years.

## Female-Specific Diseases and Conditions

Spending for several high-priority topics increased between FY 2020 and FY 2022, including Violence Against Women (41.5\% increase) and Pelvic Inflammatory Disease (25.8\% increase). However, spending for research on Fibroid Tumors (uterine) and Vulvodynia decreased by $15.1 \%$ and $37.9 \%$, respectively. The decline in research expenditure may have been caused by funding ICOs lacking meritorious applications and, therefore, supporting fewer awards than in prior years. ICOs may also shift their program priorities and reallocate resources to support other research topics that align with their scientific missions. Established in FY 2022, projects reported to the Polycystic Ovary Syndrome (PCOS) category received approximately $\$ 9.47$ million in funding.

From FY 2020 to FY 2021, the total spending for research on Cervical Cancer increased by $5.4 \%$, and the investment continued to grow. In FY 2022, the research expenditure reached nearly $\$ 146.97$ million, amounting to a $29.5 \%$ increase between FY 2020 and FY 2022. In October 2021, ORWH hosted the congressionally mandated Advancing NIH Research on the Health of Women: A 2021 Conference, which included a focus on addressing the stagnant cervical cancer survival rates. This
meeting increased the awareness and visibility of cervical cancer research and may have contributed to NIH's investments in this topic. Other femalespecific cancers include ovarian, uterine, and vaginal cancers. Ovarian Cancer research projects received $\$ 188.02$ million in FY 2020, but that decreased to $\$ 177.67$ million in FY 2022 (5.5\% reduction). Uterine Cancer research projects received $\$ 32.41$ million in FY 2020, and funding subsequently increased by $13.5 \%$ to $\$ 36.79$ million in FY 2022. Compared with research projects for other Gynecological Cancers, Vaginal Cancer research projects received less investment in FY 2020. However, the total spending for Vaginal Cancer increased by 43.2\% in FY 2022.

Studies on maternal health and maternal morbidity and mortality have gained immense attention at NIH in the past few years. Many ICOs participated in maternal health-related programs, including the Implementing a Maternal health and Pregnancy Outcomes Vision for Everyone (IMPROVE) initiative, launched in 2019 in response to high rates of pregnancy-related complications and deaths in the United States. In FY 2022, NIH appropriations included $\$ 30$ million to launch a national network of Maternal Health Research Centers of Excellence through the IMPROVE initiative. All these efforts contributed to the funding increase in Maternal Health research, from approximately $\$ 406.68$ million in FY 2020 to slightly more than $\$ 557.86$ million in FY 2022 (37.2\% increase). Established in FY 2020, the RCDC category of Maternal Morbidity and Mortality is a subcategory of Maternal Health. In FY 2020, the total spending for projects in the Maternal Morbidity and Mortality category was $\$ 223.52$ million. The amount grew to $\$ 346.27$ million in FY 2022, a 54.9\% increase.

## Diseases and Conditions that Predominately Affect Women

This section discusses diseases and health conditions identified by NIH women's health research scientists as predominately affecting women. Because these research topics also influence the health of men and children, ORWH uses the internal RCDC "Search and Visualize" intersect tool to estimate the share of spending attributable to women's health. The information below highlights the funding trends for selected topics.


Breastfeeding, Lactation, and Breast Milk research commonly focuses on women, although the study participants also include children regardless of sex. The total NIH investments in this topic grew from $\$ 96.42$ million to $\$ 141.47$ million, demonstrating a significant increase of $46.7 \%$. Of the total spending, the expenses targeting women were approximately $\$ 62.56$ million in FY 2020 and slightly under \$89.26 million in FY 2022, amounting to a $42.7 \%$ increase during this period.

Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) is much more frequently reported by women than men. Nonetheless, the
specific causes are still unknown. The total NIH investments in the ME/CFS research category decreased from \$14.63 million in FY 2020 to $\$ 12.62$ million in FY 2022, a cumulative 13.7\% decrease. Further analysis indicates that the annual spending on ME/CFS projects for women was reduced from $\$ 14.01$ million in FY 2020 to $\$ 11.87$ million in FY 2022, reflecting a $15.3 \%$ reduction. NIH has made various efforts to support ME/CFS research. Descriptions regarding the research programs, funding opportunities, scientific resources, and more are available on the Advancing ME/CFS Research webpage.

Between FY 2020 and FY 2022, several other topics had upward trends in women's health spending and total budgets. These diseases and conditions include, but are not limited to, Contraception/Reproduction, Estrogen, Infertility, Interstitial Cystitis, Osteoporosis, Pregnancy, and Rheumatoid Arthritis. Specifically, in FY 2022, more than 90\% of the total investments in Estrogen, HPV and/or Cervical Cancer vaccine, Lupus, and Pregnancy research focused on women. Dedicating substantial funds to these topics signifies NIH's commitment to promoting women's health throughout the scientific enterprise.

## Other Selected Diseases and Conditions

Many diseases and health conditions have high prevalence rates and significant impacts on women and men. This section discusses NIH's funding trends for selected topics from the RCDC list.

Aging is a topic highly relevant to both women and men. NIH's total investments in Aging research steadily increased during the reporting period, from $\$ 5.28$ billion in $F Y 2020$ to $\$ 6.04$ billion in $F Y$ 2022. However, an analysis focusing on women demonstrates that the funding amount declined slightly from $\$ 941.38$ million to $\$ 936.66$ million during this time frame ( $0.5 \%$ decline). As the U.S. encounters more challenges associated with population aging and because women have longer life expectancies than men (yet live more years with disability and chronic diseases), a research portfolio prioritizing women could generate critical insights into women's health care needs across the full life course.

Women bear a disproportionate burden of autoimmune diseases. Between FY 2020 and FY 2022, total NIH investments in Autoimmune Disease research remained relatively constant and decreased only slightly (\$1.083 billion and \$1.079 billion, respectively, a cumulative $0.4 \%$ decline). However, when we analyzed the expenditures for Autoimmune Disease research focused on women, it became clear that there was a downward funding trend during the same period.

A holistic assessment of the health of women cannot ignore mental health. Between FY 2020 and FY 2022, NIH's total expenditure on Mental Health
research increased by $12.1 \%$. Within this funding pool, women's Mental Health research spending expanded from $\$ 791$ million in FY 2020 to $\$ 954.13$ million, amounting to a significant increase of $20.6 \%$.

Pain management and substance misuse have critical implications on public health. In 2018, the \$500 million NIH-wide Helping to End Addiction Long-term Initiative (HEAL Initiative) was launched to speed up the development of scientific solutions in response to the national opioid public health crisis. The initiative focuses on pain management and addiction and has increased investments in these topics each year. Examining NIH's Chronic Pain portfolio indicates that NIH's total spending increased from $\$ 688.79$ million in FY 2020 to $\$ 801.27$ million in FY 2022. However, an analysis of the funding trends on women's Chronic Pain research reveals that the expenditures decreased by $7.7 \%$ between FY 2020 and FY 2022. Finally, NIH's total spending for the Substance Misuse category increased by 8.1\% between FY 2020 and FY 2022. In FY 2022, the spending on women's Substance Misuse research was $\$ 557.53$ million, which constituted $22 \%$ of the NIH funding portfolio in the category.

## V. Conclusion

The diseases and health conditions discussed above are essential research areas in relation to women's health; continued efforts are needed to support scientific investigations on these highpriority topics. Because many of those topics affect both women and men, ORWH will continue to collaborate with the NIH community to explore feasible methods of analyzing data for genderbased comparison that can better address public health concerns.

Table 1: NIH Research Budget for Women's Health by Disease and Health Conditions, FY 2020 to FY 2022 (Actual Obligations in Dollars)

| Disease and Health Condition Category | Women |  |  | Total |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Diseases and Conditions That Are Female Specific ${ }^{1}$ | FY 2020 | FY 2021 | FY 2022 | FY 2020 | FY 2021 | FY 2022 |
| Breast Cancer* | 731,474,089 | 717,065,908 | 730,346,402 | 788,082,599 | 730,719,306 | 738,490,735 |
| Cervical Cancer | 113,490,444 | 119,601,584 | 146,966,960 | 113,490,444 | 119,601,584 | 146,966,960 |
| Ovarian Cancer | 188,023,116 | 178,126,034 | 177,671,146 | 188,023,116 | 178,126,034 | 177,671,146 |
| Uterine Cancer | 32,408,916 | 29,411,167 | 36,792,176 | 32,408,916 | 29,411,167 | 36,792,176 |
| Vaginal Cancer | 2,143,367 | 1,975,062 | 3,068,463 | 2,143,367 | 1,975,062 | 3,068,463 |
| Endometriosis | 14,406,600 | 20,153,147 | 27,325,202 | 14,406,600 | 20,153,147 | 27,325,202 |
| Fibroid Tumors (Uterine) | 17,512,224 | 15,643,128 | 14,859,351 | 17,512,224 | 15,643,128 | 14,859,351 |
| Maternal Health | 406,679,474 | 422,148,982 | 557,863,986 | 406,679,474 | 422,148,982 | 557,863,986 |
| Maternal Morbidity and Mortality | 223,522,448 | 240,376,950 | 346,268,226 | 223,522,448 | 240,376,950 | 346,268,226 |
| Pelvic Inflammatory Disease | 5,280,250 | 5,599,157 | 6,641,838 | 5,280,250 | 5,599,157 | 6,641,838 |
| Polycystic Ovary Syndrome (PCOS)** | -- | -- | 9,470,953 | -- | -- | 9,470,953 |
| Violence Against Women | 39,319,092 | 46,065,281 | 55,644,229 | 39,319,092 | 46,065,281 | 55,644,229 |
| Vulvodynia | 2,051,163 | 1,075,056 | 1,274,126 | 2,051,163 | 1,075,056 | 1,274,126 |
| Diseases and Conditions That Predominately Affect Women ${ }^{2}$ | FY 2020 | FY 2021 | FY 2022 | FY 2020 | FY 2021 | FY 2022 |
| Breastfeeding, Lactation, and Breast Milk | 62,563,267 | 84,076,123 | 89,255,190 | 96,416,275 | 120,236,954 | 141,473,819 |
| Chronic Fatigue Syndrome (ME/CFS) | 14,012,124 | 15,984,093 | 11,865,186 | 14,626,036 | 16,833,926 | 12,617,492 |
| Contraception/Reproduction | 426,433,315 | 432,210,952 | 530,474,782 | 592,692,614 | 588,403,995 | 703,262,323 |
| Estrogen | 231,122,073 | 247,993,212 | 261,306,655 | 259,263,805 | 273,609,570 | 287,282,211 |
| Fibromyalgia | 12,943,148 | 12,890,952 | 10,624,267 | 23,843,435 | 13,280,397 | 12,121,588 |
| HPV and/or Cervical Cancer Vaccine | 45,989,089 | 46,261,546 | 59,687,589 | 46,961,325 | 46,261,546 | 61,278,308 |
| Infertility | 100,987,731 | 130,218,648 | 112,267,132 | 160,913,468 | 192,464,056 | 189,292,570 |
| Interstitial Cystitis | 7,693,999 | 12,687,216 | 16,684,148 | 12,618,011 | 16,717,380 | 20,418,745 |
| Lupus | 102,436,722 | 113,341,636 | 125,893,766 | 133,559,103 | 128,562,836 | 138,258,486 |
| Osteoporosis | 108,730,786 | 113,323,081 | 126,858,345 | 148,254,627 | 154,546,021 | 156,393,783 |
| Pregnancy | 505,716,103 | 508,796,322 | 607,499,486 | 550,452,146 | 536,814,152 | 634,948,705 |
| Rett Syndrome | 12,535,666 | 12,993,771 | 12,601,643 | 14,826,019 | 17,598,375 | 17,665,287 |
| Rheumatoid Arthritis | 68,372,076 | 72,954,836 | 73,140,266 | 86,561,708 | 93,118,852 | 91,534,418 |
| Scleroderma | 16,662,834 | 14,223,093 | 18,567,624 | 23,642,209 | 21,170,675 | 24,671,846 |
| Teenage Pregnancy | 10,579,658 | 15,581,062 | 14,122,259 | 11,420,179 | 17,818,632 | 16,515,587 |
| Other Selected Diseases and Conditions ${ }^{3}$ | FY 2020 | FY 2021 | FY 2022 | FY 2020 | FY 2021 | FY 2022 |
| Aging | 941,376,117 | 900,975,455 | 936,655,650 | 5,276,202,651 | 5,656,810,969 | 6,044,318,505 |
| Autoimmune Disease | 334,909,083 | 317,858,662 | 298,062,187 | 1,083,240,705 | 1,021,238,482 | 1,079,060,825 |
| Cardiovascular | 669,812,348 | 552,424,668 | 586,481,097 | 2,535,568,507 | 2,543,925,342 | 2,758,232,421 |
| Caregiving Research | 28,582,461 | 27,378,090 | 28,180,382 | 216,667,321 | 244,371,732 | 233,716,382 |
| Other Selected Diseases and Conditions ${ }^{3}$ | FY 2020 | FY 2021 | FY 2022 | FY 2020 | FY 2021 | FY 2022 |


| Disease and Health <br> Condition Category | Women |  |  |  |  |  |
| :--- | :--- | :--- | :--- | :--- | :--- | :--- |
| Chronic Obstructive <br> Pulmonary Disease (COPD) | $32,555,015$ | $32,792,567$ | $17,844,018$ | $120,880,627$ | $143,713,457$ | $142,545,842$ |
| Chronic Pain | $203,383,105$ | $200,077,636$ | $187,667,395$ | $688,792,004$ | $725,253,291$ | $801,270,213$ |
| Diabetes | $300,384,523$ | $230,273,907$ | $182,918,284$ | $1,155,718,274$ | $1,123,660,027$ | $1,168,901,441$ |
| Mental Health | $791,003,339$ | $827,642,570$ | $954,130,483$ | $3,576,711,907$ | $3,666,276,012$ | $4,008,249,881$ |
| Microbiome | $194,280,319$ | $222,881,698$ | $206,808,367$ | $851,651,944$ | $863,662,988$ | $917,103,766$ |
| Migraines | $9,390,005$ | $12,179,923$ | $13,660,978$ | $27,780,613$ | $40,359,849$ | $46,162,390$ |
| Multiple Sclerosis | $26,950,097$ | $19,726,840$ | $14,629,225$ | $123,956,013$ | $125,988,867$ | $121,468,111$ |
| Sexually Transmitted <br> Infections | $196,038,888$ | $182,387,466$ | $189,527,345$ | $393,894,578$ | $361,588,711$ | $366,021,907$ |
| Substance Misuse | $638,817,421$ | $615,289,634$ | $557,530,901$ | $2,292,925,527$ | $2,339,746,949$ | $2,479,724,886$ |
| Temporomandibular Muscle/ <br> Joint Disorder (TMJD) | $16,421,162$ | $13,173,355$ | $15,738,233$ | $16,869,746$ | $13,631,817$ | $34,735,752$ |
| Total Women's Health <br> Research | $4,465,880,158$ | $4,609,937,572$ | $4,592,531,730$ |  |  |  |

Source: NIH Research, Condition, and Disease Categorization (RCDC) database and the internal RCDC "Search and Visualize" intersect tool.
${ }^{1}$ RCDC diseases and health conditions identified by the NIH women's health research scientists.
*According to CDC, "about one out of every 100 breast cancers diagnosed in the United States is found in a man" (https://www.cdc.gov/cancer/breast/men/index.htm). Because breast cancer prevalence is much higher among women than men, NIH scientists agreed to include breast cancer in the "diseases and conditions that specifically affect women and girls" category.
**The Polycystic Ovary Syndrome (PCOS) category was established in FY 2022.
${ }^{2}$ RCDC diseases and health conditions identified by the NIH women's health research scientists, using the RCDC data system intersect feature to subset women's health-associated funding.
${ }^{3}$ Additional diseases and health conditions identified by the NIH Office of Research on Women's Health (ORWH), using the RCDC data system intersect feature to subset women's health-associated funding.
Note: The RCDC categories are not mutually exclusive, and individual research projects can be included in multiple reporting categories. Therefore, research spending presented in this table does not add up to $100 \%$ of NIH-funded research.

Table 2: NIH Research Budget for Women's Health by Disease and Health Conditions, FY 2020 to FY 2022 (Percentage Change in Spending)

| Disease and Health Condition Category | Women |  |  | Total |  |  |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| Diseases and Conditions That Are Female Specific ${ }^{1}$ | FY 2020 <br> FY 2021 | FY 2021 <br> FY 2022 | FY 2020 <br> FY 2022 | FY 2020 <br> FY 2021 | FY 2021 <br> FY 2022 | FY 2020 <br> FY 2022 |
| Breast Cancer* | -2.0\% | 1.9\% | -0.2\% | -7.3\% | 1.1\% | -6.3\% |
| Cervical Cancer | 5.4\% | 22.9\% | 29.5\% | 5.4\% | 22.9\% | 29.5\% |
| Ovarian Cancer | -5.3\% | -0.3\% | -5.5\% | -5.3\% | -0.3\% | -5.5\% |
| Uterine Cancer | -9.2\% | 25.1\% | 13.5\% | -9.2\% | 25.1\% | 13.5\% |
| Vaginal Cancer | -7.9\% | 55.4\% | 43.2\% | -7.9\% | 55.4\% | 43.2\% |
| Endometriosis | 39.9\% | 35.6\% | 89.7\% | 39.9\% | 35.6\% | 89.7\% |
| Fibroid Tumors (Uterine) | -10.7\% | -5.0\% | -15.1\% | -10.7\% | -5.0\% | -15.1\% |
| Maternal Health | 3.8\% | 32.1\% | 37.2\% | 3.8\% | 32.1\% | 37.2\% |
| Maternal Morbidity and Mortality | 7.5\% | 44.1\% | 54.9\% | 7.5\% | 44.1\% | 54.9\% |
| Pelvic Inflammatory Disease | 6.0\% | 18.6\% | 25.8\% | 6.0\% | 18.6\% | 25.8\% |
| Polycystic Ovary Syndrome (PCOS)** | -- | -- | -- | -- | -- | -- |
| Violence Against Women | 17.2\% | 20.8\% | 41.5\% | 17.2\% | 20.8\% | 41.5\% |
| Vulvodynia | -47.6\% | 18.5\% | -37.9\% | -47.6\% | 18.5\% | -37.9\% |
| Diseases and Conditions That Predominately Affect Women ${ }^{2}$ | FY 2020 <br> FY 2021 | FY 2021 <br> FY 2022 | FY 2020 <br> FY 2022 | FY 2020 <br> FY 2021 | FY 2021 <br> FY 2022 | FY 2020 <br> FY 2022 |
| Breastfeeding, Lactation, and Breast Milk | 34.4\% | 6.2\% | 42.7\% | 24.7\% | 17.7\% | 46.7\% |
| Chronic Fatigue Syndrome (ME/CFS) | 14.1\% | -25.8\% | -15.3\% | 15.1\% | -25.0\% | -13.7\% |
| Contraception/Reproduction | 1.4\% | 22.7\% | 24.4\% | -0.7\% | 19.5\% | 18.7\% |
| Estrogen | 7.3\% | 5.4\% | 13.1\% | 5.5\% | 5.0\% | 10.8\% |
| Fibromyalgia | -0.4\% | -17.6\% | -17.9\% | -44.3\% | -8.7\% | -49.2\% |
| HPV and/or Cervical Cancer Vaccine | 0.6\% | 29.0\% | 29.8\% | -1.5\% | 32.5\% | 30.5\% |
| Infertility | 28.9\% | -13.8\% | 11.2\% | 19.6\% | -1.6\% | 17.6\% |
| Interstitial Cystitis | 64.9\% | 31.5\% | 116.8\% | 32.5\% | 22.1\% | 61.8\% |
| Lupus | 10.6\% | 11.1\% | 22.9\% | -3.7\% | 7.5\% | 3.5\% |
| Osteoporosis | 4.2\% | 11.9\% | 16.7\% | 4.2\% | 1.2\% | 5.5\% |
| Pregnancy | 0.6\% | 19.4\% | 20.1\% | -2.5\% | 18.3\% | 15.4\% |
| Rett Syndrome | 3.7\% | -3.0\% | 0.5\% | 18.7\% | 0.4\% | 19.2\% |
| Rheumatoid Arthritis | 6.7\% | 0.3\% | 7.0\% | 7.6\% | -1.7\% | 5.7\% |
| Scleroderma | -14.6\% | 30.5\% | 11.4\% | -10.5\% | 16.5\% | 4.4\% |
| Teenage Pregnancy | 47.3\% | -9.4\% | 33.5\% | 56.0\% | -7.3\% | 44.6\% |
| Other Selected Diseases and Conditions ${ }^{3}$ | FY 2020 <br> FY 2021 | FY 2021 <br> FY 2022 | FY 2020 <br> FY 2022 | FY 2020 <br> FY 2021 | FY 2021 <br> FY 2022 | FY 2020 <br> FY 2022 |
| Aging | -4.3\% | 4.0\% | -0.5\% | 7.2\% | 6.9\% | 14.6\% |
| Autoimmune Disease | -5.1\% | -6.2\% | -11.0\% | -5.7\% | 5.7\% | -0.4\% |
| Cardiovascular | -17.5\% | 6.2\% | -12.4\% | 0.3\% | 8.4\% | 8.8\% |
| Caregiving Research | -4.2\% | 2.9\% | -1.4\% | 12.8\% | -4.4\% | 7.9\% |
| Other Selected Diseases and Conditions ${ }^{3}$ | $\begin{aligned} & \text { FY } 2020 \\ & \text { FY } 2021 \end{aligned}$ | FY 2021 <br> FY 2022 | $\begin{aligned} & \text { FY } 2020 \\ & \text { FY } 2022 \end{aligned}$ | $\begin{aligned} & \text { FY } 2020 \\ & \text { FY } 2021 \end{aligned}$ | FY 2021 <br> FY 2022 | $\begin{aligned} & \text { FY } 2020 \\ & \text { FY } 2022 \end{aligned}$ |


| Disease and Health <br> Condition Category | Women |  |  |  |  |  |
| :--- | :--- | :--- | :--- | :--- | :--- | :--- |
| Chronic Obstructive <br> Pulmonary Disease (COPD) | $0.7 \%$ | $-45.6 \%$ | $-45.2 \%$ | $18.9 \%$ | $-0.8 \%$ | $17.9 \%$ |
| Chronic Pain | $-1.6 \%$ | $-6.2 \%$ | $-7.7 \%$ | $5.3 \%$ | $10.5 \%$ | $16.3 \%$ |
| Diabetes | $-23.3 \%$ | $-20.6 \%$ | $-39.1 \%$ | $-2.8 \%$ | $4.0 \%$ | $1.1 \%$ |
| Mental Health | $4.6 \%$ | $15.3 \%$ | $20.6 \%$ | $2.5 \%$ | $9.3 \%$ | $12.1 \%$ |
| Microbiome | $14.7 \%$ | $-7.2 \%$ | $6.4 \%$ | $1.4 \%$ | $6.2 \%$ | $7.7 \%$ |
| Migraines | $29.7 \%$ | $12.2 \%$ | $45.5 \%$ | $45.3 \%$ | $14.4 \%$ | $66.2 \%$ |
| Multiple Sclerosis | $-26.8 \%$ | $-25.8 \%$ | $-45.7 \%$ | $1.6 \%$ | $-3.6 \%$ | $-2.0 \%$ |
| Sexually Transmitted <br> Infections | $-7.0 \%$ | $3.9 \%$ | $-3.3 \%$ | $-8.2 \%$ | $1.2 \%$ | $-7.1 \%$ |
| Substance Misuse | $-3.7 \%$ | $-9.4 \%$ | $-12.7 \%$ | $2.0 \%$ | $6.0 \%$ | $8.1 \%$ |
| Temporomandibular Muscle/ <br> Joint Disorder (TMJD) | $-19.8 \%$ | $19.5 \%$ | $-4.2 \%$ | $-19.2 \%$ | $154.8 \%$ | $105.9 \%$ |
| Total Women's Health <br> Research | $3.2 \%$ | $\mathbf{0 . 4 \%}$ | $2.8 \%$ |  |  |  |

Source: NIH Research, Condition, and Disease Categorization (RCDC) database and the internal RCDC "Search and Visualize" intersect tool.
${ }^{1}$ RCDC diseases and health conditions identified by the NIH women's health research scientists.
*According to CDC, "about one out of every 100 breast cancers diagnosed in the United States is found in a man" (https://www.cdc.gov/cancer/breast/men/index.htm). Because breast cancer prevalence is much higher among women than men, NIH scientists agreed to include breast cancer in the "diseases and conditions that specifically affect women and girls" category.
**The Polycystic Ovary Syndrome (PCOS) category was established in FY 2022.
${ }^{2}$ RCDC diseases and health conditions identified by the NIH women's health research scientists, using the RCDC data system intersect feature to subset women's health-associated funding.
${ }^{3}$ Additional diseases and health conditions identified by the NIH Office of Research on Women's Health (ORWH), using the RCDC data system intersect feature to subset women's health-associated funding.
Note: The RCDC categories are not mutually exclusive, and individual research projects can be included in multiple reporting categories. Therefore, research spending presented in this table does not add up to $100 \%$ of NIH-funded research.

# Report of the NIH Institutes 

## National Cancer Institute

## I. Overview

To fulfill its mission, the National Cancer Institute ( NCl ) supports research across the cancer continuum, from basic and translational research to clinical and population science studies on all types of cancer. This report highlights examples of progress being made in cancers specific to or primarily affecting women, plus sex differences in response to cancer treatment. It also highlights NCl's interest in multiple cross-cutting themes, including supporting research that addresses disparities for women from racial/ethnic and/or underserved populations that are disproportionately affected by certain cancers.

## II. Scientific Advances in Research on the Health of Women

## New Targeted Therapy for Triple-Negative

Breast Cancer. Triple-negative breast cancer is an aggressive breast cancer subtype with a poor prognosis. Until recently, chemotherapy was the only available treatment option. In 2021, data from a Phase III clinical trial evaluating a novel antibody-drug conjugate led to Food and Drug Administration approval of a biologic drug (sacituzumab govitecan). The approval is for patients with triple-negative breast cancer that is locally advanced or has metastasized and cannot be removed by surgery. Overall, for patients without brain metastases, the drug was more effective than chemotherapy regardless of a patient's age, race, and previous therapies. ${ }^{1}$

## Trametinib Increases Progression-Free Survival in Women with Low-Grade Serous Ovarian

Cancer. Low-grade serous ovarian cancer (LGSC) is a rare form of ovarian cancer that does not have an established optimal first-line treatment. Moreover, $70 \%$ of patients relapse, and subsequent
chemotherapy is ineffective. In a Phase II and III clinical trial in women with relapsed or persistent LGSC that compared physicians' choice with the targeted therapy trametinib, trametinib increased progression-free survival and objective response rate. ${ }^{2}$ As a result, trametinib was put on the National Comprehensive Cancer Network's compendium of drugs for LGSC, enabling most patients who might benefit from the drug in the United States to receive insurance coverage for trametinib treatment. Trametinib may become a new standard-of-care treatment option for women with recurrent LGSC.

Women Experience Severe Side Effects from Cancer Treatment More Frequently Than Men. Studies show that women undergoing chemotherapy experience adverse events more often than men, and those receiving immunotherapy have a nearly $50 \%$ higher risk of adverse events than men. A new analysis found that overall, women had a 34\% higher risk of adverse events than men from any therapy. It is not yet clear why these sex differences exist, but they may be caused by differences in drug metabolism, adherence to therapy, or other factors. ${ }^{3}$ This study suggests that a patient's biological sex should be included in the evaluation of risk for adverse effects.

Rising Uterine Cancer Mortality Rates Are Highest Among Black Women. There are two types of endometrial cancer: (1) endometrioid, which is more common and has better outcomes, and (2) non-endometrioid. Uterine cancer rates have increased over the past two decades and are predicted to continue rising. A recent study found that from 2010 to 2017, the rates of death from non-endometrioid tumors increased by $2.7 \%$ each year, while endometrioid death rates did not change, indicating that most of the increase in mortality is attributable to non-endometrioid uterine cancer, which disproportionately affects Black people and Hispanic people. ${ }^{4}$ Black women are also twice as likely to die of uterine cancer as other racial/ethnic groups.

## III. Future Priorities in Research on the Health of Women

NCl's research priorities important to the health of women include increasing diversity in clinical trial accrual, eliminating cancer disparities, and developing methods to deliver high-quality cancer care to all.

1. Bardia, A., Hurvitz, S. A., Tolaney, S. M., Loirat, D., Punie, K., Oliveira, M., Brufsky, A., Sardesai, S. D., Kalinsky, K., Zelnak, A. B., Weaver, R., Traina, T., Dalenc, F., Aftimos, P., Lynce, F., Diab, S., Cortés, J., O’Shaughnessy, J., Diéras, V., ... Rugo, H. S. (2021). Sacituzumab govitecan in metastatic triple-negative breast cancer. The New England Journal of Medicine, 384(16), 1529-1541. https://doi.org/10.1056/nejmoa2028485
2. Gershenson, D. M., Miller, A., Brady, W. E., Paul, J., Carty, K., Rodgers, W., Millan, D., Coleman, R. L., Moore, K. N., Banerjee, S., Connolly, K., Secord, A. A., O’Malley, D. M., Dorigo, O., Gaillard, S., Gabra, H., Slomovitz, B., Hanjani, P., Farley, J., ... Gourley, C. (2022). Trametinib versus standard of care in patients with recurrent low-grade serous ovarian cancer (Gog 281/ $\operatorname{logs}):$ An international, randomised, open-label, multicentre, phase 2/3 trial. The Lancet, 399(10324), 541-553. https://doi.org/10.1016/s0140-6736(21)02175-9
3. Unger, J. M., Vaidya, R., Albain, K. S., LeBlanc, M., Minasian, L. M., Gotay, C. C., Henry, N. L., Fisch, M. J., Lee, S. M., Blanke, C. D., \& Hershman, D. L. (2022). Sex differences in risk of severe adverse events in patients receiving immunotherapy, targeted therapy, or chemotherapy in cancer clinical trials. Journal of Clinical Oncology, 40(13), 1474-1486. https://doi.org/10.1200/ico.21.02377
4. Clarke, M. A., Devesa, S. S., Hammer, A., \& Wentzensen, N. (2022). Racial and ethnic differences in hysterectomy-corrected uterine corpus cancer mortality by stage and histologic subtype. JAMA Oncology, 8(6), 895-903. https://doi. org/doi:10.1001/jamaoncol.2022.0009

## National Eye Institute

## I. Overview

The mission of the National Eye Institute (NEI) is to eliminate vision loss and improve quality of life through vision research. Most eye diseases that are more prevalent in women than men affect the anterior segment of the eye, such as dry eye disease (DED) and Sjögren's syndrome (SS), Fuchs' endothelial corneal dystrophy (FECD), cataracts, and uveitis. Since the implementation of the NIH Policy on Sex as a Biological Variable, more subtle sex differences, such as in herpes zoster ophthalmicus (HZO) and ocular pain, have been identified. In recent years, specific receptors for sex hormones (SH) have been found on the lacrimal and meibomian glands, conjunctiva, cornea, lens, retina, and choroid. However, the idea that SH play a significant role in ocular diseases is controversial. A better understanding of the role that SH play in the pathogenesis of eye diseases is needed to improve the management of eye diseases and lay the foundation for new therapeutic strategies. ${ }^{1}$

## II. Scientific Advances in Research on the Health of Women

The Dry Eye Assessment and Management (DREAM) Study showed an association between depression and DED severity; however, the therapeutic implication is unclear. Preclinical studies have demonstrated that a nonsteroidal cofactor, $3 \beta$-hydroxysteroid dehydrogenase, and a prostaglandin analogue may be therapeutic avenues to treat DED and SS. ${ }^{2}$

FECD treatment often requires a corneal transplant. However, recently, fibroblast growth factor 1 (FGF1) was shown to drive regeneration of the corneal endothelial layer in vitro. In 2021, a therapeutic company developed an engineered human FGF1, TTHX114, which is now being evaluated in a clinical trial for the treatment of FECD. Preclinical findings also show that TTHX114 is an antiinflammatory agent that reduces the duration of corneal keratopathy and recurrent HZO. ${ }^{3}$

Recently, secondary data analysis showed sex differences in the effectiveness of the herpes zoster vaccine, suggesting the vaccine is more effective against HZO in females. ${ }^{4}$

The Society for Women's Health Research's patient toolkit on women's eye health was published to provide information on the impact of sex and gender on women's eye health across the lifespan. In FY 2021-2022 NEI began developing a free website to provide information on the effects of aging, autoimmune conditions, and hormonal changes in women that often come with visionrelated side effects.

## III. Future Priorities in Research on the Health of Women

In collaboration with ORWH, NEI will continue its commitment to supporting vision research in women through co-funding the following types of research: (1) assessing the risk of HZO and ocular inflammation following COVID-19 vaccination and the effects of the herpes zoster vaccine on COVID-19 diagnosis and severity; ${ }^{5}$ (2) secondary data analysis from the Women's Health Initiative
to examine the relationship between body mass index score and FECD and estrogen as a potential treatment; ${ }^{6}$ (3) determining sex differences in the ocular microbiome and its relevance to diseases; ${ }^{7}$ and (4) developing the electroretinogram as a diagnostic tool for understanding sex differences in retinal function and as a predictor of retinal normalcy and prognostic indicator of brain disorders. ${ }^{8}$

1. Nuzzi, R., \& Caselgrandi, P. (2022, March 17). Sex hormones and their effects on ocular disorders and pathophysiology: Current aspects and our experience. Multidisciplinary Digital Publishing Institute. https://doi. org/10.3390/ijms23063269
2. Galor, A. (2022). How depression might relate to dry eye disease. JAMA Ophthalmology, 140(4), 399. https://doi.org/10.1001/ jamaophthalmol. 2022.0146
Sasaki, L., Hamada, Y., Yarimizu, D., Suzuki, T., Nakamura, H., Shimada, A., Pham, K. T., Shao, X., Yamamura, K., Inatomi, T., Morinaga, H., Nishimura, E. K., Kudo, F., Manabe, I., Haraguchi, S., Sugiura, Y., Suematsu, M., Kinoshita, S., Machida, M., ... Doi, M. (2022). Intracrine activity involving NAD-dependent circadian steroidogenic activity governs age-associated meibomian gland dysfunction. Nature Aging, 2(2), 105-114. https://doi. org/10.1038/s43587-021-00167-8

Zhou, Y., Murrough, J., Yu, Y., Roy, N., Sayegh, R., Asbell, P., Maguire, M. G., \& Ying, G.-shuang. (2022). Association between depression and severity of dry eye symptoms, signs, and inflammatory markers in the DREAM Study. JAMA Ophthalmology, 140(4), 392. https://doi.org/10.1001/ jamaophthalmol. 2022.0140
Ziemanski, J. F., Wilson, L., Barnes, S., \& Nichols, K. K. (202AD). Prostaglandin E2 and F2A alter expression of select cholesteryl esters and triacylglycerols produced by human meibomian gland epithelial cells. Cornea, 41(1), 95-105. https://doi.org/10.1097/ico.0000000000002835
3. Dhanushkodi, N. R., Srivastava, R., Coulon, P.-G. A., Prakash, S., Roy, S., Bagnol, D., David, E. D., \& BenMohamed, L. (2021). Healing of ocular herpetic disease following treatment with an engineered FGF-1 is associated with increased corneal anti-inflammatory M2 macrophages. Frontiers in Immunology, 12. https://doi.org/10.3389/fimmu.2021.673763

Eveleth, D., Pizzuto, S., Weant, J., Jenkins-Eveleth, J., \& Bradshaw, R. A. (2020). Proliferation of human corneal endothelia in organ culture stimulated by wounding and the engineered human fibroblast growth factor 1 derivative TTHX1114. Journal of Ocular Pharmacology and Therapeutics, 36(9), 686-696. https://doi.org/10.1089/iop.2019.0119
4. Lu, A., Sun, Y., Porco, T. C., Arnold, B. F., \& Acharya, N. R. (2021). Effectiveness of the recombinant zoster vaccine for herpes zoster ophthalmicus in the United States. Ophthalmology, 128(12), 1699-1707. https://doi. org/10.1016/j.ophtha.2021.04.017
National Eye Institute. (2021, May 17). Workshop: Immunity and Inflammation in the Anterior Segment of the Eye. https:// www.nei.nih.gov/sites/default/files/2022-02/ASI Wrksh EC Summary 2022-01-31 1800 508.pdf
Sun, Y., Jackson, K., Dalmon, C. A., Shapiro, B. L., Nie, S., Wong, C., Arnold, B. F., Porco, T. C., \& Acharya, N. R. (2021). Effectiveness of the recombinant zoster vaccine among Kaiser Permanente Hawaii enrollees aged 50 and older: A retrospective cohort study. Vaccine, 39(29), 3974-3982. https://doi. org/10.1016/i.vaccine.2021.05.056
5. Testi, I., Brandão-de-Resende, C., Agrawal, R., et al. (2022). Ocular inflammatory events following COVID-19 vaccination: a multinational case series. Journal of Opthalmic Inflammation and Infection, 12(4). https://doi. org/10.1186/s12348-021-00275-x
6. Kinariwala, B. B., Xu, T. T., Baratz, K. H., Aleff, R. A., Patel, S. V., Maguire, L. J., Fautsch, M. P., Wieben, E. D., Millen, A. E., \& Patel, S. P. (2021). Relationship of body mass index with Fuchs endothelial corneal dystrophy severity and TCF4 CTG18.1 trinucleotide repeat expansion. Cornea, Publish Ahead of Print. https://doi.org/10.1097/ico.00000000000002689
7. Neuhold, L. A., Redford, M., Van Gelder, R. N., \& Nelson, K. Ocular Surface Microbiome-Best Practices for Low Biomass Research Executive Summary. National Eye Institute. https://www.nei.nih.gov/sites/default/files/2021-10/ MRDHNEI\%20Microbiome\%20Report\%20FINAL.pdf
8. Friedel, E. B., Hahn, H.-T., Maier, S., Küchlin, S., Reich, M., Runge, K., Bach, M., Heinrich, S. P., Kornmeier, J., Endres, D., Ebert, D., Domschke, K., Tebartz van Elst, L., \& Nickel, K. (2022). Structural and functional retinal alterations in patients with paranoid schizophrenia. Trans/ational Psychiatry, 12. https:// doi.org/10.1038/s41398-022-02167-7

Jimenez, N. T., Lines, J. W., Kueppers, R. B., Kofuji, P., Wei, H., Rankila, A., Coyle, J. T., Miller, R. F., \& McLoon, L. K. (2020). Electroretinographic abnormalities and sex differences detected with mesopic adaptation in a mouse model of schizophrenia: A and B wave analysis. Investigative Ophthalmology \& Visual Science, 61(2). https://doi.org/10.1167/iovs.61.2.16

## National Heart, Lung, and Blood Institute

## I. Overview

The National Heart, Lung, and Blood Institute (NHLBI) supports women's health research to better understand how heart, lung, blood, and sleep disorders affect women and to develop prevention and treatment strategies. NHLBI accounts for sex as a biological variable in all research, allowing researchers to examine sex-related factors that affect health and disease. NHLBI's women's health research also seeks to understand the factors that lead to health disparities in women who are in underserved racial and ethnic groups.

## II. Scientific Advances in Research on the Health of Women

## Treatment of Chronic Hypertension Improves Pregnancy Outcomes. Approximately half of

 American women have at least one risk factor for heart disease (such as high blood pressure, diabetes, or overweight/obesity) before pregnancy, and some racial and ethnic groups have disproportionately higher rates of these risk factors. NHLBI's Chronic Hypertension and Pregnancy trial seeks to prevent adverse pregnancy and fetal growth outcomes caused by mild chronic hypertension by focusing on interventions to control the condition safely during pregnancy. ${ }^{1}$ Results from this study show that treatment for mild chronic hypertension leads to better pregnancy outcomes and has no negative effect on fetal growth. These results led the American College ofObstetricians and Gynecologists' clinical practice to change its guidelines for treatment of mild chronic hypertension during pregnancy.

Smaller Airway Size in Women Linked to COPD Progression. Women's airways are smaller than and otherwise different from those of men, which may help explain variations in the progression of chronic obstructive pulmonary disease (COPD). Using data from the Genetic Epidemiology of COPD study, researchers studied airway and lung images from men and women, including images from 420 adults who had never smoked and 9,363 adults who were current or former smokers. ${ }^{2}$ When compared with men, women who had smoked were more likely to experience worse outcomes, have poorer respiratory symptoms, experience shortness of breath, complete a shorter distance on a 6-minute walk test, and have reduced survival.

## Hydroxyurea May Increase Adverse Pregnancy

 Outcomes in Sickle Cell Disease. Women taking hydroxyurea for sickle cell disease during pregnancy may face more adverse pregnancy outcomes than those not taking the drug, including an almost twofold increase in the rate of pregnancy loss from miscarriage or stillbirth and an increased risk of low birth weight. Researchers found that use of hydroxyurea after conception and during pregnancy was associated with the adverse outcomes, suggesting it may be safely used up to the time of conception but should be discontinued during pregnancy. ${ }^{3}$
## Workshop Addresses Comorbidities in

 Women and Girls. NHLBI hosted a virtual workshop in December 2021 to develop and support continuum-of-care models to advance the health of reproductive-age women who are in underserved racial and ethnic groups and have chronic conditions and multimorbidity. The workshop brought together various experts and stakeholders to find a path toward a continuum-of-care approach that integrates primary care, reproductive health, behavioral health, and cardiopulmonary specialties.
## III. Future Priorities in Research on the Health of Women

NHLBI has identified three key future priorities of research to improve and promote women's health: (1) reducing disparities in maternal morbidity and mortality, (2) examining how climate change affects women's health, and (3) determining how women's health is affected by sleep quality and sleep disorders.

1. Tita, A. T., Szychowski, J. M., Boggess, K., Dugoff, L., Sibai, B., Lawrence, K., Hughes, B. L., Bell, J., Aagaard, K., Edwards, R. K., Gibson, K., Haas, D. M., Plante, L., Metz, T., Casey, B., Esplin, S., Longo, S., Hoffman, M., Saade, G. R., Hoppe, K. K., ... Chronic Hypertension and Pregnancy (CHAP) Trial Consortium (2022). Treatment for mild chronic hypertension during pregnancy. The New England Journal of Medicine, 386(19), 1781-1792. https://doi.org/10.1056/NEJMoa2201295
2. Bhatt, S., Bodduluri, S., Nakhmani, A., Kim, Y., Reinhardt, J., Hoffman, E., Motahari, A., Wilson, C., Humphries, S., Regan, E., \& and DeMeo, D. (2022). Sex differences in airways at chest CT: Results from the COPDGene cohort. Radiology, 305(3), 699-708. https://doi.org/10.1148/radiol. 212985
3. Kroner, B. L., Hankins, J. S., Pugh, N., Kutlar, A., King, A. A., Shah, N. R., Kanter, J., Glassberg, J., Treadwell, M., Gordeuk, V. R., \& Sickle Cell Disease Implementation Consortium (2022). Pregnancy outcomes with hydroxyurea use in women with sickle cell disease. American Journal of Hematology, 97(5), 603-612. https://doi.org/10.1002/ajh. 26495

## National Human Genome Research Institute

## I. Overview

The National Human Genome Research Institute's (NHGRI) focus on genomic technology development has had a positive impact on the field of genomics but also in many disease-specific research efforts, including those specific to women. NHGRI also funds research that positively affects women in a more targeted manner, and NHGRI-funded research in FY 2021 and FY 2022 has led to advances in disease areas specific to women's health (such as endometrial and breast cancers) and issues affecting maternal and child health (such as prenatal genetic testing). Women are often at the center of health-related decision-making in families and bear disproportionate psychosocial burdens associated with genetic testing and participation in genomics research. NHGRI has funded research and conducted outreach activities on the ethical and psychosocial aspects of participating in genomics research through activities in the NHGRI Ethical, Legal and Social Implications (ELSI) Research Program and the intramural Social and Behavioral Research Branch.

## II. Scientific Advances in Research on the Health of Women

H3Africa Common Fund Consortium Efforts in Women's Health. Several NHGRI-led or co-funded projects within the Human Heredity and Health (H3Africa) Consortium are focused on the health of African women. One study (U54HG006938) seeks to investigate the role of the menopausal transition in cardiovascular disease risk in sub-Saharan African women. The African Female Breast Cancer Epidemiology (AFBRECANE) Study (U01HG009784) utilizes nutrition epidemiology and genomics epidemiology tools to study dietary intakes and breast cancer risk in African women. In FY 2021, NHGRI supported a first-of-its-kind study (U01MH115485) that examined the epigenomes of Tutsi women who were pregnant during the 1994 Rwandan genocide to reveal epigenetic differences genocide-exposed mothers passed on to their children. The ongoing Breast Milk Microbiota Influence on Infant Immunity and Growth (BEAMING) study investigates how the microbiota of breast milk affect infants' gut bacteria and how this in turn affects infants' growth and their ability to respond to childhood vaccination. ${ }^{1}$

> NHGRI ELSI Research Program Efforts in Prenatal Screening, Reprogenomics, and Genetic Testing in Women. NHGRI's ELSI Research Program is funding many projects focusing on access to and utilization of genetic prenatal care, screening, and testing in women. One qualitative study assesses understanding of and desire to accept prenatal genetic services among African American and Latina women, and another seeks to improve prenatal screening education among women in underrepresented and rural populations. ${ }^{2}$

NHGRI Intramural Research Program Efforts in Women's Health. One group of NHGRI intramural researchers is focused on understanding the genomic basis of endometrial cancer. Other NHGRI researchers study the genetic, genomic, and environmental factors leading to the development of autoimmune diseases. NHGRI intramural researchers head the Incidental Detection of Maternal Neoplasia Through Non-invasive CellFree DNA Analysis (IDENTIFY) study to identify the best approach for clinical follow-up if a pregnant woman's test results suggest cancer is present. ${ }^{3}$

## III. Future Priorities in Research on the Health of Women

NHGRI is a disease-agnostic institute. However, women represent over half of the participants in NHGRI-funded human subjects research, and NHGRI ensures that male and female tissue, cell lines, and model organisms are included equally in all studies examining diseases and conditions that affect both sexes. Through the aforementioned efforts, NHGRI will continue to support research on understanding the genomic basis of femalespecific conditions, understanding sex- and gender-specific drivers of disease, and improving access to and utilization of prenatal screening and genetic testing among women, especially women in underrepresented groups.

[^3]Mooney, R., Espinel, W., Elrick, A., Kehoe, K., Kohlmann, W., \& Kaphingst, K. A. (2022). Uptake of genetic counseling and multi-gene panel testing among women in the Intermountain West with previous negative BRCA1 and BRCA2 results contacted for updated testing. Journal of Genetic Counseling, 31(2), 470-478. https://doi.org/10.1002/jgc4.1513

Orellana, M., Riggan, K. A., DSouza, K., Stewart, E. A., Venable, S., Balls-Berry, J. E., \& Allyse, M. A. (2022). Perceptions of ethnoracial factors in the management and treatment of uterine fibroids. Journal of Racial and Ethnic Health Disparities, 9(4), 1184-1191. https://doi.org/10.1007/s40615-021-01059-8

Riches, N. O., Johnson, E. P., Subramaniam, A., Vora, N. L., Hardisty, E., LaRiviere, K., \& Rothwell, E. (2023). Understanding the experiences and perspectives of prenatal screening among a diverse cohort. Prenatal Diagnosis, 10.1002/ pd.6297. Advance online publication. https://doi.org/10.1002/pd. 6297
Rothwell, E., Cheek-O’Donnell, S., Johnson, E., Wilson, A., Anderson, R. A., \& Botkin, J. (2021). Exploring the use of a comic for education about expanded carrier screening among a diverse group of mothers. Journal of Communication in Healthcare, 14(3), 252-258. https://doi.org/10.1080/175 38068.2021.19093983.
3. Aguirre, A., Izadi, Z., Trupin, L., Barbour, K. E., Greenlund, K. J., Katz, P., Lanata, C., Criswell, L., Dall'Era, M., \& Yazdany, J. (2023). Race, ethnicity, and disparities in the risk of end-organ lupus manifestations following a systemic lupus erythematosus diagnosis in a multiethnic cohort. Arthritis Care \& Research, 75(1), 34-43. https://doi.org/10.1002/acr. 24892
Bush, L., Davidson, H., Gelles, S., Lea, D., \& Koehly, L. M. (2022). Experiences of families caring for children with newborn screening-related conditions: Implications for the expansion of genomics in population-based neonatal public health programs. International Journal of Neonatal Screening, 8(2), 35. https://doi.org/10.3390/iins8020035

Cleary, J. L., Manalel, J. A., Ashida, S., Marcum, C. S., Rewley, J., \& Koehly, L. (2022). Interpersonal correlates of dementia caregivers' emotional support networks: Considering family history. Research on Aging, 44(5-6), 405-413. https://doi.org/10.1177/01640275211026919
Gbenro, M. O., Jr, Martingano, A. J., \& Persky, S. (2022). Exploring the impact of genetic beliefs about specific eating behaviors on dietary self-efficacy. Journal of Behavioral Medicine, 45(3), 497-502. https://doi.org/10.1007/ s10865-022-00290-w
Hagerman, C. J., Ferrer, R. A., \& Persky, S. (2022). How beliefs about weight malleability and risk perceptions for obesity influence parents' information seeking and feeding. Journal of Health Psychology, 27(12), 2714-2728. https://doi.org/10.1177/13591053211061412

Khatri, B., Tessneer, K. L., Rasmussen, A., Aghakhanian, F., Reksten, T. R., Adler, A., Alevizos, I., Anaya, J. M., Aqrawi, L. A., Baecklund, E., Brun, J. G., Bucher, S. M., Eloranta, M. L., Engelke, F., Forsblad-d'Elia, H., Glenn, S. B., Hammenfors, D., Imgenberg-Kreuz, J., Jensen, J. L., Johnsen, S. J. A., ... Lessard, C. J. (2022). Genome-wide association study identifies Sjögren's risk loci with functional implications in immune and glandular cells. Nature Communications, 13(1), 4287. https://doi.org/10.1038/s41467-022-30773-y
Lanata, C. M., Nititham, J., Taylor, K. E., Solomon, O., Chung, S. A., Blazer, A., Trupin, L., Katz, P., Dall’Era, M., Yazdany, J., Sirota, M., Barcellos, L. F., \& Criswell, L. A. (2022). Dynamics of methylation of CpG sites associated with systemic lupus erythematosus subtypes in a longitudinal cohort. Arthritis \& Rheumatology, 74(10), 1676-1686. https://doi.org/10.1002/art. 42237

Manalel, J. A., Sumrall, S., Davidson, H., Grewal, M., Granovetter, M. A., \& Koehly, L. M. (2022). Stress, coping, and positive aspects of caregiving among caregivers of children with rare disease. Psychology \& Health, 1-17. Advance online publication. https://doi.org/10.1080/08870446.2022.2057494
Meas, R., Nititham, J., Taylor, K. E., Maher, S., Clairmont, K., Carufe, K. E. W., Kashgarian, M., Nottoli, T., Cheong, A., Nagel, Z. D., Gaffney, P. M., Criswell, L. A., \& Sweasy, J. B. (2022). A human MSH6 germline variant associated with systemic lupus erythematosus induces lupus-like disease in mice. ACR Open Rheumatology, 4(9), 760-770. https://doi.org/10.1002/acr2.11471

Rudd, M. L., Hansen, N. F., Zhang, X., Urick, M. E., Zhang, S., Merino, M. J., National Institutes of Health Intramural Sequencing Center Comparative Sequencing Program, Mullikin, J. C., Brody, L. C., \& Bell, D. W. (2022). KLF3 and PAX6 are candidate driver genes in late-stage, MSI-hypermutated endometrioid endometrial carcinomas. PLoS One, 17(1), e0251286. https:// doi.org/10.1371/iournal.pone. 0251286

Sadler, J. R., Persky, S., Gu, C., Aghababian, A. H., \& Carnell, S. (2022). Is obesity in the brain? Parent perceptions of brain influences on obesity. Pediatric Obesity, 17(5), e12881. https://doi.org/10.1111/ijpo. 12881

Turriff, A. E., Annunziata, C. M., \& Bianchi, D. W. (2022). Prenatal DNA sequencing for fetal aneuploidy also detects maternal cancer: Importance of timely workup and management in pregnant women. Journal of Clinical Oncology, 40(22), 2398-2401. https://doi.org/10.1200/JCO.22.00733

Urick, M. E., Yu, E. J., \& Bell, D. W. (2021). High-risk endometrial cancer proteomic profiling reveals that FBXW7 mutation alters L1CAM and TGM2 protein levels. Cancer, 127(16), 2905-2915. https://doi.org/10.1002/cncr. 33567

Zajdel, M., Davidson, H., Lea, D., \& Koehly, L. M. (2022). Links of we-talk to caregiver social network systems and health. Journal of Family Psychology, 36(8), 1386-1396. https://doi.org/10.1037/fam0001013

## National Institute on Aging

## I. Overview

In FYs 2021-2022, the National Institute on Aging (NIA) continued to advance research considering sex and gender, ranging from sex differences at the molecular level in exercise response to basic and clinical research exploring how both sex and gender influence dementia development, prevention, diagnosis, and response to treatment at the cell, tissue, organ, and population levels. NIA also supported research on the specific challenges to older women posed by COVID-19.

## II. Scientific Advances in Research on the Health of Women

## Blocking Follicle-Stimulating Hormone Improves Alzheimer's Symptoms in Mice.

 Levels of follicle-stimulating hormone (FSH) rise sharply in women prior to menopause. NIAfunded investigators found that using an antibody to block FSH preserves bone mass, increases lean mass, and reduces Alzheimer's disease pathology and cognitive decline in both sexes of mouse models. The intervention also reduces pathological hallmarks of AD in both sexes. Preclinical testing of an antibody to block FSH in women is underway. ${ }^{1}$
## COVID-Related Mental Health and Socioeconomic Outcomes in Women. Using data from a national survey, researchers found that nearly half of U.S. women experienced

new or worsening health-related socioeconomic risks (HRSRs) (e.g., related to food, housing, utilities, transportation difficulties, or interpersonal violence) early in the COVID-19 pandemic. Prevalence of HRSRs increased for all groups, but White women were much less likely than others to experience extreme HRSRs. Increased HRSRs were associated with high rates of depression, anxiety, and symptoms of posttraumatic stress. ${ }^{2}$

Midlife Brain and Heart Health: Associations with Health Later in Life. Investigators with the Study of Women's Health Across the Nation analyzed the association of midllife health with later-life health and cognition. No link was found between self-reported physical activity and cognitive scores over 15 years during midlife; however, certain heart disease risk factors during midlife were associated with faster rates of decline on a mental task a decade later. Declines in midlife blood vessel health occurred in both Black and White women, but specific signs of this decline varied by race/ethnicity. ${ }^{3}$

Sex Differences in Response to Endurance Exercise Training-MoTrPAC. In a study looking at the molecular effects of 8 weeks of endurance (treadmill) training versus no exercise in young adult rats, investigators with the NIHwide Molecular Transducers of Physical Activity Consortium (MoTrPAC) identified sex differences in most tissues and many organs. Analyses in humans and rats continue. ${ }^{4}$

## NIA Funding Opportunities for Research

 on Sex and Gender Differences in AD. ${ }^{5}$ NIA released two funding opportunity announcements (FOA) to understand the influences of sex and gender on AD and related dementias. One of the supported grants explored how genes, environment, and hormonal status interact at the cell, tissue, organ, and population levels to produce sex differences in disease risk and responsiveness to therapy. The FOA was reissued in 2022. A separate solicitation promoted multidisciplinary research to clarify sex and gender differences in risk, development, progression, diagnosis, and clinical presentation.
## III. Future Priorities in Research on the Health of Women

NIA will continue to support biological, behavioral, and social research on factors that may contribute to sex and gender differences in life expectancy and health, including cognitive health, in older adults. Research on menopause and other conditions that uniquely or primarily affect women will continue. Finally, NIA will prioritize efforts to ensure women's participation in clinical research, particularly recruitment and retention of women in groups that are traditionally underrepresented in research.

1. Xiong, J., Kang, S. S., Wang, Z., Liu, X., Kuo, T. C., Korkmaz, F., Padilla, A., Miyashita, S., Chan, P., Zhang, Z., Katsel, P., Burgess, J., Gumerova, A., levleva, K., Sant, D., Yu, S. P., Muradova, V., Frolinger, T., Lizneva, D., Iqbal, J., ... Ye, K. (2022). FSH blockade improves cognition in mice with Alzheimer's disease. Nature, 603(7901), 470-476. https://doi.org/10.1038/s41586-022-04463-0
2. Lindau, S. T., Makelarski, J. A., Boyd, K., Doyle, K. E., Haider, S., Kumar, S., Lee, N. K., Pinkerton, E., Tobin, M., Vu, M., Wroblewski, K. E., \& Lengyel, E. (2021). Change in health-related socioeconomic risk factors and mental health during the early phase of the COVID-19 pandemic: A national survey of U.S. women. Journal of Women's Health, 30(4), 502-513. https://doi.org/10.1089/jwh.2020.8879

Tejpal, A., Gianos, E., Cerise, J., Hirsch, J. S., Rosen, S., Kohn, N., Lesser, M., Weinberg, C., Majure, D., Satapathy, S. K., Bernstein, D., Barish, M. A., Spyropoulos, A. C., \& Brown, R. M. (2021). Sex-based differences in COVID-19 outcomes. Journal of Women's Health, 30(4), 492-501. https:// doi.org/10.1089/jwh.2020.8974

Vu, M., Makelarski, J. A., Winslow, V. A., Christmas, M. M., Haider, S., Lee, N. K., Pinkerton, E. A., Wroblewski, K. E., \& Lindau, S. T. (2021). Racial and ethnic disparities in health-related socioeconomic risks during the early COVID-19 pandemic: A national survey of U.S. women. Journal of Women's Health, 30(10), 1375-1385. https://doi.org/10.1089/jwh.2021.0230
3. Barinas-Mitchell, E., Duan, C., Brooks, M., El Khoudary, S. R., Thurston, R. C., Matthews, K. A., Jackson, E. A., Lewis, T. T., \& Derby, C. A. (2020). Cardiovascular disease risk factor burden during the menopause transition and late midlife subclinical vascular disease: Does race/ethnicity matter? Journal of the American Heart Association, 9(4), e013876. https://doi. org/10.1161/JAHA.119.013876
Derby, C. A., Hutchins, F., Greendale, G. A., Matthews, K. A., Sternfeld, B., Everson-Rose, S. A., Kazlauskaite, R., Whitmer, R. A., \& Brooks, M. M. (2021). Cardiovascular risk and midlife cognitive decline in the Study of Women's Health Across the Nation. Alzheimer's \& Dementia, 17(8), 1342-1352. https://doi.org/10.1002/alz. 12300

Greendale, G. A., Han, W., Huang, M., Upchurch, D. M., KarvonenGutierrez, C., Avis, N. E., \& Karlamangla, A. S. (2021). Longitudinal assessment of physical activity and cognitive outcomes among women at midlife. JAMA Network Open, 4(3), e213227. https://doi.org/10.1001/ jamanetworkopen.2021.3227

Samargandy, S., Matthews, K. A., Brooks, M. M., Barinas-Mitchell, E., Magnani, J. W., Janssen, I., Hollenberg, S. M., \& El Khoudary, S. R. (2020). Arterial stiffness accelerates within 1 year of the final menstrual period: The SWAN Heart Study. Arteriosclerosis, Thrombosis, and Vascular Biology, 40(4), 1001-1008. https://doi.org/10.1161/ATVBAHA.119.313622
4. MoTrPAC Study Group, Amar, D., Gay, N., Beltran, P., et al. (2022). Temporal dynamics of the multi-omic response to endurance exercise training across tissues. bioRxiv 2022.09.21.508770. https://doi. org/10.1101/2022.09.21.508770
5. Mielke M. M. (2018). Sex and gender differences in Alzheimer's disease dementia. Psychiatric Times, 35(11), 14-17. https://www.psychiatrictimes. com/view/sex-and-gender-differences-alzheimer-disease-dementia

# National Institute on Alcohol Abuse and Alcoholism 

## I. Overview

The mission of the National Institute on Alcohol Abuse and Alcoholism (NIAAA) is to generate and disseminate fundamental knowledge about the effects of alcohol on health and well-being and apply that knowledge to improve the diagnosis, prevention, and treatment of alcohol-related problems, including alcohol use disorder (AUD), across the lifespan. Over the past few decades, adult alcohol use has been increasing for women but not for men, and females show greater overall harmful effects of alcohol. Preclinical and clinical studies reveal that sex differences in drinking are influenced by changes in biology, psychology, and exposure to social and environmental inputs over a lifetime. NIAAA will inform the development of individualized prevention and treatment programs for girls and women to reduce health disparities.

## II. Scientific Advances in Research on the Health of Women

## Sex Differences in Stress-Induced Alcohol

 Intake. Clinical studies suggest women are more likely than men to relapse to alcohol drinking in response to stress. A review of recent NIAAAfunded preclinical behavioral models highlights the role amygdala-centered circuits play in sex differences related to stress-induced alcohol intake. ${ }^{1}$[^4]2022 Public Meeting of the Interagency Coordinating Committee on Fetal Alcohol Spectrum Disorders (ICCFASD). ICCFASD fosters improved communication, cooperation, and collaboration among Federal agencies that address issues related to prenatal alcohol exposure.

> Growing Alcohol Use Preceding Death by Suicide Among Women Compared with Men: Age-Specific Temporal Trends, 2003-2018. The prevalence of heavy alcohol use and the suicide mortality rate increased among men and women for about two decades, with a higher increase in women. However, though alcohol use preceding death by suicide increased among women of all ages, only middle-aged men experienced a significant increase from 2003 to $2018 .{ }^{3}$

2022 National Conference on Alcohol and Other Substance Use in Women and Girls: Advances in Prevention, Treatment, and Recovery. In October, NIAAA and the Interagency Work Group on Drinking and Drug Use in Women and Girls disseminated findings from the latest research on the prevention, diagnosis, and treatment of harmful alcohol use and other substance use among girls and women, including strategies to prevent HIV infection and progression and substance-exposed pregnancies.

## III. Future Priorities in Research on the Health of Women

NIAAA prioritizes several research directions: neuroimaging studies in women; the Model Continuums of Care Initiative to advance health equity among women and girls in racial/ethnic minority and other marginalized communities; fetal alcohol spectrum disorder intervention and prevention approaches; early liver transplantation studies for alcohol-associated liver diseases; studies on SARS-CoV-2, COVID-19, and consequences of alcohol use; studies to address alcohol and aging; studies on risk and protective factors of family health and family-level interventions; and strategies that improve stress management and emotion regulation skills for maintenance of recovery in women.

1. Mineur, Y. S., Garcia-Rivas, V., Thomas, M. A., Soares, A. R., McKee, S. A., \& Picciotto, M. R. (2022). Sex differences in stress-induced alcohol intake: A review of preclinical studies focused on amygdala and inflammatory pathways. Psychopharmacology, 239(7), 2041-2061. https://doi. org/10.1007/s00213-022-06120-w
2. Elvig, S. K., McGinn, M. A., Smith, C., Arends, M. A., Koob, G. F., \& Vendruscolo, L. F. (2021). Tolerance to alcohol: A critical yet understudied factor in alcohol addiction. Pharmacology, Biochemistry, and Behavior, 204, 173155. https://doi.org/10.1016/i.pbb.2021.173155
3. Lange, S., Kaplan, M. S., Tran, A., \& Rehm, J. (2022). Growing alcohol use preceding death by suicide among women compared with men: Age-specific temporal trends, 2003-18. Addiction, 117(9), 2530-2536. https://doi. org/10.1111/add. 15905

## National Institute of Allergy and Infectious Diseases

## I. Overview

The National Institute of Allergy and Infectious Diseases (NIAID) conducts and supports research to understand, diagnose, prevent, treat, and ultimately cure infectious and immune-mediated diseases, including diseases that affect women and girls. NIAID research activities satisfy the $21^{\text {st }}$ Century Cures Act by including women and minority populations in clinical studies that evaluate treatment and prevention options for infectious and immune-mediated diseases. In FY 2021-2022, NIAID supported research on the health of women through several initiatives, spanning diverse topic areas, including maternal immunity, sex differences, HIV/AIDS prevention, and women in the biomedical workforce.

## II. Scientific Advances in Research on the Health of Women

Building the Pregnancy Immune Atlas by Mapping the Maternal Immune System Across Pregnancy. In 2022, NIAID funded the Maternal 'Omics to Maximize Immunity program, which will characterize the immune system across pregnancy in response to vaccination for COVID-19, influenza, and pertussis. Findings will be used to create a pregnancy immune atlas that will map innate and adaptive immune responses across all trimesters.

Influenza Challenge Study Identifies Sex Differences in Influenza Symptomology. A NIAID influenza challenge study published in 2022 provided evidence that males and females have differing outcomes with influenza infection and vaccination. ${ }^{1}$ This study found that females experienced more symptoms than males and that neuraminidase inhibition titers differed between males and females at 4 and 8 weeks postchallenge, providing a potential mechanism for symptomology differences.

Centers for AIDS Research Improve Research for and Implementation of HIV Prevention and Treatment and Support Women HIV/AIDS Researchers. In 2021, NIAID funded multiple Centers for AIDS Research cores that have sections focused on (1) advancing research improving HIV prevention and treatment for those most at risk-including cisgender women, transgender individuals, and women of color-and (2) supporting women biomedical researchers studying HIV/AIDS.

Long-Acting Injectable Cabotegravir Improves HIV Prevention Options for Women. In 2022, the Food and Drug Administration approved a longacting injectable, cabotegravir, for HIV prevention following results of two NIAID-funded clinical trials (HPTN 083 and HPTN 084). Cabotegravir requires an injection once every 2 months and is a more discreet option compared with daily medications for those at risk of HIV infection, and it may help to reduce stigma, fear of violence, and judgment for women at risk. ${ }^{2}$

Infectious Diseases Clinical Research Consortium Conducting an Observational Study to Evaluate Safety and Immune Responses to COVID-19 Vaccines in Pregnant People and Postpartum Individuals. In 2021, the Infectious Diseases Clinical Research Consortium began a clinical trial to evaluate the immune responses of pregnant people and postpartum individuals (and their infants) after COVID-19 vaccination. Findings from this study will provide vital information regarding how the immune system changes across pregnancy and postpartum, as well as immune transfer of SARS-CoV-2 in pregnancy.

## III. Future Priorities in Research on the Health of Women

NIAID's strategic priorities include content areas that are relevant to the health of women. NIAID aims to include evaluation of sex as a biological variable (SABV) within the robust portfolio of basic and translational research, include women and pregnant people in clinical trials, and develop new prevention and treatment strategies for immunemediated diseases with evaluation of sex and gender differences.

[^5]
## National Institute of Arthritis and Musculoskeletal and Skin Diseases

## I. Overview

The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) supports research, research training and career development activities, and health information programs for numerous debilitating diseases affecting Americans. Many-including fibromyalgia, juvenile idiopathic arthritis, osteoarthritis, osteoporosis, rheumatoid arthritis (RA), scleroderma/systemic sclerosis, Sjögren's syndrome, and systemic lupus erythematosusdisproportionately affect women or girls.

## II. Scientific Discovery on Research on the Health of Women

Accelerating Medicines Partnership® Autoimmune and Immune-Mediated Diseases (AMP® AIM) Program. This program was launched in 2021 to deepen understanding of the cellular and molecular interactions that lead to inflammation and autoimmune diseases. AMP AIM investigators focus their research on RA, lupus, psoriasis, psoriatic arthritis, and Sjögren's syndrome, all of which disproportionately affect women. This program relates directly to goal 1 of the Trans-NIH Strategic Plan for Women's Health Research.

Accelerating Medicines Partnership Rheumatoid Arthritis and Systemic Lupus Erythematosus (AMP RA/SLE) Program. This program, funded from 2014 to 2022, uses a molecular- and cellular-level approach ("disease deconstruction") to uncover biological factors and pathways involved in RA and lupus. ${ }^{1}$ This program relates directly to goal 1 of the Trans-NIH Strategic Plan for Women's Health Research.

## NIH Pathways to Prevention Workshop

 on Appropriate Use of Drug Therapies for Osteoporotic Fracture Prevention. In a follow-up to a FY 2019 NIH Pathways to Prevention workshop on appropriate use of drug therapies for osteoporotic fracture prevention, NIAMS, the National Institute on Aging, the National Institute of Dental and Craniofacial Research, and ORWH issued a notice of special interest in FY 2020 to enhance research on improving understanding of the mechanisms of pathophysiology and pathogenesis leading to the rare conditions of atypical femoral fracture and osteonecrosis of the jaw associated with bone antiresorptive medications for osteoporosis. This program relates directly to goal 1 of the Trans-NIH Strategic Plan for Women's Health Research.The Restoring Joint Health and Function to Reduce Pain (RE-JOIN) Consortium. The REJOIN Consortium, started in FY 2022 as part of NIH's Helping to End Addiction Long-term (HEAL) Initiative, will consist of research teams working
together to map the network of sensory nerves of two joints: the temporomandibular joint and the knee. Researchers will focus on understanding how these types and patterns change with disease and aging and how they differ between individuals depending on age, sex, or disease. This program relates directly to goal 1 of the Trans-NIH Strategic Plan for Women's Health Research.

Back Pain Consortium (BACPAC) Research Program. NIAMS contributes to the HEAL Initiative by leading the BACPAC Research Program. BACPAC seeks to spur new treatments for chronic low back pain-one of the most common forms of pain among adults, including older women. ${ }^{2}$ This program relates directly to goal 1 of the Trans-NIH Strategic Plan for Women's Health Research.

## III. Future Priorities in Research on the Health of Women

Team Science Leadership Scholars Program: In FY 2022, NIAMS, ORWH, and the NIH Office of Data Science Strategy announced the formation of a cadre of scientists dedicated to women's health research through AMP AIM. The program will train women's health researchers to lead complex, data-intensive research in academia, industry, and the public sector.

[^6]
## National Institute of Biomedical Imaging and Bioengineering

## I. Overview

The National Institute of Biomedical Imaging and Bioengineering's (NIBIB) goal is to transform, through engineering, the understanding of disease and its prevention, detection, diagnosis, and treatment. During FY 2021-2022, NIBIB funded grants to support technology development related to women's health, including in relation to cancer, cardiovascular disease, and pregnancy complications. These technologies span the domains of bioimaging, bioengineering, and health informatics. NIBIB further organized a workshop, issued a call, and organized challenges such as the Rapid Acceleration of Diagnostics initiative and the NIH Technology Accelerator Challenge to accelerate technology innovation in the domain of maternal health.

## II. Scientific Advances in Research on the Health of Women

NOT-EB-21-001: Notice of Special Interest (NOSI): Small Business Initiatives for Innovative Diagnostic Technology for Improving Outcomes for Maternal Health. The purpose of this NIHwide NOSI is to invite Small Business Innovation Research and Small Business Technology Transfer applications to develop technologies to predict or indicate an increased risk for maternal morbidity and mortality (MMM). Funded applications focus on technologies for assessment of pregnancy risk and monitoring postpartum hemorrhage and blood pressure using wearable devices.

## Workshop: "Technology to Improve Maternal

 Health," January 18, 2022. NIBIB and other NIH institutes and centers conducted a workshop to identify technology gaps and how new technologies could improve maternal health and treat and/or prevent MMM. This workshop brought together technology developers, researchers, and community partners to advance interdisciplinary collaborations.Design by Biomedical Undergraduate Teams Challenge (DEBUT), 2021-2022. NIBIB, in partnership with VentureWell, challenges undergraduate student teams to develop technological solutions to unmet needs in any area of health care with this competition. FY 2021-2022 DEBUT prizes included devices and tools for women and maternal health, such as early assessment of preterm birth and a needle delivery tool for transvaginal injection.

NIH Technology Accelerator Challenge (NTAC) and Rapid Acceleration of Diagnostics Technology (RADx ${ }^{\circledR}$ Tech) for Maternal Health, 2022. NIBIB launched the NTAC series of prize competitions to accelerate the design of innovative technologies to transform public and global health and improve maternal health by diagnosing conditions related to MMM. Additionally, the Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIBIB, and the NIH Office of the Director co-sponsored the RADx ${ }^{\circledR}$ Tech for Maternal Health Challenge. This challenge offered up to $\$ 8$ million in cash prizes to accelerate the development of point-of-care and remote sensing diagnostic devices to improve maternal health outcomes in maternity care deserts.

## Diversity/Health Disparities Funding

 Opportunity Announcements (FOAs). NIBIB leads a request for applications (RFA-EB-21-001) that supports proposals developing technologies to reduce health disparities, including those experienced by women. NIBIB also participates in two FOAs (RFA-HG-21-041 and PAR-21-313) to promote diversity, including gender diversity, and provide support for new investigators to conduct small research projects within NIBIB's scientific mission areas.
## III. Future Priorities in Research on the Health of Women

NIBIB will continue to promote women's health by supporting biomedical technology and tool development via research and training grants, holding prize competitions, and continuing its collaborations across NIH and other Government agencies to leverage research efforts to benefit women's health.

# Eunice Kennedy Shriver National Institute of Child Health and Human Development 

## I. Overview

The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) leads research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all. NICHD is home to much of the Nation's leading scientific research related to women's overall health, gynecological health, pregnancy, and childbirth, as well as studies of the influences that sex and gender have on diseases and conditions related to pediatric and adolescent health and medical rehabilitation.

## II. Scientific Advances in Research on the Health of Women

Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE). NICHD and NIH colleagues launched this initiative to combat the growing problem of maternal morbidity and mortality in the U.S. This initiative supports research to reduce preventable causes of maternal deaths and improve health before, during, and after delivery. It emphasizes populations disproportionately affected by health disparities. In FY 2022, over $\$ 43$ million in activities are planned, including a range of advanced research projects to prevent maternal mortality.

Maternal Health Research Centers of Excellence. As part of the IMPROVE initiative, NIH recently issued three funding opportunity announcements (FOAs) to solicit applications to establish a national network of Maternal Health Research Centers of Excellence (RFA-HD-23-035, RFA-HD-23-036, RFA-HD-23-037). The purpose of this initiative is to generate innovative approaches to addressing preventable maternal mortality, decreasing severe maternal morbidity, and promoting maternal health
equity in partnership with one or more populations that experience maternal health disparities.

The Stillbirth Working Group of Council. This council was formed as a subgroup of NICHD's National Advisory Child Health and Human Development Council in response to a U.S. Department of Health and Human Services request to lead a congressionally mandated task force to examine stillbirth in the United States, with a focus on the following issues: (1) current barriers to collecting data on U.S. stillbirths; (2) communities at higher risk for stillbirth; (3) psychological impact and treatment for mothers following stillbirth; and (4) known risk factors for stillbirth. NICHD issued a request for information to help develop strategies to improve the scientific evidence base for stillbirth prevention.

Nonsurgical Method to Treat Endometriosis. Endometriosis frequently causes debilitating pain and infertility. To move toward new nonsurgical treatment approaches, scientists adapted an experimental therapy called nanoparticle-mediated magnetic hyperthermia. ${ }^{1}$ They showed that their nanoparticles can accumulate in endometriosis tissues in mice and are cleared from other organs days later. They administered the alternating magnetic field and found they could safely remove all endometriosis tissue within 20 minutes and apply the field locally so tissues are not affected. These early-stage findings offer a potentially safe and efficient method of removing endometriosis tissue.

## III. Future Priorities in Research on the Health of Women

NICHD is seeking to advance methods for safe, noninvasive real-time assessment of human placenta development and function across pregnancy and reissued a notice of special interest to address high-priority areas in placental research. Implementation of the recommendations from the Stillbirth Working Group of Council will begin in 2023. Other efforts include accelerating research on endometriosis and uterine fibroids.

1. Park, Y., Demessie, A. A., Luo, A., Taratula, O. R., Moses, A. S., Do, P., Campos, L., Jahangiri, Y., Wyatt, C. R., Albarqi, H. A., Farsad, K., Slayden, O. D., \& Taratula, O. (2022). Targeted nanoparticles with high heating efficiency for the treatment of endometriosis with systemically delivered magnetic hyperthermia. Small (Weinheim an der Bergstrasse, Germany), 18(24), e2107808. https://doi.org/10.1002/smll. 202107808

## National Institute on Deafness and Other Communication Disorders

## I. Overview

The National Institute on Deafness and Other Communication Disorders' (NIDCD) mission is to conduct and support research and research training in the normal and disordered process of hearing, balance, taste, smell, voice, speech, and language. NIDCD funds research related to disease prevention and health promotion; addresses special biomedical and behavioral problems experienced by people who have communication impairments; supports research evaluating approaches to identifying, preventing, screening, diagnosing, and treating communication disorders; and supports the creation of devices that substitute for lost and impaired sensory and communication function. NIDCD strives to promote women's health research, expand the understanding of sex differences, and cultivate women in biomedical careers.

## II. Scientific Advances in Research on the Health of Women

New Insights into Perrault Syndrome. The Friedman laboratory within NIDCD's Division of Intramural Research published "New insights into Perrault syndrome, a clinically and genetically heterogeneous disorder" in 2021. ${ }^{1}$ Perrault syndrome is an autosomal recessive, genetically heterogeneous disorder characterized by bilateral mild-to-severe childhood sensorineural hearing loss in both sexes and premature ovarian failure or ovarian dysfunction in females who have a 46, XX karyotype.

Defining the Language Phenotype of the FMR1 Premutation. An extramural investigator funded by NIDCD published "Family history of FXTAS is associated with age-related cognitivelinguistic decline among mothers with the FMR1 premutation." ${ }^{\text {2 }}$ This study notes that hierarchical
linear models indicated that women with the FMR1 premutation who reported a family history of fragile X-associated tremor/ataxia syndrome (FXTAS) exhibited faster age-related decline in sentence complexity than those without a family history, with that difference emerging as the women reached their mid-50s, and may be at increased risk for neurodegenerative disease.

Examining Sweet Preferences. Chemical senses are important for regulating food preferences and intake, such as excessive sugar intake, which increases risk for obesity, diabetes, and other health conditions. NIDCD is funding a randomized clinical trial on the effectiveness of systematically reducing added sugar in preschooler snacks and its impact on mothers' sweet preferences.

Estradiol Protects Against Noise-Induced Hearing Loss in Female Mice. The effects of estrogen replacement were studied on peripheral auditory physiology in the absence of noise exposure and on protection from noise-induced hearing loss (NIHL) in mice. ${ }^{3}$ Estradiol replacement protected against noiseinduced hearing loss by mitigating outer hair cell loss and cochlear synaptopathy, which suggests that the estrogen signaling pathways may be harnessed for the prevention and treatment of NIHL.

## III. Future Priorities in Research on the Health of Women

NIDCD research training/career development programs foster a diverse and innovative cadre of skilled scientists. NIDCD initiated two new programs (PAR-21-185 and PAR-21-186) to support educational activities that encourage individuals from diverse backgrounds to pursue further careers in biomedical and behavioral research through experience and mentoring activities. NIDCD also supports several F32 investigators with research focused on the advancement of women's health.

[^7]
# National Institute of Dental and Craniofacial Research 

## I. Overview

The National Institute of Dental and Craniofacial Research (NIDCR) funds clinical and basic research to understand, prevent, and treat oral diseases and craniofacial conditions, including those that disproportionately or solely affect women, such as orofacial pain conditions, temporomandibular disorders (TMDs), and Sjögren's disease. NIDCR also supports research on oral human papillomavirus; research on the oral health of pregnant women, mothers, and their children; research on gender differences; advancing the understanding of sex as a biological variable; and activities to help advance women in biomedical research careers. In October 2022, oral health was featured in ORWH's quarterly publication, Women's Health in Focus at NIH.

## II. Scientific Advances in Research on the Health of Women

## New Approaches to Relieving Symptoms of

 Sjögren's Disease. NIDCR scientists are developing gene therapy approaches to restore salivary gland function in patients with Sjögren's disease, an autoimmune disease that affects women 9 to 19 times more than men. NIDCR researchers have also developed a way to track the movement of embryonic mouse salivary gland cells and re-created the process in cells grown in a dish-an important first step toward engineering functional salivary glands. Another NIDCR study using mouse models of Sjögren's disease showed that treatment with gammaaminobutyric acid, a neurotransmitter, improved saliva and tear production when administered either before or after symptom onset, revealing a promising avenue for alleviating Sjögren's disease symptoms. ${ }^{1}$Sex Differences in Resolution of Pain. Chronic pain conditions are more common in women than men, and the intensity and duration of women's pain are higher. Using a mouse model of sexdependent development and resolution of acute and chronic pain, NIDCR-supported researchers have found that though acute pain was resolved in male and female mice that had an activated immune system response, these immune system and tissue repair responses did not occur in female mice with chronic pain. ${ }^{2}$ These findings provide insight into why pain may persist in women and which pathways could be tested further as potential targets to help improve pain treatments.

Alternative Strategies for Pain Relief. Orofacial pain affects 5-12\% of people-and women more frequently than men. NIDCR supports a variety of research to gain new insights into the molecular basis of pain. In one study, NIDCR intramural researchers discovered that low-intensity sound can blunt pain in mice and may be useful as a nonopioid strategy for pain relief. ${ }^{3}$ In a different study, NIDCR's intramural research labs showed that blocking cyclin-dependent kinase 5 (Cdk5), a protein known to play a role in pain at other body sites, reduced pain signaling in mice. These results could inform the development of safer, nonopioid pain therapies.

## III. Future Priorities in Research on the Health of Women

NIDCR is launching several initiatives to promote research on women's health. NIDCR partnered with seven other NIH institutes, centers, and offices, as well as other Federal agencies, to launch the TMD Collaborative for Improving Patient-Centered Translational Research (TMD IMPACT, RFA-DE-23-014) in 2023. TMD IMPACT will establish a national, interdisciplinary patient-centered research consortium designed to advance basic and clinical research, research training, and translation to evidence-based treatments and improved clinical care for TMDs. NIDCR is also developing an initiative on maternal health and the dental, oral, and craniofacial health and development of their children, which aims to support research on prenatal environmental and physical stressors experienced by women during pregnancy that affect
their children's oral health through altered maternal physiology. Additionally, NIDCR will continue to support research on women's health and activities for the advancement of women in biomedical research careers.

1. Nakamura, H., Tanaka, T., Zheng, C., Afione, S. A., Warner, B. M., Noguchi, M., Atsumi, T., \& Chiorini, J. A. (2022). Correction of LAMP3-associated salivary gland hypofunction by aquaporin gene therapy. Scientific Reports, 12(1), 18570. https://doi.org/10.1038/s41598-022-21374-2
Song, M., Tian, J., Middleton, B., Nguyen, C. Q., \& Kaufman, D. L. (2022). GABA administration ameliorates Sjogren's syndrome in two different mouse models. Biomedicines, 10(1), 129. https://doi.org/10.3390/ biomedicines 10010129
Wang, S., Matsumoto, K., Lish, S. R., Cartagena-Rivera, A. X., \& Yamada, K. M. (2021). Budding epithelial morphogenesis driven by cell-matrix versus cell-cell adhesion. Cell, 184(14), 3702-3716.e30. https://doi.org/10.1016/i. cell.2021.05.015
2. Mecklenburg, J., Wangzhou, A., Hovhannisyan, A. H., Barba-Escobedo, P., Shein, S. A., Zou, Y., Weldon, K., Lai, Z., Goffin, V., Dussor, G., Tumanov, A. V., Price, T. J., \& Akopian, A. N. (2022). Sex-dependent pain trajectories induced by prolactin require an inflammatory response for pain resolution. Brain, Behavior, and Immunity, 101, 246-263. https://doi.org/10.1016/i. bbi.2022.01.016
3. Zhou, W., Ye, C., Wang, H., Mao, Y., Zhang, W., Liu, A., Yang, C. L., Li, T., Hayashi, L., Zhao, W., Chen, L., Liu, Y., Tao, W., \& Zhang, Z. (2022). Sound induces analgesia through corticothalamic circuits. Science (New York, N.Y.), 377(6602), 198-204. https://doi.org/10.1126/science.abn4663

## National Institute of Diabetes and Digestive and Kidney Diseases

## I. Overview

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) supports research on some of the costliest and most common chronic diseases. Many diseases within its mission affect women solely, disproportionately, or in unique ways. Only people with uteruses develop gestational diabetes, and women are disproportionately affected by obesity. They are also most affected by chronic bladder pain syndrome. Many of these conditions also intersect with racial-ethnic health disparities that NIDDK is committed to addressing. Through NIDDK-wide efforts and NIH collaborations, NIDDK supports research important to women's health, understanding of the influences of sex and gender on health and disease, and reduction of health disparities. Provided here are some examples of many NIDDK-supported scientific advances in FYs 2021-2022.

## II. Scientific Advances in Research on the Health of Women

Scientific Discoveries Following Landmark Gestational Diabetes Studies. The landmark multiethnic, NIH-funded Hyperglycemia and Adverse Pregnancy Outcome (HAPO) Study was performed in response to the need for agreed-upon diagnostic criteria for gestational diabetes based on adverse pregnancy outcomes. The NIDDK- and Eunice Kennedy Shriver National Institute of Child Health and Human Development-funded HAPO Follow-up Study (HAPO FUS) collected data 10-14 years postdelivery to better understand the long-lasting effects of elevated maternal blood sugar levels. In this follow-up study using HAPO and HAPO FUS data, researchers showed that newborn fat mass is associated with childhood fat mass and with maternal blood sugar and body mass index. ${ }^{1}$ Additionally, newborn fat mass is a marker for future metabolic health and indicates complex interactions between the in utero environment and newborn measurements in relation to childhood measurements. ${ }^{2}$

Encouraging Research on Differences in Health Status Across Biological and Social Constructs of Identity. It is increasingly recognized that interactions among biological, social, and environmental factors play a significant role in preventing and managing human disease. Sex and gender differences and race and ethnicity are among those factors with a significant impact on human health and disease. However, consideration of these factors in research projects remains limited. Therefore, an activity in which NIDDK engaged in FY 2022 was publishing a notice to encourage investigators to consider research on differences in health status across biological and social constructs of identity. NIDDK encourages investigators to consider implications of biological sex, sexual or gender minority status, gender identity, sexual orientation, race and ethnicity, and interactions across identities and with other social and biological determinants of health.

Research on Interstitial Cystitis, Painful Bladder, and Chronic Pelvic Pain. Interstitial cystitis/bladder pain syndrome (IC/BPS)—also known as IC/painful bladder syndrome-in women and men and chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS)
in men are important research topics of NIDDK's urology program. IC/BPS is a debilitating, chronic, and painful urologic disorder. It is estimated that among U.S. adult women, $2.7 \%$ have pelvic pain and other symptoms, such as urinary urgency, that are associated with IC/BPS. ${ }^{3}$ NIDDK-supported basic and clinical research on IC/BPS and on CP/ CPPS is focused on elucidating the causes of these conditions, identifying important subsets of patients to aid diagnostic stratification, and improving treatment and interventions.

## III. Future Priorities in Research on the Health of Women

In July 2021, NIDDK conducted a detailed analysis of its portfolio related to research on women's health. The portfolio analysis identified several knowledge gaps and future research opportunities. The NIDDK Women's Health Working Group is in the process of developing ideas on how these knowledge gaps can be filled and research opportunities can be addressed (e.g., with workshops, funding opportunities, and white papers).

1. Josefson, J. L., Scholtens, D. M., Kuang, A., Catalano, P. M., Lowe, L. P., Dyer, A. R., Petito, L. C., Lowe, W. L., Jr, Metzger, B. E., \& HAPO Follow-up Study Cooperative Research Group (2021). Newborn adiposity and cord blood C-peptide as mediators of the maternal metabolic environment and childhood adiposity. Diabetes Care, 44(5), 1194-1202. https://doi. org/10.2337/dc20-2398
2. Perak, A. M., Lancki, N., Kuang, A., Labarthe, D. R., Allen, N. B., Shah, S. H., Lowe, L. P., Grobman, W. A., Lawrence, J. M., Lloyd-Jones, D. M., Lowe, W. L., Jr, Scholtens, D. M., \& HAPO Follow-Up Study Cooperative Research Group (2021). Associations of maternal cardiovascular health in pregnancy with offspring cardiovascular health in early adolescence. JAMA, 325(7), 658-668. https://doi.org/10.1001/jama.2021.0247
3. Berry, S. H., Elliott, M. N., Suttorp, M., Bogart, L. M., Stoto, M. A., Eggers, P., Nyberg, L., \& Clemens, J. Q. (2011). Prevalence of symptoms of bladder pain syndrome/interstitial cystitis among adult females in the United States. The Journal of Urology, 186(2), 540-544. https://doi.org/10.1016/i. juro.2011.03.132

## National Institute on Drug Abuse

## I. Overview

The National Institute on Drug Abuse (NIDA) advances science on drug use and addiction and applies that knowledge to improve individual and public health. Integral to this mission is the elucidation of sex and gender differences in the neurobehavioral effects of drugs, the characteristics
of substance use disorder (SUD), and SUD risk factors. This knowledge informs personalized prevention, intervention, and SUD treatment. To accomplish these goals, the institute is committed to the goals on inclusion of women in research with human subjects. NIDA also supports programs for the recruitment and career development of a diverse workforce, particularly women and people in underrepresented racial and ethnic groups. These themes cut across NIDA divisions of basic research, services, medication development, and clinical trials.

## II. Scientific Advances in Research on the Health of Women

The Adolescent Brain Cognitive Development (ABCD) Study. The ABCD Study generates publicly available data on how genetics, sex, environment, cognition, behavior, and brain structure are associated throughout adolescent development. ${ }^{1}$ Secondary data analyses aimed at identifying sex differences in genetic associations between cognitive traits and psychiatric disorders provide information that may help predict psychiatric disease risk. The results provide evidence for both a shared and a unique genetic basis between psychiatric disorders and cognitive traits and have implications for sex differences in screening. This ongoing scientific project is consistent with NIH policies for the inclusion of women and for considering sex as a biological variable (SABV).

## NIDA-Funded Research Revealing Health

 Disparities. A study analyzed Medicaid data from all 50 States from 2006 to 2014 and revealed evidence of health disparities in the quality of treatment for opioid use disorder based on sex and race/ethnicity. ${ }^{2}$ Findings from this project underscore racial/ethnic and sex health disparities, and this project is consistent with the NIH policies for the inclusion of women and consideration of SABV.NIDA-Funded Basic Research on Biological Sex Differences. The impact of social status on the brain and its role in SUD vulnerability was studied in nonhuman primates (NHPs) using PET brain imaging to quantify kappa opioid receptor (KOR)
availability. ${ }^{3}$ Results revealed opposing effects of social status in male and female NHPs on brain KOR availability and imply that social status has very different and perhaps opposing effects on vulnerability to drug-taking behavior as a result of differential regulation of the brain dynorphin opioid peptide system. This scientific project is consistent with the NIH policies for the inclusion of females and consideration of SABV.

## The NIDA Brain Development Research Consortium Workshop on Placental Function and Addictive Substances. This workshop was timely, given the crisis in maternal mortality and evidence that drug overdose is a leading cause

 of pregnancy-related deaths. ${ }^{4}$ Because drugs can interfere with placental function and the placenta is critical for maintaining the pregnancy and maternal and fetal health, drug use during pregnancy poses significant health risks. The workshop covered clinical and basic research, genetics and epigenetics, and emerging technologies.
## The NIDA Women \& Sex/Gender Differences

 Research Group (WGRG). NIDA has organized the WGRG to promote the conduct, translation, and dissemination of research on sex and gender differences in the pharmacological, neurobiological, behavioral, and socioeconomic determinants of SUD; the impact of SUD on women's health; and promotion of the careers of women scientists. The group hosted monthly discussions on research, policy updates, and training opportunities.
## III. Future Priorities in Research on the Health of Women

NIDA advances science to understand and address substance use among women. NIDA catalyzes basic research that identifies interactions between neurobiological mechanisms and socioenvironmental contexts that determine SUD risk, the impact of substance use on health and well-being, and the basis for sex and gender distinctions in this interaction. Together with priorities for health equity and participatory research, this informs the development and implementation of sex- and gender-specific prevention and treatment strategies. NIDA will also advance mechanistic research on SUD comorbidity
with other disorders affecting women. Other key priorities include research that elucidates the effects of drug use on female-specific conditions throughout the lifespan, including pregnancy and the postpartum period.

[^8]
## National Institute of Environmental Health Sciences

## I. Overview

The National Institute of Environmental Health Sciences (NIEHS) works to discover how the exposome-factors in our environments, such as chemical, physical, synthetic, and infectious agents; social stressors; diet and medications; and our own microbiomes-affects our health. The knowledge generated by this research critically informs our understanding of women's health and environmentally mediated disease throughout their lives.

## II. Scientific Advances in Research on the Health of Women

## Mapping Breast Cancer in a Gene Expression

Atlas. NIEHS grantees developed a gene expression atlas that captures the cellular makeup of the mammary gland across life stages, providing clues on how breast cancer originates. ${ }^{1}$ They integrated data from 50,000 mouse mammary cells, covering eight life stages, and 24,000 adult human mammary cells.

Use of Hair Straighteners and Relaxers Tied to Uterine Cancer. Researchers examined the association between various hair products and uterine cancer incidence among 33,947 women between 35 and 74 years old. ${ }^{2}$ The use of straightening and relaxing products in the 12 months prior to enrollment was associated with higher rates of uterine cancer. Notably, the burden of this exposure falls predominately on Black women because of their higher prevalence of straightener and relaxer use.

## Impact of Rising Global Temperatures on

 the Ovaries. A study of more than 630 women in the Environment and Reproductive Health (EARTH) Study raises concern that rising ambient temperatures worldwide may result in accelerated reproductive aging among women. ${ }^{3}$ Exposure to higher temperatures was associated with lower ovarian reserve. A $1^{\circ} \mathrm{C}$ increase in average maximum temperature during the 90 days before testing was associated with a $-1.6 \%$ lower antral follicle count.
## Workshop Explores Environmental Impacts on Women's Health Disparities and Reproductive Health. The "Environmental Impacts on Women's Health Disparities and Reproductive Health" workshop, held April 27-28, 2022, examined the effects of chemical and nonchemical stressors on adverse maternal and fetal health outcomes, discussed diseases specific to women and individuals assigned female at birth, and assessed the role of racial and ethnic disparities in these exposures.

## Exploring the Role of Vitamin D in Fertility.

 Studies of vitamin D deficiency show disrupted ovulation and subfertility. A recent study found that high levels of vitamin D were associated with a higher probability of becoming pregnant, while low levels were associated with a lower probability. Research in collaboration with the Eunice Kennedy Shriver National Institute of Child Health and Health Disparities found that estrogen was lower in vitamin D-deficient women. ${ }^{4}$
## III. Future Priorities in Research on the Health of Women

NIEHS will continue to explore the unique ways in which women's health is affected by their exposome. Focuses include critical windows of
vulnerability, such as puberty and pregnancy; diseases and disorders, including breast cancer, polycystic ovary syndrome, uterine fibroids, and autoimmune disorders; and effects on women in environmental justice communities. NIEHS will investigate emerging areas of concern, including exposures that disrupt reproductive health; climate change; chemical exposures and mental health; and the role of sleep quality in development of disease. NIEHS will work with diverse partners across the globe to contribute environmental health science knowledge toward eliminating health disparities and improving health equity for all genders.

1. Saeki, K., Chang, G., Kanaya, N., Wu, X., Wang, J., Bernal, L., Ha, D., Neuhausen, S. L., \& Chen, S. (2021). Mammary cell gene expression atlas links epithelial cell remodeling events to breast carcinogenesis. Communications Biology, 4(1), 660. https://doi.org/10.1038/s42003-021-02201-2
2. Chang, C. J., O’Brien, K. M., Keil, A. P., Gaston, S. A., Jackson, C. L., Sandler, D. P., \& White, A. J. (2022). Use of straighteners and other hair products and incident uterine cancer. Journal of the National Cancer Institute, 114(12), 1636-1645. https://doi.org/10.1093/inci/djac165
3. Gaskins, A. J., Mínguez-Alarcón, L., VoPham, T., Hart, J. E., Chavarro, J. E., Schwartz, J., Souter, I., \& Laden, F. (2021). Impact of ambient temperature on ovarian reserve. Fertility and Sterility, 116(4), 1052-1060. https://doi. org/10.1016/i.fertnstert.2021.05.091
4. Harmon, Q. E., Kissell, K., Jukic, A. M. Z., Kim, K., Sjaarda, L., Perkins, N. J., Umbach, D. M., Schisterman, E. F., Baird, D. D., \& Mumford, S. L. (2020). Vitamin D and reproductive hormones across the menstrual cycle. Human Reproduction, 35(2), 413-423. https://doi.org/10.1093/humrep/dez283

Jukic, A. M. Z., Upson, K., Harmon, Q. E., \& Baird, D. D. (2016). Increasing serum 25 -hydroxyvitamin $D$ is associated with reduced odds of long menstrual cycles in a cross-sectional study of African American women. Fertility and Sterility, 106(1), 172-179.e2. https://doi.org/10.1016/i.fertnstert.2016.03.004

Jukic, A. M., Steiner, A. Z., \& Baird, D. D. (2015). Lower plasma 25-hydroxyvitamin $D$ is associated with irregular menstrual cycles in a crosssectional study. Reproductive Biology and Endocrinology, 13, 20. https://doi. org/10.1186/s12958-015-0012-5

Jukic, A. M. Z., Wilcox, A. J., McConnaughey, D. R., Weinberg, C. R., \& Steiner, A. Z. (2018). 25-hydroxyvitamin D and long menstrual cycles in a prospective cohort study. Epidemiology, 29(3), 388-396. https://doi.org/10.1097/ EDE. 00000000000000804
Jukic, A. M. Z., Baird, D. D., Weinberg, C. R., Wilcox, A. J., McConnaughey, D. R., \& Steiner, A. Z. (2019). Pre-conception 25-hydroxyvitamin D (25(OH) D) and fecundability. Human Reproduction, 34(11), 2163-2172. https://doi. org/10.1093/humrep/dez170
Jukic, A. M. Z., Zuchniak, A., Qamar, H., Ahmed, T., Mahmud, A. A., \& Roth, D. E. (2020). Vitamin D treatment during pregnancy and maternal and neonatal cord blood metal concentrations at delivery: Results of a randomized controlled trial in Bangladesh. Environmental Health Perspectives, 128(11), 117007. https://doi.org/10.1289/EHP7265

## National Institute of General Medical Sciences

## I. Overview

In FY 2021-2022, the National Institute of General Medical Sciences (NIGMS) supported research that has increased our understanding of basic biological processes underlying conditions that are specific to women or that disproportionately affect women, as well as research on tools and methods that may lead to improved diagnosis and treatment of such conditions. Key areas of research involved basic biological underpinnings of maternal health during and after pregnancy, as well as complications such as preterm birth, and basic studies of cell growth and proliferation involving genes implicated in breast and ovarian cancers. Finally, NIGMS sought to build institutional capacity for conducting women's health research in underrepresented populations and in rural areas, where women typically have less access to robust health care.

## II. Scientific Advances in Research on the Health of Women


#### Abstract

Quantitative Metagenomics and the Vaginal Microbiome of Preterm Birth. This NIGMS-supported research program (5R35GM133745) is developing computational methods of understanding and treating microbial-related human health conditions. The longterm goal of the research is to develop a diagnostic tool based on the vaginal microbiome to predict the risk of preterm birth early in pregnancy.


> A Home mRNA Sample Kit for Studying Inflammation in Women with Long COVID. NIGMS-supported researchers who developed a home sample collection kit for collecting researchgrade mRNA from patients were awarded a supplement (R35GM128648-05S1) to study molecular mechanisms underlying inflammation
in women of understudied, underrepresented, and underreported (U3) populations who are experiencing long COVID. The researchers hope to establish the "homeRNA" kit as a broadly applicable research tool for reaching women of U3 populations.

## Modeling Rural Perinatal Health Outcomes and Service Systems to Improve Health Equity.

 This project, supported through an NIGMS award establishing the Center for American Indian and Rural Health Equity (5P20GM104417-08 [5435]), is measuring and modeling spatial variation in perinatal care access and health outcomes across Montana. A recent publication found that women in remote rural areas had limited access to obstetric care, with American Indian/Alaska Native women facing greater disparities; the researchers are also disseminating their findings to policymakers and the local community. ${ }^{1}$
## Supporting Women's Health Research in the

 IDeA States. NIGMS continued to collaborate with ORWH to increase research specifically directed at women's health and health disparities and to expand the capacity of Institutional Development Award (IDeA) States-which have historically had less NIH funding-to conduct women's health research. In addition to issuing administrative supplements in FY 2021-2022, NIGMS collaborated with ORWH to fund Centers of Biomedical Research Excellence (COBRE) focused on women's health research in IDeA States. ${ }^{2}$
## III. Future Priorities in Research on the Health of Women

NIGMS will continue to support basic biomedical research, technology development research, and research in the institute's clinical areas that focuses on conditions disproportionately affecting the health of women. NIGMS plans to continue collaborating with ORWH to build capacity for women's health research in IDeA States, broadening the impact of this research to include underserved populations of women, including those in remote or rural areas. NIGMS also continues to support projects aimed at reducing the disparities in career advancement and leadership for women in biomedical research, especially at the faculty level, to ensure that diverse perspectives are
brought to bear on pressing scientific topics, including topics affecting women's health.

1. Mabie, N. (2022). "We have no specialized care here": Reservations struggle with limited prenatal care. Missoulian. https://missoulian.com/news/local/ we-have-no-specialized-care-here-reservations-struggle-with-limited-prenatal-care/article f3330e51-7d93-58a8-b9db-b6f3f0bfb446.html

Mabie, N. (2022). "Lucky I even made it": Native Americans face barriers accessing lifesaving maternal care. Missoulian. https://missoulian.com/ news/local/lucky-i-even-made-it-native-americans-face-barriers-accessing-lifesaving-maternal-care/article f50dfef0-2420-59bc-9376-6702273c0d40. html\#tracking-source=home-top-story

Thorsen, M. L., Harris, S., McGarvey, R., Palacios, J., \& Thorsen, A. (2022). Evaluating disparities in access to obstetric services for American Indian women across Montana. Journal of Rural Health, 38, 151-160. https://doi. org/10.1111/irh. 12572
2. Centers of Biomedical Research Excellence (COBRE) Phase 1 (P20-Clinical Trial Optional). https://grants.nih.gov/grants/guide/pa-files/PAR-22-250.html
Notice of Special Interest (NOSI): Administrative Supplements for Research on Women's Health in the IDeA States. https://grants.nih.gov/grants/guide/ notice-files/NOT-GM-21-018.html

Notice of Special Interest (NOSI): Administrative Supplements for Research on Women's Health in the IDeA States. https://grants.nih.gov/grants/guide/ notice-files/NOT-GM-22-005.html
Notice of Special Interest (NOSI): Supporting Women's Health Research in the IDeA States through the Centers of Biomedical Research Excellence (COBRE) Phase I Program. https://grants.nih.gov/grants/guide/notice-files/NOT-GM-21-056.html

Notice of Special Interest (NOSI): Supporting Women's Health Research in IDeA States through the Centers of Biomedical Research Excellence (COBRE) Phase 1 Program. https://grants.nih.gov/grants/guide/notice-files/NOT-GM-23-012.html

# National Institute of Mental Health 

## I. Overview

The National Institute of Mental Health (NIMH) works with ORWH and other NIH institutes, offices, and centers (ICOs) to ensure activities consider the health needs of women and girls and focus on reducing health disparities. NIMH supports research to improve the diagnosis, treatment, and prevention of mental disorders in women. NIMH funds research on sex and gender differences in mental illnesses. NIMH encourages research on maternal and perinatal mental health. NIMH seeks to support research that translates knowledge into diagnostics, therapies, and services to improve women's mental health. And NIMH promotes training opportunities for women in mental health research and for research that meets the needs of women from diverse socioeconomic, racial, ethnic, and geographic backgrounds.

## II. Scientific Advances in Research on the Health of Women

Elevating Voices and Addressing Depression, Toxic Stress, and Equity in Group Prenatal Care. Researchers are investigating a prenatal care intervention for low-income African American women that aims to reduce perinatal depression and decrease risk for preterm birth and low birthweight. ${ }^{1}$ This NIMH-funded study, continued from prior years, aligns with objectives 1.5 and 3.1 of the Trans-NIH Strategic Plan for Women's Health Research, as it focuses on maternal health conditions and integration of interventions in public health settings.

## Women's Experiences of Sexual Assault and Harassment Linked with High Blood Pressure.

 Researchers found that women exposed to sexual violence were more likely to develop high blood pressure years later. ${ }^{2}$ This NIMH -funded study, continued from prior years, aligns with objectives 1.2, 1.3, and 1.4 of the Trans-NIH Strategic Plan for Women's Health Research, as it investigates the influences of sex, gender, and exposures on health outcomes.
## Webinar on Gender Differences in Bipolar

 Disorder. This NIMH-hosted webinar explored gender differences in bipolar disorder, with a focus on intersectionality. This activity, initiated in the past 2 years, aligns with objectives 1.2, 2.4, 3.1, and 3.2 of the Trans-NIH Strategic Plan for Women's Health Research, discussing the influence of gender on disease, recruitment of women in research, and research dissemination.
## Women Leading Mental Health Research.

 NIMH developed the Women Leading Mental Health Research effort to highlight women who are early-career scientists conducting NIMH-funded research. These activities, initiated in the past 2 years, align with objectives 4.2, 4.3, and 4.4 of the Trans-NIH Strategic Plan for Women's Health Research, as they aim to support women at all stages of their research careers.Sex as a Biological Variable (SABV). NIMH encourages the inclusion of males and females in NIMH-funded extramural and intramural studies. NIMH directs reviewers to include SABV as an
independent review factor in all funding applications. NIMH participates in the NIH-Wide SABV Working Group to contribute to the development of resources for investigators to comply with the NIH SABV policy and to develop a standardized ICO program assessment of SABV policy implementation.

## III. Future Priorities in Research on the Health of Women

NIMH continues to prioritize research on women's mental health across the lifespan (e.g., mood and psychotic disorders during perimenopause) and encourages research on the influences of sex and gender on mental illnesses, autism spectrum disorder, and suicide. NIMH also prioritizes research related to mental health during the perinatal period. NIMH encourages research to examine causes of mental health disparities, as well as research on both biological mechanisms and social factors, with the goal of reducing disparities. NIMH also seeks research that increases the use of HIV prevention strategies among women.

1. Carter, E. B., EleVATE Women Collaborative, \& Mazzoni, S. E. (2021). A paradigm shift to address racial inequities in perinatal healthcare. American Journal of Obstetrics and Gynecology, 224(4), 359-361. https://doi. org/10.1016/j.ajog.2020.11.040
2. Lawn, R. B., Nishimi, K. M., Sumner, J. A., Chibnik, L. B., Roberts, A. L., Kubzansky, L. D., Rich-Edwards, J. W., Koenen, K. C., \& Thurston, R. C. (2022). Sexual violence and risk of hypertension in women in the Nurses' Health Study II: A 7-year prospective analysis. Journal of the American Heart Association, 11(5), e023015. https://doi.org/10.1161/JAHA.121.023015
National Institute of Mental Health (2022, February 22). Women's Experiences of Sexual Assault and Harassment Linked With High Blood Pressure. [Press Release]. https://www.nimh.nih.gov/news/science-news/2022/womens-experiences-of-sexual-assault-and-harassment-linked-with-high-blood-pressure

## National Institute on Minority Health and Health Disparities

## I. Overview

The National Institute on Minority Health and Health Disparities (NIMHD) leads scientific research to improve minority health, reduce health disparities, and promote health equity. NIMHD's work aims to address health disparities among women in the designated populations with health disparities, with primary emphasis on disparities across racial and ethnic
minority groups and less privileged socioeconomic groups of any race or ethnicity. NIMHD is also focused on the intersection of women from rural and sexual and gender minority populations who identify as a racial or ethnic minority person or who are of lower socioeconomic status. Racism is a major factor at the intersection of race, gender, and socioeconomic status, and it is a driver of poorer health outcomes for women of racial and ethnic minority and other disadvantaged backgrounds. The social conditions within which women exist across the lifespan is also of research interest as major contributors to health disparities.

## II. Scientific Advances in Research on the Health of Women

This section provides highlights of select NIMHD projects addressing women's health disparities.

Maternal Outcome Monitoring and Support (MOMS)—A Mobile Health (mHealth) Symptom Self-Monitoring and Decision Support System to Reduce Racial and Ethnic Disparities in Postpartum Outcomes. The research seeks to develop an mHealth-based support system to help mothers with self-monitoring symptoms and determining when to seek care for severe maternal morbidity and postpartum depression.

Mobile Health App to Reduce Diabetes in Latina Women with Prior Gestational Diabetes. This study is testing the preliminary effectiveness of a mobile app-iHola Bebé, Adiós Diabetes!-in reducing risk factors for Type 2 diabetes in Hispanic or Latina women who have had gestational diabetes within the past 5 years. The goal is to develop a culturally tailored mHealth intervention to reduce risk factors for Type 2 diabetes.

[^9]Prenatal Care Expansion and Use of Antidiabetic
Agents During Pregnancies Among Latinas
with Emergency Medicaid. This study found
that expanded emergency Medicaid benefits
that included prenatal care were associated with
increased use of antidiabetic medications and
postpartum contraception during pregnancy. ${ }^{2}$ There
was a $27.9 \%$ increase in the receipt of antidiabetic
agents among women with diabetes receiving
prenatal care, and there was a 10.4\% increase in
insulin use among patients with gestational diabetes.

## III. Future Priorities in Research on the Health of Women

NIMHD will continue to advance research on the health of women from underserved populations in areas such as (1) maternal morbidity and mortality disparities; (2) social determinants of health; (3) prevention and intervention strategies to identify and understand mechanisms and pathways of early aging, chronic debilitating diseases, multimorbidity, and diabetes and obesity; and (4) research across the life course examining protective factors and resilience, mental health concerns, and promotion of well-being.

[^10]
## National Institute of Neurological Disorders and Stroke

## I. Overview

The mission of the National Institute of Neurological Disorders and Stroke (NINDS) is to seek fundamental knowledge about the brain and nervous system and to use that knowledge to reduce the burden of neurological disease for all. Most nervous system disorders affect men and women equally, but some have specific health implications for women (e.g., epilepsy and stroke, recovery after spinal cord and traumatic brain
injury, and autism) or disproportionately affect women (e.g., migraine, multiple sclerosis, myalgic encephalopathy/chronic fatigue syndrome, postacute sequelae of COVID-19, and diseases associated with aging). NINDS has substantial research investments in these disease areas. NINDS also supports research on the biological and social factors that underlie health disparities, most notably in stroke and dementia, and some of this work also explores the intersections of race, ethnicity, socioeconomic status, and female sex. NINDS also supports the inclusion of women in research and their representation in the biomedical research workforce.

## II. Scientific Advances in Research on Health of Women

New Research on Migraine and Headache. Headache, particularly migraine headache, predominantly affects women and represents an area where additional research is needed. In response to a December 2021 notice of special interest (NOT-NS-22-051) inviting applications on migraine headache, NINDS received a large number of applications and funded a number of the applications, including a study of the psychophysical, hormonal, and neural factors associated with migraine onset in adolescent girls (1R01NS129742-01; PI: Nahman-Averbuch), as well as several studies in the preclinical space.

Family-Friendly Environment Requirements of T32 Programs. In 2021, NINDS instituted a requirement that institutions describe their efforts to provide family-friendly environments, accommodations, and leave policies in T32 institutional research training award applications (PAR-21-149). These policies and accommodations must address timely access to affordable child care and accommodations for extended medical, family care, or emergency circumstances that may affect scientific productivity.

Science Advance: Study Shows That EpsteinBarr Virus Is Highly Associated with Multiple Sclerosis (MS). The underlying cause of MS remains unknown. One possibility is that it can be triggered by a virus, such as the Epstein-

Barr virus (EBV). Conducted in part by NINDS intramural investigators, a 2022 study reported that EBV infection dramatically increased the odds of developing MS in a study of more than 10 million active-duty U.S. military personnel between 1993 and 2013. ${ }^{1}$ The team calculated that people infected with EBV were 32 times as likely to develop MS as uninfected people. In contrast, the researchers found no such association between MS and any other human viruses. The finding suggests that prevention of EBV infection (e.g., via vaccination) could help prevent some cases of MS.

## III. Future Priorities in Research on the Health of Women

NINDS will continue to support a robust portfolio of women's health research and related activities. Guided by recent strategic planning for health equity, future priorities include enhancing community-engaged research practices, as well as understanding and intervening in social determinants of health for women and other understudied populations. Equity in the research workforce is also a high priority for NINDS. NINDS plays a strong role in several NIH-wide priority areas, including chronic pain/HEAL, post-acute sequelae of COVID-19, and maternal health and morbidity. NINDS will continue to monitor inclusion of women in its clinical research and enhance efforts where needed.

1. Bjornevik, K., Cortese, M., Healy, B. C., Kuhle, J., Mina, M. J., Leng, Y., Elledge, S. J., Niebuhr, D. W., Scher, A. I., Munger, K. L., \& Ascherio, A. (2022). Longitudinal analysis reveals high prevalence of Epstein-Barr virus associated with multiple sclerosis. Science (New York, N.Y.), 375(6578), 296-301. https://doi.org/10.1126/science.abj8222

## National Institute of Nursing Research

## I. Overview

The National Institute of Nursing Research (NINR) has demonstrated a sustained commitment to supporting research on the health of women over its 35 -year history. Approximately 20\% of NINR's budget is devoted to research on women's health. With the launch of NINR's new strategic plan in May 2022, the institute will continue supporting women's health through the NINR research lenses
of health equity, social determinants of health, community and population health, prevention and health promotion, and innovative systems and models of care. Additionally, NINR will continue its commitment to advancing the careers of women scientists through a strong emphasis on training and mentorship and a dedication to supporting the growth of future nurse scientists

## II. Scientific Advances in Research on the Health Women

## PA-18-135: Maternal Nutrition and Pre-

 pregnancy Obesity: Effects on Mothers, Infants and Children. NINR supported interdisciplinary research to improve health outcomes for women and infants in the context of maternal nutrition and pre-pregnancy obesity; three projects were funded through 2022. One study explores how social and biological determinants, including maternal weight and multilevel indicators of social disadvantage, contribute to severe maternal morbidity and related racial and ethnic health disparities. In another project, researchers are testing a patient-centered mobile health ( mHealth ) weight management program for pregnant women enrolled in the Special Supplemental Nutrition Program for Women, Infants, and Children, known as the WIC program, to promote healthy gestational weight. Finally, other researchers are testing a novel mHealth intervention for overweight and obese pregnant women that provides personalized education, support, and problem-solving skills training to achieve optimal health through healthy gestational weight goals.RFA-NR-22-002: Advancing Integrated Models (AIM) of Care to Improve Maternal Health Outcomes among Women Who Experience Persistent Disparities (R01 Clinical Trial Required); and RFA-NR-22-003: Advancing Integrated Models (AIM) of Care to Improve Maternal Health Outcomes among Women Who Experience Persistent Disparities (R21 Clinical Trial Optional). To address the public health crisis of persistent disparities in maternal health outcomes, NINR launched a funding initiative to support intervention and developmental research focused on advancing integrated models of care addressing structural inequities.

## III. Future Priorities in Research on the Health of Women

Future NINR-supported women's health research will continue to explore the biological, behavioral, environmental, social, and structural factors underlying inequities in women's health outcomes. This work will emphasize a broad examination of the social determinants of women's health, including women's life chances based on the intersection of their gender with other social identities and positions (e.g., racial and ethnic, socioeconomic status, sexual orientation, and rurality) and the real health consequences for themselves and their family, community, and society. It will also encompass the many clinical, community, and policy settings where nurses engage in prevention, treatment, care, and decision-making, including in hospitals and clinics, in schools and workplaces, in homes and long-term care facilities, in justice settings, and throughout the community. Identifying structural constraints and opportunities to achieve health equity among women will be a priority.

## National Library of Medicine

## I. Overview

As a platform for biomedical discovery, the National Library of Medicine (NLM) disseminates biomedical data and information and conducts and funds research in computational health and computational biology, supporting NIH efforts to advance research for the health of women.

In FY 2021-2022, NLM resources such as ClinicalTrials.gov, LactMed, MedlinePlus, and PubMed ensured scientists, clinicians, and the public had access to information on women's health and research 24 hours a day, 7 days a week. NLM also supported research to apply computational approaches to problems relevant to the health of women, such as cervical cancer detection and menopausal hormone therapy.

The Network of the National Library of Medicine supported projects to provide health information to diverse populations, including women. NLM's

outreach and training programs in biomedical informatics and data science helped prepare a data-driven workforce, advancing science for women's health.

## II. Scientific Advances in Research on the Health of Women

## Advancing Reproductive Health Equity in

 Afghan and Syrian Newcomers Through Digital Health Literacy. The NLM Information Resource Grants to Reduce Health Disparities program is supporting a 3 -year study (1 G08 LM01410901), led by California's Refugee Reproductive Health Network, to: (1) create a publicly available digital repository of multilingual reproductive health resources for Afghan and Syrian refugee populations; (2) enhance Afghan and Syrian refugees' reproductive health literacy in California through in-person and online training; and (3) increase the capacity of refugee programs to integrate reproductive health literacy in their programs.> Combining Machine Learning, Artificial Intelligence, and Image Processing for Cervical Cancer Detection and Research.

NLM researchers developed and applied machine learning and artificial intelligence techniques for cervical cancer detection in collaboration with the National Cancer Institute. NLM researchers are designing a novel pipeline for automated localization of possible lesions in dynamic cervical imaging to support cancer research. Findings were published in peer-reviewed scientific literature. ${ }^{1}$

## Disseminating Clinical Trial Participant

 Demographic Information via ClinicalTrials.gov. NLM's ClinicalTrials.gov includes information about enrollment and inclusion of research participants, including women and minorities, in registered studies and reported study results. In December 2021, NLM released the beta ClinicalTrials.gov site, which makes information about race and ethnicity, sex and gender, and age of participants easier to find and access.
## III. Future Priorities in Research on the Health of Women

NLM will continue to support research on the health of women by facilitating discoveries from large data sources, creating innovative ways to reach users with trusted health information, and developing
health data literacy among scientists, clinicians, librarians, and consumers.

Priorities include (1) strategies to support efficient and accurate exploration of large biomedical databases and new analytical methods; (2) creating high-quality, sustainable, and secure databases to make biomedical research available to support open science and health communication; (3) building a modern infrastructure that offers literature, data, analytical models, and new forms of scientific communications to support research, operational, and organizational needs; and (4) contributing expertise in data science, data management, infrastructure, security, and workforce development to NIH-wide priority areas and Government-wide priority areas.

1. Desai, K. T., Ajenifuja, K. O., Banjo, A., Adepiti, C. A., Novetsky, A., Sebag, C., Einstein, M. H., Oyinloye, T., Litwin, T. R., Horning, M., Olanrewaju, F. O., Oripelaye, M. M., Afolabi, E., Odujoko, O. O., Castle, P. E., Antani, S., Wilson, B., Hu, L., Mehanian, C., Demarco, M., ... Schiffman, M. (2020). Design and feasibility of a novel program of cervical screening in Nigeria: self-sampled HPV testing paired with visual triage. Infectious Agents and Cancer, 15, 60. https://doi.org/10.1186/s13027-020-00324-5
Desai, K. T., Befano, B., Xue, Z., Kelly, H., Campos, N. G., Egemen, D., Gage, J. C., Rodriguez, A. C., Sahasrabuddhe, V., Levitz, D., Pearlman, P., Jeronimo, J., Antani, S., Schiffman, M., \& de Sanjosé, S. (2022). The development of "automated visual evaluation" for cervical cancer screening: The promise and challenges in adapting deep-learning for clinical testing: Interdisciplinary principles of automated visual evaluation in cervical screening. International Journal of Cancer, 150(5), 741-752. https://doi.org/10.1002/ijc. 33879
Guo, P., Xue, Z., Angara, S., \& Antani, S. K. (2022). Unsupervised deep learning registration of uterine cervix sequence images. Cancers, 14(10), 2401. https://doi.org/10.3390/cancers14102401

Guo, P., Xue, Z., Jeronimo, J., Gage, J. C., Desai, K. T., Befano, B., García, F., Long, L. R., Schiffman, M., \& Antani, S. (2021). Network visualization and pyramidal feature comparison for ablative treatability classification using digitized cervix images. Journal of Clinical Medicine, 10(5), 953. https://doi. org/10.3390/jcm10050953

Guo, P., Xue, Z., Mtema, Z., Yeates, K., Ginsburg, O., Demarco, M., Long, L. R., Schiffman, M., \& Antani, S. (2020). Ensemble Deep Learning for Cervix Image Selection toward Improving Reliability in Automated Cervical Precancer Screening. Diagnostics (Basel, Switzerland), 10(7), 451. https:// doi.org/10.3390/diagnostics10070451
Guo, P., Xue, Z., Long, L. R., \& Antani, S. (2020). Cross-dataset evaluation of deep learning networks for uterine cervix segmentation. Diagnostics (Basel, Switzerland), 10(1), 44. https://doi.org/10.3390/diagnostics10010044

Pal, A., Xue, Z., Befano, B., Rodriguez, A. C., Long, L. R., Schiffman, M., \& Antani, S. (2021). Deep Metric Learning for Cervical Image Classification. IEEE access : practical innovations, Open Solutions, 9, 53266-53275. https://doi. org/10.1109/access.2021.3069346
Perkins, R., Jeronimo, J., Hammer, A., Novetsky, A., Guido, R., Del Pino, M., Louwers, J., Marcus, J., Resende, C., Smith, K., Egemen, D., Befano, B., Smith, D., Antani, S., de Sanjose, S., \& Schiffman, M. (2022). Comparison of accuracy and reproducibility of colposcopic impression based on a single image versus a two-minute time series of colposcopic images. Gynecologic Oncology, 167(1), 89-95. https://doi.org/10.1016/i.ygyno.2022.08.001

Xue, Z., Novetsky, A. P., Einstein, M. H., Marcus, J. Z., Befano, B., Guo, P., Demarco, M., Wentzensen, N., Long, L. R., Schiffman, M., \& Antani, S. (2020). A demonstration of automated visual evaluation of cervical images taken with a smartphone camera. International Journal of Cancer, 147(9), 2416-2423. https://doi.org/10.1002/ijc. 33029


## Report of the NIH Centers

## Fogarty International Center

## I. Overview

The Fogarty International Center (FIC) advances the NIH mission by supporting global health research conducted by U.S. and international investigators, building partnerships between research institutions in the U.S. and abroad, and training the next generation of scientists to address global health needs. ORWH collaborates with FIC to support this mission. Though FIC does not have programs with a sole focus on women's health, FIC's strategic plan demonstrates a commitment to the health of the most vulnerable and a focus on reducing health disparities. Several FIC efforts support research and research training related to conditions that disproportionately or exclusively affect women or girls and enhance the understanding of sex as a biological variable and gender differences. Scientific areas of focus include violence against women, mental health, breast and cervical cancers, HIVIAIDS, and reproductive health issues.

## II. Scientific Advances in Research on the Health of Women

The International Research Scientist Development Award supports U.S. postdoctoral scientists and junior faculty members in the formative stages of their global health research careers. The award prepares biomedical, epidemiological, clinical, social, and behavioral scientists for independent research by engaging in a mentored research and career development experience.

The Emerging Global Leader Award provides 3-5 years of research support and protected time for career development activities to an early-career research scientist from a low- or middle-income country (LMIC) who holds a junior faculty position at an LMIC academic or research institution and seeks an independent research career at that institution. FIC expects this intensive mentored research career development experience to lead to an independently funded research career at an LMIC institution.

The HIV Research Training Program seeks to strengthen the capacity of LMIC investigators and their institutions to conduct HIV-related research on the evolving HIV-related epidemics in their countries and to compete independently for research funding. Mentored research training projects address HIV-related health issues relevant to women, including AIDS-related cervical cancer and prevention of mother-to-child transmission.

The funding opportunity announcement titled Interventions for Stigma Reduction to Improve HIV/AIDS Prevention, Treatment and Care in Low- and Middle-Income Countries supports research on novel stigma reduction interventions, reducing the impact of stigma on adolescent health, developing strategies to cope with stigmatization, and improving stigma measurement. Collaborative exploratory research is expected to help build the capacity for full research programs by improving the research environment and strengthening LMIC individual and institutional research capabilities in the proposed research areas.

## The Adolescent HIV Prevention and Treatment

 Implementation Science Alliance (AHISA) enhances the effective use of evidence and helps overcome implementation challenges related to prevention, screening, and treatment of HIV among adolescents in sub-Saharan Africa by catalyzing collaboration and communication among NIH-funded implementation scientists, program implementers, and policymakers. AHISA enables the exchange of ideas and experiences in understanding factors that drive uptake and adherence to adolescent HIV strategies to bridge the gaps among research, programs, and policy.
## III. Future Priorities in Research on the Health of Women

FIC continues to build leaders in global health research and strengthen the capacity of research institutions to be sustainable platforms for cuttingedge science. FIC's research training portfolio supports U.S. and LMIC women scientists' career development through significant mentorship and research capacity building.

# National Center for Advancing Translational Sciences 

## I. Overview

The National Center for Advancing Translational Sciences (NCATS) finds and overcomes scientific and operational roadblocks that impede how research discoveries move through preclinical and clinical research channels to become health solutions. The programs highlighted below are examples of how NCATS supports research to improve women's health.

## II. Scientific Advances in Research on the Health of Women

3D Tissue Bioprinting Program to Improve Health in Pregnancy. NCATS researchers utilize 3D bioprinting to develop tissue models in microplates that mimic native human tissue's 3D structure and cellular organization. Two projects aim to improve maternal-fetal health by using these models for drug screening: a maternal-fetal interface tissue model that mimics inflammation during pregnancy, used to screen compounds that may reduce preterm birth, and a 3D placental barrier model used to evaluate drug penetration through a bioprinted placental barrier tissue.

Small-Molecule Therapeutics to Prevent Breast-to-Brain Metastases. Brain metastases occur in 10-15\% of women with Stage 4 breast cancer. Triple-negative (30\%) and HER2+ (34\%) breast cancers are more likely to metastasize to the brain and have poor outcomes. Seeing as many therapeutic agents cannot cross the blood-brain barrier, NCATS investigators have been collaborating with extramural researchers to develop high-throughput screening approaches to identify molecules for treating breast-to-brain metastases. Using the current hematogenic HER+/ ERa+ breast-to-brain metastasis human cell model, over 6,500 compounds-including about 2,500 cancer drugs-were screened. The team also

discovered a mechanism by which the metastatic breast cancer cells use resident brain cells to avoid being killed by drugs that target the HER2 receptor.

Tissue Chips Program. A tissue chip project aims to develop extracellular vesicle-based therapeutics against preterm birth using an organ-on-chip model that aims to reproduce the structure, function, and responses of the maternal-fetal tissue interface. The chip will re-create healthy and inflammatory conditions, as fetal immune responses are a key trigger of spontaneous preterm birth. The goal is to offer a personalized maternal-fetal interface model to test potential treatments and streamline clinical trials.

## Sex Differences in Determinants of Severe COVID-19 Outcomes-Findings from the National COVID Cohort Collaborative (N3C). N3C examined whether comorbidities and

 biomarkers affect COVID-19 differently in men and women. Researchers evaluated the association of comorbidities, inflammatory biomarkers, and severe outcomes in over 570,000 adult patients admitted for COVID-19 at hospitals (in 2020-2021). The study found sex differences in mortality associated with some comorbidities and biomarkers,highlighting the importance of sex-disaggregated research in COVID-19. ${ }^{1}$

Advancement of Women in Biomedical Careers.
The Women Scientists Advisors group within the Division of Preclinical Innovation (DPI) developed a new initiative in 2022 to engage women scientists from DPI with the community, particularly students in grades $\mathrm{K}-12$. This initiative increases the visibility of women scientists and encourages the development of students' scientific literacy while showing that science and scientists are relatable and anyone can have a job in science.

## III. Future Priorities in Research on the Health of Women

The NCATS vision is to get more treatments to all people more quickly by discovering new technologies and other approaches that could greatly accelerate the process of developing and deploying solutions that can be used by all translational researchers.

1. Yoshida, Y., Chu, S., Fox, S., Zu, Y., Lovre, D., Denson, J. L., Miele, L., \& Mauvais-Jarvis, F. (2022). Sex differences in determinants of COVID-19 severe outcomes - Findings from the National COVID Cohort Collaborative (N3C). BMC Infectious Diseases, 22(1), 784. https://doi.org/10.1186/s12879-022-07776-7

# National Center for Complementary and Integrative Health 

## I. Overview

The National Center for Complementary and Integrative Health (NCCIH) is committed to funding research for diverse populations and promoting a diverse scientific workforce. We support training, career development, and research opportunities directed at women's health.

## II. Scientific Advances in Research on the Health of Women

Diets Higher in Omega-3 Fatty Acids Reduce Headache Frequency and Severity in People with Frequent Migraines. In this study, 182 people who had migraines were randomly assigned to consume one of three diets for 16 weeks: a diet with increased eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA) and a linoleic acid level the same as the average U.S. intake; a diet with increased EPA and DHA and reduced linoleic acid; or a control diet with levels of EPA, DHA, and linoleic acid the same as average U.S. intakes. ${ }^{1}$ The results of the study indicate that an increased intake of the omega-3 fatty acids EPA and DHA can reduce the frequency and severity of headaches and that reducing intake of the omega-6 fatty acid linoleic acid may lead to additional improvement. This study provides a biologically plausible demonstration that pain can be treated through dietary alterations, thus opening the door to new approaches for managing chronic pain.

## New Analysis Shows Racial and Ethnic

 Differences in the Relationship Between Pregnancy and High-Impact Pain. Non-Hispanic White women in the United States are less likely to have high-impact pain when they are pregnant than at other times in their lives, but this pattern is not seen in non-Hispanic Black or Hispanic White women, according to a new analysis of nationalsurvey data. ${ }^{2}$ Previous studies both in animals and in human populations have provided evidence that pregnancy is associated with a reduction in sensitivity to pain. The investigators who conducted this analysis suggested that future research to identify the factors responsible for racial and ethnic differences in high-impact pain across pregnancy status will help improve the understanding and treatment of pain for all women.

## III. Future Priorities in Research on the Health of Women

NCCIH will continue to further research on women's health and sex as a biological variable by developing and testing interventions using complementary health approaches for managing symptoms such as perinatal and postpartum depression, stress, anxiety, pain, and sleep disturbance and assessing their impact on maternal health outcomes. NCCIH will also support research on the use of complementary health approaches to support pregnant women and parenting women with opioid use disorder. Additionally, NCCIH intends to support research on the contributions of sex, gender, and the intersection of sex and gender on the mechanisms of action of complex interventions, including various mind and body approaches and natural products. NCCIH will also conduct research that investigates the influence of sex and gender on the use of complementary health approaches to improving health outcomes among diverse populations, including genderdiverse populations.

1. Ramsden, C. E., Zamora, D., Faurot, K. R., MacIntosh, B., Horowitz, M., Keyes, G. S., Yuan, Z. X., Miller, V., Lynch, C., Honvoh, G., Park, J., Levy, R., Domenichiello, A. F., Johnston, A., Majchrzak-Hong, S., Hibbeln, J. R., Barrow, D. A., Loewke, J., Davis, J. M., Mannes, A., ... Mann, J. D. (2021). Dietary alteration of $\mathrm{n}-3$ and $\mathrm{n}-6$ fatty acids for headache reduction in adults with migraine: randomized controlled trial. The BMJ, 374, n1448. https://doi. org/10.1136/bmj.n1448
2. Thomas, D. A., \& Nahin, R. L. (2022). Cross-sectional analyses of high-impact pain across pregnancy status by race and ethnicity. Journal of Women's Health, 31(11), 1575-1580. https://doi.org/10.1089/jwh.2021.0308


## Report of the NIH Offices

## Office of AIDS Research

## I. Overview

Although over half of people with HIV worldwide are women and despite NIH's inclusion policies and policy on sex as a biological variable (SABV), our understanding of HIV in women is limited. Women with HIV and women at high risk for acquisition of HIV are underrepresented across the HIV research continuum, which severely limits the understanding of the pathogenesis of infection and comorbid diseases. The lack of consideration of SABV and the underrepresentation of women and sexual and gender minorities in clinical research further the limit availability of safe and effective HIV prevention, treatment, and cure modalities. As HIV affects girls and women differently across the life course, the HIV research agenda for women should be tailored appropriately. The Office of AIDS Research (OAR), in strategic partnership with ORWH, continues to address these critical gaps in the NIH portfolio through stimulating expanded research focused on the intersection of HIV and women's health, especially through collaborative opportunities.

## II. Scientific Advances in Research on the Health of Women

OAR-ORWH HIV \& Women Signature Program.
OAR's signature program on HIV and women is a partnership with ORWH aimed at promoting the NIH vision for women's health, in which all individuals assigned female at birth and transgender women receive evidence-based, gender-affirming, tailored HIV prevention, care, and treatment. This program also supports women in scientific careers reaching their full potential. A multidisciplinary approach is crucial to improving the health of women with HIV. OAR and ORWH are uniquely positioned to catalyze innovative research on HIV and women. Coordination between ORWH and OAR is crucial to advancing HIV research for women. NIH policies, resources for investigators, and targeted research funding can work together to ensure that every woman and girl living with or affected by HIV benefits from the best research possible. An intersectional, equity-informed, datadriven approach to research on HIV and women is the cornerstone of this new collaboration.

## Engagement and Information Dissemination.

 OAR has been actively engaged with the HIV/AIDS research community in support of research for women living with and at risk for HIV. Often there is limited awareness of NIH's women's health initiatives within the HIV research community. These engagements reinforce the importance of information dissemination and are critical to advancing research at the intersection of HIV and women's health. Presentations on HIV and women in FY 2021-2022 included (1) "Research Gaps \& Priorities in HIV and COVID Research in Women" at the Inter-CFAR Women and HIV Symposium on October 12, 2021, (2) "A Look at the Numbers: Women's Representation in NIH HIV Studies" at the annual convening of the Well Project's Women's Research Initiative on HIV/AIDS on May 13, 2022, (3) "NIH OAR: Microbicide Research Update for MATRIX" at the USAID-MATRIX Partners Interaction Meeting on July 11, 2022, and (4) "NIH OAR Update: Women's Health and HIV Research Activities in FY22" at the National Institute of Allergy and Infectious Diseases' AIDS Research Advisory Committee meeting on September 12, 2022.
## III. Future Priorities in Research on the Health of Women

Over the past 40 years, we have achieved remarkable milestones in the effort to end HIV, including the development of highly effective antiretroviral therapies, better understanding of the nuances of viral transmission, and breakthroughs in prevention and implementation science. NIH is committed to advancing even more progress, in which the inclusion of women and girls is pivotal. Despite tremendous scientific advances, women, girls, and people of trans experience remain disproportionately affected by HIV. Women with HIV have higher rates of non-AIDS comorbidities than men, and much remains unknown about sex differences when it comes to a cure for HIV. Prioritizing the inclusion of diverse populations of women in prevention-, therapeutic-, and curerelated research is an essential component of ending the HIV epidemic. OAR, in partnership with ORWH, is uniquely positioned to catalyze an innovative, intersectional, equity-informed, datadriven approach to research on HIV and women.

## Office of Behavioral and Social Sciences Research

## I. Overview

The mission of the Office of Behavioral and Social Sciences Research (OBSSR) is to enhance the impact of health-related behavioral and social sciences research, coordinate this research across the NIH biomedical enterprise, and communicate scientific findings to stakeholders within and outside of the Federal Government. Although OBSSR is not specifically focused on women's health or womenfocused research, several activities align with those of ORWH.

## II. Scientific Advances in Research on the Health of Women

## Impact of State-Level Policies on Maternal

 Mortality. "Impact of State-Level Policies on Maternal Mortality" (3R01HD096070-03S1) was an administrative supplement initiated in FY 2021 to come from a notice of special interest on firearm injury and mortality. The study estimated the impact of four State-level policies shaping access to and ownership of firearms on incidence of pregnancyassociated homicide. Findings have yielded 10 papers in peer-reviewed journals and directly apply to goal 1 of the Trans-NIH Strategic Plan for Women's Health Research, to advance rigorous research that is relevant to the health of women.
## Improving Patient Adherence to Treatment

 and Prevention Regimens to Promote Health. OBSSR led Improving Patient Adherence to Treatment and Prevention Regimens to Promote Health, which yielded one relevant award in FY 2022. The Together Everyone Achieves More Physical Activity (TEAM-PA) trial (R01HL160618-01) is based on the fact that African American women experience persistent disparities in chronic diseases and premature death across the lifespan. The study evaluated the efficacy of a group-based social affiliationintervention for increasing physical activity among inactive African American women based on a cultural values framework. This project is relevant to goal 3 of the Trans-NIH Strategic Plan for Women's Health Research, to enhance dissemination and implementation of evidence to improve the health of women.

## Sponsored and Led Meetings and Webinars.

 OBSSR has sponsored and led several meetings and webinars from accomplished speakers on topics related to women's health. The 2021 NIH Behavioral and Social Sciences Research Festival included "Enhanced Perinatal Programs for People in Prisons," presented by Dr. Rebecca Shlafer. The 2021 OBSSR Director's Webinar featured "Quality of Care, Disparities, and the Healthcare Crisis for Moms and Babies of Color," by Dr. Elizabeth Howell, while the 2022 webinar featured "Innovative Approaches to Understanding Eating Disorders," by Dr. Cynthia Bulik. The 2020 Matilda White Early Stage Investigator Paper Awardee, Dr. Jaime Slaughter-Acey, presented "Skin Tone and Prenatal Care Outcomes Among African American Women." These presentations align with goal 2 of the Trans-NIH Strategic Plan for Women's Health Research, to develop methods and leverage data sources considering sex and gender influences that enhance research for the health of women.
## III. Future Priorities in Research on the Health of Women

Many topics related to women's health align with OBSSR's priorities, particularly those articulated in its three scientific priorities and four crosscutting themes. These include, but are not limited to, workforce opportunities for women in science, enhancements to research that includes women, and policy-related issues affecting women. OBSSR leads few funding opportunities as a coordinating office, but those it does may align with the priorities of ORWH in terms of proposed research topics from applicants.

## Office of Disease Prevention

## I. Overview

The Office of Disease Prevention (ODP) is responsible for assessing, facilitating, and stimulating research on disease prevention and disseminating the results of this research to improve public health. Many ODP activities are focused on increasing the scope, quality, implementation, and impact of research related to the health of women. For example, ODP collaborates with the U.S. Preventive Services Task Force, the Community Preventive Services Task Force, and the Healthy People initiative to identify and address research needs and gaps in women's health. ODP co-funds research that addresses topics relevant to women's health, including maternal morbidity and mortality, cancer, heart health, health disparities, physical activity, osteoporosis, social determinants of health (SDOH), and well-being.

## II. Scientific Advances in Research on the Health of Women

Reducing Racial Disparities in Maternal Morbidity and Mortality. Health information technology (IT) is a promising way to address racial and ethnic, socioeconomic, and geographic disparities in maternal morbidity and mortality (MMM). This is especially relevant given that approximately $60 \%$ of maternal deaths are considered preventable. Interventions that leverage health IT tools to target the underlying drivers of disparities at the patient, clinician, and health care system levels could reduce disparities in quality of care throughout the continuum (antepartum, intrapartum, and postpartum) of maternity care. This article presents an overview of the research (and gaps) on the potential of health IT tools to document SDOH and community-level geocoded data in electronic health record-based clinical decision support systems, minimize implicit bias,
and improve adherence to clinical guidelines and coordinated care to inform multilevel (patient, clinician, system) interventions throughout the continuum of maternity care for health disparity populations. ${ }^{1}$ Telemedicine models for improving access in rural areas and new technologies for risk assessment and disease management (e.g., regarding preeclampsia) also are discussed.

## Prevention Research Related to the Health of Women. ODP led or joined several funding opportunity announcements supporting prevention research related to the health of women (e.g., Notice of Special Interest: Administrative Supplements for NIH grants to Add or Expand Research Focused on Maternal Mortality).

## Methods in Prevention Research for Women's

 Health. ODP promotes the use and development of the best available methods in prevention research, including those that consider sex and gender influences in research. The office disseminates information about research design, measurement, intervention, data analysis, and other methods through its Methods: Mind the Gap and Prevention in Focus webinar series. A recent Prevention in Focus webinar highlighted the FIERCE Exercise Study, a community-based cancer prevention trial in metabolically unhealthy Black women.
## III. Future Priorities in Research on the Health of Women

ODP supports prevention research relevant to the health of women. Future research priorities include (1) closing research gaps identified by the ODP Pathways to Prevention (P2P) program (the P2P program uses an unbiased, evidence-based process to identify research gaps in a scientific area of broad public health importance); (2) addressing and closing research gaps identified by the U.S. Preventive Services Task Force, the Community Preventive Services Task Force, and the Healthy People 2030 initiative; (3) reducing health disparities among pregnant people and postpartum people; and (4) supporting prevention-related funding opportunity announcements relevant to women's health, including Research on Addressing Violence to Improve Health Outcomes and Administrative Supplements for Research on Women's Health in the IDeA States.

# Office of Dietary Supplements 

## I. Overview

The Office of Dietary Supplements (ODS) works in collaboration with other NIH institutes, centers, and offices (ICOs) to stimulate and support a full range of biomedical research, including research on patterns of dietary supplement use in the U.S. population, as well as understanding the health impacts of dietary supplements. Through its Grants Co-Funding Program, ODS provides co-funding support for extramural research grants-including investigatorinitiated research projects, as well as NIH-wide and ICO- sponsored initiatives. ODS will continue to use National Health and Nutrition Examination Survey data to investigate dietary supplement usage and quality, with particular focus on ingredients (nutrients and supplements) of public health concern (iron, iodine, folic acid and folate, prenatal and infant and child multivitamins, and herbal supplements). In addition, the NIH Consortium for Advancing Research on Botanicals and Other Natural Products (CARBON) Program, which ODS manages in collaboration with NIH partners, supports studies on the safety and mechanisms of action of botanicals in areas relevant to women's health, such as resilience to social and psychological stressors, immune function, and healthy aging.

## II. Scientific Advances in Research on the Health of Women

ODS supports research that strengthens the knowledge and understanding of dietary supplement use and health effects in the U.S. population, including research that addresses preventable maternal morbidity and mortality. ODS participates as a co-funding partner in the Maternal Health Research Centers of Excellence (CoE) funding opportunity announcements (FOAs), which are part of the multipronged Implementing

a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) initiative. The CoE FOAs include RFA-HD-23-035, RFA-HD-23-036, and RFA-HD-23-037. The CoEs will include innovative approaches to addressing preventable maternal mortality, decreasing severe maternal morbidity, and promoting maternal health equity. They will use integrated multilevel approaches encompassing structural, social, and biobehavioral research strategies to address the multiple contributing factors that lead to adverse maternal health outcomes and health disparities. ODS is interested in approaches that may address nutrient deficiencies and/or dietary supplement use associated with pregnancy and contributing comorbid conditions.

ODS contributes to the dissemination of research results on dietary supplements to foster an enhanced quality of life and health for the U.S. population. In this published study, ODS and NIH partners embarked on an assessment of the scientific evidence and knowledge gaps that affect the precise determination of nutrient levels (specifically calcium, iron, and folic acid) that confer benefits to various subpopulations of women in the United States. ${ }^{1}$ Also, ODS coauthored a study to determine the long-term impact of periconceptional folic acid supplementation on DNA methylation patterns. ${ }^{2}$

## III. Future Priorities in Research on the Health of Women

Future ODS priorities in research on the health of women include activities that evaluate dietary prenatal supplement use in pregnant women and lactating women and that identify the potential for improvements to formulations and dosages of ingredients in prenatal supplements in order to maximize maternal health benefits and reduce harm associated with morbidity and mortality in pregnant women and lactating women. In addition, future priorities at ODS will focus on elucidating mechanisms and measures of resilience outcomes from complex botanical supplements.

[^11]
## ICOs' Crosscutting Integrative Topics in Research on the Health of Women

NIH Institutes, Centers, and Offices (ICOs) support research within their respective missions that improves the health of women across the life course. Some crucial research topics-such as aging and social determinants of health-span or crosscut ICO mission areas. As these crosscutting topics require an integrated approach to advance basic science and translational research and enhance women's well-being, ICOs partner and collaborate to support activities in these areas. The resulting NIH collaborative programs and activities (e.g., initiatives, research networks, and funding opportunities) emphasize interdisciplinary science.

During the development of this biennial report focused on research on the health of women at NIH, ICOs used the NIH Strategic Plan Tracking and Reporting Tool (START) to submit brief descriptions of their research and activities in crosscutting areas by selecting topics provided in a drop-down list and entering others (not included in the drop-down menu). This chapter briefly describes some of the collaborative efforts on crosscutting topics related to the health of women provided in the START submissions and highlights examples of programs in those areas. ICO collaborations in these areas may enhance impact, bridge research gaps, and offer novel approaches to accelerate biomedical advances that improve health outcomes for all women.

> The Strategic Tracking and Reporting Tool (START) serves both as a resource-by bringing information from across NIH into one platform—and a tool that allows for data analyses and reporting. NIH entities may use the module to develop strategic plans; design implementation plans to accomplish
> the goals of the strategic plan; identify metrics and measures to track progress on strategic priorities; collect and collate data based on the metrics and measures; and create visualizations, dashboards, and reports.

Aging-Age is a biological variable that influences body systems and processes, pathophysiology, risk for and progression of disease, and health outcomes. Age is a risk factor for conditions that affect quality of life, limit functioning, and may diminish the ability to live independently-such as Alzheimer's disease and related dementias (AD/ ADRD). These diseases disproportionately affect women as there is evidence of sex differences on the APOe4 allele, which increases a person's chance for developing late-onset AD. ${ }^{1}$ Therefore, the interactions of sex as a biological variable (SABV) and gender as a social determinant of health (SDOH) with aging represent crucial crosscutting topics for NIH research.

NIH-supported longitudinal studies-such as the Study of Women's Health Across the Nation (SWAN) and the Healthy Aging in Neighborhoods of Diversity across the Life Span (HANDLS) studyprovide a wealth of information for NIH researchers to identify how gender differences in early-life SDOH (e.g., adverse childhood experiences and educational attainment) affect later-life health conditions. Through ICO collaboration, NIH supports interdisciplinary research to understand how sex and gender interact with other biological (e.g., genetic and hormonal) and SDOH factors (e.g., race and ethnicity, habitation status, and care status) to affect aging and the aging process, as well as age-related diseases and conditions that are unique to- or more common in- women. ICOs address health equity by supporting research on women who experience health disparities (i.e., those in underserved racial and ethnic groups) in older age. In the crucial topic of AD/ADRD, studies supported by multiple ICOs aim to understand how genes, environment, and hormonal status interact at multiple levels to contribute to sex differences in disease risk, clinical progression, and treatment response (NOT-AG-21-050, RFA-AG-21-029, NOT-AG-22-025).

ICOs support collaborative research focused on the menopausal transition, which is associated
with increased risk for multiple individual conditions such as cardiovascular disease, dementia, and cancer, as well as multimorbidity as women grow older. In addition to research on biological, psychosocial, and health-related changes that occur around menopause via SWAN, ICOs collaboratively support basic science to elucidate the mechanisms that regulate aging of reproductive tissues and treatment studies through an initiative called Menopause Strategies: Finding Lasting Answers for Symptoms and Health (MsFLASH). Investigators have also tracked women's health outcomes by different type, route, and dosage of menopausal hormone therapy. ${ }^{2}$

An important but often neglected area of research that ICOs are addressing together is prevention of HIV among older women, as well as the significant knowledge gaps about sexual reproductive health and menopause. NIH also sponsors research on the onset and worsening of mood and psychotic disorders during the menopausal transition (PAR-22-035).

## Autoimmune Diseases-Autoimmune diseases

 occur when the immune system attacks the body's own organs, tissues, and cells, and can be complex, diverse, and often disabling. These conditions include more than 80 illnesses (e.g., rheumatoid arthritis, systemic lupus erythematosus, and $\mathrm{Sj}_{\mathrm{j}} \mathrm{g}$ ren's syndrome) that can affect specific organs or multiple organ systems.Some research suggests that autoimmunity is increasing in the United States. Autoimmune diseases often co-occur, and their burden accumulates over time. ${ }^{3}$ An estimated $8 \%$ of the U.S. population of all ages has an autoimmune disease, with women constituting nearly $80 \%$ of this group. ${ }^{4}$ Women of color are disproportionately affected by some conditions. ${ }^{5}$ Autoimmune diseases are thought to result from a combination of genetics and environmental exposures (e.g., infections, chemicals, and pollutants). Many autoimmune diseases are understudied, and treatment options are currently limited.

ICOs collaborate to support interdisciplinary research that elucidates the molecular and cellular interactions in unique and shared inflammatory pathways in autoimmune diseases. Researchers
aim to fill gaps in knowledge about the influences of intersecting factors such as sex and gender, age, race and ethnicity, and environmental exposures. ICOs sponsor research on the immunological basis of autoimmune disease onset and progression, including sex differences in immune system biology, differentially upregulated genes, and the influence of sex hormones. ${ }^{6}$ Other research on sex differences in immune system plasticity (NOT-DE-22-005) seeks to facilitate the development of novel, personalized, immunomodulatory-based therapies.

ICOs also support research on the development of improved diagnostic tools and studies that evaluate treatment and prevention strategies for autoimmune diseases. For example, NIH-supported scientists studying Sjögren's syndrome-which disrupts the ability to produce tears and saliva, causing painful dry eyes and mouth, are advancing gene therapy approaches and exploring promising pharmacotherapeutics for these symptoms. Other collaborative efforts focused on the effects of autoimmune diseases include the Accelerating Medicines Partnership® Autoimmune and ImmuneMediated Diseases (AMP® AIM), Accelerating Medicines Partnership® Rheumatoid Arthritis and Systemic Lupus Erythematosus, and Autoimmunity Centers of Excellence. In the new AMP® Systems Biology of Inflammation program, investigators compare biological pathways across conditions and systems to explain how inflammation affects disease progression and therapeutic response.

Maternal Morbidity and Mortality (MMM)—U.S. rates of maternal morbidity and pregnancy-related deaths, of which more than $80 \%$ are preventable, continue to increase and are higher than those of peer nations. ${ }^{7}$ MMM in the U.S. is driven by structural barriers and bias impacting health outcomes for patients from underrepresented communities such as African American women and residents of rural communities. These structures are marked by social and economic factors that disadvantage some and advantage others. Such factors are referred to as the SDOH. Advancing maternal health equity is emphasized in ICO efforts in this crosscutting topic, along with the life course perspective. Research aims to better understand how health before the reproductive years and prior to pregnancy affects risk for MMM.

Another crucial subtopic in MMM is studying how health conditions experienced during pregnancy, delivery, and the postpartum period may increase the risk for a range of diseases later in life, including type 2 diabetes mellitus, hypertension, cardiovascular disease, pelvic floor disorders, and depression. ${ }^{8,9,10,11}$

NIH supports this work, for example, by examining the links between hypertensive disorders of pregnancy (HDP) and cardiovascular disease. ${ }^{12}$ ORWH shares this and other relevant findings on the Maternal Morbidity \& Mortality Web Portal, a centralized hub highlighting research efforts across the federal government, funding opportunities, and federal resources on the topic of MMM.

ICOs collaborate to support research on the conditions that contribute to MMM (e.g., mental health and substance use disorders, hemorrhage, cardiac and coronary conditions, pregnancyrelated hypertension, and infection), as well as the structural and health care system factors that may delay or disrupt maternal care in the Implementing a Maternal health and PRegnancy Outcomes Vision for Everyone (IMPROVE) initiative. To promote maternal health equity, ICOs have come together to inform policy change, generate data to promote evidence-based care (NOT-HD-22-043), and to establish a national network of Maternal Health Research Centers of Excellence (RFA-HD-23-035, RFA-HD-23-036, RFA-HD-23-037). Research at these centers will generate innovative approaches to address preventable maternal mortality, decrease severe maternal morbidity, and work in partnership with communities that experience maternal health disparities. The field has developed evidence-driven practices for improving the quality and safety of perinatal care, and ICOs partner to promote their integration into maternity care through IMPROVE's Maternal Health Community Implementation Project.

Other programs (RFA-NR-22-002, RFA-NR-22-003) support intervention and developmental research focused on advancing integrated models of care addressing structural inequities in maternal health. States that are part of the Institutional Development Award (IDeA) program are among those with the highest U.S. maternal mortality rates. ORWH has collaborated with NIGMS and other ICs to award administrative supplements to eligible IDeA
grants (NOT-GM-21-056, NOT-GM-22-005, NOT-GM-21-018) to build research capacity and address important issues of women's health in the IDeA states.

## Mental Health and Substance Use (Opioids/ Pain)-Mental health disorders, substance use disorders (SUDs), and chronic pain often intersect to reduce overall well-being and negatively affect health outcomes. ${ }^{13}$ Several mental disorders like depression, postpartum depression, anxiety, and eating disorders are more common among women, and they can also affect women and men differently in terms of symptom patterns or course of illness.

Mental health disorders frequently co-occur with SUDs, including opioid use disorder, which is a significant concern given the ongoing U.S. overdose crisis and increasing availability of counterfeit pills containing contaminated fentanyl. Women and men may experience SUD differentlywith women experiencing greater sensitivity and craving, quicker development of the condition, and having legal concerns about seeking treatment while pregnant. Both sex- and gender-related factors contribute to these differences. Among other motivations, women report that they use substances to self-treat mental health problems or cope with pain. ${ }^{14}$ Studies suggest that chronic pain is more common among women and that they experience pain-associated conditions unique to them (e.g., endometriosis) or more often than men (e.g., migraine).

These intersecting conditions represent a highpriority crosscutting topic for ICOs. Efforts include supporting studies on perinatal mental health (NOT-MH-21-270, RFA-MH-21-240), including among women experiencing disparities (e.g., Elevating Voices, Addressing Depression, Toxic Stress and Equity in Group Prenatal Care and the Reach Out, Stay Strong, Essentials for mothers of newborns [ROSE] Program). Research also focuses on the influences that sex and gender have on adolescent brain development and the mental health of girls and young women (NOT-MH-22-245) and preventing HIV infection among women of color (RFA-MH-21-150). The collaborative NIH Helping to End Addiction Long-term ${ }^{\text {TM }}$ (HEAL) Initiative and its multiple funding opportunities accelerate scientific solutions. The HEAL Initiative
works to curb the national opioid public health crisis and improve pain management. To reduce opioid overdose and relapse among underserved women, ICOs work together through the Justice Community Opioid Innovation Network. The HEAL Initiative's Restoring Joint Health and Function to Reduce Pain Consortium will address sex differences in conditions more prevalent among women (e.g., knee osteoarthritis and temporomandibular disorders [TMD]. Other efforts include the HEAL Pain Management Effectiveness Research Network, TMD IMPACT, the Centers to Advance Research in Endometriosis, the Back Pain Consortium Research Program, and the Multidisciplinary Approach to the Study of Chronic Pelvic Pain Research Network.

Social Determinants of Health (SDOH)—Nonmedical conditions in the environments where people are born, live, learn, work, play, worship, and age that influence a wide range of health risks and outcomes are known as SDOH. They cover multiple domains: economic (e.g., food security), education, health care (e.g., access to and quality of), neighborhood and built environment (e.g., access to affordable healthful foods and safe places for physical activity), and social and community (e.g., structural inequities, policies, and environmental exposures). As a social and cultural variable, gender interacts with other SDOH. For example, structural inequities can influence employment opportunities and income, which go on to affect neighborhood environment and health care access. Differences in SDOHparticularly along the lines of race and ethnicity, educational attainment, income, geography, and their intersection-tend to accumulate over the life course, associate with lifestyle risk factors, and contribute to the marked health disparities and inequities in our country. ${ }^{15,16}$ Social and cultural identities can interact to influence SDOH and experiences of structural inequity, a concept known as intersectionality.

ICOs collaborate to address intersectionality and the historical exclusion of some groups of women from biomedical research through the U3 ("understudied, underrepresented, and underreported") Administrative Supplement Program. Other examples include the Model Continuums of Care Initiative and its various funding opportunities that focus on implementation and dissemination science to advance racial equity
and end health disparities among women and girls. The NIH Common Fund established two highly innovative programs invested in addressing SDOH and health disparities, and advancing health equity:

1. The Transformative Research to Address Health Disparities and Advance Health Equity initiative supports research projects to address health disparities and advance health equity. The initiative is committed to expanding the research base dedicated to health disparities research at institutions with limited NIH funding serving Pell grant-supported students or those from nationally underrepresented backgrounds.
2. The Community Partnerships to Advance Science for Society (ComPASS) program focuses on advancing the science of health disparities and advancing health equity research. The program's overarching aim is to develop an NIH-wide strategy to address structural factors that impact multiple dimensions of health.

Additionally, NIH's longitudinal studies, including HANDLS, SWAN, and the Baltimore Longitudinal Study of Aging, provide rich information on SDOH and the health outcomes of diverse groups of women.

Violence-ICOs have also made efforts to address gender-based violence. NIH's Office of Behavioral and Social Science Research (OBSSR) initiated an NIH -wide violence research workgroup that published a paper on NIH's investment in the subject across various settings, including gender-based and intimate partner violence (IPV). OBSSR, along with 12 other ICOs, including ORWH, released a Notice of Special Interest (NOSI): Research on Addressing Violence to Improve Health Outcomes, to address the role of violence, including IPV, in health outcomes and integrating interventions in the healthcare setting. OBSSR also collaborated with the NIH Sexual and Gender Minority Research Office (SGMRO) and other ICOs to host a multiphase Scientific Workshop on Violence \& Related Health Outcomes in Sexual \& Gender Minority Communities that focused on structural determinants of health (e.g., social, economic, and political mechanisms that generate social class inequalities), IPV, and current violence interventions.


1. Hsu, M., Dedhia, M., Crusio, W. E., Delprato, A. (2019). Sex differences in gene expression patterns associated with the APOE4 allele. F1000Research, 8, 387. https://doi.org/10.12688/f1000research.18671.2
2. Baik, S. H., Baye, F., McDonald, C. J., (2022). Effects of hormone therapy on survival, cancer, cardiovascular and dementia risks in 7 million menopausal women over age 65: A retrospective observational study. medRxiv. https:// doi.org/10.1101/2022.05.25.22275595
3. Conrad, N., Misra, S., Verbakel, J. Y., Verbeke, G., Molenberghs, G., Taylor, P. N., Mason, J., Sattar, N. ... Cambridge, G. (2023). Incidence, prevalence, and co-occurrence of autoimmune disorders over time and by age, sex, and socioeconomic status: A population-based cohort study of 22 million individuals in the UK. Lancet, 401(10391), 1878-1890. https://doi. org/10.1016/S0140-6736(23)00457-9
4. Fairweather, D., Rose, N. R. (2004). Women and autoimmune diseases. Emerging Infection Diseases, 10(11), 2005-2011. https://doi.org/10.3201/ eid1011.040367
5. Roberts, M. H., Erdei, E. (2020). Comparative United States autoimmune disease rates for 2010-2016 by sex, geographic region, and race. Autoimmunity Reviews, 19(1), 102423. https://doi.org/10.1016/j. autrev.2019.102423
6. Gupta, S., Nakabo, S., Blanco, L. J., Wigerblad, G., Goel, R. R., Mistry, P. ... Kaplan, M. J. (2020). Sex differences in neutrophil biology modulate response to type I interferons and immunometabolism. Proc Natl Acad Sci U SA, 117(28), 16481-16491. https://doi.org/10.1073/pnas. 2003603117
7. Hoyert, D.L. (2023). Maternal mortality rates in the United States, 2021. National Center for Health Statistics E-Stats. https://dx.doi.org/10.15620/ cdc:124678
8. Lowe, W. L., Scholtens, D. M., Lowe, L. P., Kuang, A., Nodzenski, M., Talbot, O. ... Metzger, B. E. (2018). Association of gestational diabetes with maternal disorders of glucose metabolism and childhood adiposity. JAMA, 320(10), 1005-1016. https://doi.org/10.1001/jama.2018.11628
9. Grandi, S. M., Reynier, P., Platt, R. W., Basso, O., Filion, K. B. (2018). The timing of onset of hypertensive disorders in pregnancy and the risk of incident hypertension and cardiovascular disease. International Journal of Cardiology, 270, 273-275. https://doi.org/10.1016/i.ijcard.2018.06.059
10. Handa, V. L., Blomquist, J. L., McDermott, K. C., Friedman, S., Muñoz, A. (2012). Pelvic floor disorders after vaginal birth: Effect of episiotomy, perineal laceration, and operative birth. Obstetrics and Gynecology, 119(2 Pt 1), 233-239. https://doi.org/10.1097\%2FAOG.0b013e318240df4f
11. Netsi, E., Pearson, R. M., Murray, L., Cooper, P., Craske, M. G., Stein, A. (2018). Association of persistent and severe postnatal depression with child outcomes. JAMA Psychiatry, 75(3), 247-253. https://doi. org/10.1001\%2Fjamapsychiatry.2017.4363
12. Stuart, J. J., Tanz, L. J., Rimm, E. B., Spiegelman, D., Missmer, S. A., Mukamal, K. J. ... Rich-Edwards, J. W. (2022). Cardiovascular risk factors mediate the long-term maternal risk associated with hypertensive disorders of pregnancy. J Am Coll Cardiol, 79(19), 1901-1913. https://doi.org/10.1016/i. jacc.2022.03.335
13. National Institute on Drug Abuse. (2021). Part 2: Co-occurring substance use disorder and physical comorbidities. Common Comorbidities with Substance Use Disorders Research Report. Retrieved from https://nida.nih. gov/publications/research-reports/common-comorbidities-substance-use-disorders/part-2-co-occurring-substance-use-disorder-physical-comorbidities
14. National Institute of Drug Abuse. (2020). Substance use in women. DrugFacts. Retrieved from https://nida.nih.gov/publications/drugfacts/ substance-use-in-women
15. Puka, K., Buckley, C., Mulia, N., Lasserre, A. M., Rehm, J. Probst, C. (2022). Educational attainment and lifestyle risk factors associated with all-cause mortality in the U.S. JAMA Health Forum, 3(4) e220401. https://doi. org/10.1001/jamahealthforum.2022.0401
16. National Academies of Sciences, Engineering, and Medicine; National Academy of Medicine; Committee on the Future of Nursing 2020-2030. (2021). Social determinants of health and health equity. In Flaubert, J. L., Le Menestrel, S., Williams, D. R., et al., (Eds.), The future of nursing 2020-2030: Charting a path to achieve health equity. Retrieved from https://www.ncbi. nlm.nih.gov/books/NBK573923/

## Appendix A. Summaries of Research Co-Funded by ORWH

| FY | RFA Title | Title | Contact PI Name | Institution | Grant | ORWH Program | Appl Id | RePORTER <br> Project Info |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2021 | Addressing Racial Disparities in Maternal Mortality and Morbidity (R01 Clinical Trial Optional) | Preconception and prenatal stress effects on cardiovascular disease risk in black women | Hipwell, Alison E | University of Pittsburgh | 3 R01 HL157787-02S1 | U3 Admin Supplement | 10451147 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp - Clinical Trial Optional) | The Impact of Opioids on Chronic Pain: Clinical Research and Career Training in Spinal Cord fMRI and Brain Reward Systems | Martucci, Katherine Theresa | Duke University | 3 R00 DA040154-05S1 | Careers | 10282724 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp - Clinical Trial Optional) | Role of nuclear pore-regulated mechanisms in prostate cancer aggressiveness | Rodriguez-Bravo, Veronica | Thomas Jefferson University | 3 R01 CA237398-02S1 | Careers | 10272909 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp - Clinical Trial Optional) | Investigation of a novel prelimbic cortical peptidergic population in binge drinking behavior | Crowley, Nicole Ashley | The Pennsylvania State University | 3 R21 AA028088-02S1 | Careers | 10263516 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Computational methods using electronic health records and registry data to detect and predict clinical outcomes in rheumatic disease | Gianfrancesco, Milena Anne | University of California, San Francisco | 3 K01 AR075085-03S1 | Careers | 10400540 | RePORTER <br> Project Info |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Understanding the role of social networks in methadone maintenance treatment retention and antiretroviral therapy adherence among people who inject drugs in Tanzania | Saleem, Haneefa Tasleem | Johns Hopkins University | 3 K01 DA047142-02S1 | Careers | 10293105 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Testing cortisol dysregulation as a mediator between early stress and adolescent cardiovascular health | Doom, Jenalee Rae | University of Denver (Colorado Seminary) | 3 K01 HL143159-03S1 | Careers | 10408236 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |


| FY | RFA Title | Title | Contact PI Name | Institution | Grant | ORWH Program | Appl Id | RePORTER <br> Project Info |
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| 2021 | Administrative <br> Supplements to <br> Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Systems Science Informed Multilevel Theoretical Model of Cardiovascular Health in Native Hawaiians | Ing, Claire Townsend | University of Hawaii at Manoa | 3 K01 HL146930-03S1 | Careers | 10411862 | RePORTER <br> Project Info |
| 2021 | Administrative <br> Supplements to <br> Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | The role of Hippo signaling in palate development | Goodwin, Alice Fitzgerald | University of California, San Francisco | 3 K08 DE028011-04S1 | Careers | 10370207 | RePORTER <br> Project Info |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | CRISPR-Cas9 editing in C9orf72 patient derived iPSC | Clelland, Claire | University of California, San Francisco | 3 K08 NS112330-02S1 | Careers | 10405372 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Thalamic Contributions to Functional Network Abnormalities in Alzheimer's Disease | Fredericks, Carolyn Anne | Yale University | 3 K23 AG059919-04S1 | Careers | 10415553 | RePORTER <br> Project Info |
| 2021 | Administrative <br> Supplements to <br> Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | My Best Alaskan Life: Community Based Research with Adolescents to Address Sexual and Reproductive Health | Barnes, Brian M | University of Alaska Fairbanks | 3 P20 GM103395-21S3 | SRP | 10393826 | RePORTER <br> Project Info |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Idaho INBRE <br> Women's health: contribution of mammary mitochondrial dysfunction to poor milk production in diabetic mothers | Bohach, Carolyn Hovde | University of Idaho | 3 P20 GM103408-21S2 | SRP | 10379717 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Administrative <br> Supplements to <br> Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Appalachian Center for Cellular transport in Obesity Related Disorders (ACCORD) | Sundaram, Uma | Marshall University | 3 P20 GM121299-04S1 | SRP | 10394550 | RePORTER <br> Project Info |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Wyoming Sensory <br> Biology COBRE | Sun, Qian-Quan | University of Wyoming | 3 P20 GM121310-05S2 | SRP | 10395258 | RePORTER <br> Project Info |


| FY | RFA Title | Titte | Contact PI Name | Institution | Grant | ORWH Program | Appl Id | RePORTER <br> Project Info |
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| 2021 | Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Metabolic Basis of Disease | Stephens, Jacqueline M | Louisiana State <br> University, <br> Pennington <br> Biomedical <br> Research <br> Center | 3 P20 GM135002-02S1 | SRP | 10395284 | RePORTER <br> Project Info |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Hopkins Center to Promote resilience in persons and families living with multiple chronic conditions (the PROMOTE Center) | Szanton, Sarah L | Johns Hopkins University | 3 P30 NR018093-04S1 | U3 Admin Supplement | 10334705 | RePORTER <br> Project Info |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | NOSI: Biobehavioral basis of knee osteoarthritis pain | Cruz-Almeida, Yenisel | University of Florida | 3 R01 AG067757-02S3 | U3 Admin Supplement | 10331506 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Enhancing the Diversity of Participants in the WISDOM Clinical Trial: Practical Challenges and Ethical Implications | Esserman, Laura J | University of California, San Francisco | 3 R01 CA237533-02S1 | SRP | 10367828 | RePORTER <br> Project Info |
| 2021 | Administrative <br> Supplements to <br> Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Investigating the validity and equivalence of the measurement of minority stress in predicting substance use among SGM individuals | Flentje, Annesa | University of California, San Francisco | 3 R01 DA052016-02S1 | SRP | 10332588 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Development of medial efferent mechanisms in children | Mishra, Srikanta | University of Texas Rio Grande Valley | 3 R01 DC01804601A1S1 | Sex and <br> Gender <br> Admin <br> Supplement | 10331220 | RePORTER <br> Project Info |
| 2021 | Administrative <br> Supplements to <br> Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Promoting engagement, assessing barriers, and evaluating self-efficacy in yoga research among women from underrepresented racial and ethnic backgrounds | Huang, Alison | University of California, San Francisco | 3 R01 DK116712-04S1 | U3 Admin Supplement | 10331675 | RePORTER <br> Project Info |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Wildfire Smoke and Severe Maternal Morbidity in California | Padula, Amy Michelle | University of California, San Francisco | 3 R01 ES031261-02S2 | U3 Admin Supplement | 10331248 | RePORTER <br> Project Info |


| FY | RFA Title | Title | Contact PI Name | Institution | Grant | ORWH Program | Appl Id | RePORTER <br> Project Info |
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| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Sex differences in in vitro and in vivo glaucoma models may predict gender specific dose adjustment needs | Acharya, Suchismita | University of North Texas Health Science Center | 3 R01 EY029823-02S1 | Sex and <br> Gender <br> Admin <br> Supplement | 10333877 | RePORTER <br> Project Info |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Sex and Gender <br> Supplement to <br> Elastase and Elastin <br> Peptide Activity in <br> Age-Related Macular <br> Degeneration | Rohrer, Baerbel | Medical <br> University of South Carolina | 3 R01 EY030072-02S1 | Sex and <br> Gender <br> Admin <br> Supplement | 10334019 | RePORTER <br> Project Info |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | An internet-based preconception cohort study in North America and Denmark | Wise, Lauren A | Boston University Medical Campus | 3 R01 HD086742-05S2 | SRP | 10434313 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Inflammatory <br> Processes in Adolescent Girls with Primary Dysmenorrhea | Payne, Laura Allen | McLean Hospital | 3 R01 HD093680-04S2 | SRP | 10466339 | RePORTER <br> Project Info |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Roles of $X$ - and Y-palindromic Genes in Mammalian Fertility | Mueller, Jacob L | University of Michigan at Ann Arbor | 3 R01 HD094736-04S1 | Sex and <br> Gender <br> Admin <br> Supplement | 10331090 | RePORTER <br> Project Info |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Patient navigation to improve outcomes among low-income women in the postpartum period | Yee, Lynn M | Northwestern University at Chicago | 3 R01 HD098178-03S1 | U3 Admin Supplement | 10331608 | RePORTER <br> Project Info |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Multigenerational Effects of Gestational Testosterone Excess | Padmanabhan, Vasantha | University of Michigan at Ann Arbor | 3 R01 HD099096-02S1 | SRP | 10472234 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Meeting women where they are: Multilevel intervention addressing racial disparities in maternal morbidity and mortality Administrative Supplement | Meghea, Cristian Ioan | Michigan State University | 3 R01 MD016003-02S1 | U3 Admin Supplement | 10330748 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |


| FY | RFA Title | Title | Contact PI Name | Institution | Grant | ORWH Program | Appl Id | RePORTER <br> Project Info |
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| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Sex hormones and post-traumatic stress disorder (PTSD) | Duncan, Laramie | Stanford University | 3 R01 MH123486-02S1 | Careers | 10398466 | RePORTER <br> Project Info |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Supplement to Effects of global brain health on sensorimotor recovery after stroke | Liew, Sook-Lei | University of Southern California | 3 R01 NS115845-02S1 | Careers | 10386724 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Social and Economic Determinants of Maternal Morbidity in the United States | Markowitz, Sara | National <br> Bureau of Economic Research | 3 R03 HD100709-02S1 | U3 Admin Supplement | 10336069 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Supplement: <br> Development of an Integrated 3D Human Osteo-Mucosal Model | Tayebi, Lobat | Marquette University | $\begin{aligned} & 3 \text { R15 DE027533- } \\ & \text { 01A1S3 } \end{aligned}$ | Careers | 10403365 | RePORTER <br> Project Info |
| 2021 | Administrative <br> Supplements to <br> Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Aging in the time of COVID: Racism, Isolation, and Meaning | Campbell, Katherine Ann | St. Catherine University | 3 R25 AG060892-03S1 | SRP | 10365002 | RePORTER <br> Project Info |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Deciphering the role of chemical signals in inflammation with open microfluidic functional assays Admin Supp 2021 | Theberge, Ashleigh Brooks | University of Washington | 3 R35 GM128648-04S1 | Careers | 10439375 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Inferring the evolutionary history of admixed populations | Goldberg, Amy | Duke University | 3 R35 GM133481-03S1 | Careers | 10446815 | RePORTER <br> Project Info |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Targeting blastic plasmacytoid dendritic cell neoplasm (BPDCN) | Lane, Andrew A | Dana-Farber Cancer Institute | 3 R37 CA225191-04S1 | Sex and <br> Gender <br> Admin <br> Supplement | 10332257 | RePORTER <br> Project Info |


| FY | RFA Title | Title | Contact Pl Name | Institution | Grant | ORWH Program | Appl Id | RePORTER <br> Project Info |
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| 2021 | Administrative <br> Supplements to <br> Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | The Study of <br> Women's Health Across the Nation (SWAN): The Impact of Midlife and the Menopause Transition on Health and Functioning in Early Old Age | Brooks, Maria Mori | University of Pittsburgh | 3 U19 AG063720-02S1 | SRP | 10447272 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Palliative Care <br> Research <br> Cooperative Group (PCRC): Refinement and Expansion | Kutner, Jean S | University of Colorado Denver | 3 U2C NR014637-09S1 | U3 Admin Supplement | 10331658 | RePORTER <br> Project Info |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Arsenic Metabolism, <br> Menopause and Diabetes in the Strong Heart Study | Ofotokun, Ighowwerha | Emory University | 3 U54 AG062334-04S1 | U3 Admin Supplement | 10331523 | RePORTER <br> Project Info |
| 2021 | Administrative <br> Supplements to <br> Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Channeling the voice of underserved communities on nutritional insufficiency and unaddressed needs on maternal infant health | Cruz-Correa, Marcia Roxana | University of Puerto Rico, Medical Sciences Campus | 3 U54 GM133807-02S3 | SRP | 10395287 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Strengthening Stakeholder Engagement in Human Research Protections | Mermelstein, Robin J | University of Illinois at Chicago | 3 UL1 TR002003-06S2 | SRP | 10363791 | RePORTER <br> Project Info |
| 2021 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Consortium for large-scale production and phenotyping of knockout mice (UM1) | Dickinson, Mary E | Baylor College of Medicine | $\begin{aligned} & 3 \text { UM1 HG006348- } \\ & \text { 10S3 } \end{aligned}$ | SRP | 10399851 | RePORTER <br> Project Info |
| 2021 | Building <br> Interdisciplinary <br> Research Careers in <br> Women's Health (K12) | Kentucky BIRCWH Program: Training the Next Generation of Women's Health Researchers | Curry, Thomas E | University of Kentucky | 5 K12 DA035150-10 | BIRCWH | 10224151 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Building Interdisciplinary Research Careers in Women's Health (K12) | Building Interdisciplinary Research Careers in Women's Health in Pittsburgh | Sadovsky, Yoel | Magee- <br> Womens Research Institute and Foundation | 5 K12 HD043441-20 | BIRCWH | 10242763 | RePORTER <br> Project Info |
| 2021 | Building Interdisciplinary Research Careers in Women's Health (K12) | Building Interdisciplinary Research Careers in Women's Health | Amundsen, Cindy | Duke University | 5 K12 HD043446-20 | BIRCWH | 10232363 | RePORTER <br> Project Info |


| FY | RFA Title | Title | Contact PI Name | Institution | Grant | ORWH Program | Appl Id | RePORTER <br> Project Info |
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| 2021 | Building <br> Interdisciplinary <br> Research Careers in <br> Women's Health (K12) | Building Interdisciplinary Research in Women's Health | Krousel-Wood, Marie | Tulane University of Louisiana | 5 K12 HD043451-20 | BIRCWH | 10231084 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Building <br> Interdisciplinary <br> Research Careers in <br> Women's Health (K12) | Building Interdisciplinary Research Careers in Women's Health | Hartmann, Katherine E | Vanderbilt <br> University <br> Medical Center | 5 K12 HD043483-21 | BIRCWH | 10248390 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Building Interdisciplinary Research Careers in Women's Health (K12) | Oregon BIRCWH: Scholars in Women's Health Research Across the Lifespan | Guise, JeanneMarie | Oregon Health <br> \& Science <br> University | 5 K12 HD043488-20 | BIRCWH | 10229486 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Building <br> Interdisciplinary <br> Research Careers in <br> Women's Health (K12) | Building Interdisciplinary Women's Health at MUSC | McGinty, Jacqueline F | Medical University of South Carolina | 5 K12 HD055885-15 | BIRCWH | 10237319 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Building <br> Interdisciplinary <br> Research Careers in <br> Women's Health (K12) | University of MN Building Interdisciplinary Research Careers in Women's Health | Berge, Jerica M | University of Minnesota | 5 K12 HD055887-15 | BIRCWH | 10237921 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Building <br> Interdisciplinary <br> Research Careers in <br> Women's Health (K12) | The Colorado Building Interdisciplinary Research Careers in Women's Health Program | Regensteiner, Judith G | University of Colorado Denver | 5 K12 HD057022-15 | BIRCWH | 10238113 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Building <br> Interdisciplinary <br> Research Careers in <br> Women's Health (K12) | Tufts BIRCWH Program | Freund, Karen | Tufts University, Boston | 5 K12 HD092535-05 | BIRCWH | 10229457 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Building Interdisciplinary Research Careers in Women's Health (BIRCWH); K12 Clinical Trial Optional | Building <br> Interdisciplinary <br> Research Careers in <br> Women's Health at UC Davis | Lane, Nancy E | University of California, Davis | 5 K12 HD051958-17 | BIRCWH | 10205116 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Building Interdisciplinary Research Careers in Women's Health (BIRCWH); K12 Clinical Trial Optional | Hormones and Genes in Women's Health: <br> From Bench to Bedside | Goldstein, Jill M | Brigham and Women's Hospital | 5 K12 HD051959-17 | BIRCWH | 10205117 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Building Interdisciplinary Research Careers in Women's Health (BIRCWH); K12 Clinical Trial Optional | UTMB Women's Health Research Scholars Program | Berenson, Abbey B | University of Texas Medical Branch at Galveston | 5 K12 HD052023-17 | BIRCWH | 10206206 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Building Interdisciplinary Research Careers in Women's Health (BIRCWH); K12 Clinical Trial Optional | UCSF-Kaiser <br> Department of Research Building Interdisciplinary Research Careers in Women's Health (BIRCWH) Program | Brindis, Claire D | University of California, San Francisco | 5 K12 HD052163-22 | BIRCWH | 10201684 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |


| FY | RFA Title | Title | Contact PI Name | Institution | Grant | ORWH <br> Program | Appl Id | RePORTER <br> Project Info |
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| 2021 | Building Interdisciplinary Research Careers in Women's Health (BIRCWH); K12 Clinical Trial Optional | Mayo Clinic Building Interdisciplinary Research Careers in Women's Health | Kantarci, Kejal | Mayo Clinic Rochester | 5 K12 HD065987-12 | BIRCWH | 10204063 | RePORTER <br> Project Info |
| 2021 | Building Interdisciplinary Research Careers in Women's Health (BIRCWH); K12 Clinical Trial Optional | The Johns Hopkins Clinical Research Scholars in Women's Health (BIRCWH) | Ford, Daniel Ernest | Johns Hopkins University | 5 K12 HD085845-07 | BIRCWH | 10227668 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Building Interdisciplinary Research Careers in Women's Health (BIRCWH); K12 Clinical Trial Optional | Emory University BIRCWH Program | Ofotokun, Ighovwerha | Emory University | 5 K12 HD085850-07 | BIRCWH | 10224282 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Building Interdisciplinary Research Careers in Women's Health (BIRCWH); K12 Clinical Trial Optional | University of Wisconsin Building Interdisciplinary Research Careers in Women's Health (BIRCWH) Scholars Program | Burnside, Elizabeth S | University of WisconsinMadison | 5 K12 HD101368-02 | BIRCWH | 10169485 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Building Interdisciplinary Research Careers in Women's Health (BIRCWH); K12 Clinical Trial Optional | UIC Building Interdisciplinary Research Careers in Women's Health Program | Maki, Pauline M | University of Illinois Chicago | 5 K12 HD101373-02 | BIRCWH | 10159299 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Centers of Biomedical Research Excellence (COBRE) (P20) | COBRE-DIABETES | Gerschenson, Mariana | University of Hawaii at Manoa | 3 P20 GM113134-05S1 | U3 Admin Supplement | 10387025 | RePORTER <br> Project Info |
| 2021 | Clinical and Translational Science Award (U54) | The University of Iowa Clinical and Translational Science Award | Winokur, Patricia | University of lowa | 3 UL1 TR002537-04S1 | U3 Admin Supplement | 10488387 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Clinical and Translational Science Award (U54) | The Harvard Clinical and Translational Science Center | Nadler, Lee <br> Marshall | Harvard <br> Medical School | 3 UL1 TR002541-04S3 | SRP | 10457151 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Centers to Advance <br> Research in <br> Endometriosis (CARE) <br> (P01 Clinical Trial Not <br> Allowed) | Collaborative Center to Develop Improved Diagnostic and Therapeutic Approaches to Endometriosis | Young, Steven L | University of North Carolina at Chapel Hill | 1 P01 HD106485-01 | SRP | 10309090 | RePORTER <br> Project Info |
| 2021 | Digital Healthcare Interventions to Address the Secondary Health Effects Related to Social, Behavioral, and Economic Impact of COVID-19 (R01 Clinical Trial Optional) | Bridging gaps in healthcare services for new families due to COVID-19 | Miller, Emily Stinnett | Northwestern University at Chicago | 1 R01 HD105499-01 | SRP | 10244731 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |


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| 2021 | Digital Healthcare Interventions to Address the Secondary Health Effects Related to Social, Behavioral, and Economic Impact of COVID-19 (R01 Clinical Trial Optional) | mHealth Mindfulness Intervention for Pregnant Black and Latina Women at Risk of Postpartum Depression | Kubo, Ai | Kaiser <br> Foundation Research Institute | 1 R01 MH126580-01 | SRP | 10244836 | RePORTER <br> Project Info |
| 2021 | Emerging Questions in Cancer Systems Biology (U01) | Quantifying Multiscale <br> Competitive <br> Landscapes of Clonal Diversity in Glioblastoma | Swanson, Kristin R | Mayo Clinic Arizona | 3 U01 CA220378-05S1 | Sex and <br> Gender <br> Admin <br> Supplement | 10411429 | RePORTER <br> Project Info |
| 2021 | Fogarty Global Health Training Program (D43) | The UJMT Global Consortium: building research capacity through mentored training | Chi, Benjamin H | University of North Carolina at Chapel Hill | 3 D43 TW009340-10S2 | SRP | 10455265 | RePORTER <br> Project Info |
| 2021 | Fogarty Global Health Training Program (D43) | University of California Global Health Institute Program for Fellows and Scholars | Cohen, Craig R | University of California, San Francisco | 5 D43 TW009343-10 | SRP | 10200925 | RePORTER <br> Project Info |
| 2021 | Fogarty Global Trauma and Injury Research Training Program (D43 Clinical Trial Optional) | ICREATE: Increasing Capacity for Injury Research in Eastern Europe | Hamann, Cara | University of lowa | 2 D43 TW007261-16 | SRP | 10393849 | RePORTER <br> Project Info |
| 2021 | Fogarty Global Trauma and Injury Research Training Program (D43 Clinical Trial Optional) | Strengthening Injury Control Research in Ghana and West Africa | Donkor, Peter | Kwame <br> Nkrumah University of Science and Technology | 2 D43 TW007267-16 | SRP | 10393721 | RePORTER <br> Project Info |
| 2021 | Fundamental Science Research on Mind and <br> Body Approaches (R01 <br> - Clinical Trial Optional) | Elucidating Neural Mechanisms and Sex Differences in Response to Mindfulness Based Stress Reduction in Generalized Anxiety Disorder | Simon, Naomi M | New York University School of Medicine | 1 R01 AT011257-01A1 | SRP | 10297715 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | HEAL Initiative: HEALthy Brain and Child Development Study (Collaborative U01- Clinical Trial Not Allowed) | 1/6 HBCD Prenatal Experiences and Longitudinal Development (PRELUDE) Consortium | Ou, Xiawei | Arkansas Children's Research Institute | 1 U01 DA055352-01 | SRP | 10379773 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Mentored Patient- <br> Oriented Research Career Development Award (Parent K23 Independent Clinical Trials Not Allowed) | Renal Circulatory <br> Adaptation in Healthy <br> and Complicated <br> Pregnancies | Tangren, Jessica Sheehan | Massachusetts General Hospital | 3 K23 DK120874-03S1 | Careers | 10432925 | RePORTER <br> Project Info |
| 2021 | NATIVE AMERICAN <br> RESEARCH CENTERS <br> FOR HEALTH <br> (NARCH) (S06) | ANTHC NARCH X | Ferucci, Elizabeth D | Alaska Native Tribal Health Consortium | 5 S06 GM127911-04 | SRP | 10226057 | RePORTER <br> Project Info |


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| 2021 | NHLBI Clinical Ancillary <br> Studies (R01 - Clinical Trial Optional) | Effect of Intensive Medical Treatment on Quantified Coronary Artery Plaque Components with Serial Coronary CTA in Women with NonObstructive CAD | Dey, Damini | Cedars-Sinai <br> Medical Center | 5 R01 HL151266-02 | SRP | 10247453 | RePORTER <br> Project Info |
| 2021 | NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed) | A quantitative framework to examine sex differences in musculoskeletal scaling and function | Blemker, Silvia Salinas | University of Virginia | 1 R01 AR078396-01A1 | SRP | 10220349 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed) | Urine cadmium and risk of fracture and bone loss | Meliker, Jaymie R | State University of New York at Stony Brook | 1 R01 AR081125-01A1 | Sex and Gender R01 | 10307007 | RePORTER <br> Project Info |
| 2021 | NIH Research Project <br> Grant (Parent R01 <br> Clinical Trial Not <br> Allowed) | Role of microbiotaTLR7/8 Interaction in systemic lupus erythematosus | Vasu, Chenthamarakshan | Medical University of South Carolina | 3 R01 Al138511-03S1 | Sex and <br> Gender <br> Admin <br> Supplement | 10462246 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed) | Role of Gut <br> Microbiota in Bone <br> Mass Heritability and <br> Skeletal Response <br> to PTH | Pacifici, Roberto | Emory University | 3 R01 DK119229-03S1 | Sex and <br> Gender <br> Admin <br> Supplement | 10451987 | RePORTER <br> Project Info |
| 2021 | NIH Research Project <br> Grant (Parent R01 <br> Clinical Trial Not Allowed) | Neurogenic <br> Inflammatory <br> Response to RSV | Piedimonte, Giovanni | Tulane University of Louisiana | 3 R01 HL061007-17S1 | SRP | 10477513 | RePORTER <br> Project Info |
| 2021 | NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed) | Motivational <br> Determinants of Postpartum Lifestyle Behaviors, Weight Retention, and Metabolic Syndrome | Brown, Susan Denise | University of California at Davis | 3 R01 HL142996-03S1 | Sex and <br> Gender <br> Admin <br> Supplement | 10462352 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed) | Inter-generational Link of CardioMetabolic Risk: Integrate Multi-OMICs with Birth Cohort | Wang, Xiaobin | Johns Hopkins University | 5 R01 HD098232-03 | SRP | 10130579 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | NIH Research Project Grant (Parent R01) | MicroRNA-based therapy for rheumatoid arthritis | Ahmed, SalahUddin | Washington State University | 3 R01 AR072615-04S1 | Sex and <br> Gender <br> Admin <br> Supplement | 10475349 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | NIH Research Project Grant (Parent R01) | Natural History of Viral Induced Airway Dysfunction and Asthma in Minority Children | Burchard, Esteban Gonzalez | University of California, San Francisco | 3 U01 HL138626-03S2 | U3 Admin Supplement | 10369849 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | NIH Science Education Partnership Award (SEPA) (R25 - Clinical Trial Not Allowed) | Xavier University of LouisianaMobile Outreach for Laboratory Enrichment (XULAMOLE) | Ali, Mehnaaz Fatima | Xavier University of Louisiana | 1 R25 GM137382-01A1 | Careers | 10216663 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |


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| 2021 | Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium Clinical Research Centers (U01 Clinical Trial Optional) | The Truly Healthy Bladder 2: <br> Understanding Normal As A Pathway <br> To Prevention of Lower Urinary Tract Symptoms In Women | Miller, Janis M | University of Michigan at Ann Arbor | 3 U01 DK106893-07S1 | SRP | 10413278 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium Clinical Research Centers (U01 Clinical Trial Optional) | Penn+Plus Clinical Research Center | Newman, Diane K | University of Pennsylvania | 5 U01 DK106892-07 | SRP | 10260537 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium Clinical Research Centers (U01 Clinical Trial Optional) | PLUS Loyola Clinical Center | Mueller, Elizabeth Rose | Loyola <br> University <br> Chicago | 5 U01 DK106898-07 | SRP | 10260566 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Research Project Grant (Parent R01 Clinical Trial Not Allowed) | Elucidating <br> Genotype-Phenotype <br> Relationship of <br> Polygenic Dilated <br> Cardiomyopathies | Wu, Joseph C | Stanford University | 3 R01 HL130020-06S2 | Sex and <br> Gender <br> Admin <br> Supplement | 10451146 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Research Project Grant (Parent R01 Clinical Trial Not Allowed) | Kisspeptins in the Airway | Venkatachalem, Sathish | North Dakota State University | 3 R01 HL146705-02S1 | Sex and <br> Gender <br> Admin <br> Supplement | 10464150 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Research Project Grant (Parent R01 Clinical Trial Not Allowed) | Kisspeptins in the Airway | Venkatachalem, Sathish | North Dakota State University | 5 R01 HL146705-02 | SRP | 10119319 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Research Project Grant <br> (Parent R01 Clinical <br> Trial Required) | Alcohols Effects on Affective, Cognitive, and Behavioral Responses in a Virtual Reality Dating Simulation | Abbey, Antonia | Wayne State University | 1 R01 AA028815-01 | Careers | 10100038 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Research Project Grant (Parent R01 Clinical Trial Required) | Neural Mechanisms of Immersive Virtual Reality in Chronic Pain | Colloca, Luana | University of Maryland, Baltimore | 1 R01 AT011347-01A1 | SRP | 10314729 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Research Project Grant (Parent R01 Clinical Trial Required) | A Randomized Control Trial to improve metabolic outcomes in African American pregnant women | Izci Balserak, Bilgay | University of Illinois at Chicago | 1 R01 MD015724-01A1 | SRP | 10296816 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Research Project Grant (Parent R01 Clinical Trial Required) | Reducing Alcohol Involved Sexual violence in higher Education (RAISE) | Miller, Elizabeth | University of Pittsburgh | 2 R01 AA023260-06A1 | Careers | 10118899 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Research Supplements to Promote Re-Entry into Biomedical and Behavioral Research Careers (Admin Supp - Clinical Trial Not Allowed) | The Role of TRIM28 Phosphorylation in the Mechanical Regulation of Skeletal Muscle - Re-entry Supplement | Hornberger, Troy A | University of WisconsinMadison | 3 R01 AR074932-02S1 | Careers | 10285337 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |


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| 2021 | Research to Understand and Inform Interventions that Promote the Research Careers of Individuals in the Biomedical Sciences (R01 - Clinical Trial Not Allowed) | Peer Mentoring to Overcome Obstacles for Midcareer Women Clinician-Scientists in Academic Medicine | Jagsi, Reshma | University of Michigan at Ann Arbor | 5 R01 GM139842-02 | Careers | 10267186 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Specialized Centers of Research Excellence (SCORE) on Sex Differences (U54 Clinical Trial Optional) | YALE-SCORE ON SEX DIFFERENCES IN ALCOHOL USE DISORDER | McKee, Sherry Ann | Yale University | 5 U54 AA027989-02 | SCORE | 10122868 | RePORTER <br> Project Info |
| 2021 | Specialized Centers of <br> Research Excellence <br> (SCORE) on Sex <br> Differences (U54 <br> Clinical Trial Optional) | Center for Stress and <br> Neural Regulation of <br> Reproductive Aging <br> Health Outcomes | Joffe, Hadine | Brigham and Women's Hospital | 5 U54 AG062322-02 | SCORE | 10168419 | RePORTER <br> Project Info |
| 2021 | Specialized Centers of <br> Research Excellence <br> (SCORE) on Sex <br> Differences (U54 <br> Clinical Trial Optional) | The Microvascular <br> Aging and <br> Eicosanoids - <br> Womens Evaluation <br> of Systemic Aging <br> Tenacity (MAE- <br> WEST) (You are <br> never too old to <br> become younger!) <br> Specialized Center for <br> Research Excellence <br> (SCORE) | Cheng, Susan | Cedars-Sinai <br> Medical Center | 5 U54 AG065141-02 | SCORE | 10198755 | RePORTER <br> Project Info |
| 2021 | Specialized Centers of Research Excellence (SCORE) on Sex Differences (U54 Clinical Trial Optional) | Sex related differences in Brain Gut Microbiome Interactions in Irritable Bowel Syndrome | Mayer, Emeran A | University of California, Los Angeles | 5 U54 DK123755-02 | SCORE | 10149308 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Specialized Centers of Research Excellence (SCORE) on Sex Differences (U54 Clinical Trial Optional) | Sex Differences in Major Depression: Impact of Prenatal Stress-Immune and Autonomic Dysregulation | Goldstein, Jill M | Massachusetts General Hospital | 5 U54 MH118919-02 | SCORE | 10089485 | RePORTER <br> Project Info |
| 2021 | Specialized Centers of Research Excellence (SCORE) on Sex Differences (U54) | Sex-Specific Effects of Endocrine Disruption on Aging and Alzheimer's Disease | Kantarci, Kejal | Mayo Clinic <br> Rochester | 5 U54 AG044170-09 | SCORE | 10174619 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Specialized Centers of Research Excellence (SCORE) on Sex Differences (U54) | Bioenergetic and Metabolic Consequences of the Loss of Gonadal Function | Kohrt, Wendy M | University <br> of Colorado Denver | 5 U54 AG062319-09 | SCORE | 10225529 | RePORTER <br> Project Info |
| 2021 | Specialized Centers of Research Excellence (SCORE) on Sex Differences (U54) | Sex and Age Differences in Immunity to Influenza (SADII) | Klein, Sabra L | Johns Hopkins University | 5 U54 AG062333-04 | SCORE | 10213168 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Specialized Centers of Research Excellence (SCORE) on Sex Differences (U54) | Emory Specialized Center of Research Excellence (SCORE) on Sex Differences | Ofotokun, Ighovwerha | Emory University | 5 U54 AG062334-04 | SCORE | 10231027 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |


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| 2021 | Specialized Centers of Research Excellence (SCORE) on Sex Differences (U54) | MUSC Specialized Center of Research Excellence on Sex Differences | McRae-Clark, Aimee L | Medical University of South Carolina | 5 U54 DA016511-19 | SCORE | 10226023 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Specialized Centers of Research Excellence (SCORE) on Sex Differences (U54) | Sex Differences in the Metabolic Syndrome | Reue, Karen | University of California, Los Angeles | 5 U54 DK120342-04 | SCORE | 10225900 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | The NCI Transition Career Development Award (K22) | Defining the role of SWI/SNF chromatin remodeling complex mutations during melanoma progression | Shain, Alan Hunter | University of California, San Francisco | 3 K22 CA217997-03S1 | Careers | 10468456 | RePORTER <br> Project Info |
| 2021 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Interactions of Sex and Gender Factors in Risk for Alzheimers Disease: Links Between Stress, Neural Activity, Inflammation, and Memory | Kirkland Caldwell, Jessica | Cleveland Clinic Lerner College of Medicine CWRU | 1 R01 AG074392-01 | Sex and Gender R01 | 10307848 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Sex and gender differences in lupus intersection between immunometabolism, epigenetic remodeling and cardiac involvement | Jefferies, Caroline | Cedars-Sinai Medical Center | 1 R01 Al164504-01 | Sex and Gender R01 | 10308290 | RePORTER <br> Project Info |
| 2021 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Gender and Sex Hormone Influences on Cannabis Use Disorder Remission | Tomko, Rachel Lynn | Medical University of South Carolina | 1 R01 DA054617-01 | Sex and Gender R01 | 10307840 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Pathways to Oral Health Among Lowincome Pregnant Urban Women | Russell, Stefanie L | New York University | 1 R01 DE029963-01A1 | Sex and Gender R01 | 10308267 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Networks Tools to Understand Sex- and Gender-Specific Drivers of Disease | Demeo, Dawn L | Brigham and Women's Hospital | 1 R01 HG011393-01A1 | Sex and Gender R01 | 10307441 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Elucidating the phenome-wide impact of sex and gender on disease | Davis, Lea K | Vanderbilt University Medical Center | 1 R01 HG011405-01A1 | Sex and Gender R01 | 10308237 | RePORTER <br> Project Info |
| 2021 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Credentialing novel cardiovascular disease genes in women by sexspecific genomic investigation of insulin resistance | Majithia, Amit | University of California, San Diego | 1 R01 HL159760-01 | Sex and Gender R01 | 10308343 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Gonadal hormones as mediators of sex and gender influences in asthma | Silveyra, Patricia | Trustees of Indiana University | 1 R01 HL159764-01 | Sex and Gender R01 | 10308138 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |


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| 2021 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Harnessing the power of technology to develop a populationbased HIV prevention program for trans girls | Ybarra, Michele L | Center For Innovative Public Health Research | 1 R01 NR020309-01 | Sex and Gender R01 | 10308350 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Hormonal control of HIV latency | Bosque, Alberto | George <br> Washington <br> University | 5 R01 Al154518-02 | Sex and Gender R01 | 10201490 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Implicit Bias in the Evidence: An Evaluation of FemalePredominant Disease | Simard, Julia F | Stanford University | 5 R01 Al154533-02 | Sex and Gender R01 | 10268253 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | The impact of sex and gender on disease progression, from developmental origins | Pisarska, Margareta | Cedars-Sinai <br> Medical Center | 5 R01 Al154535-02 | Sex and Gender R01 | 10260551 | RePORTER <br> Project Info |
| 2021 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Sex Determines Age-related Changes in the Repertoire and Function of Natural Antibodies Protective against Streptococcus pneumoniae with Increasing Age | Holodick, Nichol Elizabeth | Western <br> Michigan <br> University <br> School of <br> Medicine | 5 R01 Al154539-02 | Sex and Gender R01 | 10267224 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Sex, Gender and the Immunopathogenesis of HIV | Scully, Eileen Patricia | Johns Hopkins University | 5 R01 Al154541-02 | Sex and Gender R01 | 10214530 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Substance use and DNA methylation at the intersection of sex and gender | Flentje, Annesa | University of California, San Francisco | 5 R01 DA052016-02 | Sex and Gender R01 | 10269916 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Gender and sex differences in phthalate-induced toxicity in the reproductive system | Flaws, Jodi A | University of Illinois at UrbanaChampaign | 5 R01 ES032163-02 | Sex and Gender R01 | 10240715 | RePORTER <br> Project Info |
| 2021 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Dissection of the mechanisms underlying sex-influenced cardiovascular disease | Shavit, Jordan A | University of Michigan at Ann Arbor | 5 R01 ES032255-02 | Sex and Gender R01 | 10240707 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2021 | Training Modules to Enhance the Rigor and Reproducibility of Biomedical Research (R25 Clinical Trial Not Allowed) | Addressing Sex <br> as a Biological <br> Variable in Preclinical <br> Pharmacology <br> and Neuroscience <br> Research: Accounting <br> for Neglected <br> Factors and Applying <br> Practical Solutions to <br> Enhance Rigor and <br> Reproducibility | Ferland-Beckham, Chantelle | Cohen <br> Veterans <br> Bioscience, Inc. | 5 R25 GM133017-03 | SRP | 10197959 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |


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| 2021 | Urgent Competitive <br> Revision to Existing <br> NIH Grants and <br> Cooperative <br> Agreements (Urgent <br> Supplement - Clinical <br> Trial Optional) | Community Events and Pathways to Inequities in Birth Outcomes | Hardeman, Rachel R | University of Minnesota | 3 R01 HD103684-01S1 | SRP | 10392743 | RePORTER <br> Project Info |
| 2021 | Urgent Competitive <br> Revision to Existing <br> NIH Grants and <br> Cooperative <br> Agreements (Urgent <br> Supplement - Clinical <br> Trial Optional) | Impacts of COVID-19 and racial discrimination on mental, physical, and psychophysiological health in Black pregnant and postpartum persons | Michopoulos, Vasiliki | Emory University | 3 R01 MH115174-04S1 | SRP | 10393125 | RePORTER <br> Project Info |
| 2021 | Urgent Competitive <br> Revision to Existing <br> NIH Grants and <br> Cooperative <br> Agreements (Urgent <br> Supplement - Clinical <br> Trial Optional) | Evaluation and validation of a novel instrument to assess the psychosocial and drug history backgrounds of pregnant women with or without Opioid Use Disorder | Preis, Heidi | State University of New York at Stony Brook | 3 R21 DA049827-02S1 | SRP | 10382639 | RePORTER Project Info |
| 2021 | Women's Reproductive Health Research (WRHR) Career Development Program (K12 Clinical Trial Optional) | OHSU Womens <br> Reproductive Health <br> Research K12 <br> Program | Caughey, Aaron B | Oregon Health \& Science University | 5 K12 HD085809-07 | Careers | 10227806 | RePORTER <br> Project Info |
| FY | RFA Title | Title | Contact PI Name | Institution | Grant | ORWH <br> Program | Appl Id |  |
| 2022 | Administrative <br> Supplements to <br> Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Progressive Muscle Relaxation for Chronic Pain in an Acute Care Setting | Minen, Mia | New York University School of Medicine | 3 K23 AT009706-05S1 | Careers | 10648574 | RePORTER <br> Project Info |
| 2022 | Academic Research Enhancement Award for UndergraduateFocused Institutions (R15 Clinical Trial Not Allowed) | Prebiotic Activity of Pinto Beans and Metabolic Outcomes in Estrogen Deficiency | Lucas, Edralin A | Oklahoma <br> State <br> University- <br> Stillwater | 1 R15 AT011962-01 | SRP | 10439276 | RePORTER <br> Project Info |
| 2022 | Accelerating Basic and <br> Translational Research <br> in Hidradenitis <br> Suppurativa (R21 <br> Clinical Trial Not <br> Allowed) | Genetic risk of hidradenitis suppurativa in African Americans | Mi, Qing-Sheng | Henry Ford Health System | 3 R21 AR07908901A1S1 | Sex and <br> Gender <br> Admin <br> Supplement | 10703531 | RePORTER <br> Project Info |
| 2022 | Accelerating <br> Medicines Partnership <br> Autoimmune and <br> Immune-Mediated <br> Diseases: Disease <br> Teams for Rheumatoid <br> Arthritis, Lupus, <br> Psoriatic Spectrum <br> Diseases, and Sjgrens <br> Syndrome (UC2 <br> Clinical Trial Optional) | Lupus Omics Cutaneous Kidney Investigative Team (LOCKIT) | Buyon, Jill P | New York University School of Medicine | 1 UC2 AR081039-01 | SRP | 10452169 | RePORTER <br> Project Info |


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| 2022 | Accelerating <br> Medicines Partnership <br> Autoimmune and Immune-Mediated Diseases: Technology and Analytic Cores (TACs) and Research Management Unit (RMU) (UC2 Clinical Trial Not Allowed) | Integrative analysis of high dimensional tissue molecular data to define key biological systems in autoimmune diseases (SBC) | Raychaudhuri, Soumya | Brigham and Women's Hospital | 1 UC2 AR081023-01 | SRP | 10450354 | RePORTER <br> Project Info |
| 2022 | Accelerating Medicines Partnership Autoimmune and Immune-Mediated Diseases: Technology and Analytic Cores (TACs) and Research Management Unit (RMU) (UC2 Clinical Trial Not Allowed) | Single cell and spatial genomic analyses of specimens from patients with autoimmune diseases (Technology Core) | Brenner, Michael B | Brigham and Women's Hospital | 1 UC2 AR081031-01 | SRP | 10451924 | RePORTER <br> Project Info |
| 2022 | Accelerating <br> Medicines Partnership <br> Autoimmune and Immune-Mediated Diseases: Technology and Analytic Cores (TACs) and Research Management Unit (RMU) (UC2 Clinical Trial Not Allowed) | Accelerating <br> Medicines <br> Partnership- <br> Autoimmune and Immunologic Disease Tissue Research Core | Guthridge, Joel Marvin | Oklahoma <br> Medical <br> Research <br> Foundation | 1 UC2 AR081032-01 | Careers | 10452026 | RePORTER <br> Project Info |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Therapeutic activation of AMPK for the aging right heart | Bruns, Danielle Reuland | University of Wyoming | 3 K01 AG058810-04S1 | Sex and <br> Gender <br> Admin <br> Supplement | 10555925 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to <br> Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Admin Supplement for Retention of K Awardees: Contributions of Hypoglycemia and Hyperglycemia to Adverse Geriatric Outcomes in NH Residents | Lee, Alexandra Kathryn | University of California, San Francisco | 3 K01 AG073532-02S1 | Careers | 10614349 | RePORTER <br> Project Info |
| 2022 | Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Role of periostin expressing cells in intramembranous bone regeneration | Ko, Frank | Rush University Medical Center | 3 K01 AR077679-02S1 | Sex and <br> Gender <br> Admin <br> Supplement | 10556659 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Implementation of PrEP for Women Who Inject Drugs through Practice Facilitation in Primary and Reproductive Health Care | Starbird, Laura | University of Pennsylvania | 3 K01 DA051348-02S1 | Careers | 10518544 | RePORTER <br> Project Info |


| FY | RFA Title | Title | Contact PI Name | Institution | Grant | ORWH Program | Appl Id | RePORTER <br> Project Info |
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| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Admin SupplementInfant multisensory integration and speech development: A multimodal imaging study | Shen, Guannan | Children's Hospital of Philadelphia | 3 K01 DC019443-02S1 | Careers | 10635107 | RePORTER <br> Project Info |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Application of novel biomarkers to measure health impacts of anthropogenic change in the Amazon | Feingold, Beth | State University of New York at Albany | 3 K01 TW011478-03S1 | Careers | 10649933 | RePORTER <br> Project Info |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Prolonged Local <br> Melatonin Delivery for <br> Recurrent Laryngeal <br> Nerve Neuropraxia | Kita, Ashley | University of California, Los Angeles | 3 K08 DC019957-01S1 | Careers | 10635982 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Estrogen as a Regulator of the Sphingolipid Balance in the Human Microcirculation | Freed, Julie K | Medical College of Wisconsin | 3 K08 HL141562-04S1 | Sex and <br> Gender <br> Admin <br> Supplement | 10556913 | RePORTER <br> Project Info |
| 2022 | Administrative <br> Supplements to <br> Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Impact of Diet Induced Obesity on Acute Lung Injury | Plataki, Maria | Weill Medical College of Cornell University | $\begin{aligned} & 3 \text { K08 HL157728- } \\ & \text { 01A1S1 } \end{aligned}$ | Careers | 10632732 | RePORTER <br> Project Info |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Supplement for Kentucky BIRCWH Program: Training the Next Generation of Women's Health Scholars | Curry, Thomas E | University of Kentucky | 3 K12 DA035150-11S1 | BIRCWH | 10682952 | RePORTER <br> Project Info |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Building Interdisciplinary Research Careers in Women's Health in Pittsburgh | Sadovsky, Yoel | Magee- <br> Womens <br> Research Institute and Foundation | 3 K12 HD043441-21S1 | BIRCWH | 10675213 | RePORTER <br> Project Info |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Building Interdisciplinary Research Careers in Women's Health (K12) - BIRCWH administrative supplement | Amundsen, Cindy | Duke University | 3 K12 HD043446-21S1 | BIRCWH | 10684414 | RePORTER <br> Project Info |


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| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Building Interdisciplinary Research Careers in Women's Health <br> - Administrative Supplement | Krousel-Wood, Marie | Tulane University of Louisiana | 3 K12 HD043451-21S1 | BIRCWH | 10676018 | RePORTER <br> Project Info |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Building <br> Interdisciplinary <br> Research Careers in <br> Women's Health | Hartmann, Katherine E | Vanderbilt University Medical Center | 3 K12 HD043483-22S1 | BIRCWH | 10674088 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Oregon BIRCWH K12 4th Scholar Supplement | Myatt, Leslie | Oregon Health <br> \& Science <br> University | 3 K12 HD043488-21S1 | BIRCWH | 10677421 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Building Interdisciplinary Research Careers in Women's Health at UC Davis | Lane, Nancy E | University of California, Davis | 3 K12 HD051958-18S1 | BIRCWH | 10676527 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to <br> Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Hormones and Genes in Women's Health: <br> From Bench to Bedside | Goldstein, Jill M | Brigham and Women's Hospital | 3 K12 HD051959-18S1 | BIRCWH | 10671336 | RePORTER <br> Project Info |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Administrative <br> Supplement to UTMB <br> Women's Health <br> Research Scholars <br> Program | Berenson, Abbey B | University of Texas Medical Branch at Galveston | 3 K12 HD052023-18S1 | BIRCWH | 10682979 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | UCSF-Kaiser <br> Department of Research Building Interdisciplinary Research Careers in Women's Health (BIRCWH) Program | Brindis, Claire D | University of California, San Francisco | 3 K12 HD052163-23S1 | BIRCWH | 10672871 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | University of Minnesota BIRCWH K12 Administrative Supplement | Berge, Jerica M | University of Minnesota | 3 K12 HD055887-16S1 | BIRCWH | 10682797 | RePORTER <br> Project Info |


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| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | The Colorado Building Interdisciplinary Research Careers in Women's Health Program Administrative Supplement | Regensteiner, Judith G | University of Colorado Denver | 3 K12 HD057022-16S1 | BIRCWH | 10677413 | RePORTER <br> Project Info |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Mayo Clinic Building Interdisciplinary <br> Research Careers in Women's Health | Kantarci, Kejal | Mayo Clinic Rochester | 3 K12 HD065987-13S1 | BIRCWH | 10674365 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | The Johns Hopkins Clinical Research Scholars in Women's Health (BIRCWH) | Ford, Daniel Ernest | Johns Hopkins University | 3 K12 HD085845-08S1 | BIRCWH | 10683615 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Emory University BIRCWH Program | Ofotokun, Ighovwerha | Emory University | 3 K12 HD085850-08S1 | BIRCWH | 10676664 | RePORTER <br> Project Info |
| 2022 | Administrative <br> Supplements to <br> Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Transforming Training to Increase Diversity in the Tufts BIRCWH Program | Freund, Karen | Tufts University | 3 K12 HD092535-06S1 | BIRCWH | 10678506 | RePORTER <br> Project Info |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | University of Wisconsin Building Interdisciplinary Research Careers in Women's Health (BIRCWH) Scholars Program | Burnside, Elizabeth S | University of WisconsinMadison | 3 K12 HD101368-03S1 | BIRCWH | 10669991 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | UIC Building Interdisciplinary Research Careers in Women's Health Program | Maki, Pauline M | University of Illinois Chicago | 3 K12 HD101373-03S1 | BIRCWH | 10681107 | RePORTER <br> Project Info |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | BIRCWH Supplement | Kornstein, Susan G | Virginia <br> Commonwealth University | 3 K12 HD108269-01S1 | BIRCWH | 10683574 | RePORTER <br> Project Info |


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| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Computational <br> Speech Analysis <br> in Alzheimer's <br> Disease and Other <br> Neurocognitive <br> Disorders <br> (Supplement) | Pressman, Peter Scott | University of Colorado Denver | 3 K23 AG063900-03S1 | Careers | 10594271 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Neurobiological <br> Mechanisms of Stress <br> in Youth with Chronic <br> Widespread Pain - <br> Supplement | Nelson, Sarah Mary | Boston Children's Hospital | 3 K23 AT010643-03S1 | Careers | 10604412 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Increasing Referrals <br> to Medications <br> for Opioid Use <br> Disorders from Drug <br> Treatment Courts using Organizational <br> Linkage Intervention | Pivovarova, Ekaterina | University of Massachusetts Chan Medical School | 3 K23 DA049953-02S1 | Careers | 10513740 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to <br> Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Changes in cognition and psychiatric disorder symptoms during cannabis abstinence using a novel discordant twin design | Ross, Jessica Megan | University of Colorado Denver | 3 K23 DA054212-01S1 | Careers | 10527851 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to <br> Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Early Biomarkers of Alzheimer's Disease: Using Speech Markers to Detect Mild Cognitive Impairment | Eshghi, Marziye | MGH Institute of Health Professions | 3 K23 DC019179-02S1 | Careers | 10635160 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Respiratory Viral Determinants of Chronic Lung Allograft Dysfunction | Fisher, Cynthia E | University of Washington | 3 K23 HL143050-05S1 | Careers | 10629762 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | The influence of ward capacity strain on outcomes among survivors of acute respiratory failure | Kohn, Rachel | University of Pennsylvania | 3 K23 HL146894-04S1 | Careers | 10627125 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Insomnia Treatment and Cardiometabolic Health in Older Adults with Posttraumatic Stress Disorder | Kelly, Monica | University of California, Los Angeles | 3 K23 HL157754- <br> 01A1S1 | Careers | 10630503 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |


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| 2022 | Administrative <br> Supplements to <br> Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Deriving a de novo adolescent addiction treatment from developmental brain data | Feldstein Ewing, Sarah W | University of Rhode Island | 3 K24 AA026876-05S1 | Careers | 10605635 | RePORTER <br> Project Info |
| 2022 | Administrative <br> Supplements to <br> Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Mapping impact and developing mitigation strategies for climate changemental health nexus in the context of vulnerable adolescent populations in Kenya | Kumar, Manasi | University of Nairobi | 3 K43 TW010716-05S1 | SRP | 10672516 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to <br> Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | GABA and NPY <br> Signaling Interact to Shape Inhibition in the Auditory Tectothalamic Pathway | Silveira, Marina Augusto | University of Michigan | 3 K99 DC01941501A1S1 | Careers | 10634797 | RePORTER <br> Project Info |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Mechanisms of Basal Forebrain Control Over Sensory Processing | Moss, Elizabeth Hanson | Baylor College of Medicine | 3 K99 DC019505-02S1 | Careers | 10634890 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Cancer Center Support Grant | Eberlein, Timothy J | Washington University in St. Louis | 3 P30 CA091842-21S2 | U3 Admin Supplement | 10556707 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Nucleus accumbens neuronal ensembles in drugs and natural rewards seeking | Bobadilla, Ana Clara | University of Wyoming | 3 R00 DA046522-04S1 | Careers | 10601912 | RePORTER <br> Project Info |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | The significance of nominally nonresponsive neural dynamics in auditory perception and behavior | Insanally, Michele | University of Pittsburgh | 3 R00 DC015543-05S1 | Careers | 10634831 | RePORTER <br> Project Info |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Significant Life Event <br> Supplement-Neural mechanisms of auditory plasticity and perceptual learning | Caras, Melissa Lynne | University of Maryland, College Park | 3 R00 DC016046-05S2 | Careers | 10616993 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |


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| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Mechanisms regulating afferent innervation in the dental pulp | Peters, Sarah | Ohio State University | 3 R00 DE027706-05S1 | Careers | 10599553 | RePORTER <br> Project Info |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Community-Level <br> Effects of Structural <br> Racism on Women's <br> Circadian Rhythm <br> Pattern and Heath | Condon, Eileen | University of Connecticut | 3 R00 NR018876-04S1 | U3 Admin Supplement | 10558928 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Healthcare-Seeking and Violence against American Indian and Alaska Native Women: Examining the Impact of the COVID-19 Pandemic | Lee, Juliet P | Pacific Institute for Research and Evaluation | 3 R01 AA028236-02S1 | U3 Admin Supplement | 10559049 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Administrative <br> Supplement to Sleep <br> Fragmentation and <br> Alzheimer's Disease | Murphy, Michael Paul | University of Kentucky | 3 R01 AG068215-03S1 | Sex and <br> Gender <br> Admin <br> Supplement | 10555721 | RePORTER <br> Project Info |
| 2022 | Administrative <br> Supplements to <br> Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Administrative <br> Supplement to <br> Recognize Excellence <br> in DEIA Mentorship | Kwon, Ronald Y | University of Washington | 3 R01 AR074417-02S2 | Careers | 10604074 | RePORTER <br> Project Info |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Influence of sex and sex hormones on modeling- and remodeling-based bone formation | Liu, Xiaowei Sherry | University of Pennsylvania | 3 R01 AR077598-02S1 | Sex and <br> Gender <br> Admin <br> Supplement | 10556506 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Geneticallyengineered stem cells for self-regulating arthritis therapy | Guilak, Farshid | Washington University in St. Louis | 3 R01 AR080902-01S1 | Careers | 10630757 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to <br> Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Sex and racial/ethnic differences in B-ALL genomics | Spector, Logan G | University of Minnesota | 3 R01 CA23970101A1S2 | Sex and <br> Gender <br> Admin <br> Supplement | 10555358 | RePORTER <br> Project Info |


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| 2022 | Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Regulation of 5-HT circuits by CRF and GABA in opioid addiction and stressinduced relapse | Kirby, Lynn G | Temple University | 3 R01 DA045771-04S1 | Sex and <br> Gender <br> Admin <br> Supplement | 10556667 | RePORTER <br> Project Info |
| 2022 | Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Teen Mothers' <br> Prenatal Cannabis Use and Co-Use with Tobacco | De Genna, Natacha Marie | University of Pittsburgh | 3 R01 DA046401-04S1 | U3 Admin Supplement | 10555381 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Violence Across the Lifespan - Opioids Maternal Brain | Swain, James Edward | State University of New York at Stony Brook | 3 R01 DA047336-04S1 | U3 Admin Supplement | 10558931 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Functional Integration of Newborn Olfactory Sensory Neurons in the Healthy and Regenerating Olfactory System | Cheetham, Claire Elizabeth Jane | University of Pittsburgh | 3 R01 DC018516-02S1 | Careers | 10630475 | RePORTER <br> Project Info |
| 2022 | Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Multi-level factors affecting postpartum contraception during incarceration | Arora, Kavita Shah | University of North Carolina at Chapel Hill | 3 R01 HD098127-04S1 | U3 Admin Supplement | 10557980 | RePORTER <br> Project Info |
| 2022 | Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Defining the Mechanism of Meiotic Initiation Through Autophagy Pathway | Wang, Ning | University of Kansas Medical Center | 3 R01 HD103888-03S1 | Sex and <br> Gender <br> Admin <br> Supplement | 10556093 | RePORTER <br> Project Info |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Inflammation, Aging, Microbes, Obstructive Lung Disease, and Diffusion Abnormalities (I AM OLD-DA): <br> Pulmonary function in females, evaluating the menopausal transition and immune activation (pFEMI). | Huang, Laurence | University of California, San Francisco | 3 R01 HL128156-07S2 | Sex and <br> Gender <br> Admin <br> Supplement | 10556269 | RePORTER <br> Project Info |
| 2022 | Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Molecular mechanisms of sex difference in COVID-19 enabling novel therapeutics | Cai, Hua Linda | University of California, Los Angeles | 3 R01 HL142951-03S1 | Sex and <br> Gender <br> Admin <br> Supplement | 10555078 | RePORTER <br> Project Info |


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| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Trajectories of ovarian reserve and cardiovascular risk in Black and White women | Woo, Jessica G | Cincinnati <br> Children's <br> Hospital <br> Medical Center | 3 R01 HL15810001A1S1 | U3 Admin Supplement | 10559092 | RePORTER <br> Project Info |
| 2022 | Administrative <br> Supplements to <br> Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Minding the gap: a multidisciplinary approach to reducing maternal health disparities in Georgia | Jamieson, Denise Jean | Emory University | 3 R01 MD016031-03S1 | U3 Admin Supplement | 10559304 | RePORTER <br> Project Info |
| 2022 | Administrative <br> Supplements to <br> Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Modeling the impact of Women's Specific Health Factors in PD outcomes in Latinas | Fernandez Mata, Ignacio | Cleveland Clinic Lerner College of Medicine | 3 R01 NS112499-03S1 | U3 Admin Supplement | 10558903 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | DEIA Mentorship Supplement | Ingram, Katherine Heimburger | Kennesaw State University | 3 R15 HD102957-01S1 | Careers | 10606244 | RePORTER <br> Project Info |
| 2022 | Administrative <br> Supplements to <br> Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Optimizing Intervention Options for Toddlers with Early Social Communication Delays: A Continuity Supplement | Hampton, Lauren Hazledine | University of Texas at Austin | 3 R21 DC018908-02S2 | Careers | 10636249 | RePORTER <br> Project Info |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Testing a Biosocial Model of Borderline Personality Features in Youth | Babinski, Dara E | Penn State Health Milton S. Hershey Medical Center | 3 R21 MH125052-02S1 | Sex and <br> Gender <br> Admin <br> Supplement | 10556483 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to <br> Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Increasing HIV/ STI Home Testing, Linkage to Care, and Linkage to PrEP via a Digital Intervention among Black Women in a Geographic Hotspot | Nydegger, Lies | University of Texas at Austin | 3 R34 MH128054-02S1 | U3 Admin Supplement | 10559293 | RePORTER <br> Project Info |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Deciphering the role of chemical signals in inflammation with open microfluidic functional assays | Theberge, Ashleigh Brooks | University of Washington | 3 R35 GM128648-05S1 | U3 Admin Supplement | 10556928 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |


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| 2022 | Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Genetic Risk <br> Analysis in Ovarian <br> Cancer (GRACE) <br> Administrative <br> Supplement | Hunter, Jessica Ezzell | Kaiser <br> Foundation Research Institute | 3 U01 CA244323-03S1 | SRP | 10593883 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Continuation of the NuMoM2b Heart Health Study | McNeil, Rebecca Boehm | $\begin{array}{\|l} \text { Research } \\ \text { Triangle } \\ \text { Institute } \end{array}$ | 3 U01 HL145358-03S3 | SRP | 10695578 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Administrative <br> Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | Early Intervention to Promote Cardiovascular Health of Mothers and Children (ENRICH) Multisite Resource and Coordinating Center | Minkovitz, Cynthia S | Johns Hopkins University | 3 U24 HL163114-01S1 | SRP | 10685009 | RePORTER <br> Project Info |
| 2022 | Administrative Supplements to Existing NIH Grants and Cooperative Agreements (Parent Admin Supp Clinical Trial Optional) | MUSC Specialized Center of Research Excellence on Sex Differences--BIRCWH Scholars Innovation Program | McRae-Clark, Aimee L | Medical University of South Carolina | 3 U54 DA016511-20S1 | SCORE | 10696691 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | American Women: Assessing Risk Epidemiologically (AWARE) (R01 Clinical Trial Optional) | Enhanced COhort methods for HIV <br> Research and Epidemiology (ENCORE) among transgender women in the United States | Wirtz, Andrea L | Johns Hopkins University | 1 R01 Al172092-01 | SRP | 10537314 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | American Women: <br> Assessing Risk <br> Epidemiologically <br> (AWARE) (R01 Clinical <br> Trial Optional) | Examining Social Ecological and Network Factors to Assess Epidemiological Risk in a Large National Cohort of Cisgender Women | Schnall, Rebecca | Columbia University Irving Medical Center | 1 R01 Al172469-01 | SRP | 10543645 | RePORTER <br> Project Info |
| 2022 | American Women: Assessing Risk Epidemiologically (AWARE) (R01 Clinical Trial Optional) | CAMELLIA Cohort: <br> A longitudinal study to understand sexual health and prevention among women in Alabama | Elopre, Latesha Ellen | University of Alabama at Birmingham | 1 R01 HD110097-01 | SRP | 10538855 | RePORTER <br> Project Info |
| 2022 | Building Interdisciplinary Research Careers in Women's Health (BIRCWH); K12 Clinical Trial Optional | Building Interdisciplinary Research Careers in Women's Health at UC Davis | Lane, Nancy E | University of California, Davis | 5 K12 HD051958-18 | BIRCWH | 10421369 | RePORTER <br> Project Info |
| 2022 | Building Interdisciplinary Research Careers in Women's Health (BIRCWH); K12 Clinical Trial Optional | Hormones and Genes in Women's Health: <br> From Bench to Bedside | Goldstein, Jill M | Brigham and Women's Hospital | 5 K12 HD051959-18 | BIRCWH | 10434856 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |


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| 2022 | Building Interdisciplinary Research Careers in Women's Health (BIRCWH); K12 Clinical Trial Optional | UTMB Women's Health Research Scholars Program | Berenson, Abbey B | University of Texas Medical Branch at Galveston | 5 K12 HD052023-18 | BIRCWH | 10462504 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Building Interdisciplinary Research Careers in Women's Health (BIRCWH); K12 Clinical Trial Optional | UCSF-Kaiser <br> Department of Research Building Interdisciplinary Research Careers in Women's Health (BIRCWH) Program | Brindis, Claire D | University of California, San Francisco | 5 K12 HD052163-23 | BIRCWH | 10436222 | RePORTER <br> Project Info |
| 2022 | Building Interdisciplinary Research Careers in Women's Health (BIRCWH); K12 Clinical Trial Optional | Mayo Clinic Building Interdisciplinary Research Careers in Women's Health | Kantarci, Kejal | Mayo Clinic <br> Rochester | 5 K12 HD065987-13 | BIRCWH | 10425303 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Building Interdisciplinary Research Careers in Women's Health (BIRCWH); K12 Clinical Trial Optional | The Johns Hopkins Clinical Research Scholars in Women's Health (BIRCWH) | Ford, Daniel Ernest | Johns Hopkins University | 5 K12 HD085845-08 | BIRCWH | 10457011 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Building Interdisciplinary Research Careers in Women's Health (BIRCWH); K12 Clinical Trial Optional | Emory University BIRCWH Program | Ofotokun, Ighowwerha | Emory University | 5 K12 HD085850-08 | BIRCWH | 10424533 | RePORTER <br> Project Info |
| 2022 | Building Interdisciplinary Research Careers in Women's Health (BIRCWH); K12 Clinical Trial Optional | University of Wisconsin Building Interdisciplinary Research Careers in Women's Health (BIRCWH) Scholars Program | Burnside, Elizabeth S | University of WisconsinMadison | 5 K12 HD101368-03 | BIRCWH | 10424428 | RePORTER <br> Project Info |
| 2022 | Building Interdisciplinary Research Careers in Women's Health (BIRCWH); K12 Clinical Trial Optional | UIC Building Interdisciplinary Research Careers in Women's Health Program | Maki, Pauline M | University of Illinois Chicago | 5 K12 HD101373-03 | BIRCWH | 10434722 | RePORTER <br> Project Info |
| 2022 | Building Interdisciplinary Research Careers in Women's Health Program (BIRCWH) (K12 Clinical Trial Optional) | Building Interdisciplinary Research Careers in Women's Health | Kornstein, Susan G | Virginia <br> Commonwealth University | 1 K12 HD108269-01 | BIRCWH | 10427815 | RePORTER <br> Project Info |
| 2022 | Building Interdisciplinary Research Careers in Women's Health Program (BIRCWH) (K12 Clinical Trial Optional) | Kentucky BIRCWH Program: Training the Next Generation of Women's Health Scholars | Curry, Thomas E | University of Kentucky | 2 K12 DA035150-11 | BIRCWH | 10428147 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |


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| 2022 | Building Interdisciplinary Research Careers in Women's Health Program (BIRCWH) (K12 Clinical Trial Optional) | Building Interdisciplinary Research Careers in Women's Health in Pittsburgh | Sadovsky, Yoel | Magee- <br> Womens <br> Research <br> Institute and <br> Foundation | 2 K12 HD043441-21 | BIRCWH | 10425904 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Building Interdisciplinary Research Careers in Women's Health Program (BIRCWH) (K12 Clinical Trial Optional) | Building Interdisciplinary Research Careers in Women's Health (K12) | Amundsen, Cindy | Duke University | 2 K12 HD043446-21 | BIRCWH | 10427750 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Building Interdisciplinary Research Careers in Women's Health Program (BIRCWH) (K12 Clinical Trial Optional) | Building Interdisciplinary Research Careers in Women's Health | Krousel-Wood, Marie | Tulane University of Louisiana | 2 K12 HD043451-21 | BIRCWH | 10427839 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Building Interdisciplinary Research Careers in Women's Health Program (BIRCWH) (K12 Clinical Trial Optional) | Building Interdisciplinary Research Careers in Women's Health | Hartmann, Katherine E | Vanderbilt University Medical Center | 2 K12 HD043483-22 | BIRCWH | 10425633 | RePORTER <br> Project Info |
| 2022 | Building Interdisciplinary Research Careers in Women's Health Program (BIRCWH) (K12 Clinical Trial Optional) | Oregon BIRCWH: Scholars in Women's Health Research Across the Lifespan | Myatt, Leslie | Oregon Health \& Science University | 2 K12 HD043488-21 | BIRCWH | 10425885 | RePORTER <br> Project Info |
| 2022 | Building <br> Interdisciplinary Research Careers in Women's Health Program (BIRCWH) (K12 Clinical Trial Optional) | University of MN Building Interdisciplinary Research Careers in Women's Health | Berge, Jerica M | University of Minnesota | 2 K12 HD055887-16 | BIRCWH | 10426871 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Building Interdisciplinary Research Careers in Women's Health Program (BIRCWH) (K12 Clinical Trial Optional) | The Colorado Building Interdisciplinary Research Careers in Women's Health Program | Regensteiner, Judith G | University of Colorado Denver | 2 K12 HD057022-16 | BIRCWH | 10425628 | RePORTER <br> Project Info |
| 2022 | Building Interdisciplinary Research Careers in Women's Health Program (BIRCWH) (K12 Clinical Trial Optional) | Tufts BIRCWH Program | Freund, Karen | Tufts University | 2 K12 HD092535-06 | BIRCWH | 10427678 | RePORTER <br> Project Info |
| 2022 | Centers to Advance Research in Endometriosis (CARE) (P01 Clinical Trial Not Allowed) | Collaborative Center to Develop Improved Diagnostic and Therapeutic Approaches to Endometriosis | Young, Steven L | University of North Carolina at Chapel Hill | 5 P01 HD106485-02 | SRP | 10474470 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |


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| 2022 | Early Intervention to Promote Cardiovascular Health of Mothers and Children (ENRICH) Multisite Clinical Centers (Collaborative UG3/UH3 Clinical Trial Required) | Colorado Nurse <br> Family Heart Trial for the ENRICH program | Sauder, Katherine A | University of Colorado Denver | 1 UG3 HL162967-01 | SRP | 10426544 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Early Intervention to Promote Cardiovascular Health of Mothers and Children (ENRICH) Multisite Clinical Centers (Collaborative UG3/UH3 Clinical Trial Required) | Enhancing <br> Cardiovascular Health Equity in Mothers and Children Through Home Visiting | Haire-Joshu, Debra | Washington University in St. Louis | 1 UG3 HL162970-01 | SRP | 10426758 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Early Intervention to Promote Cardiovascular Health of Mothers and Children (ENRICH) Multisite Clinical Centers (Collaborative UG3/UH3 Clinical Trial Required) | Early Intervention to Promote <br> Cardiovascular Health of Mothers and Children in Northern Appalachia | Paul, Ian M | Pennsylvania <br> State Health <br> Milton S. <br> Hershey <br> Medical Center | 1 UG3 HL162971-01 | SRP | 10426872 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Early Intervention to Promote Cardiovascular Health of Mothers and Children (ENRICH) Multisite Clinical Centers (Collaborative UG3/UH3 Clinical Trial Required) | ENRICH ALABAMA: <br> Improving cardiovascular health of women and children through a novel home visiting intervention | Dutton, Gareth R | University of Alabama at Birmingham | 1 UG3 HL162973-01 | SRP | 10426961 | RePORTER <br> Project Info |
| 2022 | Early Intervention to Promote Cardiovascular Health of Mothers and Children (ENRICH) Multisite Clinical Centers (Collaborative UG3/UH3 Clinical Trial Required) | Expanding the Family <br> Check-Up in Early <br> Childhood to Promote <br> Cardiovascular Health <br> of Mothers and Young <br> Children (ENRICH) | Catov, Janet M | Magee- <br> Womens <br> Research <br> Institute and <br> Foundation | 1 UG3 HL163116-01 | SRP | 10427592 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Early Intervention to Promote Cardiovascular Health of Mothers and Children (ENRICH) Multisite Clinical Centers (Collaborative UG3/UH3 Clinical Trial Required) | 2-Generation Interventions to Improve <br> Cardiovascular Health in Indiana and Illinois Through Home Visiting (2-NOURISH) | Tandon, Shiv Darius | Northwestern University at Chicago | 1 UG3 HL163121-01 | SRP | 10427796 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |


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| 2022 | Early Intervention to Promote Cardiovascular Health of Mothers and Children (ENRICH) Multisite Clinical Centers (Collaborative UG3/UH3 Clinical Trial Required) | Healthy Hearts/ <br> Corazones Saludables: <br> Partnership <br> to promote <br> cardiovascular health <br> in Hispanic and non- <br> Hispanic mothers and children in US home <br> visiting programs | Phelan, Suzanne | California <br> Polytechnic <br> State <br> University, San <br> Luis Obispo | 1 UG3 HL163508-01 | SRP | 10435253 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Early Intervention to Promote <br> Cardiovascular Health of Mothers and Children (ENRICH) Multisite Resource and Coordinating Center (U24 Clinical Trial Required) | Early Intervention to Promote <br> Cardiovascular Health of Mothers and Children (ENRICH) Multisite Resource and Coordinating Center | Minkovitz, Cynthia S | Johns Hopkins University | 1 U24 HL163114-01 | SRP | 10427496 | RePORTER <br> Project Info |
| 2022 | Feasibility Studies that Explore Healthy and Diseased Temporomandibular Joints (TMJ) using Single Cell MultiOmic Analyses (UH2/ UH3 Clinical Trial Not Allowed) | Single cell analysis of healthy and diseased temporomandibular joint synovial fluid | Tomlinson, Ryan | Thomas Jefferson University | 1 UH2 DE032204-01 | SRP | 10524512 | $\begin{aligned} & \frac{\text { RePORTER }}{\text { Project Info }} \end{aligned}$ |
| 2022 | Feasibility Studies that Explore Healthy and Diseased Temporomandibular Joints (TMJ) using Single Cell MultiOmic Analyses (UH2/ UH3 Clinical Trial Not Allowed) | Local and Systemic Multi-Omics of TMJ Disorders | Kapila, Sunil D | University of California, Los Angeles | 1 UH2 DE032208-01 | SRP | 10524689 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | HEAL Initiative: HEALthy Brain and Child Development Study (Collaborative U01- Clinical Trial Not Allowed) | 22/24 Healthy <br> Brain and Child <br> Development National Consortium | Howell, Brittany Rollins | Virginia <br> Polytechnic Institute and State University | 1 U01 DA055357-01 | SRP | 10379510 | RePORTER <br> Project Info |
| 2022 | HEAL Initiative: HEALthy Brain and Child Development Study (Collaborative U01- Clinical Trial Not Allowed) | 1/6 HBCD Prenatal <br> Experiences and Longitudinal Development (PRELUDE) Consortium | Ou, Xiawei | Arkansas <br> Children's <br> Research <br> Institute | 5 U01 DA055352-02 | SRP | 10494233 | RePORTER <br> Project Info |
| 2022 | Improving Outcomes in Cancer TreatmentRelated Cardiotoxicity (R01 Clinical Trial Optional) | Cardioprotective Therapy for Doxorubicin Using iPSC Microtissue and CRISPR Screening | Wu, Joseph C | Stanford University | 5 R01 HL150693-02 | Sex and <br> Gender <br> Admin <br> Supplement | 10463762 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Innovations in HIV <br> Prevention, Testing, <br> Adherence and <br> Retention to Optimize <br> HIV Prevention and <br> Care Continuum <br> Outcomes (R01 Clinical <br> Trial Optional) | Characterizing intersecting sexual, gender, and racebased stigmas affecting communities of US transgender women and cisgender men who are sexually active with men | Baral, Stefan David | Johns Hopkins University | 5 R01 NR020437-02 | SRP | 10492621 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |


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| 2022 | Launching Future <br> Leaders in Global <br> Health (LAUNCH) <br> Research Training <br> Program (D43 Clinical <br> Trial Optional) | UJMT LAUNCH: <br> Training the next generation of leaders in global health research | Chi, Benjamin H | University of North Carolina at Chapel Hill | 3 D43 TW009340-11S9 | SRP | 10677901 | RePORTER <br> Project Info |
| 2022 | Launching Future Leaders in Global Health (LAUNCH) Research Training Program (D43 Clinical Trial Optional) | University of California Launching Future Leaders in Global Health Research Training Program | Cohen, Craig R | University of California, San Francisco | 3 D43 TW009343-11S6 | SRP | 10677896 | RePORTER <br> Project Info |
| 2022 | Launching Future <br> Leaders in Global <br> Health (LAUNCH) <br> Research Training <br> Program (D43 Clinical <br> Trial Optional) | Global Health Equity <br> Scholars Program | Ko, Albert Icksang | Yale University | 3 D43 TW010540-06S5 | SRP | 10677527 | RePORTER <br> Project Info |
| 2022 | Leveraging Existing Large Databases and Cohorts to Better Understand the Risks and Benefits of LongTerm Osteoporosis Therapy and Drug Holiday (R01 Clinical Trial Not Allowed) | Benefits and Harms of Longterm Osteoporosis Pharmacotherapy: Impact of Treatment Length, Type, Switching, and Holidays | Hayes, Kaleen Nicole | Brown University | 1 R01 AG078759-01 | Sex and Gender R01 | 10515946 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Leveraging Existing Large Databases and Cohorts to Better Understand the Risks and Benefits of LongTerm Osteoporosis Therapy and Drug Holiday (R01 Clinical Trial Not Allowed) | Comparative <br> Effectiveness and Safety of Osteoporosis Drug Therapies | Brito Campana, Juan $P$ | Mayo Clinic <br> Rochester | 1 R01 AG079113-01 | Sex and Gender R01 | 10514723 | RePORTER <br> Project Info |
| 2022 | Leveraging Existing Large Databases and Cohorts to Better Understand the Risks and Benefits of LongTerm Osteoporosis Therapy and Drug Holiday (R01 Clinical Trial Not Allowed) | Calculator for Length of Use of Bisphosphonates (CLUB) | Carbone, Laura D | Augusta University | 1 R01 AG079118-01 | Sex and Gender R01 | 10515879 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Leveraging Existing Large Databases and Cohorts to Better Understand the Risks and Benefits of LongTerm Osteoporosis Therapy and Drug Holiday (R01 Clinical Trial Not Allowed) | Pooling International Cohort Studies of Long-Term Bisphosphonate Use and Atypical Femur Fractures | Bauer, Douglas C | University of California, San Francisco | 1 R01 AR082562-01 | Sex and Gender R01 | 10516684 | RePORTER <br> Project Info |


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| 2022 | Limited Competition: Knockout Mouse Phenotyping Project Data Coordination Center and Database (UM1 Clinical Trial Not Allowed) | Mouse Phenotyping Informatics Infrastructure Data acquisition, integration, analysis and translation of high throughput mammalian phenotyping data | Parkinson, Helen Elizabeth | European <br> Molecular <br> Biology <br> Laboratory | 2 UM1 HG006370-11 | SRP | 10516810 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Mentored PatientOriented Research Career Development Award (Parent K23) | Couple-based lifestyle intervention to prevent type 2 diabetes | Baucom, Katherine Jane Williams | University of Utah | 3 K23 DK115820-05S2 | U3 Admin Supplement | 10669853 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Mentored Clinical <br> Scientist Research Career Development Award (Parent K08 - No Independent Clinical Trials) | Dissecting a novel prefrontal cortical pathway regulating feeding behavior | Ross, Rachel A | Albert Einstein College of Medicine | 3 K08 DK118201-05S3 | Careers | 10682056 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Mentored PatientOriented Research Career Development Award (Parent K23 Independent Clinical Trial Required) | Pathogenesis of Heart Failure with Preserved Ejection Fraction in Chronic Kidney Disease | Mehta, Rupal | Northwestern University at Chicago | 3 K23 HL150236-02S1 | Careers | 10690290 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Mentored PatientOriented Research Career Development Award (Parent K23 Independent Clinical Trial Not Allowed) | OVARIAN <br> RESERVE IN POST-MENARCHAL FEMALES WITH SICKLE CELL ANEMIA | Pecker, Lydia | Johns Hopkins University | 3 K23 HL146841-03S1 | U3 Admin Supplement | 10690200 | RePORTER <br> Project Info |
| 2022 | Mood and Psychosis Symptoms during the Menopause Transition (R01 Clinical Trial Optional) | Examining the Effects <br> of Estradiol on <br> Neural and Molecular <br> Response to Rewards <br> in Perimenopausal- <br> Onset Anhedonia and <br> Psychosis | Dichter, Gabriel S | University of North Carolina at Chapel Hill | 1 R01 MH128238-01 | SRP | 10348271 | RePORTER <br> Project Info |
| 2022 | NHLBI Clinical Ancillary Studies (R01 - Clinical Trial Optional) | Effect of Intensive Medical Treatment on Quantified Coronary Artery Plaque Components with Serial Coronary CTA in Women with NonObstructive CAD | Dey, Damini | Cedars-Sinai Medical Center | 5 R01 HL151266-03 | Sex and Gender R01 | 10470831 | RePORTER <br> Project Info |
| 2022 | NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed) | Making the invisible visible: An automated clinical decision support tool for Intimate Partner Violence Risk and Severity Prediction (AIRS) | Khurana, Bharti | Brigham and Women's Hospital | 1 R01 EB032384-01A1 | SRP | 10522589 | $\frac{\text { RePORTER }}{}$ |
| 2022 | NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed) | Oxytocin neural circuitry involvement in juvenile social play | Veenema, <br> Alexandra H | Michigan State University | 1 R01 MH125806-01A1 | SRP | 10363314 | RePORTER <br> Project Info |


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| 2022 | NIH Research Project <br> Grant (Parent R01 <br> Clinical Trial Not <br> Allowed) | Epithelial stem cell regulation of pregnancy establishment | Jin, Shiying | University of MissouriColumbia | 1 R56 HD104821-01A1 | SRP | 10367597 | RePORTER <br> Project Info |
| 2022 | NIH Research Project <br> Grant (Parent R01 <br> Clinical Trial Not <br> Allowed) | Cytokines and Inflammatory Bowel Disease | Cominelli, Fabio | Case Western Reserve University | 3 R01 DK042191-30S1 | Sex and <br> Gender <br> Admin <br> Supplement | 10671267 | RePORTER <br> Project Info |
| 2022 | NIH Research Project <br> Grant (Parent R01 <br> Clinical Trial Not <br> Allowed) | Urine cadmium and risk of fracture and bone loss | Meliker, Jaymie R | State University of New York at Stony Brook | 5 R01 AR081125-02 | Sex and Gender R01 | 10491320 | RePORTER <br> Project Info |
| 2022 | NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed) | Building a causal pathway framework to identify interventions to eliminate racial/ ethnic disparities in severe maternal morbidity | Carmichael, Suzan L | Stanford University | 5 R01 NR020335-02 | SRP | 10490296 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | NIH Research Project Grant (Parent R01) | Electronic Tools to Increase Recognition and Improve Primary Care Management for Hypertension in Chronic Kidney Disease | Samal, Lipika | Brigham and Women's Hospital | 3 R01 DK116898-05S1 | U3 Admin Supplement | 10689403 | RePORTER <br> Project Info |
| 2022 | NIH-DOD-VA Pain <br> Management <br> Collaboratory - <br> Pragmatic Clinical <br> Trials Demonstration <br> Projects (UG3/UH3) | Chiropractic Care for Veterans: A Pragmatic Randomized Trial Addressing Dose Effects for CLBP | Long, Cynthia R | Palmer College of Chiropractic | 5 UH3 AT009761-06 | SRP | 10473773 | RePORTER <br> Project Info |
| 2022 | NIMH Exploratory/ Developmental Research Grant (R21 - Clinical Trial Not Allowed) | Discriminating hormonal and sex chromosomal origins of sex differences in the septohippocampal circuit | Bangasser, Debra A | Temple University | 1 R21 MH129020-01 | SRP | 10389770 | RePORTER <br> Project Info |
| 2022 | National Cancer Institute's InvestigatorInitiated Early Phase Clinical Trials for Cancer Treatment and Diagnosis (R01 Clinical Trial Required) | Optimizing radiation therapy through the manipulation of glutamine metabolism | Schwarz, Julie Kristina | Washington University in St. Louis | 2 R01 CA181745-06A1 | SRP | 10441995 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Native American Research Centers for Health (NARCH) (S06 Clinical Trial Optional) | Lakota Center for Health Research | Henderson, Jeffrey A | Black Hills <br> Center For <br> American <br> Indian Health | 1 S06 GM146079-01 | SRP | 10436760 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium Clinical Research Centers (U01 Clinical Trial Optional) | Prevention of LUTS: <br> Bladder Health <br> Clinical Center, UC <br> San Diego Site | Lukacz, Emily S | University of California, San Diego | 5 U01 DK106827-08 | SRP | 10455103 | RePORTER <br> Project Info |


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| 2022 | Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium Clinical Research Centers (U01 Clinical Trial Optional) | NORTHWESTERN UNIVERSITY PLUS CLINICAL SITE | Griffith, James William | Northwestern University at Chicago | 5 U01 DK126045-03 | SRP | 10455019 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Research Project Grant (Parent R01 Clinical Trial Not Allowed) | Assessing the Influence of the Human Lipidome on Risk of Diabetes in a Minority Population | Curran, Joanne E | University of Texas Rio Grande Valley | 3 R01 DK127636-02S1 | U3 Admin Supplement | 10671833 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Research Supplements to Promote Diversity in Health-Related Research (Admin Supp Clinical Trial Not Allowed) | A novel cellautonomous role for $\beta$-adrenergic receptor signaling in osteoclasts | Motyl, Katherine Jean | MaineHealth | 3 R01 AR076349-02S1 | Careers | 10608343 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Research Supplements to Promote Diversity in Health-Related Research (Admin Supp Clinical Trial Not Allowed) | Diversity Supplement for: Role of TNFalpha in discogenic pain progression and as a treatment target | latridis, James C | Icahn School of Medicine at Mount Sinai | 3 R01 AR07885701A1S1 | Careers | 10631481 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Research Supplements to Promote Diversity in Health-Related Research (Admin Supp Clinical Trial Not Allowed) | Socioeconomic Disparities in Cognitive and Neural Development in the First 3 years | Noble, Kimberly G | Columbia <br> University <br> Teachers <br> College | 3 R01 HD093707-05S1 | Careers | 10489568 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Research on Interventions that Promote the Careers of Individuals in the Biomedical Research Enterprise (R01 Clinical Trial Not Allowed) | Sexual harassment Training Of Principal investigators (STOP) | Salles, Arghavan | Stanford University | 1 R01 GM147063-01 | Careers | 10506655 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Research on Interventions that Promote the Careers of Individuals in the Biomedical Research Enterprise (R01 Clinical Trial Not Allowed) | Indiana CARES <br> (Creating <br> Accountability and Building Relationships to Eradicate Sex Harassment) | Stockdale, <br> Margaret S | Indiana <br> University- <br> Purdue <br> University <br> Indianapolis | 1 R01 GM147151-01 | Careers | 10508266 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Specialized Centers of Research Excellence (SCORE) on Sex Differences (U54 Clinical Trial Optional) | YALE-SCORE ON SEX DIFFERENCES <br> IN ALCOHOL USE DISORDER | Mckee, Sherry Ann | Yale University | 5 U54 AA027989-03 | Careers | 10357878 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Specialized Centers of <br> Research Excellence <br> (SCORE) on Sex <br> Differences (U54 <br> Clinical Trial Optional) | Center for Stress and Neural Regulation of Reproductive Aging Health Outcomes | Joffe, Hadine | Brigham and Women's Hospital | 5 U54 AG062322-03 | SCORE | 10424519 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |


| FY | RFA Title | Title | Contact PI Name | Institution | Grant | ORWH Program | Appl Id | RePORTER Project Info |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2022 | Specialized Centers of Research Excellence (SCORE) on Sex Differences (U54 Clinical Trial Optional) | The Microvascular <br> Aging and <br> Eicosanoids - <br> Womens Evaluation <br> of Systemic Aging <br> Tenacity (MAE- <br> WEST) (You are <br> never too old to <br> become younger!) <br> Specialized Center for <br> Research Excellence <br> (SCORE) | Cheng, Susan | Cedars-Sinai Medical Center | 5 U54 AG065141-03 | SCORE | 10450755 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Specialized Centers of <br> Research Excellence <br> (SCORE) on Sex <br> Differences (U54 <br> Clinical Trial Optional) | Sex related differences in Brain Gut Microbiome Interactions in Irritable Bowel Syndrome | Mayer, Emeran A | University of California, Los Angeles | 5 U54 DK123755-03 | SCORE | 10461213 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Specialized Centers of <br> Research Excellence <br> (SCORE) on Sex <br> Differences (U54 <br> Clinical Trial Optional) | Sex Differences in Major Depression: Impact of Prenatal Stress-Immune and Autonomic Dysregulation | Goldstein, Jill M | Massachusetts General Hospital | 5 U54 MH118919-03 | SCORE | 10349458 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Specialized Centers of Research Excellence (SCORE) on Sex Differences (U54) | Sex-Specific Effects of Endocrine Disruption on Aging and Alzheimer's Disease | Kantarci, Kejal | Mayo Clinic <br> Rochester | 5 U54 AG044170-10 | SCORE | 10414010 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Specialized Centers of Research Excellence (SCORE) on Sex Differences (U54) | Bioenergetic and Metabolic Consequences of the Loss of Gonadal Function | Kohrt, Wendy M | University of Colorado Denver | 5 U54 AG062319-10 | SCORE | 10456782 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Specialized Centers of Research Excellence (SCORE) on Sex Differences (U54) | Sex and Age Differences in Immunity to Influenza (SADII) | Klein, Sabra L | Johns Hopkins University | 5 U54 AG062333-05 | SCORE | 10460494 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Specialized Centers of Research Excellence (SCORE) on Sex Differences (U54) | Emory Specialized Center of Research Excellence (SCORE) on Sex Differences | Ofotokun, Ighowwerha | Emory University | 5 U54 AG062334-05 | SCORE | 10459325 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Specialized Centers of Research Excellence (SCORE) on Sex Differences (U54) | MUSC Specialized Center of Research Excellence on Sex Differences | McRae-Clark, Aimee L | Medical University of South Carolina | 5 U54 DA016511-20 | SCORE | 10457841 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | Specialized Centers of <br> Research Excellence <br> (SCORE) on Sex <br> Differences (U54) | Sex Differences in the Metabolic Syndrome | Reue, Karen | University of California, Los Angeles | 5 U54 DK120342-05 | SCORE | 10447051 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | The Role of Menopause-Driven DNA Damage and Epigenetic Dysregulation in Alzheimer's Disease | Wahlestedt, Claes Robert | University of Miami School of Medicine | 1 R01 AG079373-01 | Sex and Gender R01 | 10531959 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | The role of sex in GABAergic-mediated, Alzheimer's diseaserelated episodic memory impairments from mid to late life | Eich, Teal S | University of Southern California | 1 R01 AG079512-01 | Sex and Gender R01 | 10540130 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |


| FY | RFA Title | Title | Contact PI Name | Institution | Grant | ORWH Program | Appl Id | RePORTER <br> Project Info |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2022 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | THE IMPACT OF ADVANCED AGE AND SEX ON HUMORAL IMMUNITY TO STREPTOCOCCUS PNEUMONIAE | Haas, Karen M | Wake Forest University Health Sciences | 1 R01 Al164489-01A1 | Sex and Gender R01 | 10532071 | RePORTER <br> Project Info |
| 2022 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | The roles of genetics, hormones, and gender in sexually dimorphic immune response | Triche, Timothy J | Van Andel Institute | 1 R01 Al171984-01 | Sex and Gender R01 | 10532061 | RePORTER <br> Project Info |
| 2022 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Sex/Gender influences on periodontal disease and diabetes: A population science approach, with software | Bandyopadhyay, Dipankar | Virginia <br> Commonwealth University | 1 R01 DE031134-01A1 | Sex and Gender R01 | 10531704 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Sexually dimorphic pain signaling mechanisms | Donnelly, Christopher Ryan | Duke University | 1 R01 DE032227-01 | Sex and Gender R01 | 10531991 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | A novel approach for equitable characterization of gender and its use in exposing subgroup discrepancies in polygenic score associations | Michaelson, Jacob James | University of lowa | 1 R01 HG012697-01 | Sex and Gender R01 | 10532075 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Stress, inflammation and coronary endothelial injury in preeclampsia | Hays, Allison | Johns Hopkins University | 1 R01 HL159715-01A1 | Sex and Gender R01 | 10531778 | RePORTER <br> Project Info |
| 2022 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Mechanisms of sex-biased risk and resiliency in aneurysm and dissection | Parker, Sarah J | Cedars-Sinai Medical Center | 1 R01 HL165471-01 | Sex and Gender R01 | 10532033 | RePORTER <br> Project Info |
| 2022 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Interactions of Sex and Gender Factors in Risk for Alzheimer's Disease: Links Between Stress, Neural Activity, Inflammation, and Memory | Kirkland Caldwell, Jessica | Cleveland Clinic Lerner College of Medicine CWRU | 5 R01 AG074392-02 | Sex and Gender R01 | 10456936 | RePORTER <br> Project Info |
| 2022 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Implicit Bias in the Evidence: An Evaluation of FemalePredominant Disease | Simard, Julia F | Stanford University | 5 R01 Al154533-03 | Sex and Gender R01 | 10468199 | RePORTER <br> Project Info |
| 2022 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | The impact of sex and gender on disease progression, from developmental origins | Pisarska, Margareta | Cedars-Sinai Medical Center | 5 R01 Al154535-03 | Sex and Gender R01 | 10469623 | RePORTER <br> Project Info |


| FY | RFA Title | Title | Contact PI Name | Institution | Grant | ORWH <br> Program | Appl Id | RePORTER <br> Project Info |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2022 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Sex Determines Age-related Changes in the Repertoire and Function of Natural Antibodies Protective against Streptococcus pneumoniae with Increasing Age | Holodick, Nichol Elizabeth | Western <br> Michigan <br> University <br> School of <br> Medicine | 5 R01 Al154539-03 | Sex and Gender <br> R01 | 10470184 | RePORTER <br> Project Info |
| 2022 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Substance use and DNA methylation at the intersection of sex and gender | Flentje, Annesa | University of California, San Francisco | 5 R01 DA052016-03 | Sex and <br> Gender <br> R01 | 10458728 | RePORTER <br> Project Info |
| 2022 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Gender and Sex Hormone Influences on Cannabis Use Disorder Remission | Tomko, Rachel Lynn | Medical University of South Carolina | 5 R01 DA054617-02 | Sex and <br> Gender <br> R01 | 10435554 | RePORTER <br> Project Info |
| 2022 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Pathways to Oral Health Among Lowincome Pregnant Urban Women | Russell, Stefanie L | New York University | 5 R01 DE029963-02 | Sex and Gender <br> R01 | 10456211 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Gender and sex differences in phthalate-induced toxicity in the reproductive system | Flaws, Jodi A | University of Illinois UrbanaChampaign | 5 R01 ES032163-03 | Sex and Gender <br> R01 | 10445315 | RePORTER <br> Project Info |
| 2022 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Dissection of the mechanisms underlying sex-influenced cardiovascular disease | Shavit, Jordan A | University of Michigan at Ann Arbor | 5 R01 ES032255-03 | Sex and Gender R01 | 10407073 | RePORTER <br> Project Info |
| 2022 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Networks Tools to Understand Sex- and Gender-Specific Drivers of Disease | Demeo, Dawn L | Brigham and Women's Hospital | 5 R01 HG011393-02 | Sex and <br> Gender <br> R01 | 10479131 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Elucidating the phenome-wide impact of sex and gender on disease | Davis, Lea K | Vanderbilt University Medical Center | 5 R01 HG011405-02 | Sex and Gender R01 | 10491882 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Credentialing novel cardiovascular disease genes in women by sexspecific genomic investigation of insulin resistance | Majithia, Amit | University of California, San Diego | 5 R01 HL159760-02 | Sex and Gender R01 | 10475209 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |
| 2022 | The Intersection of Sex and Gender Influences on Health and Disease (R01 Clinical Trial Optional) | Gonadal hormones as mediators of sex and gender influences in asthma | Silveyra, Patricia | Trustees of Indiana University | 5 R01 HL159764-02 | Sex and <br> Gender <br> R01 | 10448428 | $\frac{\text { RePORTER }}{\text { Project Info }}$ |


| FY | RFA Title | Title | Contact PI Name | Institution | Grant | ORWH <br> Program | Appl Id | RePORTER <br> Project Info |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2022 | Understanding and Addressing the Impact of Structural Racism and Discrimination on Minority Health and Health Disparities (R01 Clinical Trial Optional) | Investigating structural maternal health inequities among Black reproductive aged women in Georgia: a mixed methods and multi-level approach | Boulet, Sheree L | Emory <br> University | 1 R01 HD109005-01 | SRP | 10474830 | $\begin{aligned} & \text { RePORTER } \\ & \text { Project Info } \end{aligned}$ |

## Appendix B: Data Sources and Definitions

## NIH Workforce Demographic Composition

## Definitions

Produced by the Office of Equity, Diversity, and Inclusion, Data Analytics Branch. Data are included for onboard employees classified as permanent or temporary full-time, part-time, or intermittent, at the end of fiscal year 2022. Data for Contractors, Fellows, Trainees, Commissioned Corps, and Advisory Council (including El and ZZ pay plans) are not included. Not identified race and ethnicity, sex, and disability include missing values. To maintain confidentiality and protect individual identification from deductive disclosure risk, values of less than four are suppressed for reporting purposes and designated with an asterisk. Total calculations shown may not match that derived from detailed data presented due to rounding. Data source: nVision that includes pay period ending 09/30/22; downloaded on 02/14/23.

Data source: nVision that includes 09/30/22 pay period; downloaded on 02/14/23. For Supervisory Levels, the data combine employees whose positions are coded under Supervisory Status Codes 2, 4, and 5, as defined by OPM regulation, compared to all other staff.

Grade and play plan groups: Wage Grade (pay plans WG, WL, WS); General Schedule (GS) or Equivalent (Title 5 pay plans GM and GS; Title 38 pay plans GP and GR); Title 42 (pay plans AD, RF, RG, RS); and Other pay plans (ES and EX, Executive Services: SL, Senior Leadership; ST, Senior Technical)

Included in overall NIH totals are those staff currently employed by the Advanced Research Projects Agency for Health (ARPA-H). On March 15, 2022, the FY 2022 Consolidated Appropriations Act (Public Law 117-103) was signed into law authorizing the establishment of ARPA-H within the U.S. Department of Health and Human Services. The director of ARPA-H reports to the HHS Secretary.

Program type: Extramural, Intramural, and Other program types are grouped based on organizational codes. For further details, please visit the Office of Extramural Research and the Intramural Research Program sites. Other program units often have larger administrative roles, but this can vary across NIH organizational units.

Workforce type: Scientific occupations directly lead, conduct, or provide oversight for basic and clinical research conducted at the NIH. Health and research occupations directly support this basic and clinical research and include many allied health professions. Infrastructure employees are those not classified as Scientific or Health and Research, and include administrative, maintenance, and other support staff such as accountants, budget officers, and engineers.

Race and Ethnicity: Data aggregation on race and ethnicity was completed using the multiracial allocation method based on EEOC guidance and the Ethnicity and Race Indicator (ERI) code that federal agencies use to store race and ethnicity information provided via form SF-181. Data for employees represented in this reporting are selfidentified; those classified in the five racial groups and two or more race group are all non-Hispanic or Latino. Hispanic or Latino employees are included in that category regardless of their race selection(s).

## NIH Grant Funding and Success Rate

## Definitions

R01-equivalent grants: R01-equivalent grants are defined as activity codes DP1, DP2, DP5, R01, R37, R56, RF1, RL1, U01, and R35 from select National Institute of General Medical Sciences and National Human Genome Research Institute program announcements. Some of these activities may not be in use by NIH every year.

Race and ethnicity: NIH adopted the 1997 Office of Management and Budget (OMB) revised minimum standards for maintaining, collecting, and presenting data on race and ethnicity for all grant applications, contract and intramural proposals, and active research grants, cooperative agreements, and contract and intramural projects. The minimum standards are described in the 1997 OMB Statistical Policy Directive No. 15. The standards include two ethnic categories ("Hispanic or Latino" and "Not Hispanic or Latino") and five racial categories ("American Indian or Alaska Native," "Asian," "Black or African American," "Native Hawaiian or Other Pacific Islander," and "White"). "Person reporting more than one race" under "race" indicates that an investigator indicated more than one race. "Withheld" under "race" indicates that the investigator chose to not disclose that information. "Unknown" indicates that item was not completed and was missing in the IMPAC II database. Race and ethnicity are self-reported and subject to change. For this report, the combination of race and ethnicity is applied where Hispanic ethnicity takes priority over race. "Other" includes non-Hispanic people who are in one of the following racial categories: "American Indian or Alaska Native," "More Than One Race," "Native Hawaiian or Other Pacific Islander," and "Unknown or Withheld."

Research project grants (RPGs): RPGs are defined as activity codes DP1, DP2, DP3, DP4, DP5, P01, PN1, PM1, R00, R01, R03, R15, R16, R21, R22, R23, R29, R33, R34, R35, R36, R37, R50, R55, R56, R61, RC1, RC2, RC3, RC4, RF1, RL1, RL2, RL9, RM1, SI2, UA5, UC1, UC2, UC3,

UC4, UC7, UF1, UG3, UH2, UH3, UH5, UM1, UM2, U01, U19, U34, and U3R. Research projects were first coded to the National Library of Medicine in FY 2007. Some of these activities may not be in use by NIH every year.

Success rate: The success rate is the percentage of reviewed grant applications that received funding; if a grant is submitted multiple times in the same FY, it is counted in the denominator (and potentially in the numerator) only once.

Funding rate: The funding rate is the number of distinct supported investigators divided by the number of distinct supported and unsupported investigators in a given FY, excluding applications withdrawn prior to review.

Figure 5: Number of Supported PIs on RPGs by Sex and Fiscal Year


| Year | Female | Male | Unknown/withheld sex |
| :---: | :---: | :---: | :---: |
| 2016 | 3517 | 7700 | 217 |
| 2017 | 3538 | 7519 | 242 |
| 2018 | 4137 | 8032 | 312 |
| 2019 | 4209 | 8062 | 417 |
| 2020 | 4502 | 8162 | 470 |
| 2021 | 4623 | 8114 | 482 |
| 2022 | 4893 | 8138 | 504 |

Source: Data were drawn from the frozen success rate demographic data set on February 14, 2023.

Figure 7: NIH Total RPG Funding Rates and Success Rates by Sex Category and Fiscal Year


Source: Data were drawn from the frozen success rate demographic data set on February 14, 2023. The "Mixed R01-Equivalent" category includes mixed-sex MPI teams with at least one PI of unknown/withheld sex. This category only applies to MPI applications.

Figure 6: Female PIs Supported with R01-Equivalent Grants Broken Down by Ethnicity/Race and Fiscal Year


| Year | Hispanic | White | Black | Asian | Other |
| :---: | :---: | :---: | :---: | :---: | :---: |
| 2016 | $4.1 \%$ | $70.6 \%$ | $1.4 \%$ | $20 \%$ | $4 \%$ |
| 2017 | $5 \%$ | $68 \%$ | $2 \%$ | $20 \%$ | $5 \%$ |
| 2018 | $5 \%$ | $68 \%$ | $2 \%$ | $21 \%$ | $5 \%$ |
| 2019 | $5 \%$ | $65 \%$ | $2 \%$ | $22 \%$ | $6 \%$ |
| 2020 | $5 \%$ | $68 \%$ | $2 \%$ | $20 \%$ | $5 \%$ |
| 2021 | $5 \%$ | $65 \%$ | $2 \%$ | $21 \%$ | $6 \%$ |
| 2022 | $6.0 \%$ | $63.0 \%$ | $2.9 \%$ | $22 \%$ | $6 \%$ |

Source: Data were drawn from frozen success rate demographic data set on February 14, 2023.

Figure 8: NIH Total R01-Equivalent Grant Funding Rates for Female Supported Pls by Ethnicity/Race and Fiscal Year


Source: Data were drawn from the frozen success rate demographic data set on February 14, 2023.

## Data for NIH Grant Funding and Success Rates

Figure 9: NIH Total R01-Equivalent Grant Funding Rates by Sex of the Supported PIs, Type of PI, and Fiscal Year


| Year | Funding rate for <br> female first-time <br> contact Pls | Funding rate for <br> female established <br> contact Pls | Funding rate for <br> male first-time <br> contact Pls | Funding rate for <br> male established <br> contact Pls |
| :---: | :---: | :---: | :---: | :---: |
| 2021 | $22.1 \%$ | $26.5 \%$ | $22.0 \%$ | $25.9 \%$ |
| 2022 | $26.0 \%$ | $28.4 \%$ | $22.2 \%$ | $27.4 \%$ |

Source: Data were drawn from the frozen success rate demographic data set on February 14, 2023.

Figure 10: Research Grant Investigators: Percentage of Female Supported Pls by Award Mechanism and Fiscal Year


| Year | RPG | Center | Other Research | Research <br> Career | SBIR/STTR |
| :---: | :---: | :---: | :---: | :---: | :---: |
| 2016 | $32 \%$ | $23 \%$ | $36 \%$ | $50 \%$ | $21 \%$ |
| 2017 | $32 \%$ | $25 \%$ | $36 \%$ | $50 \%$ | $19 \%$ |
| 2018 | $33 \%$ | $26 \%$ | $38 \%$ | $51 \%$ | $21 \%$ |
| 2019 | $34 \%$ | $26 \%$ | $39 \%$ | $53 \%$ | $22 \%$ |
| 2020 | $35 \%$ | $29 \%$ | $40 \%$ | $54 \%$ | $21 \%$ |
| 2021 | $36 \%$ | $30 \%$ | $40 \%$ | $54 \%$ | $21 \%$ |
| 2022 | $37 \%$ | $31 \%$ | $40 \%$ | $57 \%$ | $24 \%$ |

Source: Data were drawn from the frozen success rate demographic data set on December 16, 2022.

Data were produced by the Division of Statistical Analysis and Reporting within the NIH Office of Extramural Research's Office of Research Reporting and Analysis. Analysis is restricted to investigators who have reported their sex. Data on sex profiles are maintained by the investigator in the NIH eRA system and are subject to change. The $x$-axis in each graph represents the fiscal year. Data include direct budget authority only and include all competing applications. Graphs presenting data on contact Pls exclude awards issued through supplemental COVID-19 appropriations. Special supplemental COVID-19 appropriations may include (1) H.R. 6074 (Public Law 116-123), the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 and (2) H.R. 748 (Public Law 116-136), the Coronavirus Aid, Relief, and Economic Security (CARES) Act.

Figure 10 Notes:
Centers: Center grants are awarded to institutions on behalf of program directors and groups of collaborating investigators. They support long-term, multidisciplinary programs of research and development.

Other Research: These are grants to institutions to provide developmental opportunities for investigators at various stages of their biomedical research careers. The programs are research careers, cancer education cooperative clinical research, biomedical research support, minority biomedical research support, and other areas of research.

Research Career: These are awards for candidates who wish to further develop their careers in biomedical, behavioral, and clinical research. Applicants are generally required to hold a research or health professional doctoral degree or its equivalent; eligibility for some career development awards is limited to only applicants with health professional doctoral degrees.

SBIR/STTR: These are Small Business Innovation Research and Small Business Technology Transfer awards.

# Appendix C. Aggregate Enrollment Data and Tables 

## Section 1 Metrics Based on Aggregate Enrollment by Sex/Gender

Table 1A: Total Enrollment for All National Institutes of Health (NIH) Clinical Research from
FY 2012 to FY 2022

| Fiscal Year | Total Enrollment | Total Females | \% <br> Females | Total Males | \% Males | Total Unknown | $\begin{gathered} \% \\ \text { Unknown } \end{gathered}$ | Enrollment in Femaleonly | \% Femaleonly | Enrollment in Maleonly | \% Maleonly | Females, <br> Excluding <br> Female-only | \% Females, Excluding Femaleonly | Males, Excluding Male-only | \% Males, Excluding Male-only |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2012 | 17,655,238 | 10,071,897 | 57.0 | 7,382,884 | 41.8 | 200,457 | 1.1 | 3,713,994 | 21.0 | 1,096,914 | 6.2 | 6,357,903 | 36.0 | 6,285,970 | 35.6 |
| 2013 | 17,580,725 | 9,961,014 | 56.7 | 7,397,295 | 42.1 | 222,416 | 1.3 | 3,522,251 | 20.0 | 1,174,274 | 6.7 | 6,438,763 | 36.6 | 6,223,021 | 35.4 |
| 2014 | 28,565,995 | 16,353,416 | 57.2 | 11,038,679 | 38.6 | 1,173,900 | 4.1 | 3,550,006 | 12.4 | 429,440 | 1.5 | 12,803,410 | 44.8 | 10,609,239 | 37.1 |
| 2015 | 21,453,866 | 13,278,481 | 61.9 | 7,829,861 | 36.5 | 345,524 | 1.6 | 3,828,704 | 17.8 | 280,567 | 1.3 | 9,449,777 | 44.0 | 7,549,294 | 35.2 |
| 2016 | 39,712,265 | 20,983,081 | 52.8 | 17,865,381 | 45.0 | 863,803 | 2.2 | 2,985,796 | 7.5 | 217,876 | 0.5 | 17,997,285 | 45.3 | 17,647,505 | 44.4 |
| 2017 | 20,068,789 | 9,470,264 | 47.2 | 10,127,155 | 50.5 | 471,370 | 2.3 | 1,299,004 | 6.5 | 919,239 | 4.6 | 8,171,260 | 40.7 | 9,207,916 | 45.9 |
| 2018 | 12,814,162 | 6,711,564 | 52.4 | 5,668,475 | 44.2 | 434,123 | 3.4 | 1,445,846 | 11.3 | 918,805 | 7.2 | 5,265,718 | 41.1 | 4,749,670 | 37.1 |
| 2019 | 13,241,413 | 6,894,390 | 52.1 | 5,930,000 | 44.8 | 417,023 | 3.1 | 1,545,776 | 11.7 | 878,398 | 6.6 | 5,348,614 | 40.4 | 5,051,602 | 38.2 |
| 2020 | 13,705,659 | 7,552,684 | 55.1 | 5,532,650 | 40.4 | 620,325 | 4.5 | 1,840,890 | 13.4 | 121,670 | 0.9 | 5,711,794 | 41.7 | 5,410,980 | 39.5 |
| 2021 | 12,937,156 | 7,572,143 | 58.5 | 5,047,190 | 39.0 | 317,823 | 2.5 | 1,908,556 | 14.8 | 146,782 | 1.1 | 5,663,587 | 43.8 | 4,900,408 | 37.9 |
| 2022 | 10,751,975 | 5,996,249 | 55.8 | 4,454,456 | 41.4 | 301,270 | 2.8 | 865,470 | 8.0 | 67,251 | 0.6 | 5,130,779 | 47.7 | 4,387,205 | 40.8 |

Table 1B: Total Enrollment for NIH Clinical Research at U.S. Sites from FY 2017 to FY 2022

| Fiscal Year | Total Enrollment | Total <br> Females | \% Females | Total Males | $\begin{gathered} \% \\ \text { Males } \end{gathered}$ | Total Unknown | $\begin{gathered} \text { \% } \\ \text { Unknown } \end{gathered}$ | Enrollment in Femaleonly | \% Femaleonly | Enrollment in Maleonly | \% Maleonly | Females, <br> Excluding <br> Female-only | \% Females, Excluding Femaleonly | Males, Excluding Male-only | \% Males, Excluding Male-only |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2017 | 13,231,166 | 6,491,639 | 49.1 | 6,302,343 | 47.6 | 437,184 | 3.3 | 1,010,384 | 7.6 | 871,532 | 6.6 | 5,481,255 | 41.4 | 5,430,811 | 41.0 |
| 2018 | 10,578,286 | 5,413,405 | 51.2 | 4,775,856 | 45.1 | 389,025 | 3.7 | 1,147,146 | 10.8 | 886,491 | 8.4 | 4,266,259 | 40.3 | 3,889,365 | 36.8 |
| 2019 | 10,356,075 | 5,185,006 | 50.1 | 4,853,379 | 46.9 | 317,690 | 3.1 | 1,205,796 | 11.6 | 817,553 | 7.9 | 3,979,210 | 38.4 | 4,035,826 | 39.0 |
| 2020 | 11,080,871 | 6,062,190 | 54.7 | 4,480,382 | 40.4 | 538,299 | 4.9 | 1,452,673 | 13.1 | 72,788 | 0.7 | 4,609,517 | 41.6 | 4,407,594 | 39.8 |
| 2021 | 9,957,714 | 5,819,297 | 58.4 | 3,902,545 | 39.2 | 235,872 | 2.4 | 1,536,710 | 15.4 | 95,723 | 1.0 | 4,282,587 | 43.0 | 3,806,822 | 38.2 |
| 2022 | 8,755,755 | 4,834,272 | 55.2 | 3,682,475 | 42.1 | 239,008 | 2.7 | 665,346 | 7.6 | 52,357 | 0.6 | 4,168,926 | 47.6 | 3,630,118 | 41.5 |

Table 1C: Total Enrollment for Extramural NIH Clinical Research at U.S. Sites from FY 2017 to FY 2022

| Fiscal Year | Total Enrollment | Total <br> Females | \% <br> Females | Total Males | $\begin{gathered} \text { \% } \\ \text { Males } \end{gathered}$ | Total Unknown | $\begin{gathered} \text { \% } \\ \text { Unknown } \end{gathered}$ | Enrollment in Femaleonly | \% Femaleonly | Enrollment in Maleonly | \% Maleonly | Females, Excluding Female-only | \% Females, Excluding Femaleonly | Males, Excluding Male-only | \% Males, Excluding Male-only |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2017 | 10,730,843 | 5,264,128 | 49.1 | 5,136,833 | 47.9 | 329,882 | 3.1 | 868,102 | 8.1 | 861,158 | 8.0 | 4,396,026 | 41.0 | 4,275,675 | 39.8 |
| 2018 | 9,074,769 | 4,650,602 | 51.2 | 4,068,126 | 44.8 | 356,041 | 3.9 | 1,065,792 | 11.7 | 876,842 | 9.7 | 3,584,810 | 39.5 | 3,191,284 | 35.2 |
| 2019 | 8,617,428 | 4,294,606 | 49.8 | 4,059,871 | 47.1 | 262,951 | 3.1 | 1,089,780 | 12.6 | 807,425 | 9.4 | 3,204,826 | 37.2 | 3,252,446 | 37.7 |
| 2020 | 9,365,822 | 5,184,613 | 55.4 | 3,697,229 | 39.5 | 483,980 | 5.2 | 1,337,059 | 14.3 | 61,624 | 0.7 | 3,847,554 | 41.1 | 3,635,605 | 38.8 |
| 2021 | 8,467,215 | 5,072,738 | 59.9 | 3,195,055 | 37.7 | 199,422 | 2.4 | 1,420,731 | 16.8 | 83,887 | 1.0 | 3,652,007 | 43.1 | 3,111,168 | 36.7 |
| 2022 | 7,350,581 | 4,181,202 | 56.9 | 2,964,338 | 40.3 | 205,041 | 2.8 | 624,397 | 8.5 | 44,707 | 0.6 | 3,556,805 | 48.4 | 2,919,631 | 39.7 |

Table 1D: Total Enrollment for Intramural NIH Clinical Research at U.S. Sites from FY 2017 to FY 2022

| Fiscal Year | Total Enrollment | Total Females | $\begin{gathered} \% \\ \text { Females } \end{gathered}$ | Total Males | \% Males | Total <br> Unknown | $\begin{gathered} \text { \% } \\ \text { Unknown } \end{gathered}$ | Enrollment in Femaleonly | \% Femaleonly | Enrollment in Maleonly | \% Maleonly | Females, <br> Excluding <br> Female-only | \% Females, Excluding Femaleonly | Males, Excluding Male-only | \% Males, Excluding Male-only |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2017 | 2,500,323 | 1,227,511 | 49.1 | 1,165,510 | 46.6 | 107,302 | 4.3 | 142,282 | 5.7 | 10,374 | 0.4 | 1,085,229 | 43.4 | 1,155,136 | 46.2 |
| 2018 | 1,503,517 | 762,803 | 50.7 | 707,730 | 47.1 | 32,984 | 2.2 | 81,354 | 5.4 | 9,649 | 0.6 | 681,449 | 45.3 | 698,081 | 46.4 |
| 2019 | 1,738,647 | 890,400 | 51.2 | 793,508 | 45.6 | 54,739 | 3.1 | 116,016 | 6.7 | 10,128 | 0.6 | 774,384 | 44.5 | 783,380 | 45.1 |
| 2020 | 1,715,049 | 877,577 | 51.2 | 783,153 | 45.7 | 54,319 | 3.2 | 115,614 | 6.7 | 11,164 | 0.7 | 761,963 | 44.4 | 771,989 | 45.0 |
| 2021 | 1,490,499 | 746,559 | 50.1 | 707,490 | 47.5 | 36,450 | 2.4 | 115,979 | 7.8 | 11,836 | 0.8 | 630,580 | 42.3 | 695,654 | 46.7 |
| 2022 | 1,405,174 | 653,070 | 46.5 | 718,137 | 51.1 | 33,967 | 2.4 | 40,949 | 2.9 | 7,650 | 0.5 | 612,121 | 43.6 | 710,487 | 50.6 |

Table 1E: Total Enrollment for All NIH-Defined Phase III Clinical Trials from FY 2012 to FY 2022

| Fiscal Year | Total Enrollment | Total <br> Females | \% Females | Total Males | $\begin{gathered} \% \\ \text { Males } \end{gathered}$ | Total Unknown | $\begin{gathered} \% \\ \text { Unknown } \end{gathered}$ | Enrollment <br> in Femaleonly | \% Femaleonly | Enrollment in Maleonly | \% Maleonly | Females, Excluding Female-only | \% Females, Excluding Femaleonly | Males, Excluding Male-only | \% Males, Excluding Male-only |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2012 | 603,136 | 374,819 | 62.1 | 197,019 | 32.7 | 31,298 | 5.2 | 58,916 | 9.8 | 10,288 | 1.7 | 315,903 | 52.4 | 186,731 | 31.0 |
| 2013 | 691,023 | 506,732 | 73.3 | 179,220 | 25.9 | 5,071 | 0.7 | 217,869 | 31.5 | 12,406 | 1.8 | 288,863 | 41.8 | 166,814 | 24.1 |
| 2014 | 797,264 | 478,222 | 60.0 | 314,310 | 39.4 | 4,732 | 0.6 | 32,310 | 4.1 | 4,267 | 0.5 | 445,912 | 55.9 | 309,951 | 38.9 |
| 2015 | 1,619,508 | 1,091,910 | 67.4 | 507,561 | 31.3 | 20,037 | 1.2 | 29,368 | 1.8 | 4,267 | 0.3 | 1,062,542 | 65.6 | 503,294 | 31.1 |
| 2016 | 2,130,389 | 1,396,503 | 65.6 | 710,818 | 33.4 | 23,068 | 1.1 | 35,463 | 1.7 | 7,480 | 0.4 | 1,361,040 | 63.9 | 703,338 | 33.0 |
| 2017 | 907,643 | 535,440 | 59.0 | 371,636 | 40.9 | 567 | 0.1 | 154,733 | 17.0 | 10,800 | 1.2 | 380,707 | 41.9 | 360,836 | 39.8 |
| 2018 | 417,713 | 260,652 | 62.4 | 155,960 | 37.3 | 1,101 | 0.3 | 116,019 | 27.8 | 10,131 | 2.4 | 144,633 | 34.6 | 145,829 | 34.9 |
| 2019 | 329,747 | 202,483 | 61.4 | 119,369 | 36.2 | 7,895 | 2.4 | 91,232 | 27.7 | 374 | 0.1 | 111,251 | 33.7 | 118,995 | 36.1 |
| 2020 | 349,651 | 216,040 | 61.8 | 127,864 | 36.6 | 5,747 | 1.6 | 81,462 | 23.3 | 3,914 | 1.1 | 134,578 | 38.5 | 123,950 | 35.4 |
| 2021 | 666,800 | 407,857 | 61.2 | 252,659 | 37.9 | 6,284 | 0.9 | 109,763 | 16.5 | 8,036 | 1.2 | 298,094 | 44.7 | 244,623 | 36.7 |
| 2022 | 1,237,477 | 750,136 | 60.6 | 443,341 | 35.8 | 44,000 | 3.6 | 168,146 | 13.6 | 11,282 | 0.9 | 581,990 | 47.0 | 432,059 | 34.9 |

Table 1F: Total Enrollment for All NIH-Defined Phase III Clinical Trials at U.S. Sites from FY 2017 to FY 2022

| Fiscal Year | Total Enrollment | Total Females | $\begin{gathered} \% \\ \text { Females } \end{gathered}$ | Total Males | $\begin{gathered} \% \\ \text { Males } \end{gathered}$ | Total Unknown | $\begin{gathered} \text { \% } \\ \text { Unknown } \end{gathered}$ | Enrollment <br> in Femaleonly | \% Female- | Enrollment in Maleonly | \% Male only | Females, Excluding Female-only | \% Females, Excluding Femaleonly | Males, Excluding Male-only | \% Males, Excluding Male-only |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2017 | 550,782 | 330,307 | 60.0 | 220,245 | 40.0 | 230 | 0.0 | 138,934 | 25.2 | 8,207 | 1.5 | 191,373 | 34.7 | 212,038 | 38.5 |
| 2018 | 335,391 | 209,985 | 62.6 | 124,830 | 37.2 | 576 | 0.2 | 98,685 | 29.4 | 7,468 | 2.2 | 111,300 | 33.2 | 117,362 | 35.0 |
| 2019 | 230,040 | 148,099 | 64.4 | 81,012 | 35.2 | 929 | 0.4 | 78,234 | 34.0 | 150 | 0.1 | 69,865 | 30.4 | 80,862 | 35.2 |
| 2020 | 189,745 | 121,041 | 63.8 | 66,765 | 35.2 | 1,939 | 1.0 | 56,547 | 29.8 | 3,155 | 1.7 | 64,494 | 34.0 | 63,610 | 33.5 |
| 2021 | 441,034 | 276,006 | 62.6 | 163,123 | 37.0 | 1,905 | 0.4 | 75,855 | 17.2 | 6,836 | 1.5 | 200,151 | 45.4 | 156,287 | 35.4 |
| 2022 | 1,007,948 | 609,104 | 60.4 | 360,665 | 35.8 | 38,179 | 3.8 | 112,245 | 11.1 | 8,493 | 0.8 | 496,859 | 49.3 | 352,172 | 34.9 |

Table 1G: Total Enrollment for Extramural NIH-Defined Phase III Clinical Trials at U.S. Sites from FY 2017 to FY 2022

| Fiscal Year | Total Enrollment | Total <br> Females | \% <br> Females | Total Males | $\begin{gathered} \text { \% } \\ \text { Males } \end{gathered}$ | Total Unknown | \% <br> Unknown | Enrollment in Femaleonly | \% Femaleonly | Enrollment in Maleonly | \% Maleonly | Females, <br> Excluding <br> Female-only | \% Females, Excluding Femaleonly | Males, Excluding Male-only | \% Males, Excluding Male-only |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2017 | 540,640 | 322,436 | 59.6 | 217,976 | 40.3 | 228 | 0.0 | 132,912 | 24.6 | 8,191 | 1.5 | 189,524 | 35.1 | 209,785 | 38.8 |
| 2018 | 327,633 | 206,817 | 63.1 | 120,274 | 36.7 | 542 | 0.2 | 98,429 | 30.0 | 7,468 | 2.3 | 108,388 | 33.1 | 112,806 | 34.4 |
| 2019 | 218,431 | 140,865 | 64.5 | 76,657 | 35.1 | 909 | 0.4 | 72,785 | 33.3 | 132 | 0.1 | 68,080 | 31.2 | 76,525 | 35.0 |
| 2020 | 177,995 | 113,844 | 64.0 | 62,232 | 35.0 | 1,919 | 1.1 | 51,098 | 28.7 | 3,132 | 1.8 | 62,746 | 35.3 | 59,100 | 33.2 |
| 2021 | 429,318 | 268,903 | 62.6 | 158,541 | 36.9 | 1,874 | 0.4 | 70,405 | 16.4 | 6,835 | 1.6 | 198,498 | 46.2 | 151,706 | 35.3 |
| 2022 | 1,001,372 | 602,969 | 60.2 | 360,224 | 36.0 | 38,179 | 3.8 | 106,795 | 10.7 | 8,493 | 0.8 | 496,174 | 49.5 | 351,731 | 35.1 |

Table 1H: Total Enrollment for Intramural NIH-Defined Phase III Clinical Trials at U.S. Sites from FY 2017 to FY 2022

| Fiscal Year | Total Enrollment | Total Females | $\begin{gathered} \% \\ \text { Females } \end{gathered}$ | Total <br> Males | $\begin{gathered} \text { \% } \\ \text { Males } \end{gathered}$ | Total Unknown | $\begin{gathered} \text { \% } \\ \text { Unknown } \end{gathered}$ | Enrollment <br> in Femaleonly | \% Femaleonly | Enrollment in Maleonly | \% Maleonly | Females, <br> Excluding <br> Female-only | \% Females, Excluding Femaleonly | Males, Excluding Male-only | \% Males, Excluding Male-only |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2017 | 10,142 | 7,871 | 77.6 | 2,269 | 22.4 | 2 | 0.0 | 6,022 | 59.4 | 16 | 0.2 | 1,849 | 18.2 | 2,253 | 22.2 |
| 2018 | 7,758 | 3,168 | 40.8 | 4,556 | 58.7 | 34 | 0.4 | 256 | 3.3 | 0 | 0.0 | 2,912 | 37.5 | 4,556 | 58.7 |
| 2019 | 11,609 | 7,234 | 62.3 | 4,355 | 37.5 | 20 | 0.2 | 5,449 | 46.9 | 18 | 0.2 | 1,785 | 15.4 | 4,337 | 37.4 |
| 2020 | 11,750 | 7,197 | 61.3 | 4,533 | 38.6 | 20 | 0.2 | 5,449 | 46.4 | 23 | 0.2 | 1,748 | 14.9 | 4,510 | 38.4 |
| 2021 | 11,716 | 7,103 | 60.6 | 4,582 | 39.1 | 31 | 0.3 | 5,450 | 46.5 | 1 | 0.0 | 1,653 | 14.1 | 4,581 | 39.1 |
| 2022 | 6,576 | 6,135 | 93.3 | 441 | 6.7 | 0 | 0.0 | 5,450 | 82.9 | 0 | 0.0 | 685 | 10.4 | 441 | 6.7 |

## Section 2 Aggregate Enrollment of Racial and Ethnic Minorities: Clinical Research

Table 2A: Total Enrollment and Minority Enrollment for All NIH Clinical Research from FY 2012 to FY 2022

| Fiscal Year | Total Enrollees | Minority Enrollees | \% Minority Enrollees |
| :---: | :---: | :---: | :---: |
| 2012 | $17,655,238$ | $6,446,175$ | 36.5 |
| 2013 | $17,580,725$ | $6,687,678$ | 38.0 |
| 2014 | $28,565,995$ | $9,582,978$ | 33.5 |
| 2015 | $21,453,866$ | $8,602,086$ | 40.1 |
| 2016 | $39,712,265$ | $14,987,425$ | 37.7 |
| 2017 | $20,068,789$ | $10,075,058$ | 50.2 |
| 2018 | $12,814,162$ | $4,621,528$ | 36.1 |
| 2019 | $13,241,413$ | $5,306,702$ | 40.1 |
| 2020 | $13,705,659$ | $5,422,277$ | 39.6 |
| 2021 | $12,937,156$ | $5,404,584$ | 41.8 |
| 2022 | $10,751,975$ | $4,403,282$ | 41.0 |

Table 2B: Total Enrollment and Minority Enrollment for NIH Clinical Research at U.S. Sites from FY 2017 to FY 2022

| Fiscal Year | Total Enrollees | Minority Enrollees | \% Minority Enrollees |
| :---: | :---: | :---: | :---: |
| 2017 | $13,231,166$ | $3,742,781$ | 28.3 |
| 2018 | $10,578,286$ | $3,094,979$ | 29.3 |
| 2019 | $10,356,075$ | $3,097,390$ | 29.9 |
| 2020 | $11,080,871$ | $3,559,530$ | 32.1 |
| 2021 | $9,957,714$ | $3,068,827$ | 30.8 |
| 2022 | $8,755,755$ | $2,676,974$ | 30.6 |

Table 2C: Total Enrollment and Minority Enrollment for Extramural NIH Clinical Research at U.S. Sites from FY 2017 to FY 2022

| Fiscal Year | Total Enrollees | Minority Enrollees | \% Minority Enrollees |
| :---: | :---: | :---: | :---: |
| 2017 | $10,730,843$ | $3,240,677$ | 30.2 |
| 2018 | $9,074,769$ | $2,863,823$ | 31.6 |
| 2019 | $8,617,428$ | $2,781,206$ | 32.3 |
| 2020 | $9,365,822$ | $3,255,607$ | 34.8 |
| 2021 | $8,467,215$ | $2,784,242$ | 32.9 |
| 2022 | $7,350,581$ | $2,421,663$ | 32.9 |

Table 2D: Total Enrollment and Minority Enrollment for Intramural NIH Clinical Research at U.S. Sites from FY 2017 to FY 202

| Fiscal Year | Total Enrollees | Minority Enrollees | \% Minority Enrollees |
| :---: | :---: | :---: | :---: |
| 2017 | $2,500,323$ | 502,104 | 20.1 |
| 2018 | $1,503,517$ | 231,156 | 15.4 |
| 2019 | $1,738,647$ | 316,184 | 18.2 |
| 2020 | $1,715,049$ | 303,923 | 17.7 |
| 2021 | $1,490,499$ | 284,585 | 19.1 |
| 2022 | $1,405,174$ | 255,311 | 18.2 |

Table 2E: Total Enrollment for All NIH Clinical Research by Race from FY 2017 to FY 2022

| Fiscal Year | Total Enrollment | Number of Inclusion Data Records | Minority Enrollment | \% Minority <br> Enrollment | American Indian/ Alaska Native | \% American Indian/ Alaska Native | Asian | \% Asian | Black/ <br> African <br> American | \% Black/ <br> African <br> American | Native Hawailan/ Other Pacific Islander | \% Native Hawailan/ Other Pacific Islander | White | \% White | More Than One Race | \% More Than One Race | Unknown/ Not Reported | \% Unknown/ Not Reported |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2017 | 20,068,789 | 14,580 | 10,075,058 | 50.2 | 130,608 | 0.7 | 6,041,535 | 30.1 | 2,325,409 | 11.6 | 27,863 | 0.1 | 9,399,014 | 46.8 | 438,059 | 2.2 | 1,706,301 | 8.5 |
| 2018 | 12,814,162 | 16,209 | 4,621,528 | 36.1 | 124,447 | 1.0 | 1,158,703 | 9.0 | 2,045,956 | 16.0 | 31,054 | 0.2 | 7,500,227 | 58.5 | 360,906 | 2.8 | 1,592,869 | 12.4 |
| 2019 | 13,241,413 | 20,976 | 5,306,702 | 40.1 | 332,839 | 2.5 | 1,265,006 | 9.6 | 2,382,720 | 18.0 | 25,109 | 0.2 | 7,557,649 | 57.1 | 275,442 | 2.1 | 1,402,648 | 10.6 |
| 2020 | 13,705,659 | 23,856 | 5,422,277 | 39.6 | 125,107 | 0.9 | 970,380 | 7.1 | 2,686,063 | 19.6 | 32,470 | 0.2 | 7,583,104 | 55.3 | 358,092 | 2.6 | 1,950,443 | 14.2 |
| 2021 | 12,937,156 | 25,941 | 5,404,584 | 41.8 | 96,787 | 0.7 | 1,550,921 | 12.0 | 2,289,189 | 17.7 | 83,879 | 0.6 | 6,902,298 | 53.4 | 254,814 | 2.0 | 1,759,268 | 13.6 |
| 2022 | 10,751,975 | 27,970 | 4,403,282 | 41.0 | 97,684 | 0.9 | 767,592 | 7.1 | 2,105,927 | 19.6 | 27,827 | 0.3 | 6,238,462 | 58.0 | 291,913 | 2.7 | 1,222,570 | 11.4 |

Table 2F: Total Enrollment for All NIH Clinical Research by Ethnicity from FY 2017 to FY 2022
Fiscal Year $\left.\begin{array}{c|c|c|c|c|c|c|}\hline \text { Not } \\ \text { Hispanic }\end{array} \begin{array}{c}\text { \% Not } \\ \text { Hispanic }\end{array} \begin{array}{c}\text { Hispanic/ } \\ \text { Latino }\end{array} \begin{array}{c}\text { Hispanic/ } \\ \text { Latino }\end{array} \quad \begin{array}{c}\text { Unknown/ } \\ \text { Not } \\ \text { Reported }\end{array} \quad \begin{array}{c}\text { Unknown/ } \\ \text { Not } \\ \text { Reported }\end{array}\right]$

Table 2G: Total Enrollment for All NIH Clinical Research at U.S. Sites by Race from FY 2017 to FY 2022

| Fiscal Year | Total Enrollment | Minority Enrollment | \% Minority <br> Enrollment | American Indian/ Alaska Native | \% American Indian/ Alaska Native | Asian | \% Asian | Black/ African American | \% Black/ African American | Native Hawailian/ Other Pacific Islander | \% Native Hawailian/ Other Pacific Islander | White | \% White | More Than One Race | \% More Than One Race | Unknown/ Not Reported | \% Unknown/ Not Reported |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2017 | 13,231,166 | 3,742,781 | 28.3 | 117,270 | 0.9 | 422,203 | 3.2 | 1,808,949 | 13.7 | 27,601 | 0.2 | 8,859,771 | 67.0 | 390,899 | 3.0 | 1,604,473 | 12.1 |
| 2018 | 10,578,286 | 3,094,979 | 29.3 | 97,257 | 0.9 | 423,422 | 4.0 | 1,488,023 | 14.1 | 30,573 | 0.3 | 6,792,076 | 64.2 | 297,436 | 2.8 | 1,449,499 | 13.7 |
| 2019 | 10,356,075 | 3,097,390 | 29.9 | 106,917 | 1.0 | 330,178 | 3.2 | 1,621,811 | 15.7 | 23,396 | 0.2 | 6,824,704 | 65.9 | 218,035 | 2.1 | 1,231,034 | 11.9 |
| 2020 | 11,080,871 | 3,559,530 | 32.1 | 112,525 | 1.0 | 440,262 | 4.0 | 1,654,856 | 14.9 | 28,495 | 0.3 | 6,776,754 | 61.2 | 295,884 | 2.7 | 1,772,095 | 16.0 |
| 2021 | 9,957,714 | 3,068,827 | 30.8 | 91,862 | 0.9 | 496,889 | 5.0 | 1,294,819 | 13.0 | 79,643 | 0.8 | 6,391,668 | 64.2 | 203,826 | 2.0 | 1,399,007 | 14.0 |
| 2022 | 8,755,755 | 2,676,974 | 30.6 | 90,784 | 1.0 | 294,709 | 3.4 | 1,135,239 | 13.0 | 23,235 | 0.3 | 5,923,932 | 67.7 | 222,613 | 2.5 | 1,065,243 | 12.2 |

Table 2H: Total Enrollment for All NIH Clinical Research at U.S. Sites by Ethnicity from FY 2017 to FY 2022

Fiscal Year $\left.$\begin{tabular}{c|c|c|c|c|c|c|}
\hline Not <br>
Hispanic

 

\% Not <br>
Hispanic

 

Hispanic/ <br>
Latino

 

Hispanic/ <br>
Latino

$\quad$

Unknown/ <br>
Not <br>
Reported

 

Unknown/ <br>
Not <br>
Reported
\end{tabular} \right\rvert\,

Table 2I: Total Enrollment for Extramural NIH Clinical Research at U.S. Sites by Race from FY 2017 to FY 2022

| Fiscal Year | Total <br> Enrollment | Minority Enrollment | \% Minority <br> Enrollment | American Indian/ Alaska Native | \% American Indian/ Alaska Native | Asian | \% Asian | Black/ <br> African American | \% Black/ <br> African <br> American | Native Hawailian/ Other Pacific Islander | \% Native Hawailan/ Other Pacific Islander | White | \% White | More Than One Race | \% More Than One Race | Unknown/ <br> Not Reported | \% Unknown/ Not Reported |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2017 | 10,730,843 | 3,240,677 | 30.2 | 86,996 | 0.8 | 361,873 | 3.4 | 1,543,732 | 14.4 | 22,115 | 0.2 | 6,997,681 | 65.2 | 377,235 | 3.5 | 1,341,211 | 12.5 |
| 2018 | 9,074,769 | 2,863,823 | 31.6 | 70,274 | 0.8 | 398,335 | 4.4 | 1,363,141 | 15.0 | 26,622 | 0.3 | 5,611,705 | 61.8 | 287,841 | 3.2 | 1,316,851 | 14.5 |
| 2019 | 8,617,428 | 2,781,206 | 32.3 | 77,900 | 0.9 | 296,726 | 3.4 | 1,462,620 | 17.0 | 18,794 | 0.2 | 5,509,710 | 63.9 | 205,164 | 2.4 | 1,046,514 | 12.1 |
| 2020 | 9,365,822 | 3,255,607 | 34.8 | 83,909 | 0.9 | 405,980 | 4.3 | 1,502,915 | 16.0 | 24,347 | 0.3 | 5,479,939 | 58.5 | 283,073 | 3.0 | 1,585,659 | 16.9 |
| 2021 | 8,467,215 | 2,784,242 | 32.9 | 63,795 | 0.8 | 467,057 | 5.5 | 1,151,252 | 13.6 | 75,551 | 0.9 | 5,252,659 | 62.0 | 191,669 | 2.3 | 1,265,232 | 14.9 |
| 2022 | 7,350,581 | 2,421,663 | 32.9 | 63,379 | 0.9 | 264,041 | 3.6 | 1,001,673 | 13.6 | 19,304 | 0.3 | 4,829,861 | 65.7 | 211,295 | 2.9 | 961,028 | 13.1 |

Table 2J: Total Enrollment for Extramural NIH Clinical Research at U.S. Sites by Ethnicity from FY 2017 to FY 2022
Fiscal Year $\left.\begin{array}{c|c|c|c|c|c|c|}\hline \text { Not } \\ \text { Hispanic }\end{array} \begin{array}{c}\text { \% Not } \\ \text { Hispanic }\end{array} \begin{array}{c}\text { Hispanic/ } \\ \text { Latino }\end{array} \begin{array}{c}\text { Hispanic/ } \\ \text { Latino }\end{array} \quad \begin{array}{c}\text { Unknown/ } \\ \text { Not } \\ \text { Reported }\end{array} \begin{array}{c}\text { Unknown/ } \\ \text { Not } \\ \text { Reported }\end{array}\right]$

Table 2K: Total Enrollment for Intramural NIH Clinical Research at U.S. Sites by Race from FY 2017 to FY 2022

| Fiscal Year | Total Enrollment | Minority Enrollment | \% Minority Enrollment | American Indian/ Alaska Native | \% American Indian/ Alaska Native | Asian | \% Asian |  | \% Black/ <br> African <br> American | Native Hawailan/ Other Pacific Islander | \% Native Hawailan/ Other Pacific Islander | White | \% White | More Than One Race | \% More <br> Than One Race | Unknown/ Not Reported | \% <br> Unknown/ Not Reported |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2017 | 2,500,323 | 502,104 | 20.1 | 30,274 | 1.2 | 60,330 | 2.4 | 265,217 | 10.6 | 5,486 | 0.2 | 1,862,090 | 74.5 | 13,664 | 0.5 | 263,262 | 10.5 |
| 2018 | 1,503,517 | 231,156 | 15.4 | 26,983 | 1.8 | 25,087 | 1.7 | 124,882 | 8.3 | 3,951 | 0.3 | 1,180,371 | 78.5 | 9,595 | 0.6 | 132,648 | 8.8 |
| 2019 | 1,738,647 | 316,184 | 18.2 | 29,017 | 1.7 | 33,452 | 1.9 | 159,191 | 9.2 | 4,602 | 0.3 | 1,314,994 | 75.6 | 12,871 | 0.7 | 184,520 | 10.6 |
| 2020 | 1,715,049 | 303,923 | 17.7 | 28,616 | 1.7 | 34,282 | 2.0 | 151,941 | 8.9 | 4,148 | 0.2 | 1,296,815 | 75.6 | 12,811 | 0.7 | 186,436 | 10.9 |
| 2021 | 1,490,499 | 284,585 | 19.1 | 28,067 | 1.9 | 29,832 | 2.0 | 143,567 | 9.6 | 4,092 | 0.3 | 1,139,009 | 76.4 | 12,157 | 0.8 | 133,775 | 9.0 |
| 2022 | 1,405,174 | 255,311 | 18.2 | 27,405 | 2.0 | 30,668 | 2.2 | 133,566 | 9.5 | 3,931 | 0.3 | 1,094,071 | 77.9 | 11,318 | 0.8 | 104,215 | 7.4 |

Table 2L: Total EnrollIment for Intramural NIH Clinical Research at U.S. Sites by Ethnicity from FY 2017 to FY 2022
Fiscal Year $\left.\begin{array}{c|c|c|c|c|c|c|}\hline \text { Not } \\ \text { Hispanic }\end{array} \begin{array}{c}\text { \% Not } \\ \text { Hispanic }\end{array} \begin{array}{c}\text { Hispanic/ } \\ \text { Latino }\end{array} \begin{array}{c}\text { \% } \\ \text { Hispanic// } \\ \text { Latino }\end{array} \quad \begin{array}{c}\text { Unknown// } \\ \text { Not } \\ \text { Reported }\end{array} \begin{array}{c}\text { Unknown/ } \\ \text { Not } \\ \text { Reported }\end{array}\right]$

## Section 3 Aggregate Enrollment of Racial and Ethnic Minorities: NIH-Defined Phase III Clinical Trials

Table 3A: Total Enrollment and Minority Enrollment for All NIH-Defined Phase III Clinical Trials from FY 2012 to FY 2022

| Year | Total Enrollees | Minority Enrollees | \% Minority Enrollees |
| :---: | :---: | :---: | :---: |
| 2012 | 603,136 | 396,714 | 65.8 |
| 2013 | 691,023 | 526,422 | 76.2 |
| 2014 | 797,264 | 627,456 | 78.7 |
| $2015^{*}$ | $1,619,508$ | $1,492,248$ | 92.1 |
| $2016^{*}$ | $2,130,389$ | $1,992,237$ | 93.5 |
| 2017 | 907,643 | 459,046 | 50.6 |
| 2018 | 417,714 | 160,615 | 38.5 |
| 2019 | 329,747 | 153,529 | 46.6 |
| 2020 | 349,651 | 234,614 | 67.1 |
| 2021 | 666,800 | 468,980 | 70.3 |
| 2022 | $1,237,477$ | 474,392 | 38.3 |

*FY 2015 and FY 2016 include data from large foreign Phase III trials, which tend to have larger numbers of participants than domestic Phase III trials.

Table 3B: Total Enrollment and Minority
Enrollment at U.S. Sites for All NIH-Defined Phase III Clinical Trials from FY 2017 to FY 2022

| Fiscal Year | Total Enrollees | Minority Enrollees | \% Minority Enrollees |
| :---: | :---: | :---: | :---: |
| 2017 | 550,782 | 123,247 | 22.4 |
| 2018 | 335,391 | 104,170 | 31.1 |
| 2019 | 230,040 | 70,390 | 30.6 |
| 2020 | 189,745 | 84,422 | 44.5 |
| 2021 | 441,034 | 254,858 | 57.8 |
| 2022 | $1,007,948$ | 265,512 | 26.3 |

Table 3C: Total Enrollment and Minority Enrollment at U.S. Sites for Extramural NIHDefined Phase III Clinical Trials from FY 2017 to FY 2022

| Fiscal Year | Total Enrollees | Minority Enrollees | \% Minority Enrollees |
| :---: | :---: | :---: | :---: |
| 2017 | 540,640 | 119,772 | 22.2 |
| 2018 | 327,633 | 102,285 | 31.2 |
| 2019 | 218,431 | 66,730 | 30.5 |
| 2020 | 177,995 | 80,594 | 45.3 |
| 2021 | 429,318 | 251,021 | 58.5 |
| 2022 | $1,001,372$ | 262,625 | 26.2 |

Table 3D: Total Enrollment and Minority Enrollment at U.S. Sites for Intramural NIHDefined Phase III Clinical Trials from FY 2017 to FY 2022

| Fiscal Year | Total Enrollees | Minority Enrollees | \% Minority Enrollees |
| :---: | :---: | :---: | :---: |
| 2017 | 10,142 | 3,475 | 34.3 |
| 2018 | 7,758 | 1,885 | 24.3 |
| 2019 | 11,609 | 3,660 | 31.5 |
| 2020 | 11,750 | 3,828 | 32.6 |
| 2021 | 11,716 | 3,837 | 32.8 |
| 2022 | 6,576 | 2,887 | 43.9 |

Table 3E: Total Enrollment for All NIH-Defined Phase III Clinical Trials by Race from FY 2017 to FY 2022

| Fiscal Year | Total Enrollment | Number if Inclusion Data Records | Minority Enrollment | \% Minority <br> Enrollment | American Indian/ Alaska Native | \% American Indian/ Alaska Native | Asian | \% Asian | Black/ <br> African <br> American | \% Black/ <br> African <br> American | Native Hawailan/ Other Pacific Islander | \% Native Hawailan/ Other Pacific Islander | White | \% White | More Than One Race | \% More Than One Race | Unknown/ Not Reported | Unknown/ Not Reported |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2017 | 907,643 | 618 | 459,046 | 50.6 | 2,410 | 0.3 | 274,218 | 30.2 | 133,842 | 14.7 | 618 | 0.1 | 451,173 | 49.7 | 4,341 | 0.5 | 41,041 | 4.5 |
| 2018 | 417,714 | 717 | 160,615 | 38.5 | 2,390 | 0.6 | 18,961 | 4.5 | 79,604 | 19.1 | 847 | 0.2 | 269,943 | 64.6 | 15,298 | 3.7 | 30,670 | 7.3 |
| 2019 | 329,747 | 664 | 153,529 | 46.6 | 2,591 | 0.8 | 20,263 | 6.1 | 97,737 | 29.6 | 377 | 0.1 | 178,855 | 54.2 | 3,630 | 1.1 | 26,294 | 8.0 |
| 2020 | 349,651 | 907 | 234,614 | 67.1 | 2,127 | 0.6 | 69,041 | 19.7 | 105,705 | 30.2 | 601 | 0.2 | 134,340 | 38.4 | 11,724 | 3.4 | 26,113 | 7.5 |
| 2021 | 666,800 | 1,010 | 468,980 | 70.3 | 2,736 | 0.4 | 117,449 | 17.6 | 135,936 | 20.4 | 1,264 | 0.2 | 358,909 | 53.8 | 18,429 | 2.8 | 32,077 | 4.8 |
| 2022 | 1,237,477 | 1,165 | 474,392 | 38.3 | 6,085 | 0.5 | 83,387 | 6.7 | 200,413 | 16.2 | 2,319 | 0.2 | 820,771 | 66.3 | 23,081 | 1.9 | 101,421 | 8.2 |

Table 3F: Total Enrollment for All NIH-Defined Phase III Clinical Trials by Ethnicity from FY 2017 to FY 2022

| Fiscal Year | Not <br> Hispanic | \% Not <br> Hispanic | Hispanic/ <br> Latino | \% <br> Hispanic// <br> Latino | Unknown// <br> Not <br> Reported | Unknown/ <br> Not <br> Reported |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2017 | 790,092 | 87.0 | 49,999 | 5.5 | 67,552 | 7.4 |
| 2018 | 354,752 | 84.9 | 49,446 | 11.8 | 13,515 | 3.2 |
| 2019 | 284,424 | 86.3 | 32,586 | 9.9 | 12,737 | 3.9 |
| 2020 | 285,393 | 81.6 | 50,794 | 14.5 | 13,464 | 3.9 |
| 2021 | 439,338 | 65.9 | 207,740 | 31.2 | 19,722 | 3.0 |
| 2022 | 954,765 | 77.2 | 183,317 | 14.8 | 99,395 | 8.0 |

Table 3G: Total Enrollment for All NIH-Defined Phase III Clinical Trials at U.S. Sites by Race from FY 2017 to FY 2022

| Fiscal Year | Total Enrollment | Minority Enrollment | \% Minority <br> Enrollment | American Indian/ Alaska Native | \% American Indian/ Alaska Native | Asian | \% Asian | Black/ <br> African <br> American | \% Black/ <br> African <br> American | Native Hawailan/ Other Pacific Istander | \% Native Hawailan/ Other Pacific Istander | White | \% White | More Than One Race | \% More Than One Race |  | \% Unknown/ <br> Not Reported |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2017 | 550,782 | 123,247 | 22.4 | 2,305 | 0.4 | 12,042 | 2.2 | 71,387 | 13.0 | 551 | 0.1 | 431,587 | 78.4 | 4,223 | 0.8 | 28,687 | 5.2 |
| 2018 | 335,391 | 104,170 | 31.1 | 2,249 | 0.7 | 8,992 | 2.7 | 49,346 | 14.7 | 769 | 0.2 | 249,110 | 74.3 | 11,905 | 3.5 | 13,020 | 3.9 |
| 2019 | 230,040 | 70,390 | 30.6 | 2,512 | 1.1 | 5,543 | 2.4 | 41,586 | 18.1 | 356 | 0.2 | 168,437 | 73.2 | 3,124 | 1.4 | 8,482 | 3.7 |
| 2020 | 189,745 | 84,422 | 44.5 | 2,039 | 1.1 | 6,130 | 3.2 | 36,582 | 19.3 | 562 | 0.3 | 119,154 | 62.8 | 10,582 | 5.6 | 14,696 | 7.7 |
| 2021 | 441,034 | 254,858 | 57.8 | 2,580 | 0.6 | 10,227 | 2.3 | 62,810 | 14.2 | 1,232 | 0.3 | 328,474 | 74.5 | 14,919 | 3.4 | 20,792 | 4.7 |
| 2022 | 1,007,948 | 265,512 | 26.3 | 4,850 | 0.5 | 21,571 | 2.1 | 114,952 | 11.4 | 2,253 | 0.2 | 766,316 | 76.0 | 11,185 | 1.1 | 86,821 | 8.6 |

Table 3H: Total Enrollment for AII NIH-Defined Phase III Clinical Trials at U.S. Sites by Ethnicity from FY 2017 to FY 2022
Fiscal Year $\left.\begin{array}{c|c|c|c|c|c|c|}\text { Not } \\ \text { Hispanic }\end{array} \begin{array}{c}\text { \% Not } \\ \text { Hispanic }\end{array} \begin{array}{c}\text { Hispanic/ } \\ \text { Latino }\end{array} \begin{array}{c}\text { \% } \\ \text { Hispanic/ } \\ \text { Latino }\end{array} \quad \begin{array}{c}\text { Unknown/ } \\ \text { Not } \\ \text { Reported }\end{array} \begin{array}{c}\text { Unknown/ } \\ \text { Not } \\ \text { Reported }\end{array}\right]$

Table 3I: Total Enrollment for Extramural NIH-Defined Phase III Clinical Trials at U.S. Sites by Race from FY 2017 to FY 2022

| Fiscal Year | Total Enrollment | Minority Enrollment | \% Minority Enrollment | American Indian/ Alaska Native | \% American Indian/ Alaska Native | Asian | \% Asian | Black/ African American | \% Black/ African American | Native Hawaiian/ Other Pacific Islander | \% Native Hawailan/ Other Pacific Islander | White | \% White | More Than One Race | \% More Than One Race | Unknown/ Not Reported | $\begin{gathered} \text { \% } \\ \text { Unknown/ } \\ \text { Not } \\ \text { Reported } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2017 | 540,640 | 119,772 | 22.2 | 1,842 | 0.3 | 11,726 | 2.2 | 69,164 | 12.8 | 545 | 0.1 | 424,758 | 78.6 | 4,174 | 0.8 | 28,431 | 5.3 |
| 2018 | 327,633 | 102,285 | 31.2 | 1,975 | 0.6 | 8,711 | 2.7 | 48,436 | 14.8 | 768 | 0.2 | 243,227 | 74.2 | 11,681 | 3.6 | 12,835 | 3.9 |
| 2019 | 218,431 | 66,730 | 30.5 | 2,009 | 0.9 | 5,183 | 2.4 | 39,266 | 18.0 | 354 | 0.2 | 160,313 | 73.4 | 3,056 | 1.4 | 8,250 | 3.8 |
| 2020 | 177,995 | 80,594 | 45.3 | 1,393 | 0.8 | 5,761 | 3.2 | 34,248 | 19.2 | 561 | 0.3 | 111,061 | 62.4 | 10,516 | 5.9 | 14,455 | 8.1 |
| 2021 | 429,318 | 251,021 | 58.5 | 1,909 | 0.4 | 9,853 | 2.3 | 60,488 | 14.1 | 1,231 | 0.3 | 320,435 | 74.6 | 14,855 | 3.5 | 20,547 | 4.8 |
| 2022 | 1,001,372 | 262,625 | 26.2 | 4,169 | 0.4 | 21,357 | 2.1 | 113,286 | 11.3 | 2,253 | 0.2 | 762,486 | 76.1 | 11,144 | 1.1 | 86,677 | 8.7 |

Table 3J: Total Enrollment for Extramural NIH-Defined Phase III Clinical Trials at U.S. Sites by Ethnicity from FY 2017 to FY 2022

Fiscal Year \begin{tabular}{c|c|c|c|c|c|c|}
\hline Not <br>

Hispanic \& \begin{tabular}{c}
\% Not <br>
Hispanic

 \& 

Hispanic/ <br>
Latino

 \& 

\% <br>
Hispanic// <br>
Latino

 \& 

Unknown// <br>
Not <br>
Reported

 \& 

Unknown/ <br>
Not <br>
Reported
\end{tabular} <br>

\hline 2017 \& 440,370 \& 81.5 \& 37,948 \& 7.0 \& 62,322 \& 11.5 <br>
\hline 2018 \& 285,642 \& 87.2 \& 35,502 \& 10.8 \& 6,489 \& 2.0 <br>
\hline 2019 \& 192,300 \& 88.0 \& 19,599 \& 9.0 \& 6,532 \& 3.0 <br>
\hline 2020 \& 137,997 \& 77.5 \& 32,347 \& 18.2 \& 7,651 \& 4.3 <br>
\hline 2021 \& 240,642 \& 56.1 \& 173,648 \& 40.4 \& 15,028 \& 3.5 <br>
\hline 2022 \& 790,271 \& 78.9 \& 120,706 \& 12.1 \& 90,395 \& 9.0 <br>
\hline
\end{tabular}

Table 3K: Total Enrollment for Intramural NIH-Defined Phase III Clinical Trials at U.S. Sites by Race from FY 2017 to FY 2022

| Fiscal Year | Total Enrollment | Minority Enrollment | \% Minority <br> Enrollment | American Indian/ Alaska Native | \% American Indian/ Alaska Native | Asian | \% Asian | Black/ <br> African <br> American | \% Black/ African American | Native Hawailian/ Other Pacific Islander | \% Native <br> Hawailan/ <br> Other <br> Pacific <br> Islander | White | \% White | More Than One Race | \% More Than One Race | Unknown/ Not Reported | $\begin{gathered} \text { \% } \\ \text { Unknown/ } \\ \text { Not } \\ \text { Reported } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2017 | 10,142 | 3,475 | 34.3 | 463 | 4.6 | 316 | 3.1 | 2,223 | 21.9 | 6 | 0.1 | 6,829 | 67.3 | 49 | 0.5 | 256 | 2.5 |
| 2018 | 7,758 | 1,885 | 24.3 | 274 | 3.5 | 281 | 3.6 | 910 | 11.7 | 1 | 0.0 | 5,883 | 75.8 | 224 | 2.9 | 185 | 2.4 |
| 2019 | 11,609 | 3,660 | 31.5 | 503 | 4.3 | 360 | 3.1 | 2,320 | 20.0 | 2 | 0.0 | 8,124 | 70.0 | 68 | 0.6 | 232 | 2.0 |
| 2020 | 11,750 | 3,828 | 32.6 | 646 | 5.5 | 369 | 3.1 | 2,334 | 19.9 | 1 | 0.0 | 8,093 | 68.9 | 66 | 0.6 | 241 | 2.1 |
| 2021 | 11,716 | 3,837 | 32.8 | 671 | 5.7 | 374 | 3.2 | 2,322 | 19.8 | 1 | 0.0 | 8,039 | 68.6 | 64 | 0.5 | 245 | 2.1 |
| 2022 | 6,576 | 2,887 | 43.9 | 681 | 10.4 | 214 | 3.3 | 1,666 | 25.3 | 0 | 0.0 | 3,830 | 58.2 | 41 | 0.6 | 144 | 2.2 |

Table 3L: Total Enrollment for Intramural NIH-Defined Phase III Clinical Trials at U.S. Sites by Ethnicity from FY 2017 to FY 2022
Fiscal Year $\left.\begin{array}{c|c|c|c|c|c|c|}\hline \text { Hispanic }\end{array} \begin{array}{c}\text { \% Not } \\ \text { Hispanic }\end{array} \begin{array}{c}\text { Hispanic/ } \\ \text { Latino }\end{array} \begin{array}{c}\text { \%ispanic/ } \\ \text { Latino }\end{array} \quad \begin{array}{c}\text { Unknown/ } \\ \text { Not } \\ \text { Reported }\end{array} \begin{array}{c}\text { \% } \\ \text { Unknown/ } \\ \text { Not } \\ \text { Reported }\end{array}\right]$

## Section 4 Aggregate Enrollment of Females and Males by Race and Ethnicity for NIH Clinical Research

Table 4A: Minority Enrollment by Sex/Gender for All NIH Clinical Research from FY 2017 to FY 2022

| Year | Sex/Gender | Total Minority <br> Enrollees | \% of Minority <br> Enrollees | Total <br> Enrollees | \% Total |
| :---: | :--- | :---: | :---: | :---: | :---: |
|  | Female | $4,664,388$ | 49.3 | $9,470,264$ | 47.2 |
|  | Male | $5,364,942$ | 53.0 | $10,127,155$ | 50.5 |
|  | Unknown | 45,728 | 9.7 | 471,370 | 2.3 |
| $\mathbf{2 0 1 8}$ | Female | $2,610,070$ | 38.9 | $6,711,564$ | 52.4 |
|  | Male | $1,967,116$ | 34.7 | $5,668,475$ | 44.2 |
|  | Unknown | 44,342 | 10.2 | 434,123 | 3.4 |
| $\mathbf{2 0 1 9}$ | Female | $3,027,503$ | 43.9 | $6,894,390$ | 52.1 |
|  | Male | $2,219,465$ | 37.4 | $5,930,000$ | 44.8 |
|  | Unknown | 59,734 | 14.3 | 417,023 | 3.1 |
| $\mathbf{2 0 2 0}$ | Female | $3,133,281$ | 41.5 | $7,552,684$ | 55.1 |
|  | Male | $2,202,943$ | 39.8 | $5,532,650$ | 40.4 |
|  | Unknown | 86,053 | 13.9 | 620,325 | 4.5 |
|  | Female | $3,295,858$ | 43.5 | $7,572,143$ | 58.5 |
|  | Male | $2,016,535$ | 40.0 | $5,047,190$ | 39.0 |
|  | Unknown | 92,191 | 29.0 | 317,823 | 2.5 |
|  | Female | $2,590,412$ | 43.2 | $5,996,249$ | 55.8 |
|  | Male | $1,743,520$ | 39.1 | $4,454,456$ | 41.4 |
|  | Unknown | 69,350 | 23.0 | 301,270 | 2.8 |

Table 4B: Minority Enrollment by Sex/Gender for All NIH Clinical Research at U.S. Sites from FY 2017 to FY 2022

| Year | Sex/Gender | Total Minority <br> Enrollees | \% of Minority <br> Enrollees | Total <br> Enrollees | \% Total |
| :---: | :--- | :---: | :---: | :---: | :---: |
|  | Female | $1,962,988$ | 30.2 | $6,491,639$ | 49.1 |
|  | Male | $1,751,515$ | 27.8 | $6,302,343$ | 47.6 |
|  | Unknown | 28,278 | 6.5 | 437,184 | 3.3 |
| $\mathbf{2 0 1 8}$ | Female | $1,715,543$ | 31.7 | $5,413,405$ | 51.2 |
|  | Male | $1,360,919$ | 28.5 | $4,775,856$ | 45.1 |
|  | Unknown | 18,517 | 4.8 | 389,025 | 3.7 |
| $\mathbf{2 0 1 9}$ | Female | $1,680,226$ | 32.4 | $5,185,006$ | 50.1 |
|  | Male | $1,406,011$ | 29.0 | $4,853,379$ | 46.9 |
|  | Unknown | 11,153 | 3.5 | 317,690 | 3.1 |
| $\mathbf{2 0 2 0}$ | Female | $2,075,929$ | 34.2 | $6,062,190$ | 54.7 |
|  | Male | $1,459,907$ | 32.6 | $4,480,382$ | 40.4 |
|  | Unknown | 23,694 | 4.4 | 538,299 | 4.9 |
| $\mathbf{2 0 2 1}$ | Female | $1,900,460$ | 32.7 | $5,819,297$ | 58.4 |
|  | Male | $1,145,124$ | 29.3 | $3,902,545$ | 39.2 |
|  | Unknown | 23,243 | 9.9 | 235,872 | 2.4 |
| $\mathbf{2 0 2 2}$ | Female | $1,591,251$ | 32.9 | $4,834,272$ | 55.2 |
|  | Male | $1,069,343$ | 29.0 | $3,682,475$ | 42.1 |
|  | Unknown | 16,380 | 6.9 | 239,008 | 2.7 |

Table 4C: Minority Enrollment by Sex/Gender for Extramural NIH Clinical Research at U.S. Sites from FY 2017 to FY 2020

| Year | Sex/Gender | Total Minority <br> Enrollees | \% of Minority <br> Enrollees | Total <br> Enrollees | \% Total |
| :---: | :--- | :---: | :---: | :---: | :---: |
|  | Female | $1,685,598$ | 32.0 | $5,264,128$ | 49.1 |
|  | Male | $1,528,194$ | 29.7 | $5,136,833$ | 47.9 |
|  | Unknown | 26,885 | 8.1 | 329,882 | 3.1 |
| $\mathbf{2 0 1 8}$ | Female | $1,581,696$ | 34.0 | $4,650,602$ | 51.2 |
|  | Male | $1,264,241$ | 31.1 | $4,068,126$ | 44.8 |
|  | Unknown | 17,886 | 5.0 | 356,041 | 3.9 |
| $\mathbf{2 0 1 9}$ | Female | $1,490,090$ | 34.7 | $4,294,606$ | 49.8 |
|  | Male | $1,281,235$ | 31.6 | $4,059,871$ | 47.1 |
|  | Unknown | 9,881 | 3.8 | 262,951 | 3.1 |
| $\mathbf{2 0 2 0}$ | Female | $1,893,445$ | 36.5 | $5,184,613$ | 55.4 |
|  | Male | $1,339,392$ | 36.2 | $3,697,229$ | 39.5 |
|  | Unknown | 22,770 | 4.7 | 483,980 | 5.2 |
| $\mathbf{2 0 2 1}$ | Female | $1,726,701$ | 34.0 | $5,072,738$ | 59.9 |
|  | Male | $1,035,204$ | 32.4 | $3,195,055$ | 37.7 |
|  | Unknown | 22,337 | 11.2 | 199,422 | 2.4 |
| $\mathbf{2 0 2 2}$ | Female | $1,444,064$ | 34.5 | $4,181,202$ | 56.9 |
|  | Male | 962,053 | 32.5 | $2,964,338$ | 40.3 |
|  | Unknown | 15,546 | 7.6 | 205,041 | 2.8 |

Table 4D: Minority Enrollment by Sex/Gender for Intramural NIH Clinical Research at U.S. Sites from FY 2017 to FY 2022

| Year | Sex/Gender | Total Minority <br> Enrollees | \% of Minority <br> Enrollees | Total <br> Enrollees | \% Total |
| :---: | :--- | :---: | :---: | :---: | :---: |
|  | Female | 277,390 | 22.6 | $1,227,511$ | 49.1 |
|  | Male | 223,321 | 19.2 | $1,165,510$ | 46.6 |
|  | Unknown | 1,393 | 1.3 | 107,302 | 4.3 |
| $\mathbf{2 0 1 8}$ | Female | 133,847 | 17.5 | 762,803 | 50.7 |
|  | Male | 96,678 | 13.7 | 707,730 | 47.1 |
|  | Unknown | 631 | 1.9 | 32,984 | 2.2 |
| $\mathbf{2 0 1 9}$ | Female | 190,136 | 21.4 | 890,400 | 51.2 |
|  | Male | 124,776 | 15.7 | 793,508 | 45.6 |
|  | Unknown | 1,272 | 2.3 | 54,739 | 3.1 |
| $\mathbf{2 0 2 0}$ | Female | 182,484 | 20.8 | 877,577 | 51.2 |
|  | Male | 120,515 | 15.4 | 783,153 | 45.7 |
|  | Unknown | 924 | 1.7 | 54,319 | 3.2 |
| $\mathbf{2 0 2 1}$ | Female | 173,759 | 23.3 | 746,559 | 50.1 |
|  | Male | 109,920 | 15.5 | 707,490 | 47.5 |
|  | Unknown | 906 | 2.5 | 36,450 | 2.4 |
| $\mathbf{2 0 2 2}$ | Female | 147,187 | 22.5 | 653,070 | 46.5 |
|  | Male | 107,290 | 14.9 | 718,137 | 51.1 |
|  | Unknown | 834 | 2.5 | 33,967 | 2.4 |

Table 4E: Minority Enrollment by Sex/Gender for All NIH-Defined Phase III Clinical Trials from FY 2017 to FY 2022

| Year | Sex/Gender | Total Minority Enrollees | \% of Minority Enrollees | Total Enrollees | \% Total |
| :---: | :---: | :---: | :---: | :---: | :---: |
| 2017 | Female | 272,200 | 50.8 | 535,440 | 59.0 |
|  | Male | 186,587 | 50.2 | 371,636 | 40.9 |
|  | Unknown | 259 | 45.7 | 567 | 0.1 |
| 2018 | Female | 103,639 | 39.8 | 260,652 | 62.4 |
|  | Male | 56,626 | 36.3 | 155,960 | 37.3 |
|  | Unknown | 350 | 31.8 | 1,101 | 0.3 |
| 2019 | Female | 95,900 | 47.4 | 202,483 | 61.4 |
|  | Male | 57,207 | 47.9 | 119,369 | 36.2 |
|  | Unknown | 422 | 5.3 | 7,895 | 2.4 |
| 2020 | Female | 143,149 | 66.3 | 216,040 | 61.8 |
|  | Male | 87,244 | 68.2 | 127,864 | 36.6 |
|  | Unknown | 4,221 | 73.4 | 5,747 | 1.6 |
| 2021 | Female | 280,861 | 68.9 | 407,857 | 61.2 |
|  | Male | 183,592 | 72.7 | 252,659 | 37.9 |
|  | Unknown | 4,527 | 72.0 | 6,284 | 0.9 |
| 2022 | Female | 295,318 | 39.4 | 750,136 | 60.6 |
|  | Male | 173,359 | 39.1 | 443,341 | 35.8 |
|  | Unknown | 5,715 | 13.0 | 44,000 | 3.6 |

Table 4F: Minority Enrollment by Sex/Gender for All NIH-Defined Phase III Clinical Trials at U.S.
Sites from FY 2017 to FY 2022

| Year | Sex/Gender | Total Minority <br> Enrollees | \% of Minority <br> Enrollees | Total <br> Enrollees | \% Total |
| :---: | :--- | :---: | :---: | :---: | :---: |
|  | Female | 75,081 | 22.7 | 330,307 | 60.0 |
|  | Male | 48,134 | 21.9 | 220,245 | 40.0 |
|  | Unknown | 32 | 13.9 | 230 | 0.0 |
| $\mathbf{2 0 1 8}$ | Female | 63,253 | 30.1 | 209,985 | 62.6 |
|  | Male | 40,831 | 32.7 | 124,830 | 37.2 |
|  | Unknown | 86 | 14.9 | 576 | 0.2 |
| $\mathbf{2 0 1 9}$ | Female | 44,424 | 30.0 | 148,099 | 64.4 |
|  | Male | 25,808 | 31.9 | 81,012 | 35.2 |
|  | Unknown | 158 | 17.0 | 929 | 0.4 |
| $\mathbf{2 0 2 0}$ | Female | 54,453 | 45.0 | 121,041 | 63.8 |
|  | Male | 29,502 | 44.2 | 66,765 | 35.2 |
|  | Unknown | 467 | 24.1 | 1,939 | 1.0 |
|  | Female | 158,599 | 57.5 | 276,006 | 62.6 |
|  | Male | 96,107 | 58.9 | 163,123 | 37.0 |
|  | Unknown | 152 | 8.0 | 1,905 | 0.4 |
| $\mathbf{2 0 2 2}$ | Female | 170,300 | 28.0 | 609,104 | 60.4 |
|  | Male | 95,034 | 26.3 | 360,665 | 35.8 |
|  | Unknown | 178 | 0.5 | 38,179 | 3.8 |

Table 4G: Minority Enrollment by Sex/Gender for Extramural NIH-Defined Phase III Clinical Trials at U.S. Sites from FY 2017 to FY 2022

| Year | Sex/Gender | Total Minority <br> Enrollees | \% of Minority <br> Enrollees | Total <br> Enrollees | \% Total |
| :---: | :--- | :---: | :---: | :---: | :---: |
|  | Female | 72,140 | 22.4 | 322,436 | 59.6 |
|  | Male | 47,601 | 21.8 | 217,976 | 40.3 |
|  | Unknown | 31 | 13.6 | 228 | 0.0 |
| $\mathbf{2 0 1 8}$ | Female | 62,460 | 30.2 | 206,817 | 63.1 |
|  | Male | 39,757 | 33.1 | 120,274 | 36.7 |
|  | Unknown | 68 | 12.5 | 542 | 0.2 |
| $\mathbf{2 0 1 9}$ | Female | 41,801 | 29.7 | 140,865 | 64.5 |
|  | Male | 24,790 | 32.3 | 76,657 | 35.1 |
|  | Unknown | 139 | 15.3 | 909 | 0.4 |
| $\mathbf{2 0 2 0}$ | Female | 51,716 | 45.4 | 113,844 | 64.0 |
|  | Male | 28,430 | 45.7 | 62,232 | 35.0 |
|  | Unknown | 448 | 23.3 | 1,919 | 1.1 |
| $\mathbf{2 0 2 1}$ | Female | 155,879 | 58.0 | 268,903 | 62.6 |
|  | Male | 95,021 | 59.9 | 158,541 | 36.9 |
|  | Unknown | 121 | 6.5 | 1,874 | 0.4 |
| $\mathbf{2 0 2 2}$ | Female | 167,699 | 27.8 | 602,969 | 60.2 |
|  | Male | 94,748 | 26.3 | 360,224 | 36.0 |
|  | Unknown | 178 | 0.5 | 38,179 | 3.8 |

Table 4H: Minority Enrollment by Sex/Gender for Intramural NIH-Defined Phase III Clinical Trials at U.S. Sites from FY 2017 to FY 2022

| Year | Sex/Gender | Total Minority <br> Enrollees | \% of Minority <br> Enrollees | Total <br> Enrollees | \% Total |
| :---: | :--- | :---: | :---: | :---: | :---: |
|  | Female | 2,941 | 37.4 | 7,871 | 77.6 |
|  | Male | 533 | 23.5 | 2,269 | 22.4 |
|  | Unknown | 1 | 50.0 | 2 | 0.0 |
| $\mathbf{2 0 1 8}$ | Female | 793 | 25.0 | 3,168 | 40.8 |
|  | Male | 1,074 | 23.6 | 4,556 | 58.7 |
|  | Unknown | 18 | 52.9 | 34 | 0.4 |
| $\mathbf{2 0 1 9}$ | Female | 2,623 | 36.3 | 7,234 | 62.3 |
|  | Male | 1,018 | 23.4 | 4,355 | 37.5 |
|  | Unknown | 19 | 95.0 | 20 | 0.2 |
| $\mathbf{2 0 2 0}$ | Female | 2,737 | 38.0 | 7,197 | 61.3 |
|  | Male | 1,072 | 23.6 | 4,533 | 38.6 |
|  | Unknown | 19 | 95.0 | 20 | 0.2 |
| $\mathbf{2 0 2 1}$ | Female | 2,720 | 38.3 | 7,103 | 60.6 |
|  | Male | 1,086 | 23.7 | 4,582 | 39.1 |
|  | Unknown | 31 | 100.0 | 31 | 0.3 |
| $\mathbf{2 0 2 2}$ | Female | 2,601 | 42.4 | 6,135 | 93.3 |
|  | Male | 286 | 64.9 | 441 | 6.7 |
|  | Unknown | 0 | 0.0 | 0 | 0.0 |

Table 4I: Enrollment of Females and Males for AII NIH-Defined Clinical Research by Race and Ethnicity from FY 2021 to 2022

| Fiscal Year | Sex/ Gender | Minority | \% Minority | $\begin{gathered} \text { Total } \\ \text { Enrollment } \end{gathered}$ | \% Total | Americar Indian/ Alaska Native | \% American Indian/ Alaska Native | Asian | \% Asian | Black/ <br> African American | \% Black/ African American | $\begin{aligned} & \text { Native } \\ & \text { Hawailian/ } \\ & \text { Other } \\ & \text { Pacific } \\ & \text { Islander } \end{aligned}$ | \% Native <br> Hawailian/ <br> Other <br> Pacific <br> Islander | White | \%White | More Than One Race | $\begin{aligned} & \text { \% More } \\ & \text { Than One } \end{aligned}$ | Unknown/ Not Reported | $\begin{gathered} \text { \% } \\ \hline \text { Unknown/ } \\ \text { Not } \\ \text { Reported } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2021 | Female | 3,295,858 | 43.5 | 7,572,143 | 58.5 | 55,984 | 0.7 | 963,278 | 12.7 | 1,392,649 | 18.4 | 44,193 | 0.6 | 4,037,094 | 53.3 | 145,474 | 1.9 | 933,471 | 12.3 |
| 2021 | Male | 2,016,535 | 40.0 | 5,047,190 | 39.0 | 40,262 | 0.8 | 565,616 | 11.2 | 880,182 | 17.4 | 39,492 | 0.8 | 2,842,637 | 56.3 | 102,412 | 2.0 | 576,589 | 11.4 |
| 2021 | Unknown | 92,191 | 29.0 | 317,823 | 2.5 | 541 | 0.2 | 22,027 | 6.9 | 16,358 | 5.1 | 194 | 0.1 | 22,567 | 7.1 | 6,928 | 2.2 | 249,208 | 78.4 |
| 2022 | Female | 2,590,412 | 43.2 | 5,996,249 | 55.8 | 56,214 | 0.9 | 419,988 | 7.0 | 1,276,954 | 21.3 | 15,407 | 0.3 | 3,515,480 | 58.6 | 164,616 | 2.7 | 547,590 | 9.1 |
| 2022 | Male | 1,743,520 | 39.1 | 4,454,456 | 41.4 | 40,352 | 0.9 | 337,622 | 7.6 | 817,181 | 18.3 | 12,158 | 0.3 | 2,705,309 | 60.7 | 120,440 | 2.7 | 421,394 | 9.5 |
| 2022 | Unknown | 69,350 | 23.0 | 301,270 | 2.8 | 1,118 | 0.4 | 9,982 | 3.3 | 11,792 | 3.9 | 262 | 0.1 | 17,673 | 5.9 | 6,857 | 2.3 | 253,586 | 84.2 |


| Fiscal Year | Not <br> Hispanic | \% Not <br> Hispanic | Hhispanic/ <br> Latino | \% <br> Hispanic/ <br> Latino | Unknown/ <br> Not <br> Reported | \%nknown/ <br> Not <br> Reported |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2021 | $6,064,750$ | 80.1 | 797,932 | 10.5 | 709,461 | 9.4 |
| 2021 | $4,144,316$ | 82.1 | 475,840 | 9.4 | 427,034 | 8.5 |
| 2021 | 95,320 | 30.0 | 52,274 | 16.4 | 170,229 | 53.6 |
| 2022 | $4,827,752$ | 80.5 | 778,230 | 13.0 | 390,267 | 6.5 |
| 2022 | $3,609,639$ | 81.0 | 506,945 | 11.4 | 337,872 | 7.6 |
| 2022 | 47,219 | 15.7 | 45,383 | 15.1 | 208,668 | 69.3 |

Table 4J: U.S. Site Enrollment of Females and Males for All NIH-Defined Clinical Research by Race and Ethnicity from FY 2021 to 2022

| Fiscal Year | Sex/ Gender | Minority | \% Minority | American <br> Indian/ <br> Alaska <br> Native | $\begin{gathered} \% \\ \hline \text { American } \\ \text { Indian/ } \\ \text { Alaska } \\ \text { Native } \\ \hline \end{gathered}$ | Asian | \% Asian | Black/ <br> African <br> American | \% Black/ Arrican American | Native Hawailan/ Other Pacific Islander | \% Native <br> Hawailian/ <br> Other Pacific <br> Islander | White | \% White | More Than One Race | \% More Than One Race | Unknown/ Not Reported | $\begin{gathered} \% \\ \text { Unknown/ } \\ \text { Not } \\ \text { Reported } \end{gathered}$ | Not Hispanic | \% Not Hispanic | Hispanic/ Latino | $\begin{gathered} \text { \% } \\ \text { Hispanic/ } \\ \text { Latino } \end{gathered}$ | Unknown/ Not Reported | $\begin{gathered} \text { \% } \\ \text { Unknown/ } \\ \text { Not } \\ \text { Reported } \end{gathered}$ |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2021 | Female | 1,900,460 | 32.7 | 53,219 | 0.9 | 322,593 | 5.5 | 803,440 | 13.8 | 41,974 | 0.7 | 3,711,620 | 63.8 | 125,958 | 2.2 | 760,493 | 13.1 | 4,572,598 | 78.6 | 634,890 | 10.9 | 611,809 | 10.5 |
| 2021 | Male | 1,145,124 | 29.3 | 38,111 | 1.0 | 172,378 | 4.4 | 486,393 | 12.5 | 37,555 | 1.0 | 2,658,928 | 68.1 | 76,170 | 2.0 | 433,010 | 11.1 | 3,105,857 | 79.6 | 391,383 | 10.0 | 405,305 | 10.4 |
| 2021 | Unknown | 23,243 | 9.9 | 532 | 0.2 | 1,918 | 0.8 | 4,986 | 2.1 | 114 | 0.0 | 21,120 | 9.0 | 1,698 | 0.7 | 205,504 | 87.1 | 62,582 | 26.5 | 14,957 | 6.3 | 158,333 | 67.1 |
| 2022 | Female | 1,591,251 | 32.9 | 52,152 | 1.1 | 176,388 | 3.6 | 688,204 | 14.2 | 13,041 | 0.3 | 3,301,773 | 68.3 | 130,619 | 2.7 | 472,095 | 9.8 | 3,869,175 | 80.0 | 618,826 | 12.8 | 346,271 | 7.2 |
| 2022 | Male | 1,069,343 | 29.0 | 38,003 | 1.0 | 117,087 | 3.2 | 442,112 | 12.0 | 10,014 | 0.3 | 2,606,644 | 70.8 | 89,873 | 2.4 | 378,742 | 10.3 | 2,954,002 | 80.2 | 431,873 | 11.7 | 296,600 | 8.1 |
| 2022 | Unknown | 16,380 | 6.9 | 629 | 0.3 | 1,234 | 0.5 | 4,923 | 2.1 | 180 | 0.1 | 15,515 | 6.5 | 2,121 | 0.9 | 214,406 | 89.7 | 29,645 | 12.4 | 8,346 | 3.5 | 201,017 | 84.1 |

Table 4K: U.S. Site Enrollment of Females and Males for NIH-Defined Extramural Clinical Research by Race and Ethnicity from FY 2021 to FY 2022

| Fiscal Year | Sex/ Gender | Minority | \% Minority | American <br> Indian/ <br> Alaska <br> Native | \% American Indian/ Alaska Native | Asian | \% Asian | Black/ Arrican American | \% Black/ African American | Native <br> Hawailan/ Other Pacific Islander | \% Native Hawailan/ Other Pacific Islander | White | \%White | More Than One Race | \% More <br> Than One <br> Race | Unknown/ <br> Not Reported | \% Unknown/ Not Reported | Not Hispanic | \% Not Hispanic | Hispanic/ Latino | $\begin{gathered} \% \\ \text { Hispanic/ } \\ \text { Latino } \end{gathered}$ | Unknown/ <br> Not <br> Reported | \% Unknown/ Not Reported |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2021 | Female | 1,726,701 | 34.0 | 38,033 | 0.7 | 307,543 | 6.1 | 713,587 | 14.1 | 39,805 | 0.8 | 3,156,909 | 62.2 | 119,066 | 2.3 | 697,795 | 13.8 | 3,898,880 | 76.9 | 586,982 | 11.6 | 586,876 | 11.6 |
| 2021 | Male | 1,035,204 | 32.4 | 25,261 | 0.8 | 157,636 | 4.9 | 432,801 | 13.5 | 35,641 | 1.1 | 2,075,053 | 64.9 | 70,942 | 2.2 | 397,721 | 12.4 | 2,450,497 | 76.7 | 367,310 | 11.5 | 377,248 | 11.8 |
| 2021 | Unknown | 22,337 | 11.2 | 501 | 0.3 | 1,878 | 0.9 | 4,864 | 2.4 | 105 | 0.1 | 20,697 | 10.4 | 1,661 | 0.8 | 169,716 | 85.1 | 59,200 | 29.7 | 14,267 | 7.2 | 125,955 | 63.2 |
| 2022 | Female | 1,444,064 | 34.5 | 37,593 | 0.9 | 161,113 | 3.9 | 604,681 | 14.5 | 10,940 | 0.3 | 2,806,479 | 67.1 | 124,100 | 3.0 | 436,296 | 10.4 | 3,272,234 | 78.3 | 589,919 | 14.1 | 319,049 | 7.6 |
| 2022 | Male | 962,053 | 32.5 | 25,186 | 0.8 | 101,734 | 3.4 | 392,153 | 13.2 | 8,186 | 0.3 | 2,008,318 | 67.7 | 85,102 | 2.9 | 343,659 | 11.6 | 2,291,937 | 77.3 | 406,285 | 13.7 | 266,116 | 9.0 |
| 2022 | Unknown | 15,546 | 7.6 | 600 | 0.3 | 1,194 | 0.6 | 4,839 | 2.4 | 178 | 0.1 | 15,064 | 7.3 | 2,093 | 1.0 | 181,073 | 88.3 | 26,372 | 12.9 | 7,683 | 3.7 | 170,986 | 83.4 |

Table 4L: U.S. Site Enrollment of Females and Males for NIH-Defined Intramural Clinical Research by Race from FY 2021 to FY 2022

| Fiscal Year | Sex/ Gender | Minority | \% Minority | American <br> Indian/ <br> Alaska <br> Native | \% American Indian/ Alaska Native | Asian | \% Asian | Black/ African American | \% Black/ African American | Native Hawailan/ Other Pacific Islander | \% Native <br> Hawailan/ <br> Other Pacific <br> Islander | White | \% White | More Than One Race | \% More Than One Race | Unknown/ <br> Not Reported | \% Unknown/ Not Reported | Not Hispanic | \% Not Hispanic | Hispanic/ Latino | Hispanic/ <br> Latino | Unknown/ <br> Not Reported | Unknown <br> Not Reported |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2021 | Female | 173,759 | 23.3 | 15,186 | 2.0 | 15,050 | 2.0 | 89,853 | 12.0 | 2,169 | 0.3 | 554,711 | 74.3 | 6,892 | 0.9 | 62,698 | 8.4 | 673,718 | 90.2 | 47,908 | 6.4 | 24,933 | 3.3 |
| 2021 | Male | 109,920 | 15.5 | 12,850 | 1.8 | 14,742 | 2.1 | 53,592 | 7.6 | 1,914 | 0.3 | 583,875 | 82.5 | 5,228 | 0.7 | 35,289 | 5.0 | 655,360 | 92.6 | 24,073 | 3.4 | 28,057 | 4.0 |
| 2021 | Unknown | 906 | 2.5 | 31 | 0.1 | 40 | 0.1 | 122 | 0.3 | 9 | 0.0 | 423 | 1.2 | 37 | 0.1 | 35,788 | 98.2 | 3,382 | 9.3 | 690 | 1.9 | 32,378 | 88.8 |
| 2022 | Female | 147,187 | 22.5 | 14,559 | 2.2 | 15,275 | 2.3 | 83,523 | 12.8 | 2,101 | 0.3 | 495,294 | 75.8 | 6,519 | 1.0 | 35,799 | 5.5 | 596,941 | 91.4 | 28,907 | 4.4 | 27,222 | 4.2 |
| 2022 | Male | 107,290 | 14.9 | 12,817 | 1.8 | 15,353 | 2.1 | 49,959 | 7.0 | 1,828 | 0.3 | 598,326 | 83.3 | 4,771 | 0.7 | 35,083 | 4.9 | 662,065 | 92.2 | 25,588 | 3.6 | 30,484 | 4.2 |
| 2022 | Unknown | 834 | 2.5 | 29 | 0.1 | 40 | 0.1 | 84 | 0.2 | 2 | 0.0 | 451 | 1.3 | 28 | 0.1 | 33,333 | 98.1 | 3,273 | 9.6 | 663 | 2.0 | 30,031 | 88.4 |

Table 4M: Enrollment of Females and Males for All NIH-Defined Phase III Trials by Race and Ethnicity from FY 2021 to FY 2022

| Fiscal Year | Sex/ Gender | Minority | \% Minority | Total Enrollment | \% Total | American Indian/ Alaska Native | \% American Indian/ Alaska Native | Asian | \% Asian | Black/ African American | \% Black/ African American | Native Hawailian/ Other Pacific Islander | \% Native Hawailian/ Other Pacific Islander | White | \% White | More Than One Race | \% More <br> Than One Race | Unknown/ <br> Not <br> Reported | \% <br> Unknown/ Not Reported |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2021 | Female | 280,861 | 68.9 | 407,857 | 61.2 | 1,704 | 0.4 | 62,060 | 15.2 | 81,433 | 20.0 | 806 | 0.2 | 228,749 | 56.1 | 11,563 | 2.8 | 21,542 | 5.3 |
| 2021 | Male | 183,592 | 72.7 | 252,659 | 37.9 | 1,027 | 0.4 | 55,366 | 21.9 | 50,186 | 19.9 | 456 | 0.2 | 129,797 | 51.4 | 6,849 | 2.7 | 8,978 | 3.6 |
| 2021 | Unknown | 4,527 | 72.0 | 6,284 | 0.9 | 5 | 0.1 | 23 | 0.4 | 4,317 | 68.7 | 2 | 0.0 | 363 | 5.8 | 17 | 0.3 | 1,557 | 24.8 |
| 2022 | Female | 295,318 | 39.4 | 750,136 | 60.6 | 3,672 | 0.5 | 44,694 | 6.0 | 122,219 | 16.3 | 1,391 | 0.2 | 524,884 | 70.0 | 12,940 | 1.7 | 40,336 | 5.4 |
| 2022 | Male | 173,359 | 39.1 | 443,341 | 35.8 | 2,408 | 0.5 | 37,712 | 8.5 | 73,760 | 16.6 | 924 | 0.2 | 295,452 | 66.6 | 10,117 | 2.3 | 22,968 | 5.2 |
| 2022 | Unknown | 5,715 | 13.0 | 44,000 | 3.6 | 5 | 0.0 | 981 | 2.2 | 4,434 | 10.1 | 4 | 0.0 | 435 | 1.0 | 24 | 0.1 | 38,117 | 86.6 |

Fiscal Year \(\left.$$
\begin{array}{c|c|c|c|c|c|c|}\hline \text { Not } \\
\text { Hispanic }\end{array}
$$ $$
\begin{array}{c}\text { \% Not } \\
\text { Hispanic }\end{array}
$$ $$
\begin{array}{c}\text { "Hispanic/ } \\
\text { Latino }\end{array}
$$ \begin{array}{c}\% <br>
Hispanic/ <br>

Latino\end{array}\right) \left.\)| Unknown// |
| :---: |
| Not |
| Reported |$~$| Unknown/ |
| :---: |
| Not |
| Reported | \right\rvert\,

Table 4N: U.S. Site Enrollment of Females and Males for NIH-Defined Phase III Trials by Race and Ethnicity from FY 2021 and FY 2022

| Fiscal Year | Sex/ Gender | Minority | $\begin{aligned} & \text { \% } \\ & \text { Minority } \end{aligned}$ | American Indian/ Alaska Native | \% American Indian/ Alaska Native | Asian | \% Asian | Black/ Arrican American | \% Black/ African American | Native <br> Hawailan/ <br> Other Pacific <br> Islander | \% Native Hawailan/ Other Pacific Islander | White | \%White | More Than One Race | \% More <br> Than One Race | Unknown/ <br> Not <br> Reported | \% Unknown/ Not Reported | Not Hispanic | $\begin{gathered} \text { \% Not } \\ \text { Hispanic } \end{gathered}$ | Hispanic/ Latino | $\begin{gathered} \text { \% } \\ \text { Hispanic/ } \\ \text { Latino } \end{gathered}$ | Unknown/ Not Reported | \% Unknown/ Not Reported |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2021 | Female | 158,599 | 57.5 | 1,682 | 0.6 | 6,511 | 2.4 | 41,194 | 14.9 | 788 | 0.3 | 203,953 | 73.9 | 10,167 | 3.7 | 11,711 | 4.2 | 164,768 | 59.7 | 105,089 | 38.1 | 6,149 | 2.2 |
| 2021 | Male | 96,107 | 58.9 | 893 | 0.5 | 3,700 | 2.3 | 21,598 | 13.2 | 442 | 0.3 | 124,226 | 76.2 | 4,736 | 2.9 | 7,528 | 4.6 | 86,663 | 53.1 | 68,980 | 42.3 | 7,480 | 4.6 |
| 2021 | Unknown | 152 | 8.0 | 5 | 0.3 | 16 | 0.8 | 18 | 0.9 | 2 | 0.1 | 295 | 15.5 | 16 | 0.8 | 1,553 | 81.5 | 329 | 17.3 | 104 | 5.5 | 1,472 | 77.3 |
| 2022 | Female | 170,300 | 28.0 | 3,028 | 0.5 | 13,837 | 2.3 | 74,453 | 12.2 | 1,362 | 0.2 | 479,591 | 78.7 | 7,639 | 1.3 | 29,194 | 4.8 | 503,363 | 82.6 | 76,540 | 12.6 | 29,201 | 4.8 |
| 2022 | Male | 95,034 | 26.3 | 1,817 | 0.5 | 7,714 | 2.1 | 40,429 | 11.2 | 888 | 0.2 | 286,428 | 79.4 | 3,523 | 1.0 | 19,866 | 5.5 | 292,562 | 81.1 | 44,498 | 12.3 | 23,605 | 6.5 |
| 2022 | Unknown | 178 | 0.5 | 5 | 0.0 | 20 | 0.1 | 70 | 0.2 | 3 | 0.0 | 297 | 0.8 | 23 | 0.1 | 37,761 | 98.9 | 466 | 1.2 | 73 | 0.2 | 37,640 | 98.6 |

Table 40: U.S. Site Enrollment of Females and Males for NIH-Defined Extramural Phase III Trials by Race and Ethnicity from FY 2021 to FY 2022

| Fiscal Year | Sex/ Gender | Minority | \% Minority | American Indian/ Alaska Native |  | Asian | \% Asian | Black/ Arrican American | \% Black/ Arrican Americal | Native Hawailan/ Other Pacific Islander | \% Native <br> Hawailan/ <br> Other Pacific <br> Islander | White | \%White | More Than One Race | \% More <br> Than One Race | Unknown/ <br> Not <br> Reported | \% Unknown/ Not Reported | Not Hispanic | \% Not Hispanic | Hispanic/ Latino | Hispanic/ <br> Latino | Unknown/ Not Reported | \% Unknown/ Not Reported |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2021 | Female | 155,879 | 58.0 | 1,164 | 0.4 | 6,304 | 2.3 | 39,482 | 14.7 | 788 | 0.3 | 199,438 | 74.2 | 10,136 | 3.8 | 11,591 | 4.3 | 158,065 | 58.8 | 104,742 | 39.0 | 6,096 | 2.3 |
| 2021 | Male | 95,021 | 59.9 | 740 | 0.5 | 3,533 | 2.2 | 20,988 | 13.2 | 441 | 0.3 | 120,702 | 76.1 | 4,704 | 3.0 | 7,433 | 4.7 | 82,248 | 51.9 | 68,833 | 43.4 | 7,460 | 4.7 |
| 2021 | Unknown | 121 | 6.5 | 5 | 0.3 | 16 | 0.9 | 18 | 1.0 | 2 | 0.1 | 295 | 15.7 | 15 | 0.8 | 1,523 | 81.3 | 329 | 17.6 | 73 | 3.9 | 1,472 | 78.5 |
| 2022 | Female | 167,699 | 27.8 | 2,497 | 0.4 | 13,649 | 2.3 | 72,840 | 12.1 | 1,362 | 0.2 | 475,930 | 78.9 | 7,610 | 1.3 | 29,081 | 4.8 | 497,617 | 82.5 | 76,199 | 12.6 | 29,153 | 4.8 |
| 2022 | Male | 94,748 | 26.3 | 1,667 | 0.5 | 7,688 | 2.1 | 40,376 | 11.2 | 888 | 0.2 | 286,259 | 79.5 | 3,511 | 1.0 | 19,835 | 5.5 | 292,188 | 81.1 | 44,434 | 12.3 | 23,602 | 6.6 |
| 2022 | Unknown | 178 | 0.5 | 5 | 0.0 | 20 | 0.1 | 70 | 0.2 | 3 | 0.0 | 297 | 0.8 | 23 | 0.1 | 37,761 | 98.9 | 466 | 1.2 | 73 | 0.2 | 37,640 | 98.6 |

Table 4P: U.S. Site Enrollment of Females and Males for NIH-Defined Intramural Phase III Trials by Race and Ethnicity from FY 2021 to FY 2022

| Fiscal Year | Sex/ Gender | Minority | \% Minority | American Indian/ Alaska Native |  | Asian | \%Asian | Black/ African American | \% Black/ Arrican Americal | Native <br> Hawailan/ <br> Other Pacific <br> Islander | \% Native <br> Hawailan/ Other Pacific Islander | White | \% White | More Than One Race | \% More <br> Than One Race | Unknown/ <br> Not Reported | \% Unknown/ <br> Not Reported | Not Hispanic | \% Not Hispanic | Hispanic/ Latino | Hispanic/ <br> Latino | Unknown/ <br> Not <br> Reported | \% Unknown/ Not Reported |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2021 | Female | 2,720 | 38.3 | 518 | 7.3 | 207 | 2.9 | 1,712 | 24.1 | 0 | 0.0 | 4,515 | 63.6 | 31 | 0.4 | 120 | 1.7 | 6,703 | 94.4 | 347 | 4.9 | 53 | 0.7 |
| 2021 | Male | 1,086 | 23.7 | 153 | 3.3 | 167 | 3.6 | 610 | 13.3 | 1 | 0.0 | 3,524 | 76.9 | 32 | 0.7 | 95 | 2.1 | 4,415 | 96.4 | 147 | 3.2 | 20 | 0.4 |
| 2021 | Unknown | 31 | 100.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 1 | 3.2 | 30 | 96.8 | 0 | 0.0 | 31 | 100.0 | 0 | 0.0 |
| 2022 | Female | 2,601 | 42.4 | 531 | 8.7 | 188 | 3.1 | 1,613 | 26.3 | 0 | 0.0 | 3,661 | 59.7 | 29 | 0.5 | 113 | 1.8 | 5,746 | 93.7 | 341 | 5.6 | 48 | 0.8 |
| 2022 | Male | 286 | 64.9 | 150 | 34.0 | 26 | 5.9 | 53 | 12.0 | 0 | 0.0 | 169 | 38.3 | 12 | 2.7 | 31 | 7.0 | 374 | 84.8 | 64 | 14.5 | 3 | 0.7 |
| 2022 | Unknown | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 | 0 | 0.0 |

## Section 5 Valid Analysis Requirement for NIH-Funded Phase III Clinical Trials

Table 5: Valid Analysis Requirements for Extramural NIH-Defined Phase III Clinical Trials, FY 2019 to FY 2022

| Fiscal Year | Total IERs | IERs Requiring Race- <br> Ethnicity Valid Analysis | \% IERs Requiring Race- <br> Ethnicity Valid Analysis | IERs Requiring Sex- <br> Gender Valid Analysis | \% IERs Requiring Sex- <br> Gender Valid Analysis |
| :---: | :---: | :---: | :---: | :---: | :---: | :---: |
| 2019 | 664 | 622 | 93.7 | 625 | 94.1 |
| 2020 | 907 | 853 | 94.0 | 800 | 88.2 |
| 2021 | 1,010 | 961 | 95.1 | 900 | 89.1 |
| 2022 | 1,166 | 1138 | 97.6 | 1,076 | 92.3 |

Note: Plans for valid analysis methodologies specified in the project application are reported for all IERs, including IERs that have no reported actual enrollment at the time of reporting.

## Section 6 Age-Related Data Based on Inclusion Enrollment Records (IERs)

Table 6: Age Distribution for all NIH-Defined Clinical Research, FY 2021-2022
$\left.\begin{array}{|c|c|c|c|c|c|}\hline \text { Fiscal Year } & \begin{array}{c}\text { "Children } \\ \text { (<18 years)" }\end{array} & \begin{array}{c}\text { "Adults } \\ \text { (18-64 years)" }\end{array} & \begin{array}{c}\text { "Older Adults } \\ \text { (65+ years)" }\end{array} & \begin{array}{c}\text { "Unknown } \\ \text { or }\end{array} \\ \text { Not Reported" }\end{array}\right\}$

# Appendix D. Inclusion Certification Forms 

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Michael F. Chiang, MD
Director
National Eye Institute

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## Fiscal Year 2022

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Gary H. Gibbons, M.D.
Director
NHLBI

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> Docusigned by:
> Eric Ereen

|  | Dr. Eric Green |
| :--- | :--- |
| Director |  |
| NHGRI |  |
|  | February, 2023 |

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Signature
Richard J. Hodes, M.D.
Director
National Institute on Aging

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$\frac{01 / 30 / 2023}{\text { Date }}$

Signature Date

ICO's Director's Name: George F. Koob
Title: Director
ICO Name: National Institute on Alcohol Abuse and Alcoholism

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Dr. Bruce Tromberg
Director
NIBIB

March 17, 2023

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Diana W. Bianchi -S

Digitally signed by Diana W. Bianchi -S Date: 2023.02.21 16:56:25 -05'00'

Diana Bianchi, M.D. Director<br>Eunice Kennedy Shriver National Institute of Child Health and Human Development February, 2023

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## Digitally signed by Debara L. <br> Debara L. Tucci -S Tucci-S

Date: 2023.01.06 10:18:46-05'00'
Debara L. Tucci, M.D., M.S., M.B.A.

Director
National Institute on
Deafness and Other
Communication Disorders
January, 2023

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D'Souza, Rena Digitally signed by D Souza, Rena (NIH/NIDCR) [E]
(NIH/NIDCR) [E] Date: 2023.0.0.03 10:55:41 -05'00'

Rena D'Souza, DDS, MS, PhD<br>Director<br>NIDCR

January 2023

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Title Director, NIDDK
ICO Name National Institute of Diabetes and Digestive and Kidney Diseases

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Director,
National Institute on Drug Abuse

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Signature
Date

## Rick Woychik, Ph.D.

Director
National Institute of Environmental Health Sciences

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National Institute of Mental
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Eliseo Pérez-Stable, MD
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NIMHD

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Walter J.
Koroshetz -S $\quad \begin{aligned} & \text { Digitally signed by Walter J. } \\ & \text { Koroshetz -S } \\ & \text { Date: 2023.02.27 18:40:43 } \\ & -05^{\prime} 00^{\prime}\end{aligned}$
Walter J. Koroshetz, MD
Director
National Institute of Neurological Disorders and Stroke
February, 2023

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## Shannon N Digitally signed by Shannon N. Zenk -S <br> Zenk -S $\quad \begin{aligned} & \text { Date: 2023.02.02 } \\ & \text { 19:39:46-05'00' }\end{aligned}$

Shannon N. Zenk, Ph.D., M.P.H., RN, FAAN
Director
NINR

February, 2023

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Director
National Library of Medicine

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$$
\begin{array}{ll}
\text { Peter H. } \\
\text { Kilmarx-S }
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& \text { Kilmarx -S } \\
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\end{aligned} \quad \begin{aligned}
& \text { Peter Kilmarx, Acting Director } \\
& \text { Fogarty International Center }
\end{aligned}
$$

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## Joni L. Rutter, PhD

Director
National Center for Advancing Translational Sciences

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| Helene | Digitally signed by Helene Langevin - |
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| angevin | Date: 2023.02. |

Helene Langevin Director
NCCIH

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Signature

February 28, 2023
Date

Maureen M. Goodenow, Ph.D.
Associate Director for AIDS Research
Director, Office of AIDS Research
National Institutes of Health

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Date

David M. Murray, Ph.D.
Director
Office of Disease Prevention

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| David M. |
| :--- | :--- |
| Murray -S |$\quad$| Digitally signed by David M. |
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| Murray -S |
| Date: 2023.02.23 14:38:45 |
| $-05 ' 00 '$ |

David Murray, Ph.D.
Acting Director
Office of Dietary Supplements

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ICO Director's Name: Christopher J Lync
Title: Acting Director
ICO Name: Office of Nutrition Research

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Franziska B. $\begin{gathered}\text { Digitally signed by } \\ \text { Franziska B. Grieder -s }\end{gathered}$
Grieder -S $\begin{gathered}\text { Date: 2023.02.23 } \\ \text { 12:17:03-05'00' }\end{gathered}$

Dr. Franziska B. Grieder, DVM, Ph.D.
Director
Office of Research Infrastructure Programs

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[^0]:    1 Ten Hagen, K. G., Wolinetz, C., Clayton, J. A., \& Bernard, M. A. (2022). Community voices: NIH working toward inclusive excellence by promoting and supporting women in science. Nature Communications, 13(1), 1682. https://doi.org/10.1038/s41467-022-28665-2

[^1]:    " The congressionally requested "Advancing NIH Research on the Health of Women: A 2021 Conference," October 20, 2021, hosted in conjunction with the Advisory Committee on Research on Women's Health (ACRWH);

[^2]:    Data for employees represented in this reporting are self-identified; those classified in the five racial groups and two or more race group are all non-Hispanic or Latino. Hispanic or Latino employees are included in that category regardless of their race selection(s). Produced by the Office of Equity, Diversity, and Inclusion, Data Analytics Branch. Data are included for onboard employees classified as permanent or temporary full-time, part-time, or intermittent, at the end of fiscal year 2022. Data for Contractors, Fellows, Trainees, Commissioned Corps, and Advisory Council (including El and ZZ pay plans) are not included. Not identified race and ethnicity include missing values. Total calculations shown may not match that derived from detailed data presented due to rounding. Data source: nVision that includes pay period ending $09 / 30 / 22$; downloaded on 02/14/23.

[^3]:    1. Bigman, G., Adebamowo, S. N., Yawe, K. T., Yilkudi, M., Olaomi, O., Badejo, O., Famooto, A., Ezeome, E., Salu, I. K., Miner, E., Anosike, I., Achusi, B., \& Adebamowo, C. (2022). Leisure-time physical activity is associated with reduced risks of breast cancer and triple negative breast cancer in Nigerian women. Cancer Epidemiology, 79, 102195. https://doi.org/10.1016/i.canep.2022.102195
    Bigman, G., Adebamowo, S. N., Yawe, K. T., Yilkudi, M., Olaomi, O., Badejo,
    O., Famooto, A., Ezeome, E., Salu, I. K., Miner, E., Anosike, I., Achusi, B., \& Adebamowo, C. (2022). A matched case-control study of bean intake and breast cancer risk in urbanized Nigerian women. Cancer Causes \& Control, 33(7), 959-969. https://doi.org/10.1007/s10552-022-01584-9

    Boua, P. R., Brandenburg, J. T., Choudhury, A., Sorgho, H., Nonterah, E. A., Agongo, G., Asiki, G., Micklesfield, L., Choma, S., Gómez-Olivé, F. X., Hazelhurst, S., Tinto, H., Crowther, N. J., Mathew, C. G., Ramsay, M., AWI-Gen Study, \& H3Africa Consortium (2022). Genetic associations with carotid intima-media thickness link to atherosclerosis with sex-specific effects in sub-Saharan Africans. Nature Communications, 13(1), 855. https://doi. org/10.1038/s41467-022-28276-x
    Musanabaganwa, C., Wani, A. H., Donglasan, J., Fatumo, S., Jansen, S., Mutabaruka, J., Rutembesa, E., Uwineza, A., Hermans, E. J., Roozendaal, B., Wildman, D. E., Mutesa, L., \& Uddin, M. (2022). Leukocyte methylomic imprints of exposure to the genocide against the Tutsi in Rwanda: a pilot epigenome-wide analysis. Epigenomics, 14(1), 11-25. https://doi. org/10.2217/epi-2021-0310

    Nonterah, E. A., Boateng, D., Crowther, N. J., Klipstein-Grobusch, K., Oduro, A. R., Agongo, G., Mohamed, S. F., Boua, P. R., Choma, S. S. R., Norris, S. A., Tollman, S. M., Bots, M. L., Ramsay, M., \& Grobbee, D. (2022). Carotid atherosclerosis, microalbuminuria, and estimated 10-year atherosclerotic cardiovascular disease risk in sub-Saharan Africa. JAMA Network Open, 5(4), e227559. https://doi.org/10.1001/iamanetworkopen.2022.7559

    Valley-Omar, Z., Maart, S., Seele, K., \& Gray, C. M. (2021). Characterization of the novel HLA-DQB1*05:272 allele in a South African patient by next-generation sequencing. HLA, 97(2), 173-174. https://doi.org/10.1111/tan. 14143
    2. Allyse, M. A., \& Michie, M. (2022). Prenatal genetics in a post-Roe United States. Cell Reports Medicine, 3(7), 100690. https://doi.org/10.1016/i. xcrm.2022.100690

    Crawford, A., Hopkin, A., Rindler, M., Johnson, E., Clark, L., \& Rothwell, E. (2021). Women's experiences with palliative care during pregnancy. Journal of Obstetric, Gynecologic, and Neonatal Nursing, 50(4), 402-411. https://doi. org/10.1016/i.jogn.2021.02.009
    Huang, L., Riggan, K. A., Ashby, G. B., Rivera-Chiauzzi, E. Y., \& Allyse, M. A. (2022). Pregnant and postpartum patients' views of COVID-19 vaccination. Journal of Community Health, 47(5), 871-878. https://doi.org/10.1007/ s10900-022-01118-z

[^4]:    Tolerance to Alcohol: A Critical yet Understudied Factor in Alcohol Addiction. Women more commonly than men experience motivational withdrawal characterized by negative emotional symptoms called hyperkatifeia. Alcohol tolerance appears to reflect underlying neuroadaptive processes critically linked to motivational withdrawal. ${ }^{2}$

[^5]:    1. Giurgea, L. T., Cervantes-Medina, A., Walters, K. A., Scherler, K., Han, A., Czajkowski, L. M., Baus, H. A., Hunsberger, S., Klein, S. L., Kash, J. C., Taubenberger, J. K., \& Memoli, M. J. (2022). Sex differences in influenza: The challenge study experience. The Journal of Infectious Diseases, 225(4), 715-722. https://doi.org/10.1093/infdis/iiab422
    2. National Institute of Allergy and Infectious Disease. (2020, November 9). Statement-NIH Study Finds Long-Acting Injectable Drug Prevents HIV Acquisition in Cisgender Women. [Press release]. https://www.niaid.nih. gov/news-events/statement-nih-study-finds-long-acting-injectable-drug-prevents-hiv-acquisition

    National Institutes of Health. (2021, December 21). NIH celebrates FDA approval of long-acting injectable drug for HIV prevention. [Press release]. https://www.nih.gov/news-events/news-releases/nih-celebrates-fda-approval-long-acting-injectable-drug-hiv-prevention
    Notice of NIH Participation in PAR-17-237: Centers for AIDS Research (P30). https://grants.nih.gov/grants/guide/pa-files/PAR-17-237.html

[^6]:    1. Chalmers, S. A., Ayilam Ramachandran, R., Garcia, S. J., Der, E., Herlitz, L., Ampudia, J., Chu, D., Jordan, N., Zhang, T., Parodis, I., Gunnarsson, I., Ding, H., Shen, N., Petri, M., Mok, C. C., Saxena, R., Polu, K. R., Connelly, S., Ng, C. T., Mohan, C., Putterman, C. (2022). The CD6/ALCAM pathway promotes lupus nephritis via T cell-mediated responses. The Journal of Clinical Investigation, 132(1), e147334. https://doi.org/10.1172/JCl147334
    Jonsson, A. H., Zhang, F., Dunlap, G., Gomez-Rivas, E., Watts, G. F. M., Faust, H. J., Rupani, K. V., Mears, J. R., Meednu, N., Wang, R., Keras, G., Coblyn, J. S., Massarotti, E. M., Todd, D. J., Anolik, J. H., McDavid, A., Accelerating Medicines Partnership RA/SLE Network, Wei, K., Rao, D. A., Raychaudhuri, S., Brenner, M. B. (2022). Granzyme K+ CD8 T cells form a core population in inflamed human tissue. Science Translational Medicine, 14(649), eabo0686. https://doi.org/10.1126/scitransImed.abo0686
    2. Keller, A. V., Torres-Espin, A., Peterson, T. A., Booker, J., O’Neill, C., Lotz, J. C., Bailey, J. F., Ferguson, A. R., \& Matthew, R. P. (2022). Unsupervised machine learning on motion capture data uncovers movement strategies in low back pain. Frontiers in Bioengineering and Biotechnology, 10, 868684. https://doi. org/10.3389/fbioe.2022.868684
[^7]:    1. Faridi, R., Rea, A., Fenollar-Ferrer, C., O’Keefe, R. T., Gu, S., Munir, Z., Khan, A. A., Riazuddin, S., Hoa, M., Naz, S., Newman, W. G., \& Friedman, T. B. (2022). New insights into Perrault syndrome, a clinically and genetically heterogeneous disorder. Human Genetics, 141(3-4), 805-819. https://doi. org/10.1007/s00439-021-02319-7
    2. Klusek, J., Fairchild, A., Moser, C., Mailick, M. R., Thurman, A. J., \& Abbeduto, L. (2022). Family history of FXTAS is associated with age-related cognitivelinguistic decline among mothers with the FMR1 premutation. Journal of Neurodevelopmental Disorders, 14(1), 7. https://doi.org/10.1186/s11689-022-09415-3
[^8]:    1. Gui, Y., Zhou, X., Wang, Z., Zhang, Y., Wang, Z., Zhou, G., Zhao, Y., Liu, M., Lu, H., \& Zhao, H. (2022). Sex-specific genetic association between psychiatric disorders and cognition, behavior and brain imaging in children and adults. Translational Psychiatry, 12(1), 347. https://doi.org/10.1038/s41398-022-02041-6
    2. Landis, R. K., Levin, J. S., Saloner, B., Gordon, A. J., Dick, A. W., Sherry, T. B., Leslie, D. L., Sorbero, M., \& Stein, B. D. (2022). Sociodemographic differences in quality of treatment to Medicaid enrollees receiving buprenorphine. Substance Abuse, 43(1), 1057-1071. https://doi.org/10.1080/08897077.2022.2060424
    3. Johnson, B. N., Kumar, A., Su, Y., Singh, S., Sai, K. K. S., Nader, S. H., Li, S., Reboussin, B. A., Huang, Y., Deep, G., \& Nader, M. A. (2023). PET imaging of kappa opioid receptors and receptor expression quantified in neuronderived extracellular vesicles in socially housed female and male cynomolgus macaques. Neuropsychopharmacology, 48(2), 410-417. https://doi. org/10.1038/s41386-022-01444-9
    4. Bruzelius E., \& Martins, S. S. (2022). US trends in drug overdose mortality among pregnant and postpartum persons, 2017-2020. JAMA, 328(21), 2159-2161. https://doi.org/10.1001/jama.2022.17045
[^9]:    High Consumption of Red Meat Is Associated with Excess Mortality Among African American
    Women. Using data from the Black Women's Health Study, researchers identified 5,054 deaths, which included 1,354 cardiovascular deaths and 1,801 cancer deaths. ${ }^{1}$ Red meat consumption was associated with increased all-cause and cardiovascular mortality among African American or Black women, regardless of whether women consumed processed or unprocessed red meat.

[^10]:    1. Sheehy, S., Palmer, J. R., \& Rosenberg, L. (2020). High consumption of red meat is associated with excess mortality among African-American women. The Journal of Nutrition, 150(12), 3249-3258. https://doi.org/10.1093/jn/nxaa282
    2. Rodriguez, M. I., Martinez Acevedo, A., Swartz, J. J., Caughey, A. B., Valent, A., \& McConnell, K. J. (2022). Association of prenatal care expansion with use of antidiabetic agents during pregnancies among Latina emergency Medicaid recipients with gestational diabetes. JAMA Network Open, 5(4), e229562. https://doi.org/10.1001/iamanetworkopen.2022.9562
[^11]:    1. Brown, L. L., Cohen, B. E., Edwards, E., Gustin, C. E., \& Noreen, Z. (2021). Physiological need for calcium, iron, and folic acid for women of various subpopulations during pregnancy and beyond. Journal of Women's Health, 30(2), 207-211. https://doi.org/10.1089/jwh.2020.8873
    2. Crider, K. S., Wang, A., Ling, H., Potischman, N., Bailey, R. L., Lichen, Y., Pfeiffer, C. M., Killian, J. K., Rose, C., Sampson, J., Zhu, L., Berry, R. J., Linet, M., Yu, W., \& Su, L. J. (2023). Maternal periconceptional folic acid supplementation and DNA methylation patterns in adolescent offspring. The Journal of Nutrition, 152(12), 2669-2676. https://doi.org/10.1093/in/nxac184
[^12]:    Christine Hunter, Ph.D., ABPP (CAPT, USPHS)
    Acting Director, Office of Behavioral and Social Sciences Research
    Division of Program Coordination, Planning, and Strategic Initiatives
    National Institutes of Health

