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2022 TRIENNIAL ADVISORY COUNCIL REPORTS CERTIFYING COMPLIANCE WITH THE NIH POLICY ON INCLUSION GUIDELINES Fiscal Years 2019 - 2021

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2019-2021 Triennial Advisory Council Report Certifying Compliance with Inclusion Guidelines

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I. Background/Overview

A. Mission Statement

The NICHD was established by President John F. Kennedy, with the support of Congress, in 1962 to study the "complex process of human development from conception to old age." The mission of the NICHD is to lead research and raining to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all.

B. Description of NICHD Portfolio

The NICHD was established as the first NIH institute to focus on the entire life process rather than a specific disease or body system. In pursuit of its broad mission, the NICHD conducts and supports initiatives and projects that study physical and intellectual developmental disabilities, fertility, pregnancy, and childhood diseases; supports laboratory research, clinical trials, and epidemiological studies that explore health processes; examines the impact of disabilities, diseases, and variations on the lives of individuals; and sponsors training programs for scientists, health care providers, and researchers to ensure that NICHD research can continue.

Division of Extramural Research (DER)

DER develops, implements, and coordinates cross-cutting, multidisciplinary research activities within NICHD's mission. The research portfolio is quite broad, including biological, behavioral, and clinical research related to conception and pregnancy, normal and abnormal development in childhood, reproductive health, and population dynamics across the lifespan. While NICHD's Division of Intramural Research conducts laboratory and clinical research programs at NIH, DER coordinates and funds research and training programs across the United States and many other countries through grants and contracts.

DER advises the NICHD Director on extramural research and training policies and activities. It also provides scientific peer review, grants management, and program management and oversight for roughly 3,500 competing grant applications and over 450 new and competing awards each year. With a focus on scientific priorities and research integrity, DER leads implementation of extramural policies and procedures for NICHD. Branch overviews and targeted missions are listed below:

Child Development and Behavior Branch (CDBB)

CDBB supports basic and translational research and training that addresses the typical neurocognitive, psychological, behavioral, physical, and social-emotional development and health of infants, children, and adolescents. The branch explores how individual differences in development, as well as family and other social relationships, are affected by emerging societal trends (e.g., increased reliance on technology and digital media), as well as public health emergencies (e.g., COVID-19 pandemic). The branch also supports basic research to identify the mechanisms by which atypical development and related health outcomes in children and adolescents from diverse backgrounds (e.g., low socioeconomic status, racial/ethnic and language minorities) and subpopulations (e.g., individuals with specific learning disorders) arise from or are differentially affected by genetic and environmental risk/protective factors.

Contraception Research Branch (CRB)

CRB supports research and research training concerning the effects of contraception on human health and the development of new and improved methods of male and female contraception to prevent or reduce unintended pregnancies. CRB's research priorities for contraceptive improvement and development include basic research studies that may lead to new methods for inhibiting spermatogenesis, sperm maturation, sperm transport and motility, ovulation, and fertilization; research on multi-purpose prevention technologies and on-demand contraception, including experimental studies in animals and humans; and market and behavioral studies that examine factors that contribute to use or non-use of contraceptive devices and therapeutics under development. In addition, the branch supports research on the biological effects of contraception used as treatments for gynecological disorders and the effects of long-term contraceptive use on health.

Developmental Biology and Structural Variation Branch (DBSVB)

DBSVB focuses on the biological causes and consequences of structural birth defects. Understanding the etiology of these errors in embryonic development provides the most promising route toward improving prevention, diagnosis, and potential treatments for these often-devastating conditions. In addition to studies aimed at identifying and understanding the roles of gene variants, environmental perturbations, and other factors causing structural birth defects, DBSVB supports studies intended to advance our understanding of the fundamental processes underlying the formation and differentiation of the embryo. Major program areas for the branch include developmental genetics, including genomic analysis of human structural birth defects, systems developmental biology, early embryonic development and differentiation, biophysics/biomechanics of development, developmental neurobiology and neural crest differentiation, organogenesis, regeneration, and regenerative medicine. The branch also funds community resources, animal model systems, research tool development, and training to facilitate the efforts of the developmental biology research community.

Fertility and Infertility Branch (FIB)

FIB encourages, enables, and supports research aimed at alleviating human infertility, uncovering new possible pathways to control fertility, and expanding fundamental knowledge of processes that underlie human reproduction. To this end, FIB funds basic, clinical, and translational studies to enhance our understanding of normal reproduction and reproductive pathophysiology, as well as to enable the development of more effective strategies for the diagnosis, management, and prevention of conditions that compromise male and female fertility.

Gynecologic Health and Disease Branch (GHDB)

GHDB aims to improve women's reproductive health by guiding and supporting gynecologic research and career development programs with the vision of a future in which women lead lives free of the effects of gynecologic disorders. The branch portfolio includes studies of healthy functioning endometrium and menstruation, as well as gynecologic disorders including endometriosis, adenomyosis, fibroids, and polycystic ovary syndrome. In addition to abnormal vaginal bleeding and pain throughout the reproductive lifespan, these disorders may affect fertility potential, delay pregnancy, and contribute to maternal morbidity and adverse pregnancy outcomes. The branch has an interest in pelvic organ prolapse as well as urinary and fecal incontinence related to pelvic floor dysfunction. Obstetric fistula and female genital cutting, which affect international and U.S. immigrant communities, are also areas of interest.

Intellectual and Developmental Disabilities Branch (IDDB)

IDBB sponsors research and research training aimed at preventing and ameliorating intellectual and related developmental disabilities. When the institute was created in 1962, one of its primary charges was to encourage investigations of human development throughout the lifespan, with an emphasis on understanding intellectual and developmental disabilities (IDDs). The mission of IDDB is to support a program of research in IDDs, including common and rare neuromuscular and neurodevelopmental disorders, such as Down, Fragile X, and Rett syndromes; inborn errors of metabolism; autism spectrum disorders; and conditions currently and soon-to-be detectable through newborn screening. IDDB supports a diverse portfolio of research projects, contracts, training programs, and research centers dedicated to promoting the well-being of individuals with IDDs at all stages of development.

Maternal and Pediatric Infectious Disease Branch (MPIDB)

MPIDB supports domestic and international research, as well as research training and career development programs related to the epidemiology, diagnosis, clinical manifestations, pathogenesis, transmission, treatment, and prevention of HIV and its complications in infants, children, adolescents, and pregnant and nonpregnant people. As the HIV epidemic has evolved and other infectious diseases have emerged in the United States and globally, the branch has ensured that its funded research reflects these changes and addresses important opportunities and gaps as they arise, including HIV-associated co-infections such as tuberculosis (TB), hepatitis, and malaria. To meet the needs and ongoing challenges of other significant

infectious diseases, MPIDB coordinates research on the epidemiology, natural history, pathogenesis, transmission, treatment, and prevention of congenital infections, such as Zika virus and cytomegalovirus; emerging infectious diseases, such as COVID-19; and vaccine-preventable disease in infants, children, adolescents, and women.

Obstetric and Pediatric Pharmacology and Therapeutics Branch (OPPTB)

OPPTB supports research and research training on the development and use of safe and effective therapeutic drugs and medical devices for children and pregnant and lactating people, including during the postpartum period. The branch promotes basic, translational, and clinical research to improve the safety and efficacy of multiple types of therapeutics, such as pharmaceutical drugs, biologics, medical devices, and regenerative tissue constructs. OPPTB is responsible for developing and supporting comprehensive national efforts to increase the knowledge base for understanding how to treat diseases and conditions appropriately for people during pregnancy, the postpartum period, and lactation, and for children during infancy, childhood, adolescence, and the transition from adolescence to adulthood. This work includes expanding the genomic understanding and phenotypic characterization of drug responses and leveraging advanced multi-omics technologies, novel clinical trial approaches, data science and artificial intelligence methods, and pharmacometric modeling tools to inform prevention and treatment strategies. The goal of these efforts is to ensure that therapeutics are appropriately tested for dosing, safety, and effectiveness for individuals within the populations of interest. Individualized and precision approaches are an important component to treating diseases of these populations.

Pediatric Growth and Nutrition Branch (PGNB)

PGNB serves as the focal point for NICHD extramural research in pediatric endocrinology and nutrition and their impact on health promotion and disease prevention throughout the life course. PGNB also serves as the focal point for NICHD training in child health research. Specifically, PGNB supports research to understand the relevant biological systems and factors that influence the mechanisms of physical and neurological development beginning *in utero* and extending through the lifespan, as well as the role and impact of nutritional status in these systems; the branch also encourages research to explore the external contextual (social, behavioral, and environmental) factors that influence these processes. PGNB further supports translational and systems-based research in the application of behavioral, medical, and nutritional science to develop interventions aimed at promoting health and mitigating disease during critical periods in human development.

Pediatric Trauma and Critical Illness Branch (PTCIB)

PTCIB supports research and training aimed at preventing, treating, and reducing all forms of childhood traumatic injury and critical illness across the continuum of care. This includes research to understand the biobehavioral, psychosocial, and pathophysiologic aspects of trauma; to improve prevention, diagnosis,

and treatment of traumatic injury and critical illness in infants, children, adolescents, and young adults; and to reduce secondary injury and comorbidities.

Population Dynamics Branch (PDB)

PDB supports research, data collection, and research training in demography, reproductive health, and population health. In demography, PDB supports research on the scientific study of human populations, including fertility, pregnancy outcomes, mortality and morbidity (especially maternal, infant, child, adolescent, and young adult mortality and morbidity), migration, population distribution, population stratification (including disparities based on race, ethnicity, sex/gender, and age), nuptiality, family demography, population growth and decline, and the causes and consequences of demographic change. In reproductive health, PDB supports behavioral and social science research on family planning, infertility, and sexually transmitted infections, including HIV/AIDS. In population health, PDB supports research on how demographic, social, economic, institutional, geographic, and other factors influence human health, productivity, behavior, and development, with an emphasis on research using population-representative data or natural and policy experiments using methods that address selection and other sources of bias. Research at multiple levels of analysis, involving interdisciplinary perspectives, incorporating social determinants of health, and elucidating mechanisms leading to health disparities are encouraged.

Pregnancy and Perinatology Branch (PPB)

PPB's goals are to improve the health of women before, during, and after pregnancy; increase infant survival; and ensure the long-term health of mothers and their children. Specifically, the branch supports research to understand fetal development and improve ways to diagnose, treat, and prevent diseases in pregnant people and newborns. As the focal point for NICHD extramural research and training in maternal-fetal medicine, neonatology, and related fields, branch staff also engage with and support investigators to identify knowledge gaps and opportunities for scientific advancement.

Division of Intramural Research (DIR)

The mission of DIR is to plan and conduct NICHD's laboratory and clinical research programs to seek fundamental knowledge about the nature and behavior of living systems through basic, clinical, and population-based research. DIR uses this knowledge to illuminate developmental origins of health and disease and help ensure that women and men have good reproductive health, that children are born healthy, and that people develop to live healthy and productive lives. Research efforts are focused on the acquisition of information that will enhance our understanding of the biology of development and reproduction. Our research program emphasizes the importance of fundamental investigations into the physics, chemistry, and biology of cells; their component parts; and the processes that govern and regulate their function. As part of their investigative focus, the scientific researchers of DIR accord primary importance to the transmission of new information to future generations of scientists. Thirteen affinity

groups comprised of roughly 62 units and sections, as well as the Division of Population Health Research (DiPHR), constitute DIR.

Division of Population Health Research (DiPHR)

DiPHR's mission and vision is built upon several premises:

- Population health research focuses on health and disease outcomes in populations rather than individuals.
- A life course approach, from gametes through adulthood, is important for studying health and disease.
- Hierarchical data are required for measuring environmental exposures affecting individuals, couples, or families.
- Trans-disciplinary research teams and partnerships improve population health.
- Timely translation of research findings is vital for maintaining and improving health.

To accomplish this mission, DiPHR designs and conducts innovative etiologic and interventional research from pre-pregnancy through adulthood, translates research findings into clinical practice or public policy to maximize health and eliminate health disparities, and builds capacity through mentoring and serving our professions. DiPHR aims to be a leader in population health research by focusing on successful reproduction, the health and well-being of pregnant people and their infants, and the optimal growth and development of children and adolescents across the lifespan. With the population as its observational laboratory, the division uses collaboration, discovery, ethics, innovation, interdisciplinary teamwork, and mentoring as core values in fulfilling its mission and vision.

National Center for Medical Rehabilitation Research (NCMRR)

Through basic, translational, and clinical research, NCMRR aims to foster development of scientific knowledge needed to enhance the health, productivity, independence, and quality of life of people with physical disabilities. NCMRR supports research on the following topics: pathophysiology and management of chronically injured nervous and musculoskeletal systems (including stroke, traumatic brain injury, spinal cord injury, and orthopedic conditions); repair and recovery of motor and cognitive function; functional plasticity, adaptation, and windows of opportunity for rehabilitative interventions; rehabilitative strategies involving pharmaceutical, stimulation, neuroengineering approaches, exercise, motor training, and behavioral modifications; pediatric rehabilitation; secondary conditions associated with chronic disabilities; improved diagnosis, assessment, and outcome measures; and development of orthotics, prosthetics, and other assistive technologies and devices.

II. Strategies for Ensuring Compliance

A. Peer Review

The implementation of inclusion guidelines involves the participation of review, program, policy, and grants management staff. Inclusion is first addressed by peer review. Reviewers on NIH peer review panels are given specific guidance on reviewing inclusion on the basis of sex/gender, race, ethnicity, and age when considering clinical research applications. Reviewers evaluate applications for the appropriateness of the proposed plan for inclusion by sex/gender, race, and ethnicity. For NIH-defined Phase III clinical trials, enrollment goals are further assessed for plans to conduct valid analyses of intervention effects among sex/gender, racial, and ethnic groups. Scientific review groups assess whether the proposed study population and design for each application are acceptable or unacceptable with respect to all NIH inclusion policies, and these determinations are documented in the summary statement of the review. If any aspect of inclusion is unacceptable, there is a bar to funding; awards are not issued until the concerns are resolved. The NACHHD Advisory Council performs a second level of review of applications and issues recommendations for funding to the NICHD Director based on the overall impact scores, percentile rankings, and summary statements for applications; NICHD's research priorities; and NIH policies.

B. Program Monitoring and Grants Management Oversight

Prior to an award, program officials are responsible for reviewing the summary statement and inclusion information in the application. If any aspect of inclusion is deemed unacceptable, by either the review group or program staff, principal investigators are required to resolve these concerns prior to funding; awards are not issued until acceptable resolutions are received. Program staff monitor actual enrollment in annual progress reports and provide consultation when actual enrollment deviates substantially from planned enrollment. For clinical trials, NICHD program officials are required to assess their risk and issue a rating of low, medium, or high that guides program oversight and monitoring of the trial. For NIH-defined Phase III clinical trials, program officials monitor the requirement for sex/gender and race/ethnicity valid analyses in applications and annual progress reports. Grants management staff ensure that appropriate terms and conditions of award are included in the Notice of Award, and that this information is appropriately documented in the official grant file.

C. Intramural

All intramural clinical research studies require investigators to provide plans for the appropriate inclusion of women and minorities and/or a justification whenever representation is limited or absent. These plans are considered during the scientific review process. With the annual scientific review and IRB review renewal, the investigator documents the number, sex/gender, race, and ethnicity of those who were enrolled during the past year; any issues with enrollment are addressed and plans to increase recruitment are reviewed by both the Institute and the pertinent IRB. The Clinical Center's Office of Protocol Services (OPS)

coordinates annual reporting of demographic participant data to the Office of Extramural Research (OER) and the Office of Research on Women's Health.

D. Training Approaches

NICHD program, review, grants management, and contracts management staff participate in NIH training opportunities relevant to the policies on inclusion; newly hired staff are required to complete these trainings as soon as possible after assuming their position. Specifically, NICHD Program Officials and Scientific Review Officers attended the 2020 Inclusion Training for Program Staff and the 2020 Inclusion Training for Review Staff in April 2020. Staff may access these archived trainings on the NIH staff intranet. Other training opportunities are available live, via videocast, archived video, and/or computer-based programs.

In addition to training opportunities offered by NIH, the NICHD Office of Extramural Policy (OEP) monitors participation and provides information about upcoming training opportunities. The institute is involved in continuous training and outreach efforts with staff and the research community. These efforts are developed, overseen, and monitored by OEP, which also serves as a resource for staff and the extramural community. In October 2019, NICHD conducted training with all Extramural Staff on the consent to participate in NIH clinical research studies, consent revisions, and consent language. In 2020, NICHD provided training on the Clinical Trial Risk Tracking policies, procedures, and processes for monitoring risk. OEP staff also provide individualized one-on-one tutorials on the Human Subjects System (HSS) for tracking enrollment for active grants.

III. Analysis and Interpretation of Data

In 2018, the NIH Office of Extramural Research (OER) began requiring a uniform structure for all IC Triennial Inclusion Reports to enhance the consistency and comparability of the content and ensure compliance with NIH policies. This report follows those organizational, formatting, and table-labeling guidelines. OER generates standardized tables of aggregated annual inclusion data for FYs 2019 – 2021 by Institute or Center (IC) that can be shared in each IC's report. From those tables, we have appended the ones listed on the following page. These tables were selected to meet OER requirements and/or because they best depict the enrollment data for research projects and clinical trials supported by NICHD. (Please note that we are not able to change the formatting, table numbers, or titles.)

NICHD Enrollment Tables Included in Appendix A

Inclusion Data Records (IERs)	
Table 2-1	Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Clinical Research Reported Between Fiscal Years 2019 and 2021
Table 2-2	Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Phase III Trials Reported Between Fiscal Years 2019 and 2021
Table 2-3	Valid Analysis Requirements for NIH-Defined Phase III Extramural Grants Reported Between Fiscal Years 2019 and 2021
Enrollment by Sex/Gender	
Table 3-1-A	Total Enrollment for All NIH-Defined Extramural and Intramural Clinical Research Between Fiscal Years 2019 and 2021
Table 3-2-A	US Site Enrollment for All NIH-Defined Extramural and Intramural Clinical Research
Enrollment by Race	
Table 4-1-2-B	Total US Site Enrollment of NIH-Defined Clinical Research
Enrollment by Ethnicity	
Table 4-1-2-C	Total US Site Enrollment of NIH-Defined Clinical Research
Total Enrollment	
Table 5-1-1-C	Enrollment for All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity
Table 5-1-2-C	US Site Enrollment for NIH-Defined Extramural and Intramural Clinical Research, Sex/Gender by Race and Ethnicity
Table 5-2-2-C	ALL Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity
Age Tables	
Table 1	Age Distribution Using Broad Age Groups for NIH-Defined Extramural and Intramural Clinical Research Reported for Fiscal Year 2021
Table 2	Age Distribution Using Detailed Age Groups for NIH-Defined Extramural and Intramural Clinical Research Reported for Fiscal Year 2021

A. Inclusion Data Records (IERs)

Table 2-1 shows the number of inclusion data records (IERs) for all NICHD clinical research for Fiscal Years (FYs) 2019 – 2021; Table 2-2 shows the subset of those IERs that were Phase III clinical trials. In 2019, 1,062 of the 1,587 IERs for NICHD grants, contracts, and intramural projects had enrollment data; the 525 IERs without enrollment represent projects for which recruitment had not yet begun or enrollment had not yet been reported (Table 2-1). Among those 2019 IERs, 80 were Phase III clinical trials, and 45 of those had enrollment data (Table 2-2). While the total number of IERs increased slightly in subsequent years, the number of records with enrollment was similar: 1,073 in 2020 and 1,026 in 2021.

In addition, Tables 2-1 and 2-2 identify the number of IERs for NICHD clinical research and Phase III trials at domestic ("US Site IERs") and foreign ("Non-US Site IERs") sites. The vast majority of NICHD clinical research in FYs 2019 – 2021 was domestic, with records from U.S. sites accounting for 87% - 89% of all clinical research IERs and 82% - 89% of IERs for Phase III trials.

Tables 2-1 and 2-2 also identify the annual number of records involving only one sex/gender.[1] Among all NICHD clinical research IERs with enrollment in FYs 2019-2021, between 22% and 25% involved only women ("Female-Only IERs"), compared to 3% - 4% that involved only men ("Male-Only IERs") (Table 2-1). Among Phase III clinical trials with enrollment, no records involved only men, while 38% - 40% involved only women (Table 2-2). These sex/gender differences in NICHD enrollment are expected, as they are aligned with the requirement that inclusion of women be "appropriate to the scientific question under study." The scientific research priorities identified in the NICHD Strategic Plan 2020 include research on healthy pregnancies, early human development, gynecologic health, and therapeutics for pregnant and lactating people, all of which require greater enrollment of women than men.

Table 2-3 identifies the annual number and percentage of Phase III Clinical Trial IERs that required valid analysis by race/ethnicity or sex/gender. Importantly, these data include IERs both with and without enrollment (i.e., planned studies in addition to those that have begun enrolling participants), as plans for valid analysis are included in Phase III trial applications. For FYs 2019 – 2021, between 84% and 93% of NICHD Phase III IERs required valid analysis by race or ethnicity, while 72% - 93% required valid analysis by sex or gender (Table 2-3). The lower proportion of trials requiring valid analysis by sex/gender in some years is aligned with the disproportionate enrollment of women that is appropriate for NICHD science.

[1] This category can refer to either sex or gender. Per the NIH FAQ on Inclusion by Sex/Gender: "NIH uses sex/gender to indicate that either sex or gender may be reported for inclusion enrollment purposes…. When collecting and reporting information about sex/gender, it's important to consider what is most relevant to the scientific question under study… If both sex and gender identity are collected, investigators may choose which one to report based on the scientific question(s) that are the focus of the study."

B. Enrollment Data by Sex/Gender: Inclusion of Women

Table 3-1-A shows enrollment numbers and percentages by sex/gender for all NICHD-supported clinical research studies in FYs 2019-2021. In all years, women were most participants, ranging from 56.4% - 63.3% of people enrolled (Table 3-1-A). Between 1.7% and 2.4% of individuals were unidentified with respect to sex/gender. These sex/gender proportions are consistent with those in previous reporting periods and with the scientific priorities of NICHD. Because a relatively large proportion of NICHD studies include only women, we also analyzed the proportion of women enrolled in NICHD clinical research when all single-gender (i.e., “female-only” or “male-only”) projects were excluded. Women remained most participants in studies enrolling both men and women, ranging from 50.3% - 60.9% of participants (Table 3-1-A Supplement).

Table 3-2-A shows enrollment in NICHD clinical research at U.S. sites for FYs 2019-2021. Women also were most domestic participants, but the proportions were smaller than in all research, ranging from 54.9% to 61.5% of people enrolled (Table 3-2-A). These data suggested that women made up a larger percentage of foreign than domestic participants in NICHD clinical research. To compare foreign and domestic enrollment by gender, we calculated the proportion of male and female participants by site, excluding single-gender studies (Table 3-2-A Supplement). For domestic NICHD clinical research studies, women were between 49.7% and 54.9% of people enrolled, while for foreign studies, women ranged between 53.0% - 63.2% (Table 3-2-A Supplement).

Our supplemental analyses also revealed that the percentages of individuals in the “unknown” sex/gender category were substantially larger at U.S. sites than at non-U.S. sites. In domestic studies, persons in the “unknown” category ranged from 4.1% - 6.4% of people enrolled, compared to a range of 0.2% - 0.8% in foreign studies (Table 3-2-A Supplement). One possible explanation for this difference is that studies at U.S. sites are more likely to collect data on participants’ sexual orientation and gender identity and include sexual and gender minority (SGM) participants than studies at foreign sites. Because there are only three options for reporting inclusion by sex/gender (male, female, and unknown), some principal investigators (PIs) opt to report SGM participants in the “unknown” category.

C. Enrollment Data by Race and Ethnicity: Inclusion of Minorities

Because race and ethnicity are social categories with meanings and significance that vary across cultures and countries, our summary and analysis of NICHD’s inclusion of racial/ethnic minorities focuses mostly on data from U.S. sites. In NIH inclusion data, race and ethnicity are reported separately. Hence, data by race includes Hispanics/Latinos in the racial category with which they identify; similarly, Hispanics/Latinos can be of any race. Total minority enrollment for NIH clinical research includes all non-white participants, including people identifying as more than one race, and white Hispanics/Latinos (as Hispanics/Latinos of other races would already be included).

Tables 4-1-2-B and 4-1-2-C show inclusion in Domestic NICHD clinical research by race and ethnicity, respectively, for FYs 2019 – 2021. Nearly half of participants in domestic NICHD clinical research studies were minorities, ranging from 46.4% - 47.0% (Table 4-1-2-B). Moreover, the proportion of minority participants, by both race and ethnicity, was remarkably consistent across years, varying at most by just over one-half of one percent. Between 33.6% and 34.0% of people enrolled at U.S. sites were racial minorities (Table 4-1-2-B), and 16.5% - 17.1% identified as Hispanic/Latino (Table 4-1-2-C).

D. Enrollment Data by Sex/Gender, Race, and Ethnicity: Overall Inclusion

Tables 5-1-1-C, 5-1-2-C, and 5-2-2-C provide the numbers and percentages of annual enrollment for FYs 2019 – 2021 by sex/gender, race, and ethnicity for all NICHD clinical research (Table 5-1-1-C), clinical research at U.S. sites (5-1-2-C), and Phase III clinical trials (5-2-2-C). All three tables provide aggregated annual enrollment numbers and proportions stratified by sex/gender and then cross tabulated by ethnicity (Hispanic and non-Hispanic), race, and being a member of any minority group (racial or ethnic).

For example, Table 5-1-1-C shows that in FY 2021, 75.7% of women enrolled in NICHD clinical research were either a racial or ethnic minority, while among men the proportion of minorities enrolled was slightly lower (65.7%). By race, the distribution of women enrolled in NICHD clinical research in FY 2021 was 37.2% Black/African American, 30.6% Asian, 17.1% White, 1.4% More than One Race, 0.2% American Indian/Alaska Native, 0.1% Native Hawaiian/Pacific Islander, and 13.4% of unknown race. By ethnicity, 90.1% of women identified as not Hispanic, 7.5% as Hispanic/Latino, and 2.4% were of unknown ethnicity. Similar breakdowns by sex/gender and race or ethnicity are possible for men and people of unknown gender in each broad type of research.

E. Enrollment Data by Age: Inclusion Across the Lifespan

In response to the 21st Century Cures Act, NIH revised its policies on the inclusion of children, expanding the requirement to cover inclusion of people of all ages unless exclusion is scientifically or ethically justified. The revised NIH Inclusion of Individuals Across the Lifespan policy, which applies to all competing applications submitted on or after January 25, 2019, also requires that deidentified individual-level participant data on sex/gender, race, ethnicity, and age at enrollment be provided in progress reports. Fiscal year 2021 is the first year that age enrollment data have been available for reporting. The data by age are not complete, as many awards issued in FY 2021 were not subject to the policy because they were submitted as competing applications prior to 2019. In total, enrollment data by age in FY 2021 were required and available for 74,271 participants in NICHD clinical research (Table 1). Of those participants, 69.1% were children (<18 years), 29.5% were adults (18-64 years), 0.2% were older adults (65+ years), and 846 were unknown (Table 1). These age distributions are aligned with NICHD's scientific research priorities, many of which focus on children, the transition to adulthood, and the childbearing years.

Table 2 provides FY 2021 enrollment data by narrow age groups for NICHD clinical research, which enables a detailed analysis of the ages of child participants. Among the 51,310 children enrolled in NICHD clinical research, 41% (N= 20,890) were less than one year of age, 34% were ages 1 – 5 years (N=17,354), 18% were ages 6 – 12 years (N=9,265), 5% were ages 13 – 15 years (N=2,372), and 3% were ages 16-17 years (N=1,429).

F. Enrollment Data by NIH Research, Condition and Disease Categorization (RCDC)

To support reporting of human subjects' research, NIH has developed a system to display enrollment data according to the NIH Research, Condition and Disease Categorization (RCDC) category. This system enables filtering the inclusion database by RCDC code to examine enrollment data for clinical research projects and clinical trials on a particular condition or disease (e.g., enrollment data for studies on Down Syndrome). Inclusion enrollment data by RCDC category are available through this link: https://report.nih.gov/RISR/#/.

G. Summary

The goal of the NIH inclusion policy is not to satisfy any quotas for proportional representation, but instead to conduct biomedical and behavioral research in such a manner that the scientific knowledge acquired will be generalizable to the largest possible population in the United States. Hence, when assessing inclusion data, enrollment figures are not meant to be comparable to national census estimates. In addition, since enrollment data are aggregated, but what constitutes ethical and appropriate science is study-specific, our ability to draw conclusions from these data are limited. Determining whether inclusion is appropriate depends upon the scientific questions addressed in a particular study and the prevalence of the disease, disorder, or condition under investigation. These factors are assessed on a study-by-study basis by NICHD program staff when they review the summary statements of applications and the progress reports for awarded clinical research projects. Finally, it is important to remember that data on the inclusion by sex/gender, race, and ethnicity are based on self-identification by the participants, which accounts for many of the unknowns reported in these data tables.

IV. Highlighted Research Areas Relevant to Inclusion

Selected highlights from NICHD's research, outreach, and collaborative efforts between FY2019-2021 that are relevant to inclusion are listed below. These activities illustrate the institute's continued commitment to the inclusion of women, minorities, and individuals across the lifespan in research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all.

A. COVID-19 Research

Since the beginning of the COVID-19 pandemic, NICHD has worked to understand the effects of the virus among populations central to the NICHD mission, including pregnant and postpartum women, children and adolescents, and people with disabilities. The institute has generated research proposals and projects; collaborated with other NIH institutes, centers, and offices (ICOs) and federal agencies; and initiated studies to help build a research base on the SARS-CoV-2 virus.

Addressing the Needs of Women During the Pandemic

As the COVID-19 pandemic continued in 2021, NICHD led research to better address the needs of women. The results have helped gather evidence for women and healthcare providers to make informed decisions.

At the beginning of 2021, NICHD Director Diana W. Bianchi, M.D., and colleagues called for greater inclusion of pregnant and lactating people in COVID-19 vaccine research. Pregnant and lactating individuals need to make important decisions about their healthcare, just like everyone else. However, longstanding obstacles to including pregnant and lactating people in vaccine research, such as classifying them as a "vulnerable" research population, requires them to make decisions without the benefit of scientific evidence.

NICHD took important steps toward providing evidence to help pregnant women make decisions about vaccination. One study found that vaccines are effective in pregnant women. Inclusion of these populations in research led to the finding that pregnant women are more likely than their nonpregnant peers to have severe infection with COVID-19. The study also found that antibodies produced after vaccination travel across the placenta and through breastmilk—conferring immunity to newborns. Another study found no serious adverse effects from the vaccines in breastfeeding women or their children. The findings add evidence about the safety of COVID-19 vaccination for nursing mothers and their children.

Researchers described COVID-19 severity in a large, diverse group of pregnant patients in an observational cohort study of women who delivered at any of 33 NICHD Maternal Fetal Medicine Unit (MFMU) sites (six community and 27 academic sites) in 14 states between March 1, 2020, and July 31, 2020. Disease severity was classified by criteria established by the National Institutes of Health. The study

participants consisted of 1,219 pregnant women with a singleton gestation and a positive test result (according to a molecular or antigen test) for severe acute respiratory syndrome coronavirus 2 (SARS-COV-2) at any point during pregnancy. Both symptomatic and asymptomatic patients were included. Almost half – 47 percent – of participants were asymptomatic. Of the remaining participants, 27 percent were mildly affected, 14 percent moderately affected, 8 percent had a severe case, and 4 percent were critical. There was no trend in COVID-19 severity based on race or ethnicity. Women with severe or critical disease were more likely to be older, have higher body-mass index, and have underlying medical comorbidities such as asthma, chronic hypertension, and pregestational diabetes. Four maternal deaths were attributed to COVID-19. Women with severe-critical COVID-19 were more likely to have adverse perinatal outcomes, especially venous thromboembolism, cesarean birth, hypertensive disorders of pregnancy, and preterm birth. (2021).

The institute also launched a study to evaluate potential long-term effects of COVID-19 in pregnancy. Researchers will follow people who had SARS-CoV-2 infection (asymptomatic or symptomatic) during their pregnancies over a four-year period. The study team will also evaluate the infants who were exposed to SARS-CoV-2 *in utero* for possible neurologic symptoms and cardiovascular conditions as they grow older.

New research shows that the maternal immune response to SARS-CoV-2 is affected by the sex of the fetus. Previous studies have shown that males have a higher prevalence and increased severity of COVID-19 than females. Researchers analyzed 68 pregnancies, observing placental cells and antibody stimulation following maternal infection with SARS-CoV-2. After SARS-CoV-2 infection, pregnant individuals with male fetuses showed increased levels of cellular receptors on placental cells, protein signals resulting from viral infection, and anti-inflammatory compounds secreted by the immune system. Pregnant individuals with male fetuses also showed reduced levels of maternal antibodies against SARS-CoV-2 and impaired transfer of antibodies across the placenta. This study shows that the sex of the fetus may affect maternal immune response to SARS-CoV-2 (2021).

NICHD also funded studies to explore potential links between COVID-19 vaccination and menstruation. Some women have reported changes in menstruation after receiving the vaccines. The research, which will include five projects in geographically and demographically diverse populations, will give people more information about what to expect after vaccination and may help reduce vaccine hesitancy.

Leading Research on COVID-19 Transmission in Schools

NICHD-funded scientists, as part of NIH's RADx-UP program, are exploring how COVID-19 is transmitted in schools to gather information to help students and faculty attend school safely during the pandemic.

In April and July, NICHD announced funding for new projects to identify ways of safely returning students and staff to in-person schools in areas with vulnerable and underserved populations. The projects aim to address the needs of children with unequal access to COVID-19 testing, as well as those who face barriers to attending school remotely, such as lack of computer or internet access. Without in-person schooling, many children miss out on school-based meals, speech or occupational therapy, and after-school programs. Loss of such services disproportionately affects minorities, socially and economically disadvantaged children, children with disabilities, and those with medical complexities. Several papers from these projects were published later in the year.

One NICHD-supported study tracked COVID-19 transmission in several North Carolina school districts as the schools restarted in-person instruction for the 2020–2021 school year. The researchers found that with basic mitigation strategies, such as mask wearing and physical distancing, COVID-19 transmission in schools was very low—even when transmission in the surrounding communities was high. The findings indicate that schools practicing basic mitigation strategies can safely stay open even in areas with high community transmission.

NICHD-supported scientists in St. Louis also investigated ways to optimize safety of in-person schooling for children with intellectual and developmental disabilities (IDDs). A virtual learning environment can be difficult for children with IDDs and their families, but people with IDDs may also be more vulnerable to severe disease and complications if they are infected with the coronavirus. The study found that weekly saliva testing and other safety measures in schools—such as mask wearing and reduced class sizes—were effective in protecting staff, children, and their families.

COVID-19 in Underserved Populations (UPs)

People with disabilities—whether they be intellectual and developmental disabilities (IDDs), physical disabilities and movement problems, or learning and other disabilities—have been a focus of NICHD research since the institute's founding. Because disparities in outcomes and disproportionate effects among people with disabilities has been more pronounced during the pandemic, the institute is redoubling its efforts to better understand why and what can be done to mitigate these issues. NICHD is now studying how people with IDDs are disproportionately affected by COVID-19.

Developing & Evaluating COVID-19 Treatment Strategies for Pregnant People and Children

NICHD supports and conducts research to identify effective ways to diagnose and treat COVID-19. In addition, NICHD-supported researchers are investigating treatments for specific groups, such as pregnant women and children. Pregnant women are at higher risk for severe illness from COVID-19, but information about treatments for pregnant women is lacking. One NICHD- and NIH-supported study is evaluating the effects on pregnancy of a drug called remdesivir, which is approved by the U.S. Food and Drug

Administration for the treatment of COVID-19 in adults and children over age 12. Remdesivir can be prescribed to pregnant women if their physicians believe the drug may benefit them. However, physicians currently lack scientific evidence for the safety and efficacy of remdesivir for treating pregnant women with COVID-19. Studies like these will give healthcare providers scientific evidence to make more informed decisions when treating pregnant patients.

SARS-CoV-2 infection during pregnancy has also been linked to complications that may involve or be reflected in the placenta, including preeclampsia and preterm birth. However, because researchers used a variety of methods to diagnose infection of the placenta, it is difficult to aggregate data and compare results from different studies. To address this issue, NICHD convened an expert panel to recommend standardized criteria for defining placental infection. The panel's recommendations will make it easier to synthesize information across studies and, in turn, contribute to improved understandings of the risks of placental infection with SARS-CoV-2.

To learn more about SARS-CoV-2 infection in children, NIH launched a new research effort in March called CARING for Children with COVID. The program, which is co-led by NICHD and NHLBI, is investigating why some children are at greater risk for infection and why symptoms vary. Researchers are also studying how to identify children at risk for severe illness, including multisystem inflammatory syndrome in children (MIS-C). Although each study supported by CARING for Children with COVID has slightly different goals, all will collect data on a core set of health measures that can later be analyzed across studies. Data will be made available to allow researchers to conduct additional analyses and make more discoveries.

One study supported by this program helped explain how a treatment for MIS-C works. The treatment, called intravenous immune globulin (IVIG), depletes specific immune cells—activated neutrophils—that drive inflammation. Although more work is needed to learn why some MIS-C patients need additional anti-inflammatory treatments, the findings can help healthcare providers as they determine the most effective methods to treat patients with MIS-C.

B. Research Addressing Health Disparities

NICHD has a long history of supporting health disparities research—initially in the context of women's health, children's health, and the health of persons with disabilities, but also more recently in studies on timely issues, such as the COVID-19 pandemic.

NICHD-supported researchers reported that distributing COVID-19 vaccinations by age alone, as many states did in early 2021, may have contributed to racial/ethnic disparities in COVID-19. The researchers' models suggest that targeted distribution of COVID-19 vaccines to residents of all ages in the highest-risk neighborhoods may have been more equitable in reducing mortality risk than distribution by age-alone, as

older U.S. populations are disproportionately white, while people of color, at any age, are at higher risk of dying from COVID-19. These findings will help policy makers in areas where COVID-19 vaccines continue to be scarce.

The institute continued its support of research on health disparities in pregnancy and maternal health. Researchers supported by NICHD found that eviction during pregnancy was linked to poor birth outcomes, such as preterm births or newborns with low birth weight. The study team noted that these outcomes may have generational consequences because low birth weight and preterm infants are at higher risk for future health problems, such as diabetes and cardiovascular disease. The authors suggest that housing assistance for pregnant women can improve maternal and infant health. Another NICHD-funded team found that Medicare expansion was linked to improvements in pre-pregnancy mental health. The work suggests that expanding health insurance coverage to low-income people before pregnancy is beneficial.

NICHD research also helps pregnant women and families around the globe. Worldwide, preterm birth is the leading cause of death among children under five years old, according to the World Health Organization. Researchers in NICHD's Global Network for Women's and Children's Health Research conducted an analysis that confirmed the safety of daily low-dose aspirin to prevent preterm birth. The study evaluated the low-cost drug in first-time mothers in low- and middle-income countries.

The institute also supports general women's health research. One NICHD-funded team reported that the risk and extent of fibroids—benign tumors of the uterus—are associated with ancestry to distinct regions and populations. For Black women, West African ancestry was associated with risk for a single fibroid, while East African ancestry was associated with risk for multiple fibroids. For White women, Northern European Ancestry was protective against fibroids, while West African ancestry was associated with a risk for larger fibroids. Further studies on these differences will improve our understanding of risk factors for various characteristics of fibroids.

Improving the health of all children is also a priority for NICHD. Researchers in NICHD's Pediatric Trials Network conducted an internal evaluation of the racial and ethnic representation of all the pediatric drug studies supported by the Best Pharmaceuticals for Children Act (BPCA), a legislative mandate carried out in part by NICHD-led research. The study found no evidence of racial and ethnic bias in enrollment for BPCA studies, fulfilling the institute's expectation to ensure adequate representation of all children.

A new study characterized enrollment in observational studies of Duchenne Muscular Dystrophy (DMD). DMD is a disorder characterized by progressive muscle degeneration and weakness. Researchers examined the U.S. racial and ethnic composition of 14 U.S. based observational DMD studies. All studies cited comprised of >70% participants who self-identified as While/Caucasian, with the majority having few

racial/ethnic minority participants. Black/African American participants were particularly limited, with all by one study reporting cohorts of <5%. The numbers of American Indian/Alaska Native and Native Hawaiian/Pacific Islander participants were less than <4% in all cases. Hispanic/Latino ethnicity representation was highly variable, ranging from 3.3-26.5% of cohorts. The limited diversity found in observational studies is likely repeated in clinical trials, meaning that the investigational therapeutic is not being evaluated in a cohort that is representative of the entire population.

NICHD supports racial and ethnic diversity in studies funded under the Best Pharmaceuticals for Children Act. Testing the safety and efficacy of medications in children presents significant scientific, clinical, ethical, technical, and logistical challenges. Under the Best Pharmaceuticals for Children Act (BPCA), NIH works with industry and academic experts to identify off-patent drugs in need of further study, prioritizes needs in pediatric therapeutics, and sponsors clinical studies of on-patent drugs to establish safety and efficacy information for children. Researchers analyzed data obtained for 10,918 participants enrolled in 33 federally funded studies of drugs and devices conducted from 2008 through June 2020. Enrollment of individuals from racial and ethnic minority groups was comparable to or higher than expected for all groups except Asian Americans. American Indian and Alaska Native and multiracial enrollment significantly increased over the time period.

A team of NICHD researchers examined risk factors in adolescence for the development of elevated blood pressure and hypertension in American Indian and Alaskan Native adults. American Indians and Alaska Natives in the United States have substantially higher levels of hypertension than non-Hispanic Whites; therefore, this study examined whether the risk factors for hypertension, obesity, and overweight among AI/AN adolescents differs from those of other U.S. racial/ethnic groups, namely Hispanic, non-Hispanic White, and non-Hispanic Black adolescents. Using data from the National Longitudinal Study of Adolescent to Adult Health, which includes the largest longitudinal sample of AI/AN adolescents in the United States, this study found that, among AI/AN individuals, but not for individuals from other U.S. racial/ethnic groups, financial instability during adolescence is associated with hypertension during adulthood. Parental obesity during adolescence, which is a significant risk factor for hypertension during young adulthood for non-Hispanic Whites, is not a risk factor for AI/AN adolescents. High parental education was protective against hypertension among non-Hispanic Blacks, but not for AI/AN groups. Identifying risk factors during adolescence that are amenable to intervention are necessary to address health disparities in hypertension and high blood pressure among American Indians/Alaska Natives.

Another NICHD study suggests that male youths living in concentrated disadvantaged neighborhoods disproportionately witness and experience violence. Exposure to high levels of violence can increase the risk for both committing and being a victim of violence and can shape behaviors that increase the risk of substance abuse, injury, incarceration. Researchers studied these issues among Black male youths, aged

14-19 years, that were part of a sexual violence prevention program trial. The participants expressed visions of manhood that included many traditionally masculine attributes. The participants also expressed the importance of nontraditional attributes of masculinity, such as the role of emotional expression, moral agency, and emotional vulnerability. The most common definition of manhood focused on the theme of responsibility and the role of provider. Three influences emerged as shaping their experiences of manhood: 1) family and community connections, 2) interpersonal and structural racism, and 3) racial pride. The role of family, particularly fathers and community father figures, was reported as invaluable in aiding youths in understanding manhood and a potential path to get to manhood, as well as navigating racial identities.

Small-scale studies and observations suggest that transgender people are at a heightened risk for criminal victimization. However, there has been limited national data on this issue. In 2016, the National Crime Victimization Survey (NCVS)—the nation's primary source of nonfatal criminal victimization statistics—began documenting the sexual orientation and gender identity of respondents. To estimate the prevalence of personal and household victimizations among transgender people in the United States, NICHD researchers analyzed pooled data from the 2017 and 2018 NCVS. The scientists found that transgender people experienced violence at a higher rate compared with cisgender people. Between transgender and cisgender women, there was a large and statistically significant difference in the percentage of violent victimizations believed to be hate motivated. Rates of victimization did not differ between transgender women and men. There were no disparities in reporting victimizations to authorities; only about half of the victimizations of both transgender and cisgender people were reported.

Another NICHD study examined growth in transgender/gender-diverse youth during first year of gender-affirming treatment. Transgender/gender-diverse (TGD) youth are treated early in their pubertal development with gonadotropin-releasing hormone agonists (GnRHa) to stop innate puberty and to prevent the development of secondary sex characteristics. The suppression of normal sex steroid levels, which is the basis of the therapy, may have other physiological effects on linear growth rate (height velocity, HV) which is also dependent on sex steroids. Despite its importance, there are limited data regarding growth in this population, and providers have previously relied on HV data derived from children treated with GnRHa for central precocious puberty, who may have different HV responses to GnRHa compared to TGD youth with normal growth and pubertal development. This study describes the HV in the first year of GnRHa treatment in pubertal participants in a large multisite cohort of TGD youth in the U.S. Overall, TGD youth treated with GnRHa early in their pubertal development had growth rates like that of prepubertal children. However, when GnRH therapy was initiated at later pubertal development HV was significantly reduced compared to age matched norms. Limitations of this study include a relative lack of diversity of participants and lack of data on bone age and pretreatment HV. Although the HV in the first year of GnRHa treatment is informative, its ability to predict adult height is limited. Long-term follow-up of this cohort will determine the ultimate effects of gender-affirming treatment on adult height. The researchers

believe this may inform clinical care and clinical guidelines, and better equip clinicians to counsel transgender adolescents and their parents.

NICHD supported a study to examine gender differences in mortality from drug overdose in the U.S. Over the past 25 years, deaths from drug overdose have reached unprecedented levels. Researchers examined death certificate data covering this period from the National Center for Health Statistics (NCHS). Between 1990 and 2017, drug overdose mortality increased substantially for both men and women, with rates among men increasing from 4 to 29 deaths per 100,000, and rates among women increasing from about 3 to 14 deaths per 100,000. In 2017, life expectancy at birth was 0.8 years lower for men and 0.4 years lower for women than it would have been in the absence of drug overdose deaths. By 2017, higher drug overdose mortality among men relative to women accounted for 17% of women's life expectancy advantage. During the early stages of the drug epidemic, when prescription opioids were the primary driver of drug overdose deaths, gender differences in overdose deaths narrowed. However, later when the epidemic transitioned to illegal drugs, gender differences widened. The gender differences occurred among all racial/ethnic groups in the study.

A new study funded by NICHD explored ways in which reproductive coercion may lead to an increased risk of unintended pregnancy among women with disabilities. Nearly 1 in 10 women have a disability. Women with severe physical disabilities are about 50% more likely to experience intimate partner violence (IPV). In some cases of IPV, a partner pressures or forces a woman to become pregnant against her wishes. In a first-of-its-kind study, scientists interviewed nine women with disabilities who had unintended pregnancies because of IPV. Six women had experienced physical violence. All the women believed that having a disability increased their risk of IPV. Eight of the nine women reported that healthcare providers never asked them about IPV, and four said that their healthcare providers did not discuss birth control options with them after they gave birth. The women noted a lack of information and resources to support women with disabilities. Several women said that safety planning would have helped them, especially identifying means of transportation to a shelter and ensuring access to needed medical supplies and care if they left their partners. The results point to a need for training healthcare providers to screen women with disabilities for IPV and provide resources for safety planning.

NICHD has also funded a 15-year longitudinal investigation of links between early lower language skills link and adversity to later mental health problems. About half of adults in the United States have experienced early childhood adversity, which can include abuse and neglect, exposure to violence, family poverty, and deprivation (lack of learning and social opportunities). Children who experienced early adversity are more likely to have mental and behavioral problems, and early deprivation specifically affects self-control, language development, and reading ability. Researchers wanted to learn more about the pathways linking early deprivation to mental and behavioral problems. For a group of 2,301 children, the researchers used data collected at ages 1, 3, 5, 9, and 15. They looked at how the measures of deprivation and threat in

these data affected the children's levels of anxiety, depression, and withdrawal. The researchers found that the link between deprivation and mental health problems was mediated by language ability. These results suggest that early interventions to increase language skills could lower children's risk for mental health problems.

Prenatal exposure to alcohol is linked to a range of adverse effects, including fetal alcohol spectrum disorders, neurodevelopmental disabilities, miscarriage, stillbirth, and sudden infant death syndrome. NICHD researchers studied alcohol use among pregnant and early postpartum women in South Dakota and North Dakota. A total of 4,877 pregnant women participated. These women were recruited at 5 prenatal clinics, including 2 clinics located on American Indian (AI) reservations. Each woman provided information on their alcohol use when recruited to the study, at up to 3 prenatal visits, and at a one-month post-delivery visit. Caucasian women were more likely to report consuming alcohol during pregnancy than AI women (63% vs 52%). In contrast, AI women were more likely to report binge drinking (i.e., consuming four or more standard drinks per drinking occasion), compared with Caucasian women (41% vs 28%). AI women were less likely than their Caucasian peers to drink during the second and third trimesters. For AI women, changing residence between homes on a reservation and between reservations and cities was a significant risk factor for prenatal drinking. For Caucasian women, risk of alcohol consumption increased with age, higher household income, and minimal government support.

Another team of NICHD researchers examined the impact of neighborhood disadvantage on youth neurocognitive performance and measures of brain structure in youth, after accounting for family socioeconomic status. They analyzed data from the Adolescent Brain and Cognitive Development Study, a large long-term study of brain development and child health conducted at 21 sites in the U.S. The final analyses included 8598 children. The study results showed that an increase in neighborhood disadvantage was associated with lower neurocognitive performance. In addition, an increase of neighborhood disadvantage was associated with lower whole-brain cortical surface area and subcortical volume, as well as regional surface area differences, primarily in the frontal, parietal, and temporal lobes. These associations largely remained after adjusting for family socioeconomic status and perceptions of neighborhood safety. These neighborhood associations were largely consistent across the U.S. These findings may inform with interventions strategies to improve conditions in disadvantaged neighborhoods to improve the health and development of children and adolescents.

An NICHD study suggests that some racial/ethnic subgroups may be shouldering an unfair burden of procedure-associated negative health impacts. Hysterectomy, or removal of the uterus, is a frequent surgical procedure with major consequences for women's health and well-being. To look for evidence of health disparities by racial/ethnic identity in hysterectomy rates, researchers analyzed data on all inpatient and outpatient hysterectomy procedures performed in North Carolina from 2011 to 2014. Estimates that accounted for the portion of the population who had previously

undergone the procedure showed that non-Hispanic Black women and non-Hispanic American Indian women had higher hysterectomy rates than non-Hispanic White women. Hysterectomy rates for Hispanic and non-Hispanic Asian/Pacific Islander women were lower than the rates for non-Hispanic White women. Further research is necessary to understand the underlying causes of these differences to ensure that women of all races and ethnicities are provided with appropriate care.

To learn more about factors that impact infant birth weight, NICHD funded a study to examine how racial and ethnic disparities in human milk intake vary among very low birth weight infants. Provision of mother's milk (either through direct breastfeeding or expressed) during hospitalization has numerous health benefits for very low birth weight (VLBW) infants. Previous research has examined socioeconomic, neighborhood, and hospital characteristics that are associated with the provision of mother's milk for VLBW infants but have not accounted for the extent to which these factors may affect the association between maternal race/ethnicity and the provision of mother's milk. Understanding these factors may help identify potential interventions. This study analyzed a racially diverse group of over 14,000 VLBW infants, born from 2008 to 2011, from 119 California neonatal intensive care units. Compared with the infants of non-Hispanic white mothers, the infants of non-Hispanic black mothers were less likely to receive human milk, whereas the infants of Hispanic mothers were more likely to receive human milk. Compared with infants of more educated white mothers, infants of less educated white, black, and Asian mothers were less likely to receive human milk; however, infants of Hispanic mothers at all educational levels had similar odds of receiving human milk as infants of more educated white mothers. Infants of foreign-born mothers of most racial/ethnic groups were as likely or significantly more likely to receive human milk, compared with infants of U.S.-born white mothers. Neighborhood socioeconomic status also impacted the effects of race/ethnicity in lower-income settings. Overall, the mechanisms that contribute to racial/ethnic disparities should be considered when developing customized approaches to increase the provision of mother's milk.

NICHD also funded research to study Health Disparities in Delivery Hospitals for Black and Hispanic Women and High-Risk Infants. Black women are more likely than White women to die from a pregnancy-related cause or to experience severe health problems while they are in the hospital to give birth. Black infants are twice as likely as White infants to die in their first month of life, and Black infants born premature are at higher risk for severe health problems. Research has explored the quality of hospital care for mothers and infants separately, but researchers wanted to know whether hospitals with poor outcomes for mothers also had poor outcomes for very preterm infants. The researchers ranked New York City hospitals based on their rates of maternal and infant death and severe health problems. They found some overlap between hospitals with good or poor outcomes for women and hospitals with good or poor outcomes for very preterm infants. The researchers then categorized the hospitals based on whether they had excellent performance for women and infants, poor performance for both, or a mix. They found that hospital performance for maternal and very preterm infant outcomes were only moderately correlated. However, Black and Hispanic women were more likely to give birth at hospitals with worse outcomes for

both women and very preterm infants. The findings indicate that disparities in hospital quality may significantly contribute to ongoing racial and ethnic health disparities.

C. *Research on Intellectual and Developmental Disabilities*

People with intellectual or developmental disabilities (IDDs) are central to NICHD's mission since it was established in 1962. The institute continues to lead research on IDDs nearly six decades later.

One team of NICHD-supported researchers developed a prototype app for mobile devices that can screen children at risk for autism spectrum disorder (ASD). In the study, the app could distinguish toddlers diagnosed with ASD from typically developing toddlers by tracking their eye movements while watching videos. With more research, the app could one day screen infants and toddlers and refer them for early intervention, when chances for treatment success are greatest.

NICHD-funded researchers also reported that regular doses of the hormone oxytocin do not appear to help children with ASD. The findings contradict smaller studies that indicated the hormone could alleviate the difficulties in social functioning that are characteristic of the disorder. With this larger study, healthcare providers now have more information on appropriate therapies.

In another study funded by NICHD, researchers developed a test to evaluate the expressive language skills of people with Down syndrome. Expressive language refers to the use of words to convey meaning to others and evaluating this accurately is important because language delays are common in people with Down syndrome. Many commonly used tests of language skills are less accurate for people with Down syndrome and other developmental disabilities. The study team noted that the new test can provide a better way to evaluate language interventions or other therapies for people with Down syndrome.

NICHD-supported researchers also combined data from multiple studies to describe early patterns of developmental delays in infants and toddlers with an *FMR1* mutation, which causes Fragile X Syndrome (FXS). The study team reported that boys with FXS had delays in early learning, motor skills, and language development as young as 6 months of age, while both boys and girls with FXS had delays on all developmental domains by their second birthday. These findings highlight the importance of early identification, when interventions have the greatest potential to improve developmental outcomes.

People with IDDs have a higher risk for excess weight or obesity. NICHD supported a clinical study to evaluate weight loss interventions and methods for delivering them (i.e., face-to-face or remotely) for adolescents with IDDs and excess weight or obesity. The study evaluated a modified version of the stop light diet, which categorizes foods by energy content: green (low energy, consume freely), yellow (moderate energy, consume in moderation), and red (high energy, consume sparingly). The team found

that their enhanced stop light diet, when delivered remotely, can effectively help adolescents lose weight. Such findings are especially important considering the COVID-19 pandemic and rise in telehealth services.

NICHD-funded researchers also continue to evaluate outcomes from the Management of Myelomeningocele Study (MOMS), which compared surgical treatments for infants with spina bifida, a birth defect that occurs when the spinal column fails to close around the spinal cord. The researchers had found that surgery during pregnancy, called prenatal repair, provided better outcomes through age 2.5 years. In the latest report, the study team found that these outcomes, such as improved mobility, continued to persist among the prenatal repair group as the children enter their school-age years. These positive findings underscore the benefit of prenatal repair surgery.

D. Research on Contraception, Fertility, and Pregnancy Loss

Promoting reproductive health and supporting healthy pregnancies are key research themes for NICHD. By improving contraception, understanding fertility, and reducing pregnancy loss, NICHD-led research affects individuals and families across the country.

One team of NICHD-funded researchers reported that a hormone-releasing intrauterine device (IUD) is as effective at emergency contraception as a copper IUD. The study also suggests that the hormonal IUD may be more effective than morning after pills, which are the only type of emergency contraception approved by the U.S. Food and Drug Administration. If approved for such use, IUDs can provide additional options and benefits, such as continued contraception.

Researchers at NICHD found that low-dose aspirin may improve pregnancy chances for women with one or two prior miscarriages. The researchers concluded that taking low-dose aspirin at least four days per week could improve the odds for pregnancy and live birth. The researchers also found that cannabis use may reduce the chance of pregnancy among women who had one or two prior miscarriages. Women who said they used cannabis products—marijuana or hashish—in the weeks before pregnancy, or who had positive urine tests for cannabis use, were around 40% less likely to conceive per monthly cycle than women who did not use cannabis.

Another group of NICHD-supported researchers looked at the effects of alcohol and tobacco use on stillbirth, which is the loss of a baby at or after 20 weeks of pregnancy. The study was part of NIH's Prenatal Alcohol in SIDS and Stillbirth (PASS) Network. The team found that drinking alcohol and smoking tobacco cigarettes throughout the first trimester of pregnancy was associated with nearly three times the risk of late stillbirth (at 28 or more weeks), compared to women who did neither or had quit both before the end of the first trimester.

NICHD-funded researchers also discovered a gene involved in male infertility. Mutations in the gene *PNLDC1* appear to account for a form of male infertility in which sperm is not produced. The gene codes for an enzyme that processes a class of non-coding ribonucleic acids (RNA). These non-coding RNAs are not involved in making proteins but are believed to be involved in various functions that occur during spermatogenesis—the process by which cells in the testes produce sperm cells. The authors theorized that other genes coding for enzymes involved in processing non-coding RNAs also might be involved in infertility.

Researchers supported by the institute also made advances in understanding female reproductive health. Fallopian tubes play an essential role in female fertility by picking up eggs that are released from the ovary, transporting sperm, and nurturing early embryos. However, scientists do not know which cells from the tube are responsible for specific functions. The study team used a mouse model to clarify these roles. Cells called cilia that are in a specific area of the fallopian tube (called the infundibulum) are essential for picking up and transporting eggs. However, cilia from other parts of the tube (called the ampulla and isthmus regions) help carry sperm and embryos but are not necessary for fertility. These findings can help researchers develop better female contraceptives, understand causes of ectopic pregnancy, and more.

E. Child and Adolescent Health Research

One NICHD-led study explored links between maternal depression in pregnancy and child development. The researchers found that episodes of maternal stress or depression during pregnancy are associated with chemical modifications to placental genes. The modifications involve DNA methylation—binding of compounds known as methyl groups to DNA—which can alter a gene's activity. Some of the methylation changes associated with maternal depression occurred near genes involved in brain development. The researchers called for long-term studies to determine whether epigenetic changes in the placenta can affect children's mental health outcomes.

NICHD research also helps ensure that infants who are born preterm—before 34 weeks of gestation—get the best start in life. One NICHD-supported study reported that the standard course of antibiotics given to preterm infants at birth does not significantly alter the growth of microbiotic organisms in their gut during the first two weeks of life. The researchers had speculated that withholding the antibiotics would allow the infants' microbiome to develop, resulting in better clinical outcomes. However, the study team found no differences between infants who received the standard antibiotic treatment and those who did not. Both groups had similar microbiome compositions and similar clinical outcomes. The findings suggest that the current standard practice does not harm the infant's developing microbiome.

Another research team looked at the length of screen time viewing by children who were born extremely preterm (before 28 weeks of pregnancy). They found that more than two hours of screen time a day at

ages 6 and 7 were associated with problems with attention, impulsiveness, problem solving, and deficits with IQ. Similarly, children born extremely preterm who had a television or computer in their bedrooms were also more likely to have problems with impulse control and paying attention. The findings suggest that extended screen time may be associated with cognitive deficits and behavioral problems common to children born extremely preterm.

A different NICHD-supported study reported that a home visit program may reduce the incidence of child maltreatment. The researchers found that a program of brief home visits by nurses soon after birth—called Family Connects—can provide benefits into early childhood, reducing rates of child maltreatment and use of emergency medical care. Compared with families that received typical newborn services, families in the Family Connects home visit program in Durham County, NC, on average made 33% fewer emergency room visits and had 39% fewer investigations for child maltreatment by the time the children were 5 years old. The findings suggest that similar programs may benefit children nationwide.

In another NICHD-funded study, low-income mothers in Pittsburgh and New York who received coaching at regular doctor's visits before their child turned 6 months old were more likely to report talking, playing, and reading aloud with their children than those who did not. Their recorded interactions were also rated higher in quality. As part of the Smart Beginnings program, coaches recorded video of parent-child interactions with a book or toy at the doctor's office and gave parents feedback to help them foster their children's cognitive, language, social, and emotional growth. Scheduled during well baby checkups, this program is an efficient, cost-effective approach to reducing disparities in school readiness, according to the study authors.

NICHD also supports research to promote adolescent health and development. One study evaluated a dating violence prevention program called *Fourth R*. In a sample of Texas middle schools, seventh graders who took health classes with *Fourth R* content on healthy relationships, avoiding substance use and bullying, and conflict resolution were less likely to report being physically abusive toward a dating partner a year later compared to students in schools with a standard health curriculum. The study was the first assessment of the *Fourth R* curriculum for this age group. Additional research will help determine potential long-term effects of the program when the students transition to high school.

F. Research on Maternal Morbidity and Mortality

Maternal morbidity describes any short- or long-term health problems that result from being pregnant and giving birth. Maternal mortality refers to the death of a woman from complications of pregnancy or childbirth that occur during the pregnancy or within 6 weeks after the pregnancy ends. NICHD is one of many federal agencies working to improve maternal health and pregnancy outcomes, with the goal of preventing and treating pregnancy-related complications to reduce maternal morbidity and mortality. Our efforts aim to

improve understanding, early diagnosis, treatment, and prevention of pregnancy and birth complications, as well as improve the data collected on maternal deaths and track general trends to inform research strategies.

NICHD supported research to study homicide during pregnancy and the postpartum period in the United States. Homicide is a leading cause of death during pregnancy and the postpartum period in the United States. To estimate national pregnancy-associated homicide mortality rates, researchers examined mortality files from the National Center for Health Statistics from 2018 and 2019, identifying the deaths of all females aged 10 to 44 years. There were 3.62 homicides per 100,000 live births among females who were pregnant or within 1 year postpartum, which was 16% higher than homicide prevalence among non-pregnant and non-postpartum females of reproductive age (with a homicide rate of 3.12 deaths per 100,000 population). Homicide during pregnancy or within 42 days of the end of pregnancy exceeded all the leading causes of maternal mortality by more than twofold. Pregnancy was associated with a significantly elevated homicide risk in the Black population, and among females aged 10-24 across racial and ethnic subgroups. Pregnancy and the postpartum period are times of elevated risk for homicide among all females of reproductive age.

Maternal mortality is an issue of growing concern in the United. States. Louisiana has among the highest rate of death for pregnant women in the U.S. NICHD researchers conducted a study exploring the association between living in a "maternity care desert" (a county with no hospital offering obstetric care and no OB/GYN or certified nurse midwife providers) and risk of death during pregnancy and up to 1 year postpartum among women in Louisiana from 2016 to 2017. The results showed the risk of death during pregnancy and up to 1 year postpartum was elevated among women living in maternity care deserts compared with women in areas with greater access to maternal care. The women in maternity care deserts had a threefold higher risk for pregnancy-related deaths compared with women in areas with access to local maternal care. The researchers found that racial disparities *between* deaths of Black and White pregnant women persisted regardless of where a person lived. The findings indicate that access to quality maternity care is a critical part of maternal mortality prevention, but alone may be insufficient in reducing the persistent racial inequality in maternal health.

Another NICHD-led study concluded that people who are deaf or hard of hearing (DHH) are at risk for poorer health outcomes, in part due to communication barriers that hinder access to health care services and information. It is not clear, however, whether these increased health risks extend to pregnancy complications and the health of the newborn. Researchers looked through records from approximately 80 million hospitalizations that occurred between 2007-2016 across roughly 1,000 hospitals. They identified 5,258 delivery records for DHH women, and 8,022,680 delivery records for hearing women. Their analysis showed that the DHH women experienced higher rates of various pregnancy complications, including gestational diabetes, severe bleeding, and infection.

To assess the effects of SARS-CoV-2 infection during pregnancy, NICHD researchers analyzed data from 14 maternity hospitals in the United Kingdom, classifying women with a positive SARS-CoV-2 infection into four groups: asymptomatic (showing no symptoms), mild illness (showing any symptoms, like fever, cough, sore throat, etc.), moderate illness (showing evidence of lower respiratory disease), and severe illness (needing intensive care due to respiratory impairment or multiorgan dysfunction). The researchers found that severe cases of COVID-19 correlated with a 5-fold higher risk of developing a pregnancy complication called preeclampsia (high blood pressure after 20 weeks of gestation, or protein in the urine of women who had high blood pressure before becoming pregnant). The relative risk of developing preeclampsia with moderate or severe COVID-19 was over three times higher than in women with asymptomatic or mild infection. Patients with severe COVID-19 were also had a higher rate of preterm birth, delivering significantly earlier than women with asymptomatic or mild COVID-19. This study provides evidence that the more severe the infection with SARS-CoV-2, the greater the risk of preeclampsia and preterm birth.

Another NICHD study analyzed how pregnancy and breastfeeding affected the immune response to the COVID-19 vaccine. Metabolic changes in pregnancy can affect how an individual responds to infection or vaccination. To define potential changes in vaccine response during pregnancy and lactation, researchers studied a group of 84 pregnant, 31 lactating, and 16 non-pregnant age-matched women vaccinated with either the BioNTech/Pfizer (BNT162b2) vaccine or the Moderna/NIAID (mRNA-1273) vaccine. The researchers characterized the antibodies produced by plasma cells in response to different vaccines after the first dose and second dose of the vaccination. Though antibody levels in response to the vaccine were comparable among all three groups, the level of antibodies binding to the cells and initiating an immune response were delayed in both pregnant and lactating women after the first dose and normalized after the second dose. A vaccine booster during lactation resulted in higher levels of antibodies and non-specific immune cells, increasing antibody response more effectively than in pregnant women. These data suggest that pregnancy may promote resistance to generating antibodies that enhance inflammation, and that vaccine boosting is especially important for this vulnerable population to attain full immunity against COVID-19.

NICHD-funded researchers also found that disparities in maternal mortality between Black and white women in the United States may be larger than previously reported. By re-examining information on death certificates from 2016 and 2017, researchers found that the maternal mortality rate among non-Hispanic Black women was 3.5 times higher than among non-Hispanic white women; previous analyses had indicated a 2.5-times-higher death rate for Black women. The new analysis also revealed that these disparities were concentrated among a few causes of death. Postpartum cardiomyopathy (disease of the heart muscle) and the blood pressure disorders preeclampsia and eclampsia were leading causes of maternal death for Black women, with mortality rates five times higher than those for white women. Pregnant and postpartum Black women were also two to three times more likely than white women to die of hemorrhage (severe bleeding) or embolisms (blood vessel blockages).

Birth hospital factors have recently emerged as potential key contributors to disparities in severe maternal morbidity by race/ethnicity. Black and other minority women are at higher risk for severe maternal morbidity (SMM), which includes several serious pregnancy complications. To better understand this disparity, NICHD researchers examined data from all California live and stillbirths delivered at or beyond 20 weeks gestation from 2007 to 2012. In statistical models adjusted for sociodemographic factors, pregnancy-related factors, and clinical comorbidities, the excess risk of SMM in Black, foreign-born Hispanic, and other minority women was less than the risk in the unadjusted models, but not for US born Hispanic and Asian and Pacific Islander women. Interestingly, a simulation model that estimated the rate of SMM if all racial and ethnic minorities gave birth in the same hospitals as White women showed that there would be 156 less cases of SMM for Black women if they gave birth in the same hospitals as White women. The data showed that birth hospitals contribute to different experiences and outcomes for pregnant minority women, including increased risk for SMM.

NICHD researchers led a study to evaluate the peripartum blood transfusion rates among rural women in the United States. Maternal deaths and severe pregnancy morbidity are increasing -- a major public health problem in the United States. Peripartum blood transfusion or undergoing blood transfusion during the last month of gestation or the first few months of delivery is the most prevalent indicator of severe maternal morbidity. To assess whether rural women are at higher risk for peripartum blood transfusion, researchers analyzed data from more than 3 million singleton full-term births in 2014-2016, reflecting information available from revised U.S. birth certificates from 47 states and the District of Columbia. The analysis found that rural-dwelling women delivering in a rural county had significantly more transfusions (8.5 per 1,000-live births), compared with peers in more urban counties (2.5 per 1,000 births), and the more rural the setting, the higher the odds of transfusion. Patient-level risk factors – from anemia to demographic characteristics to pregnancy complications or type of delivery (e.g., cesarean)– did not explain the rural-urban differences, according to the analysis. Systems-level factors were the most likely explanation for the urban-rural disparity in transfusion rates. The researchers speculate that limitations in the rural maternal health work force, and/or limitations in rural hospital resources, such as supply of banked blood products, could influence rural practice patterns, perhaps by lowering the threshold for transfusion. The researchers suggested further research to inform interventions to improve maternal health care of rural women, including specifically reducing obstetric hemorrhage. Such hemorrhage is the fourth leading cause in the U.S. of maternal mortality, accounting for about 12 percent of pregnancy-related deaths, and is often considered preventable.

Reducing racial disparities in severe maternal morbidity is a priority for NICHD. Black women in the U.S. are significantly more likely than white women to die or to suffer severe complications during childbirth, even after adjusting for sociodemographic factors and comorbidities. Hospital quality improvement initiatives aim to reduce maternal morbidity and mortality by implementing evidence-based recommendations for clinical practice. Little is known, however, about whether a quality improvement

collaborative can reduce persistent racial disparities. Researchers studied the results of an initiative undertaken at 99 California hospitals to reduce the risk of severe maternal morbidity (SMM) from obstetric hemorrhage, a common major complication of childbirth. The results showed that the effort reduced the risk of SMM from hemorrhage and benefitted black women more than white women, reducing disparities.

Women with disabilities have a higher risk of birth complications and death. NICHD-supported researchers analyzed data from more than 223,000 deliveries in 19 U.S. hospitals, including about 2,200 women with a disability. The scientists found that pregnant women with disabilities had a much higher risk for severe pregnancy- and birth-related complications and death than other pregnant women. Higher risks among women with disabilities included a wide variety of pregnancy complications, such as preeclampsia, gestational diabetes, placenta previa, hemorrhage, thromboembolism, and infection.

V. CONCLUSIONS

NICHD has strived to promote the objectives of the NIH inclusion policies by implementing procedures to monitor and assure compliance with the legislative mandates and by providing appropriate training to staff. The NICHD research mission is quite broad and scientifically diverse; much of our research portfolio focuses on topics relevant to women's health, and several of our clinical trials are focused specifically on the health needs and concerns of women. The aggregated enrollment data provide an overview of our research portfolio and clearly show substantial inclusion of women and minorities as participants in clinical research projects and clinical trials supported by NICHD. Not shown in these tables is the ongoing oversight of each individual project by NICHD staff to monitor the progress made in recruitment of research participants to reach the planned enrollment goals set forth in the original application and to provide guidance to investigators as needed. Even more important than the numerical data are the numerous contributions to scientific knowledge that will be generalizable to different populations, as shown by the representative grants and publications listed at the end of this report.

From its outset over 20 years ago, implementation of the NIH inclusion policy has been science driven. The primary focus of this policy has been to identify and remedy gaps in scientific knowledge as they relate to the health of all populations in the United States. The inclusion policy is based on the ethical principles of justice and beneficence, as it strives to assure that all groups share in both the risks and potential benefits of participating in clinical research. Finally, the policy represents a partnership between researchers, NIH staff, and most importantly the millions of individuals who have agreed to participate in clinical research projects and clinical trials.

Appendix A – Inclusion Data Tables

Inclusion Data Records (IERs)

Table 2-1. Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Clinical Research Reported Between Fiscal Years 2019 and 2021

Fiscal Year	Total IERs	IERS Without Enrollment	IERs With Enrollment	US Site IERs	Non-US Site IERs	Female Only IERs	Male Only IERs	IERs Excluding Male only and Female only*
2019	1,587	525	1,062	926	136	267	46	749
2020	1,692	619	1,073	956	117	240	48	785
2021	1,805	779	1,026	893	133	230	31	765

*Inclusion Data Records (IERs) excluding male only and female only include unknown sex/gender, and combination of unknown and any sex/gender(s).

Table 2-2. Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Phase III Trials Reported Between Fiscal Years 2019 and 2021

Fiscal Year	Total IERs	IERS Without Enrollment	IERs With Enrollment	US Site IERs	Non-US Site IERs	Female Only IERs	Male Only IERs	IERs Excluding Male only and Female only*
2019	80	35	45	40	5	18	0	27
2020	88	40	48	42	6	18	0	30
2021	92	32	60	49	11	23	0	37

*Inclusion Data Records (IERs) excluding male only and female only include unknown sex/gender, and combination of unknown and any sex/gender(s).

Table 2-3. Valid Analysis Requirements for NIH-Defined Phase III Extramural Grants Reported Between Fiscal Years 2019 and 2021

Fiscal Year	Total IERs	IERs Requiring Race Ethnicity Valid Analysis	% IERs Requiring Race Ethnicity Valid Analysis	IERs Requiring Sex Gender Valid Analysis	% IERs Requiring Sex Gender Valid Analysis
2019	80	71	88.8	71	88.8
2020	88	82	93.2	82	93.2
2021	92	77	83.7	66	71.7

Current methodology to monitor valid analysis began in 2019 and differs from what was used in 2018 (N/A in 2018). 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.

Enrollment by Sex/Gender

Table 3-1-A. Total Enrollment for All NIH-Defined Extramural and Intramural Clinical Research Between Fiscal Years 2019 and 2021

Fiscal Year	Total Enrollment	Total Females	% Female	Total Males	% Male	Total Unknown	% Unknown
2019	1,559,792	986,813	63.3	546,973	35.1	26,006	1.7
2020	1,060,875	598,623	56.4	436,482	41.1	25,770	2.4
2021	1,729,600	1,093,720	63.2	600,102	34.7	35,778	2.1

Fiscal Year	Total Enrollment	Enrollment in Female-Only	% Female-Only	Enrollment in Male-Only	% Male-Only	Females, Excluding Female-Only	% Females, Excluding Female-Only	Males, Excluding Male-Only	% Males, Excluding Male-Only
2019	1,559,792	100,245	6.4	1,916	0.1	886,568	56.8	545,057	34.9
2020	1,060,875	122,389	11.5	2,447	0.2	476,234	44.9	434,035	40.9
2021	1,729,600	131,237	7.6	2,432	0.1	962,483	55.6	597,670	34.6

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

Table 3-1-A-Supplement. Enrollment for All NIH-Defined Clinical Research, Excluding Female- and Male-Only Enrollment

Fiscal Year	Total Enrollment, Excluding Single-Sex/Gender	Females, Excluding Female-Only	% Female, Excluding Single-Sex/Gender	Males, Excluding Male-Only	% Male, Excluding Single-Sex/Gender	Total Unknown	% Unknown, Excluding Single-Sex/Gender
2019	1,457,631	886,568	60.8	545,057	37.4	26,006	1.8
2020	936,039	476,234	50.9	434,035	46.4	25,770	2.8
2021	1,595,931	962,483	60.3	597,670	37.4	35,778	2.2

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

Table 3-2-A. US Site Enrollment for All NIH-Defined Extramural and Intramural Clinical Research

Fiscal Year	Total Enrollment	Total Females	% Female	Total Males	% Male	Total Unknown	% Unknown
2019	572,701	322,804	56.4	228,075	39.8	21,822	3.8
2020	685,030	375,921	54.9	283,890	41.4	25,219	3.7
2021	474,729	292,162	61.5	156,909	33.1	25,658	5.4

Fiscal Year	Total Enrollment	Enrollment in Female-Only	% Female-Only	Enrollment in Male-Only	% Male-Only	Females, Excluding Female-Only	% Females, Excluding Female-Only	Males, Excluding Male-Only	% Males, Excluding Male-Only
2019	572,701	70,322	12.3	1,916	0.3	252,482	44.1	226,159	39.5
2020	685,030	72,393	10.6	2,447	0.4	303,528	44.3	281,443	41.1
2021	474,729	72,224	15.2	1,805	0.4	219,938	46.3	155,104	32.7

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

Table 3-2-A-Supplement. US Site Enrollment for All NIH-Defined Clinical Research, Excluding Female- and Male-Only Enrollment

Fiscal Year	Total Enrollment, Excluding Female- and Male-Only	Females, Excluding Female-Only	% Female, Excluding Female- and Male-Only	Males, Excluding Male-Only	% Male, Excluding Female- and Male-Only	Total Unknown	% Unknown, Excluding Female- and Male-Only
2019	500,463	252,482	50.4	226,159	45.2	21,822	4.4
2020	610,190	303,528	49.7	281,443	46.1	25,219	4.1
2021	400,700	219,938	54.9	155,104	38.7	25,658	6.4

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

US Site Enrollment by Race

Table 4-1-2-B. Total US Site Enrollment of NIH-Defined Clinical Research

Fiscal Year	Total Enrollment	No. Inclusion Data Records	Minority Enrollment	% Minority Enrollment	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American
2019	572,701	1,395	265,984	46.4	5,260	0.9	19,572	3.4	129,189	22.6
2020	685,030	1,496	320,790	46.8	5,743	0.8	24,019	3.5	154,328	22.5
2021	474,729	1,574	223,141	47.0	3,632	0.8	17,549	3.7	117,116	24.7

Fiscal Year	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
2019	1,118	0.2	298,746	52.2	39,308	6.9	79,508	13.9
2020	1,458	0.2	350,985	51.2	45,869	6.7	102,628	15.0
2021	1,194	0.3	242,487	51.1	20,144	4.2	72,607	15.3

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

US Site Enrollment by Ethnicity

Table 4-1-2-C. Total US Site Enrollment of NIH-Defined Clinical Research

Fiscal Year	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2019	432,697	75.6	96,284	16.8	43,720	7.6
2020	508,964	74.3	117,390	17.1	58,676	8.6
2021	324,248	68.3	78,248	16.5	72,233	15.2

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

Total Enrollment: All Clinical Research

Table 5-1-1-C. Enrollment for All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity

Fiscal Year	Sex/ Gender	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic/ Latino	% Hispanic/ Latino	Unknown/ Not Reported	% Unknown/ Not Reported
2019	Female	810,374	82.1	986,813	63.3	714,622	72.4	255,718	25.9	16,473	1.7
2019	Male	420,284	76.8	546,973	35.1	424,548	77.6	109,959	20.1	12,466	2.3
2019	Unknown	5,118	19.7	26,006	1.7	4,462	17.2	1,587	6.1	19,957	76.7
2020	Female	400,298	66.9	598,623	56.4	486,234	81.2	94,025	15.7	18,364	3.1
2020	Male	283,035	64.8	436,482	41.1	359,823	82.4	55,619	12.7	21,040	4.8
2020	Unknown	1,339	5.2	25,770	2.4	4,958	19.2	419	1.6	20,393	79.1
2021	Female	827,847	75.7	1,093,720	63.2	985,094	90.1	82,183	7.5	26,443	2.4
2021	Male	394,128	65.7	600,102	34.7	543,621	90.6	29,867	5.0	26,614	4.4
2021	Unknown	10,917	30.5	35,778	2.1	11,407	31.9	353	1.0	24,018	67.1

Fiscal Year	Sex/ Gender	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
2019	Female	161,245	16.3	323,945	32.8	218,013	22.1	848	0.1	224,954	22.8	23,047	2.3	34,761	3.5
2019	Male	59,972	11.0	127,692	23.3	172,071	31.5	530	0.1	139,938	25.6	19,281	3.5	27,489	5.0
2019	Unknown	960	3.7	665	2.6	2,809	10.8	11	0.0	954	3.7	116	0.4	20,491	78.8
2020	Female	3,538	0.6	30,880	5.2	262,338	43.8	1,118	0.2	231,393	38.7	24,729	4.1	44,627	7.5
2020	Male	2,481	0.6	17,903	4.1	197,317	45.2	700	0.2	158,721	36.4	22,064	5.1	37,296	8.5
2020	Unknown	20	0.1	103	0.4	710	2.8	8	0.0	900	3.5	148	0.6	23,881	92.7
2021	Female	2,528	0.2	334,181	30.6	406,404	37.2	1,114	0.1	187,439	17.1	15,073	1.4	146,981	13.4
2021	Male	1,343	0.2	125,646	20.9	233,237	38.9	654	0.1	96,244	16.0	8,607	1.4	134,371	22.4
2021	Unknown	29	0.1	8,846	24.7	1,598	4.5	7	0.0	1,105	3.1	129	0.4	24,064	67.3

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

Total Enrollment: US Sites

Table 5-1-2-C. US Site Enrollment for NIH-Defined Extramural and Intramural Clinical Research, Sex/Gender by Race and Ethnicity

Fiscal Year	Sex/Gender	Minority	% Minority	Not Hispanic	% Not Hispanic	Hispanic/ Latino	% Hispanic/ Latino	Unknown Not Reported	% Unknown Not Reported
2019	Female	159,551	49.4	254,724	78.9	55,029	17.0	13,051	4.0
2019	Male	105,462	46.2	176,707	77.5	40,616	17.8	10,752	4.7
2019	Unknown	971	4.4	1,266	5.8	639	2.9	19,917	91.3
2020	Female	187,405	49.9	291,896	77.6	66,424	17.7	17,601	4.7
2020	Male	132,535	46.7	212,599	74.9	50,547	17.8	20,744	7.3
2020	Unknown	850	3.4	4,469	17.7	419	1.7	20,331	80.6
2021	Female	152,344	52.1	217,833	74.6	51,138	17.5	23,191	7.9
2021	Male	69,984	44.6	105,090	67.0	26,778	17.1	25,041	16.0
2021	Unknown	813	3.2	1,325	5.2	332	1.3	24,001	93.5

Fiscal Year	Sex/ Gender	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
2019	Female	3,088	1.0	11,135	3.4	82,375	25.5	727	0.2	172,077	53.3	20,838	6.5	32,564	10.1
2019	Male	2,160	0.9	8,382	3.7	46,594	20.4	380	0.2	125,715	55.1	18,354	8.0	26,490	11.6
2019	Unknown	12	0.1	55	0.3	220	1.0	11	0.1	954	4.4	116	0.5	20,454	93.7
2020	Female	3,398	0.9	13,551	3.6	94,495	25.1	950	0.3	197,072	52.4	24,055	6.4	42,400	11.3
2020	Male	2,325	0.8	10,368	3.7	59,609	21.0	500	0.2	153,027	53.9	21,666	7.6	36,395	12.8
2020	Unknown	20	0.1	100	0.4	224	0.9	8	0.0	886	3.5	148	0.6	23,833	94.5
2021	Female	2,365	0.8	11,215	3.8	84,653	29.0	845	0.3	151,036	51.7	11,979	4.1	30,069	10.3
2021	Male	1,238	0.8	6,218	4.0	32,218	20.5	342	0.2	90,365	57.6	8,037	5.1	18,491	11.8
2021	Unknown	29	0.1	116	0.5	245	1.0	7	0.0	1,086	4.2	128	0.5	24,047	93.7

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

Total Enrollment: Phase III Clinical Trial

Table 5-2-2-C. ALL Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity

Fiscal Year	Sex/ Gender	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2019	Female	15,905	58.8	27,051	87.4	20,966	77.5	5,856	21.6	229	0.8
2019	Male	2,718	75.9	3,582	11.6	2,679	74.8	806	22.5	97	2.7
2019	Unknown	50	15.1	332	1.1	35	10.5	33	9.9	264	79.5
2020	Female	19,384	58.6	33,097	83.8	24,306	73.4	8,207	24.8	584	1.8
2020	Male	4,268	72.1	5,918	15.0	4,299	72.6	1,264	21.4	355	6.0
2020	Unknown	70	14.8	474	1.2	83	17.5	37	7.8	354	74.7
2021	Female	26,736	55.3	48,355	90.4	36,574	75.6	11,108	23.0	673	1.4
2021	Male	2,832	67.2	4,216	7.9	3,632	86.1	534	12.7	50	1.2
2021	Unknown	39	4.1	943	1.8	65	6.9	26	2.8	852	90.3

Fiscal Year	Sex/ Gender	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
2019	Female	126	0.5	1,855	6.9	8,106	30.0	89	0.3	14,116	52.2	549	2.0	2,210	8.2
2019	Male	24	0.7	1,148	32.0	682	19.0	3	0.1	998	27.9	116	3.2	611	17.1
2019	Unknown	0	0.0	4	1.2	14	4.2	0	0.0	43	13.0	5	1.5	266	80.1
2020	Female	176	0.5	2,636	8.0	8,442	25.5	119	0.4	17,740	53.6	787	2.4	3,197	9.7
2020	Male	83	1.4	1,607	27.2	1,212	20.5	20	0.3	1,772	29.9	216	3.6	1,008	17.0
2020	Unknown	4	0.8	3	0.6	20	4.2	0	0.0	66	13.9	11	2.3	370	78.1
2021	Female	204	0.4	3,948	8.2	11,538	23.9	179	0.4	27,980	57.9	1,237	2.6	3,269	6.8
2021	Male	21	0.5	1,610	38.2	618	14.7	1	0.0	1,729	41.0	105	2.5	132	3.1
2021	Unknown	0	0.0	6	0.6	4	0.4	1	0.1	61	6.5	5	0.5	866	91.8

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

Age Tables

Table 1. Age Distribution Using Broad Age Groups for NIH-Defined Extramural and Intramural Clinical Research Reported for Fiscal Year 2021

Fiscal Year	Children (<18 years)	Adults (18-64 years)	Older Adults (65+ years)	Unknown or Not Reported	Total
2021	51,310	21,930	185	846	74,271
	69.1%	29.5%	0.2%	1.1%	100%

Table 2. Age Distribution Using Detailed Age Groups for NIH-Defined Extramural and Intramural Clinical Research Reported for Fiscal Year 2021

Fiscal Year	0 - 28 Days	29-364 Days	<1 year, values other than 0-28 or 29-364 days *	<1 year, Total **	1-5 Years	6-12 Years	13-15 Years	16-17 Years	18-21 Years	22-25 Years	26-34 Years	35-44 Years	45-54 Years	55-64 Years
2021	277	17,293	3,320	20,890	17,354	9,265	2,372	1,429	3,783	4,124	8,910	3,830	862	421
	0.4%	23.3%	4.5%	28.1%	23.4%	12.5%	3.2%	1.9%	5.1%	5.6%	12.0%	5.2%	1.2%	0.6%

Fiscal Year	65-69 Years	70-74 Years	75-79 Years	80-84 Years	85-89 Years	90+ Years	Unknown or Not Reported	Total
2021	92	65	14	6	3	5	846	74,271
	0.1%	0.1%	0.0%	0.0%	0.0%	0.0%	1.1%	100%

* Includes ages reported in weeks, months, or years that are equivalent to less than 1 year.

**Includes all ages equivalent to less than one year, including all those reported in days, weeks, months and years.

Appendix B. Highlighted Projects that Address Differences in Sex/Gender, Race, and/or Ethnicity

Title	Grant Number
A Digital Intervention for HIV Prevention in Black Adolescent Girls	R21HD098031
A longitudinal population-based birth cohort study to understand the past, present, and future of children and youth with traumatic brain injury	R03HD104206
A Multilevel Comprehensive Response on Uptake and Adherence to HIV Prevention Among Adolescent Girls and Young Women	R01HD094629
A Phase 1 PK and Safety Study of Velpatasvir/Sofosbuvir for Chronic Hepatitis C Infection in Pregnant Women	R21HD101996
A Pilot and Feasibility Study to Promote Physical and Food Literacy among Children with Intellectual Disabilities	R21HD099435
A Randomized Controlled Trial of a Telephone-Based Developmental Care Coordination System	R01HD092406
A trauma informed intervention to improve mental health and school success for urban eighth graders	R01HD090022
Addition of Social Needs to a Telephone-Based Developmental Care Coordination Randomized Controlled Trial in the Era of COVID	R01HD092406
Addressing socioeconomic disparities in post-stroke disability through the development of an accessible, new tool	R21HD105180
Adolescent health behaviors in the time of COVID-19	R01HD106635
Adolescent Medicine Trials Network for HIV/AIDS Interventions (ATN)	U24HD089880
Advancing Measurement and Analysis of Sensitive Behaviors in the United States	R01HD084473
Aging Language Trajectories in Premutation Carrier Mothers	R03HD098291
Alignment of PrEP use with HIV risk in young women	R21HD098923
Assessing individual, community, and financial factors in birth outcomes and associated health disparities	R21HD097599
Assessing Preferences for Use of Clinical Data Among Individuals with IDD and Their Guardians	R01HD086702
Assessing the preliminary effects of a multisectoral agricultural intervention on the sexual and reproductive health of HIV-affected adolescent girls	R21HD095739
Assessing vaginal microbial communities as a risk factor for HIV acquisition in pregnant and postpartum Kenyan women	F32HD100202
Association of the Fragile X Premutation with Cognitive and Behavioral Skills in Children	R01HD102429
Augmenting Ankle Plantarflexor Function and Walking Capacity in Children with Cerebral Palsy	R01HD107277
Autism Adaptive Community-based Treatment to Improve Outcomes using Navigators (ACTION) Network	R01HD093055
B positive_A population-based evaluation of expanded ART access in pregnancy	R01HD080465
Biological and social mediators of child wellbeing among ethnic groups in Fragile Families	R01HD076592
Birth Control to Improve Birth Spacing (BIBS): a Prospective Longitudinal Cohort Study	R21HD103977
Brain Injury Outpatient Education and Care Navigation	R01HD103700
Burden and Risk of Neurological and Cognitive Impairment in Pediatric Sickle Cell Anemia in Uganda (BRAIN SAFE II)	R01HD096559

Title	Grant Number
Caregiver Early Child Development Training for Preventing Konzo from Toxic Cassava in the DR Congo	R21HD098588
Cellular and molecular determinants of DDX3X syndrome	R01HD104609
Center for Reproductive Science and Medicine	P50HD012303
Child and Family Consequences of Congenital Zika Syndrome in Brazil	R01HD093572
Childhood Maltreatment and the Transition to Parenting: A Psychobiological Model	K01HD095535
Children of Immigrants Health Study (CIHS): An Evaluation of City and County Policies Affecting the Health of Children of Immigrants in the 2005-2019 National Health Interview Survey	R03HD104740
Community-based Adaptive autism Intervention for Toddlers	R01HD098248
Community-based Adaptive autism Intervention for Toddlers	R01HD093055
Community Events and Pathways to Inequities in Birth Outcomes	R01HD103684
Community violence and disparities in maternal and infant health: effects and mechanisms	R01HD098138
Community Intervention for HIV Testing & Care Linkage Among Young MSM in Bulgaria	R01HD085833
Covid-19 Effects on Children & Families: 2021 Follow-Up of the PSID Child Development Supplement	R01HD104671
Defining the OGT Interactive and its Role in X-Linked Intellectual Disability	F30HD098828
Determining longitudinal trends and risk factors for adolescent reproductive health	R03HD102740
Developing/Testing a Multi-level Interventions (SHIELD & IWC)	UH3HD096908
Development and assessment of population specific fetal growth references	R03HD093993
Development, Testing and Health Effects of a Multilevel Family Planning Intervention	R21HD098523
Diet and the CPT1A arctic variant: Impact on the Health of Alaska Native Children	R01HD089951
Disorders/Differences of Sex Development (DSD) - Translational Research Network	R01HD093450
Early Adversity, Childhood Educational Experiences, and Adulthood Physical Health	R01HD091132
Early origins of health disparities: Chronic inflammation	R21HD101757
Effects of age at marriage and education on health of mothers and children	R01HD095189
Effects of Medicaid expansions on infant health among Native Americans	R03HD104920
Electrophysiological Biomarkers of Neurocognitive Deficits in Fragile X Syndrome	K23HD101416
Enhancing male participation in interventions to prevent unintended pregnancy	R01HD084453
Evaluating the psychometric properties of three clinical trial outcome measures for Rett Syndrome	R21HD101075
Evaluation of a Novel Intervention for Infants at Risk for Neurodevelopmental Disorders	R21HD091547
Family Processes and Rural-urban Migration among Adolescents	R21HD091534
FANMI: Community Cohort Care for HIV-Infected Adolescent Girls in Haiti	R01HD091935
FMR1 Premutation Phenotypes in Population-Based & Clinically Ascertained Samples	R01HD082110
FMRP-mediated Regulation in Human Brain Development and Therapeutic Advancement	P50HD104458
Food insecurity and neighborhood food environment: Links to children's health	R03HD095080
Fragile Families and the Transition to Adulthood	R01HD036916
Fragile X Premutations, Mechanisms and Modifiers	P50HD104463

Title	Grant Number
Function of stimulus induced MeCP2 phosphorylation	R01HD064743
Genetic Diagnosis of Neurodevelopmental Disorders in India	R01HD093570
Genetics of Male Infertility: A Marker of Overall Health	P50HD096723
Genotype-Phenotype Relationships in Fragile X Families	R01HD036071
Global Age Patterns of Under-Five Mortality	R01HD090082
Harnessing the power of text messaging to reduce HIV incidence in adolescent males across the United States	U01HD108738
Harvard Reproductive Endocrine Sciences Center	P50HD028138
Healthcare Transitions and the Health of Adolescents and Young Adults with Intellectual or Developmental Disabilities	R01HD103720
Hormone induced mucosal susceptibility and HIV risk in South African adolescents	R01HD083030
Hormones, Immunity and HIV Risk	R01HD092016
HPV vaccination efficacy for cervical cancer prevention in young women with perinatal HIV infection	R21HD098733
Identifying and Addressing Opportunities in Primary Care to Improve Healthy Birth Intervals	R21HD104086
Identifying sources of HIV infection in adolescent girls in rural South Africa	R01HD083343
Impact of State-level Policies on Maternal Mortality	R01HD096070
Improving Methods and Measures of Reproductive Health Outcomes	R01HD092396
In Our Own Words: Peer-to-Peer Messaging to Increase Uptake of HIV Prevention Strategies among Adolescents in Kenya	R01HD094683
Incident STIs in Kenyan Girls: a prospective cohort spanning sexual debut	R01HD091996
Increased risk of STI and HIV among adolescent girls and young women due to COVID-19 and pandemic mitigation: Biological, behavioral, and psychosocial mediators	R01HD106822
Inflammation, Vaginal Microbiota, and STI/HIV Risk	R01HD092013
Improving the Detection of STIs in the Pediatric Emergency Department: A Pragmatic Trial	R01HD094213
Intensive Combination Approach to Roll back the Epidemic (iCARE) in Nigerian Adolescents	UG3HD096920
Investigating role of maternal gut microbiome in microglia-neuron dynamics and development of somatosensory circuits	5K99HD101680
Kisspeptin and Neurokinin B: Physiology in Monkey to Pathophysiology in Human	R01HD043341
Language Development in Fragile X Syndrome	R01HD024356
Large-scale Implementation of Community Co-led Maternal Sepsis Care Practices to Reduce Morbidity and Mortality from Maternal Infection	UG3HD108053
Linking HIV Prevention and post-partum care: Safety, efficacy and feasibility of cabotegravir-LA PrEP in high-risk breastfeeding population in Botswana	R01HD108047
Longitudinal behavioral, sociodemographic and contextual predictors of young adult sleep health and well-being	R01HD073352
Maternal Exposure to Childhood Abuse and Disparities in Offspring Neurodevelopment: Identifying Mechanisms	R01HD094725
Maternal Health Care Utilization and Morbidity: The First 24 Months	R15HD101793
Mechanisms Underlying Sexual Minority Health Disparities in the United States	R01HD094081
Memory Measures for Clinical Trials in Down syndrome and Fragile X syndrome	R01HD088409

Title	Grant Number
Menstrual cups, maturation of the adolescent vaginal microbiome, and STI/HIV risk	R01HD093780
mHealth-based Just-In-Time Adaptive Intervention to Improve Physical Activity Levels of Individuals with Spinal Cord Injury	R01HD103904
Mitochondrial ROS and Microglia in Rett Syndrome	R01HD08832
Mobile Diagnosis of Congenital Genetic Conditions: A Model for Screening and Surveillance in Low-Resource Settings	R21HD102988
Multi-level Emergency Department Intervention to Reduce Pregnancy Risk Among Adolescents	R21HD098086
Natural History of Shoulder Pathology in Wheelchair Users	R01HD084423
National Longitudinal Survey of Youth: Older Children	R01HD037078
NeuroDev Kenya: characterizing the epidemiology and etiology of developmental disorders on the Kenyan Coast	R01HD102975
Obstetric delivery volume, regionalization, and maternal and infant outcomes	R01HD099197
Obstetric Interventions, Neonatal Health, and Child Development	R01HD090119
O-GlcNAc dynamics and the OGT interactome in variants causal for X-linked intellectual disability	R21HD097652
Office of Dietary Supplements funded administrative supplement to: “The eXtraordinarY Babies Study: Natural History of Health and Neurodevelopment in Infants and Young Children with Sex Chromosome Trisomy”	R01HD091251
Optimizing an mHealth intervention to improve uptake and adherence of the HIV pre-exposure prophylaxis (PrEP) in vulnerable adolescents and emerging adults	R21HD107988
Optimizing Pre-exposure Prophylaxis Use among Adolescent Girls and Young Women Seeking Reproductive Health Care in Kenya	F31HD105494
Optimizing routine HIV viral load monitoring in pregnant and postpartum women	R21HD093463
Pediatric HIV/AIDS Cohort Study (PHACS) Coordinating Center (CC) (U01)	U01HD052104
Pediatric HIV/AIDS Cohort Study (PHACS): Data and Operations Center (DOC)	U01HD052102
Penn Center for Study of Epigenetics in Reproduction	P50HD068157
Physiological Reactivity and Reactive Aggression among Violence- and Trauma-Exposed Youth	SC2HD089917
Policy Change and Women's Health	R01HD095951
Population Health in Pediatric Sex Chromosome Aneuploidies	R03HD102773
Postnatal Oxytocin Treatment and Cognitive Function in Fragile X	R01HD101642
Postpartum Family Planning	R01HD091274
Predicting PrEP Uptake and Adherence Among Adolescent Girls and Young Women in Sub-Saharan Africa: Leveraging Programmatic and Clinical Trials Data - Administrative Supplement	R01HD094682
Pregnancy Context and Health Outcomes	R01HD095181
Pregnancy-Associated Mortality	R01HD092653
Pregnancy-associated mortality and morbidity due to drugs, self-harm, and violence in the United States	R01HD102319
Prenatal behavioral intervention to prevent maternal cytomegalovirus in pregnancy	R01HD098352
PrEP Adherence Among AGYW: A Multidimensional Evaluation	R01HD094630
Prenatal Opioid Exposure: Birth, health, socioeconomic, and educational outcomes of mothers and their children	R01HD102125

Title	Grant Number
Prospective determinants of unintended pregnancy and its health consequences	R03HD097360
Public Use Datasets for Reproductive Health Research	R03HD100680
Quantifying the Impact of Insurance Coverage for IVF on Maternal and Infant Health	R01HD103603
Rett syndrome, MECP2 Duplications, and Rett-related Disorders Natural History	U54HD061222
Role of individual and hospital factors in quality of care for children in EDs	R01HD103637
Role of Maternal Obesity in Epigenetic and Metabolic Programming and Lower Respiratory Infection Risk in Early Life	K23HD104933
Role of Stress in Shaping Maternal, Infant, and Child Outcomes	R01HD091405
Sex Differences in the Neuro-immune Profile of the Developing Brain	F32HD097816
Sexual Health and Behavior in a U.S. Probability Sample of Adolescents and Adults	R01HD102535
Sexual Orientation/Gender Identity, Socioeconomic Status, and Health across the Life Course	R01HD087365
Sexual Revictimization: Emotional and Psychosocial Mechanisms	R01HD062226
Strategic antiretroviral therapy and HIV testing for youth in rural Africa (SATURN)	UG3HD096915
Stress and HIV infection in South African adolescent girls	R21HD106583
Support for the Rose F. Kennedy IDDRC	U54HD090260
Suubi+Adherence-R2: Examining the longitudinal HIV treatment adherence among youth living with HIV (YLHIV) transitioning into young adulthood	R01HD074949
System and Social Determinants of the Health of Foster Children	R01HD095946
Technology-Based Intervention for Reducing Sexually Transmitted Infections and Substance Use During Pregnancy	R01HD093611
The Dynamics of Intimate Relationships and their Dissolution during Young Adulthood	R03HD099277
The Effect of Neighborhood Change on Health and Well-Being	R01HD095653
The Effects of Parenting on the Development and Behavior of Adolescents with FXS	R01HD084563
The Effects of Unintended Pregnancy on Children	R01HD100438
The eXtraordinarY Babies Study: Natural History of Health and Neurodevelopment in Infants and Young Children with Sex Chromosome Trisomy	R01HD091251
The impact of parent training on at-risk children’s biomarkers of aging	F31HD098825
The South African National HIV Pregnancy Cohort: evaluating continuity of care among women living with HIV	R01HD103466
The Transition from Childhood into Adulthood among PSID Children, 2021 and 2023	R01HD103620
Translational medicine and mechanistic studies of brain neurophysiology in Fragile X Syndrome	U54HD104461
Trends in C-Section and Induction Use among US Births and Consequences for US Birth Weight	R03HD099359
Unequal Parenthoods: Population Perspectives on Gender, Race, and Sexual Minority Disparities in Family Stress and Health During Crises	U01HD108779
University of Rochester Intellectual and Developmental Disabilities Research Center	P50HD103536
Urea Cycle Disorders Rare Diseases Clinical Research Consortia (RDCRC) for the Rare Diseases Clinical Research Network (RDCRN)	U54HD061221
Validating a Scalable, Open Science Framework for Collecting Laboratory-Grade Data Remotely in Specialized Populations	R21HD106701
Washington University Intellectual and Developmental Disabilities Research Center	P50HD103525
Women HIV Cohort Study: HIV infection and treatment among women of reproductive age	R01HD101352

Title	Grant Number
Work Conditions and the Health of Working Parents and their Children	R21HD100893

Appendix C. Highlighted Publications with Analyses on Sex/Gender, Race, and/or Ethnicity

Abbeduto L, Thurman AJ, McDuffie A, Klusek J, Feigles RT, Ted Brown W, Harvey DJ, Adayev T, LaFauci G, Dobkins C, Roberts JE. ASD Comorbidity in Fragile X Syndrome: Symptom Profile and Predictors of Symptom Severity in Adolescent and Young Adult Males. Journal of autism and developmental disorders. 2019 March;49(3):960-977. PubMed PMID: 30382442; PubMed Central PMCID: PMC6556533; DOI: 10.1007/s10803-018-3796-2.

Abdel-Rahman, Susan M, Paul, Ian M, Hornik, Chi, Sullivan, Janice E., Wade, Kelly, Delmore, Paula, Sharma, Gaurav, Benjamin, Daniel K., Zimmerman, Kanecia O. Racial and Ethnic Diversity in Studies Funded Under the Best Pharmaceuticals for Children Act. Pediatrics, 2021 May;147(5): e2020042903, doi: 10.1542/peds.2020-042903. Epub 2021 Apr 12.

Anderson AT, Luartz L, Heard-Garris N, Widaman K, Chung PJ. The Detrimental Influence of Racial Discrimination on Child Health in the United States. J Natl Med Assoc. 2020 Aug;112(4):411-422. doi: 10.1016/j.jnma.2020.04.012. Epub 2020 Jun 10.

Arcury TA, Arnold TJ, Quandt SA, Chen H, Kearney GD, Sandberg JC, Talton JW, Wiggins MF, Daniel SS. Health and Occupational Injury Experienced by Latinx Child Farmworkers in North Carolina, USA. Int J Environ Res Public Health. 2019 Dec 30;17(1):248. doi: 10.3390/ijerph17010248. PMID: 31905836; PMCID: PMC6981743.

Arnold TJ, Arcury TA, Sandberg JC, Quandt SA, Talton JW, Mora DC, Kearney GD, Chen H, Wiggins MF, Daniel SS. Heat-Related Illness Among Latinx Child Farmworkers in North Carolina: A Mixed-Methods Study. New Solut. 2020 Aug;30(2):111-126. doi: 10.1177/1048291120920571. Epub 2020 Apr 29. PMID: 32349618; PMCID: PMC7363553.

Assari S. Protective Effects of Maternal Education against Low-Birth-Weight Deliveries: Blacks' Diminished Returns. Res Health Sci. 2020;5(4):1-17. doi: 10.22158/rhs.v5n4p1. Epub 2020 Sep 15. PMID: 33117952; PMCID: PMC7591153.

Baer RJ, Yang J, Berghella V, Chambers CD, Coker TR, Kuppermann M, Oltman SP, Rand L, Ryckman KK, Muglia LJ, Chung PJ, Jelliffe-Pawlowski LL. Risk of preterm birth by maternal age at first and second pregnancy and race/ethnicity. J Perinat Med. 2018 Jul 26;46(5):539-546. doi: 10.1515/jpm-2017-0014.

Barnert ES, Abrams LS, Tesema L, Dudovitz R, Nelson BB, Coker T, Bath E, Biely C, Li N, Chung PJ. Child incarceration and long-term adult health outcomes: a longitudinal study. Int J Prison Health. 2018 Mar 12;14(1):26-33. doi: 10.1108/IJPH-09-2016-0052.

Barnert ES, Abrams LS, Dudovitz R, Coker TR, Bath E, Tesema L, Nelson BB, Biely C, Chung PJ. What Is the Relationship Between Incarceration of Children and Adult Health Outcomes? Acad Pediatr. 2019 Apr;19(3):342-350. doi: 10.1016/j.acap.2018.06.005. Epub 2018 Jun 21.

Barnert ES, Lopez N, Pettway B, Keshav N, Abrams LS, Zima B, Chung PJ. The Role of Parent Engagement in Overcoming Barriers to Care for Youth Returning Home After Incarceration. J Community Health. 2020 Apr;45(2):329-337. doi: 10.1007/s10900-019-00747-1.

Barnert ES, Lopez N, Chung PJ. Barriers to Health Care for Latino Youths During Community Reentry After Incarceration: Los Angeles County, California, 2016-2018. Am J Public Health. 2020 Jan;110(S1): S63-S70. doi: 10.2105/AJPH.2019.305374.

Berry JG, Hall M, Cohen E, Feudtner C, Chiang VW, Chung PJ, Gay JC, Shah SS, Casto E, Richardson T. Hospitals' Diversity of Diagnosis Groups and Associated Costs of Care. Pediatrics. 2021 Mar;147(3): e2020018101. doi: 10.1542/peds.2020-018101.

Bhuptani PH, Kaufman JS, Messman-Moore TL, Gratz KL, DiLillo D. Rape Disclosure and Depression Among Community Women: The Mediating Roles of Shame and Experiential Avoidance. Violence Against Women. 2019 Aug;25(10):1226-1242. doi: 10.1177/1077801218811683. Epub 2018 Nov 25. PMID: 30474500.

Censin JC, Peters SAE, Bovijn J, Ferreira T, Pulit SL, Mägi R, Mahajan A, Holmes MV, Lindgren CM. *Causal relationships between obesity and the leading causes of death in women and men.* PLoS Genet. 2019 Oct 24;15(10): e1008405. doi: 10.1371/journal.pgen.1008405. PMID: 31647808; PMCID: PMC6812754.

Chen P, Engel S, Wang C. The multivariate adaptive design for efficient estimation of the time course of perceptual adaptation. *Behav Res Methods*. 2020;52(3):1073-1090. doi:10.3758/s13428-019-01301-6.

Chen WY, Lee Y. Mother's exposure to domestic and community violence and its association with child's behavioral outcomes. J Community Psychol. 2021 Sep;49(7):2623-2638. doi: 10.1002/jcop.22508. Epub 2021 Jan 19. PMID: 33465244.

Crear-Perry J, Correa-de-Araujo R, Lewis Johnson T, McLemore MR, Neilson E, Wallace M. Social and Structural Determinants of Health Inequities in Maternal Health. J Womens Health (Larchmt). 2021 Feb;30(2):230-235. doi: 10.1089/jwh.2020.8882. Epub 2020 Nov 12. PMID: 33181043; PMCID: PMC8020519.

Davis SM, Reynolds RM, Dabelea DM, Zeitler PS, Tartaglia NR. Testosterone Treatment in Infants With 47, XXY: Effects on Body Composition. Journal of the Endocrine Society. 2019 December 1;3(12):2276-2285. PubMed PMID: 31737857; PubMed Central PMCID: PMC6846330; DOI: 10.1210/js.2019-00274.

Davis SM, DeKlotz S, Nadeau KJ, Kelsey MM, Zeitler PS, Tartaglia NR. High prevalence of cardiometabolic risk features in adolescents with 47, XXY/Klinefelter syndrome. American journal of medical genetics. Part C, Seminars in medical genetics. 2020 June;184(2):327-333. PubMed PMID: 32542985; PubMed Central PMCID: PMC7413636; DOI: 10.1002/ajmg.c.31784.

Davis SM, Soares K, Howell S, Cree-Green M, Buyers E, Johnson J, Tartaglia NR. Diminished Ovarian Reserve in Girls and Adolescents with Trisomy X Syndrome. Reproductive sciences (Thousand Oaks, Calif.). 2020 November;27(11):1985-1991. PubMed PMID: 32578162; PubMed Central PMCID: PMC7529937; DOI: 10.1007/s43032-020-00216-4.

de la Cuesta-Zuluaga J, Kelley ST, Chen Y, Escobar JS, Mueller NT, Ley RE, McDonald D, Huang S, Swafford AD, Knight R, Thackray VG. *Age- and Sex-Dependent Patterns of Gut Microbial Diversity in Human Adults.* mSystems. 2019 May 14;4(4): e00261-19. doi: 10.1128/mSystems.00261-19. PMID: 31098397; PMCID: PMC6517691.

Del Hoyo Soriano L, Thurman AJ, Harvey DJ, Ted Brown W, Abbeduto L. Genetic and maternal predictors of cognitive and behavioral trajectories in females with fragile X syndrome. Journal of neurodevelopmental disorders. 2018 June 20;10(1):22. PubMed PMID: 29925305; PubMed Central PMCID: PMC6011256; DOI: 10.1186/s11689-018- 9240-2.

Desai S, Lindberg LD, Maddow-Zimet I, Kost K. The Impact of Abortion Underreporting on Pregnancy Data and Related Research. Matern Child Health J. 2021 Aug;25(8):1187-1192. doi: 10.1007/s10995-021-03157-9. Epub 2021 Apr 30. PMID: 33929651; PMCID: PMC8279977.

Dixit A, Johns NE, Ghule M, Battala M, Begum S, Yore J, Saggurti N, Silverman JG, Reed E, Benmarhnia T, Averbach S, Raj A. Male-female concordance in reported involvement of women in contraceptive decision-making and its association with modern contraceptive use among couples in rural Maharashtra, India.

Reprod Health. 2021 Jun 30;18(1):139. doi: 10.1186/s12978-021-01187-8. PMID: 34193214; PMCID: PMC8244175.

Dyer L, Chambers BD, Crear-Perry J, Theall KP, Wallace M. The Index of Concentration at the Extremes (ICE) and Pregnancy-Associated Mortality in Louisiana, 2016-2017. Matern Child Health J. 2021 Jun 19:10.1007/s10995-021-03189-1. doi: 10.1007/s10995-021-03189-1. Epub ahead of print. PMID: 34148221; PMCID: PMC8684557.

Dyer L, Hardeman R, Vilda D, Theall K, Wallace M. Mass incarceration and public health: the association between black jail incarceration and adverse birth outcomes among black women in Louisiana. BMC Pregnancy Childbirth. 2019 Dec 27;19(1):525. doi: 10.1186/s12884-019-2690-z. PMID: 31881857; PMCID: PMC6935062.

Dudovitz RN, Biely C, Barnert ES, Coker TR, Guerrero AD, Jackson N, Schickedanz A, Szilagyi PG, Iyer S, Chung PJ. Association between school racial/ethnic composition during adolescence and adult health. Soc Sci Med. 2021 Mar; 272:113719. doi: 10.1016/j.socscimed.2021.113719. Epub 2021 Jan 29.

Ernst MM, Kogan BA, Lee PA. Gender identity: A psychosocial primer for providing care to patients with a disorder/difference of sex development and their families [individualized care for patients with intersex (Disorders/differences of sex development): Part 2]. J Pediatr Urol. 2020 Oct;16(5):606-611. doi: 10.1016/j.jpurol.2020.06.026. Epub 2020 Jul 2. PMID: 32819812; PMCID: PMC7890938.

Everett BG, Kominiarek MA, Mollborn S, Adkins DE, Hughes TL. Sexual Orientation Disparities in Pregnancy and Infant Outcomes. Matern Child Health J. 2019 Jan;23(1):72-81. doi: 10.1007/s10995-018-2595-x. PMID: 30019158; PMCID: PMC6501574.

Everett BG, Limburg A, Charlton BM, Downing JM, Matthews PA. Sexual Identity and Birth Outcomes: A Focus on the Moderating Role of Race-ethnicity. J Health Soc Behav. 2021 Jun;62(2):183-201. doi: 10.1177/0022146521997811. Epub 2021 Mar 9. PMID: 33687305.

Everett BG, Mollborn S, Jenkins V, Limburg A, Diamond LM. Racial/Ethnic Differences in Unwanted Pregnancy: Moderation by Sexual Orientation. J Marriage Fam. 2020 Aug;82(4):1234-1249. doi: 10.1111/jomf.12656. Epub 2020 Jan 10. PMID: 34121766; PMCID: PMC8188848.

Everett BG, Turner B, Hughes TL, Veldhuis CB, Paschen-Wolff M, Phillips G 2nd. Sexual Orientation Disparities in Pregnancy Risk Behaviors and Pregnancy Among Sexually Active Teenage Girls: Updates

from the Youth Risk Behavior Survey. LGBT Health. 2019 Oct;6(7):342-349. doi: 10.1089/lgbt.2018.0206. PMID: 31618165; PMCID: PMC6797072.

Font S, Cancian M, Berger LM, DiGiovanni A. Patterns of intergenerational child protective services involvement. Child Abuse Negl. 2020 Jan; 99:104247. doi: 10.1016/j.chiabu.2019.104247. Epub 2019 Nov 9. PMID: 31715518; PMCID: PMC6984680.

Fortune E, Cloud-Biebl BA, Madansingh SI, et al. Estimation of manual wheelchair-based activities in the free-living environment using a neural network model with inertial body-worn sensors [published online ahead of print, 2019 Jul 17]. *J Electromyogr Kinesiol*. 2019;102337. doi: 10.1016/j.jelekin.2019.07.007.

Francois LN, Yang J, Baer RJ, Chung PJ, Jelliffe-Pawlowski LL, Coker TR. Cross-Generational Contributors to Preterm Birth in California: Singletons Based on Race/Ethnicity. Am J Perinatol. 2019 Mar;36(4):383-392. doi: 10.1055/s-0038-1668554. Epub 2018 Aug 19.

Garcia JP, Keen KL, Seminara SB, Terasawa E. *Role of Kisspeptin and NKB in Puberty in Nonhuman Primates: Sex Differences.* Semin Reprod Med. 2019 Mar;37(2):47-55. doi: 10.1055/s-0039-3400253. Epub 2019 Dec 17. PMID: 31847024; PMCID: PMC7055930.

Gard AM, Maxwell AM, Shaw DS, Mitchell C, Brooks-Gunn J, McLanahan SS, Forbes EE, Monk CS, Hyde LW. Beyond family-level adversities: Exploring the developmental timing of neighborhood disadvantage effects on the brain. Dev Sci. 2021 Jan;24(1): e12985. doi: 10.1111/desc.12985. Epub 2020 Jun 4. PMID: 32416027; PMCID: PMC7669733.

Gassman-Pines A, Ananat EO, Fitz-Henley J 2nd. COVID-19 and Parent-Child Psychological Well-being. Pediatrics. 2020 Oct;146(4): e2020007294. doi: 10.1542/peds.2020-007294. Epub 2020 Aug 6. PMID: 32764151; PMCID: PMC7546085.

Geller A, Fagan J. Police Contact and the Legal Socialization of Urban Teens. RSF. 2019 Feb;5(1):26-49. doi: 10.7758/rsf.2019.5.1.02. PMID: 34497875; PMCID: PMC8423110.

Geller A. Youth–Police Contact: Burdens and Inequities in an Adverse Childhood Experience, 2014–2017. Am J Public Health. 2021 Jul;111(7):1300-1308. doi: 10.2105/AJPH.2021.306259. Epub 2021 May 20. PMID: 34014760; PMCID: PMC8493138.

Geronimus AT, Bound J, Mitchell C, Martinez-Cardoso A, Evans L, Hughes L, Schneper L, Notterman DA. Coming up short: Comparing venous blood, dried blood spots & saliva samples for measuring telomere length in health equity research. PLoS One. 2021 Aug 18;16(8): e0255237. doi: 10.1371/journal.pone.0255237. PMID: 34407110; PMCID: PMC8372921.

Gold S, Edin KJ, Nelson TJ. Does Time with Dad in Childhood Pay Off in Adolescence? J Marriage Fam. 2020 Oct;82(5):1587-1605. doi: 10.1111/jomf.12676. Epub 2020 Mar 9. PMID: 34393267; PMCID: PMC8356204.

Goodwin BM, Cain SM, Van Straaten MG, Fortune E, Jahanian O, Morrow MMB. Humeral elevation workspace during daily life of adults with spinal cord injury who use a manual wheelchair compared to age and sex matched able-bodied controls. *PLoS One*. 2021;16(4): e0248978. Published 2021 Apr 23. doi: 10.1371/journal.pone.0248978.

Goodwin BM, Fortune E, Van Straaten MGP, Morrow MMB. Outcome Measures of Free-Living Activity in Spinal Cord Injury Rehabilitation. *Curr Phys Med Rehabil Rep*. 2019;7(3):284-289. doi:10.1007/s40141-019-00228-5.

Goodwin BM, Jahanian O, Cain SM, Van Straaten MG, Fortune E, Morrow MM. Duration of Static and Dynamic Periods of the Upper Arm During Daily Life of Manual Wheelchair Users and Matched Able-Bodied Participants: A Preliminary Report. *Front Sports Act Living*. 2021; 3:603020. Published 2021 Mar 26. doi:10.3389/fspor.2021.603020.

Goodwin BM, Jahanian O, Van Straaten MG, et al. Application and Reliability of Accelerometer-Based Arm Use Intensities in the Free-Living Environment for Manual Wheelchair Users and Able-Bodied Individuals. *Sensors (Basel)*. 2021;21(4):1236. Published 2021 Feb 10. doi:10.3390/s21041236.

Graham ZA, Lavin KM, O'Bryan SM, et al. Mechanisms of exercise as a preventative measure to muscle wasting. *Am J Physiol Cell Physiol*. 2021;321(1):C40-C57. doi:10.1152/ajpcell.00056.2021.

Gravholt C, Tartaglia NR, Distiche C. Sex Chromosome Aneuploidy Research in 2020 – The state of care and research in the world. American Journal of Medical Genetics Part C, Seminars in Medical Genetics. 2020 Jun; 184(2): 197–201. PubMed PMID: 32496026; PubMed Central PMCID: PMC7419158; DOI: 10.1002/ajmg.c.31808.

Guerrero AD, Zhou X, Chung PJ. How Well is the Medical Home Working for Latino and Black Children? Matern Child Health J. 2018 Feb;22(2):175-183. doi: 10.1007/s10995-017-2389-6.

Guerrero AD, Biely C, Dudovitz R, Coker T, Iyer S, Barnert E, Szilagyi P, Szilagyi M, Chung PJ. Measurement and Identification of Parenting Behaviors Associated with Social-Emotional Outcomes in Children: The Racial and Cultural Appropriateness of a Commonly Used Parenting Measure. J Dev Behav Pediatr. 2021 Sep 1;42(7):524-531. doi: 10.1097/DBP.0000000000000933.

Holmes SA, Barakat N, Bhasin M, et al. Biological and behavioral markers of pain following nerve injury in humans. *Neurobiol Pain*. 2019; 7:100038. Published 2019 Dec 4. doi: 10.1016/j.ynpai.2019.100038.

Howell S, Buchanan C, Davis SM, Miyazawa H, Furuta GT, Tartaglia NR, Nguyen N. Eosinophilic esophagitis in individuals with sex chromosome aneuploidies: Clinical presentations and management implications. Mol Genet Genomic Med. 2021 Dec;9(12): e1833. doi: 10.1002/mgg3.1833. Epub 2021 Nov 5. PMID: 34738344.

Hutaff-Lee C, Bennett E, Howell S, Tartaglia N. Clinical developmental, neuropsychological, and socialemotional features of Turner syndrome. American journal of medical genetics. Part C, Seminars in medical genetics. 2019 March;181(1):126-134. PubMed PMID: 30767374; PubMed Central PMCID: PMC6487305; DOI: 10.1002/ajmg.c.31687.

Hwang W, Jung E. Unpartnered Mothers' Work-Family Conflict and Parenting Stress: The Moderating Effects of Nonstandard Work Schedules. J Fam Econ Issues. 2020 Mar;41(1):158-171. doi: 10.1007/s10834-019-09647-x. Epub 2019 Sep 21. PMID: 33897229; PMCID: PMC8064407.

Jackson DB, Del Toro J, Semenza DC, Testa A, Vaughn MG. Unpacking Racial/Ethnic Disparities in Emotional Distress Among Adolescents During Witnessed Police Stops. J Adolesc Health. 2021 Aug;69(2):248-254. doi: 10.1016/j.jadohealth.2021.02.021. Epub 2021 Apr 2. PMID: 33814280.

Jacobsen WC. THE INTERGENERATIONAL STABILITY OF PUNISHMENT: PATERNAL INCARCERATION AND SUSPENSION OR EXPULSION IN ELEMENTARY SCHOOL. J Res Crime Delinq. 2019 Aug 1;56(5):651-693. doi: 10.1177/0022427819829794. Epub 2019 Mar 11. PMID: 32377023; PMCID: PMC7202564.

Jacobsen WC, Pace GT, Ramirez NG. Punishment and Inequality at an Early Age: Exclusionary Discipline in Elementary School. Soc Forces. 2019 Mar;97(3):973-998. doi: 10.1093/sf/soy072. Epub 2018 Jul 6. PMID: 31258199; PMCID: PMC6599586.

Jaffe, Anna E et al. “Risk for Revictimization Following Interpersonal and Noninterpersonal Trauma: Clarifying the Role of Posttraumatic Stress Symptoms and Trauma-Related Cognitions.” *Journal of traumatic stress* vol. 32,1 (2019): 42-55. doi:10.1002/jts.22372

Jahanian O, Van Straaten MG, Goodwin BM, et al. Inertial Measurement Unit-Derived Ergonomic Metrics for Assessing Arm Use in Manual Wheelchair Users with Spinal Cord Injury: A Preliminary Report. *Top Spinal Cord Inj Rehabil*. 2021;27(3):12-25. doi:10.46292/sci20-00059.

Jahanian O, Van Straaten MG, Goodwin BM, et al. Shoulder magnetic resonance imaging findings in manual wheelchair users with spinal cord injury [published online ahead of print, 2020 Nov 9]. *J Spinal Cord Med*. 2020;1-11. doi:10.1080/10790268.2020.1834774.

James C, Jimenez ME, Wade R Jr, Nepomnyaschy L. Adverse Childhood Experiences and Teen Behavior Outcomes: The Role of Disability. Acad Pediatr. 2021 Nov-Dec;21(8):1395-1403. doi: 10.1016/j.acap.2021.05.006. Epub 2021 May 19. PMID: 34020101.

James S, Chang AM, Buxton OM, Hale L. Disparities in adolescent sleep health by sex and ethnoracial group. SSM Popul Health. 2020 Apr 9; 11:100581. doi: 10.1016/j.ssmph.2020.100581. PMID: 32373706; PMCID: PMC7191202.

James S, Gold S, Rouhani S, McLanahan S, Brooks-Gunn J. Adolescent Exposure to Deadly Gun Violence Within 500 Meters of Home or School: Ethnoracial and Income Disparities. Health Aff (Millwood). 2021 Jun;40(6):961-969. doi: 10.1377/hlthaff.2020.02295. PMID: 34097511.

Janusz J, Harrison C, Boada C, Cordeiro L, Howell S, Tartaglia N, Boada R. Executive function in XXY: Comparison of performance-based measures and rating scales. American journal of medical genetics. Part C, Seminars in medical genetics. 2020 June;184(2):469-481. PubMed PMID: 32519473; DOI: 10.1002/ajmg.c.31804.

Jones KA, Do S, Porras-Javier L, Contreras S, Chung PJ, Coker TR. Feasibility and Acceptability in a Community-Partnered Implementation of CenteringParenting for Group Well-Child Care. Acad Pediatr. 2018 Aug;18(6):642-649. doi: 10.1016/j.acap.2018.06.001. Epub 2018 Jun 9.

Joyce BT, Gao T, Koss K, Zheng Y, Cardenas A, Heiss J, Just A, Zhang K, van Horn L, Allen NB, Greenland P, Cohen S, Gordon-Larsen P, Mitchell C, McLanahan S, Schneper L, Notterman D, Rifas-Shiman SL, Oken E, Hivert MF, Wright R, Baccarelli A, Lloyd-Jones D, Hou L. Impact of paternal education on epigenetic ageing in adolescence and mid-adulthood: a multi-cohort study in the USA and Mexico. Int J Epidemiol. 2021 Sep 17: dyab196. doi: 10.1093/ije/dyab196. Epub ahead of print. PMID: 34534313.

Kim Y, Lee S, Jung H, Jaime J, Cubbin C. Is neighborhood poverty harmful to every child? Neighborhood poverty, family poverty, and behavioral problems among young children. J Community Psychol. 2019 Apr;47(3):594-610. doi: 10.1002/jcop.22140. Epub 2018 Nov 11. PMID: 30417383; PMCID: PMC6652175.

Lagou V, Mägi R, Hottenga JJ, Grallert H, Perry JRB, Bouatia-Naji N, Marullo L, Rybin D, Jansen R, Min JL, Dimas AS, Ulrich A, Zudina L, Gådin JR, Jiang L, Faggian A, Bonnefond A, Fadista J, Stathopoulou MG, Isaacs A, Willems SM, Navarro P, Tanaka T, Jackson AU, Montasser ME, O'Connell JR, Bielak LF, Webster RJ, Saxena R, Stafford JM, Pourcain BS, Timpson NJ, Salo P, Shin SY, Amin N, Smith AV, Li G, Verweij N, Goel A, Ford I, Johnson PCD, Johnson T, Kapur K, Thorleifsson G, Strawbridge RJ, Rasmussen-Torvik LJ, Esko T, Mihailov E, Fall T, Fraser RM, Mahajan A, Kanoni S, Giedraitis V, Kleber ME, Silbernagel G, Meyer J, Müller-Nurasyid M, Ganna A, Sarin AP, Yengo L, Shungin D, Luan J, Horikoshi M, An P, Sanna S, Boettcher Y, Rayner NW, Nolte IM, Zemunik T, Iperen EV, Kovacs P, Hastie ND, Wild SH, McLachlan S, Campbell S, Polasek O, Carlson O, Egan J, Kiess W, Willemsen G, Kuusisto J, Laakso M, Dimitriou M, Hicks AA, Rauramaa R, Bandinelli S, Thorand B, Liu Y, Miljkovic I, Lind L, Doney A, Perola M, Hingorani A, Kivimaki M, Kumari M, Bennett AJ, Groves CJ, Herder C, Koistinen HA, Kinnunen L, Faire U, Bakker SJL, Uusitupa M, Palmer CNA, Jukema JW, Sattar N, Pouta A, Snieder H, Boerwinkle E, Pankow JS, Magnusson PK, Krus U, Scapoli C, de Geus EJCN, Blüher M, Wolffenbuttel BHR, Province MA, Abecasis GR, Meigs JB, Hovingh GK, Lindström J, Wilson JF, Wright AF, Dedoussis GV, Bornstein SR, Schwarz PEH, Tönjes A, Winkelmann BR, Boehm BO, März W, Metspalu A, Price JF, Deloukas P, Körner A, Lakka TA, Keinanen-Kiukaanniemi SM, Saaristo TE, Bergman RN, Tuomilehto J, Wareham NJ, Langenberg C, Männistö S, Franks PW, Hayward C, Vitart V, Kaprio J, Visvikis-Siest S, Balkau B, Altshuler D, Rudan I, Stumvoll M, Campbell H, van Duijn CM, Gieger C, Illig T, Ferrucci L, Pedersen NL, Pramstaller PP, Boehnke M, Frayling TM, Shuldiner AR, Peyser PA, Kardia SLR, Palmer LJ, Penninx BW, Meneton P, Harris TB, Navis G, Harst PV, Smith GD, Forouhi NG, Loos RJF, Salomaa V, Soranzo N, Boomsma DI, Groop L, Tuomi T, Hofman A, Munroe PB, Gudnason V, Siscovick DS, Watkins H, Lecoeur C, Vollenweider P, Franco-Cereceda A, Eriksson P, Jarvelin MR, Stefansson K, Hamsten A, Nicholson G, Karpe F, Dermitzakis ET, Lindgren CM, McCarthy MI, Froguel P, Kaakinen MA, Lyssenko V, Watanabe RM, Ingelsson E, Florez JC, Dupuis J, Barroso I, Morris AP, Prokopenko I; Meta-Analyses of Glucose and Insulin-related traits Consortium (MAGIC). *Sex-dimorphic genetic effects and novel loci for fasting glucose and insulin variability.* Nat Commun. 2021 Jan 5;12(1):24. doi: 10.1038/s41467-020-19366-9. Erratum in: Nat Commun. 2021 Feb 8;12(1):995. PMID: 33402679; PMCID: PMC7785747.

Lavalle SN, Chou T, Hernandez J, Naing NCP, Tonsfeldt KJ, Hoffmann HM, Mellon PL. *Kiss1 is differentially regulated in male and female mice by the homeodomain transcription factor VAX1.* Mol Cell Endocrinol. 2021 Aug 20; 534:111358. doi: 10.1016/j.mce.2021.111358. Epub 2021 Jun 4. PMID: 34098016; PMCID: PMC8319105.

Lee AS, Rusch J, Lima AC, Usmani A, Huang N, Lepamets M, Vigh-Conrad KA, Worthington RE, Mägi R, Wu X, Aston KI, Atkinson JP, Carrell DT, Hess RA, O'Bryan MK, Conrad DF. *Rare mutations in the complement regulatory gene CSMD1 are associated with male and female infertility.* Nat Commun. 2019 Oct 11;10(1):4626. doi: 10.1038/s41467-019-12522-w. PMID: 31604923; PMCID: PMC6789153.

Leibbrand C, Carll E, Bruns A, Lee H. Barring progress: The influence of paternal incarceration on families' neighborhood attainment. Soc Sci Res. 2019 Nov; 84:102321. doi: 10.1016/j.ssresearch.2019.06.012. Epub 2019 Jul 3. PMID: 31674339; PMCID: PMC7141163.

Limburg A, Everett BG, Mollborn S, Kominiarek MA. Sexual Orientation Disparities in Preconception Health. J Womens Health (Larchmt). 2020 Jun;29(6):755-762. doi: 10.1089/jwh.2019.8054. Epub 2020 Feb 27. PMID: 32105564; PMCID: PMC7307698.

Loesch, Danuta Z., Tassone, Flora, Atkinson, Anna, Stimpson, Paige, Trost, Nicholas, Putney, Dean L., Storey, Elsdon. Differential Progression of Motor Dysfunction Between Male and Female Fragile X Premutation Carriers Reveals Novel Aspects of Sex-Specific Neural Involvement: https://pubmed.ncbi.nlm.nih.gov/33511153/

Lundberg I, Donnelly L. A Research Note on the Prevalence of Housing Eviction Among Children Born in U.S. Cities. Demography. 2019 Feb;56(1):391-404. doi: 10.1007/s13524-018-0735-y. PMID: 30484162; PMCID: PMC6358494.

MacCallum-Bridges CL, Margerison CE. The Affordable Care Act contraception mandate & unintended pregnancy in women of reproductive age: An analysis of the National Survey of Family Growth, 2008-2010 v. 2013-2015. Contraception. 2020 Jan;101(1):34-39. doi: 10.1016/j.contraception.2019.09.003. Epub 2019 Oct 23. PMID: 31655071; PMCID: PMC7017385.

Maddow-Zimet I, Lindberg LD, Castle K. State-Level Variation in Abortion Stigma and Women and Men's Abortion Underreporting in the USA. Popul Res Policy Rev. 2021 Dec;40(6):1149-1161. doi: 10.1007/s11113-021-09657-4. Epub 2021 May 20. PMID: 34712000; PMCID: PMC8547795.

Mallette JK, Futris TG, Oshri A, Brown GL. Paternal Support and Involvement in Unmarried Fragile Families: Impacts on Long-Term Maternal Mental Health. Fam Process. 2020 Jun;59(2):789-806. doi: 10.1111/famp.12456. Epub 2019 Apr 22. PMID: 31012095.

Margerison CE, Hettinger K, Kaestner R, Goldman-Mellor S, Gartner D. Medicaid Expansion Associated with Some Improvements in Perinatal Mental Health. Health Aff (Millwood). 2021 Oct;40(10):1605-1611. doi: 10.1377/hlthaff.2021.00776. PMID: 34606358.

Margerison CE, Kaestner R, Chen J, MacCallum-Bridges C. Impacts of Medicaid Expansion Before Conception on Prepregnancy Health, Pregnancy Health, and Outcomes. Am J Epidemiol. 2021 Aug 1;190(8):1488-1498. doi: 10.1093/aje/kwaa289. PMID: 33423053; PMCID: PMC8522774.

Margerison CE, MacCallum CL, Chen J, Zamani-Hank Y, Kaestner R. Impacts of Medicaid Expansion on Health Among Women of Reproductive Age. Am J Prev Med. 2020 Jan;58(1):1-11. doi: 10.1016/j.amepre.2019.08.019. Epub 2019 Nov 21. PMID: 31761513; PMCID: PMC6925642.

Martin S, Cordeiro L, Richardson P, Davis S, Tartaglia N. The Association of Motor Skills and Adaptive Functioning in XXY/Klinefelter and XXYY Syndromes. Physical & occupational therapy in pediatrics. 2019;39(4):446-459. PubMed PMID: 30592247; PubMed Central PMCID: PMC7425033; DOI: 10.1080/01942638.2018.1541040.

Mathew GM, Hale L, Chang AM. Sex Moderates Relationships Among School Night Sleep Duration, Social Jetlag, and Depressive Symptoms in Adolescents. J Biol Rhythms. 2019 Apr;34(2):205-217. doi: 10.1177/0748730419828102. Epub 2019 Feb 18. PMID: 30773079; PMCID: PMC6587189.

Mattlage AE, Sutter EN, Bland MD, et al. Dose of remote limb ischemic conditioning for enhancing learning in healthy young adults. *Exp Brain Res*. 2019;237(6):1493-1502. doi:10.1007/s00221-019-05519-w.

Mehta PK, Kieltyka L, Bachhuber MA, Smiles D, Wallace M, Zapata A, Gee RE. Racial Inequities in Preventable Pregnancy-Related Deaths in Louisiana, 2011-2016. Obstet Gynecol. 2020 Feb;135(2):276-283. doi: 10.1097/AOG.0000000000003591. Erratum in: Obstet Gynecol. 2020 Mar;135(3):734-735. PMID: 31923055; PMCID: PMC7299502.

Mittleman J. Sexual Minority Bullying and Mental Health from Early Childhood Through Adolescence. J Adolesc Health. 2019 Feb;64(2):172-178. doi: 10.1016/j.jadohealth.2018.08.020. Epub 2018 Nov 2. PMID: 30392862.

Morrow MM, Cutti AG, Vidt ME. Trends and advancements in shoulder biomechanics research [published online ahead of print, 2020 Feb 28]. *J Electromyogr Kinesiol*. 2020;102409. doi: 10.1016/j.jelekin.2020.102409.

Narapareddy L, Rhon-Calderon EA, Vrooman LA, Baeza J, Nguyen DK, Mesaros C, Lan Y, Garcia BA, Schultz RM, Bartolomei MS. *Sex-specific effects of in vitro fertilization on adult metabolic outcomes and hepatic transcriptome and proteome in mouse.* FASEB J. 2021 Apr;35(4): e21523. doi: 10.1096/fj.202002744R. PMID: 33734487; PMCID: PMC8132511.

Neul JL, Skinner SA, Annese F, Lane J, Heydemann P, Jones M, Kaufmann WE, Glaze DG, Percy AK. Metabolic Signatures Differentiate Rett Syndrome from Unaffected Siblings. Frontiers in integrative neuroscience. 2020; 14:7. PubMed PMID: 32161522; PubMed Central PMCID: PMC7052375; DOI: 10.3389/fnint.2020.00007.

Ophir A, Polos J. Care Life Expectancy: Gender and Unpaid Work in the Context of Population Aging. Popul Res Policy Rev. 2021 Feb 15:1-31. doi: 10.1007/s11113-021-09640-z. Epub ahead of print. PMID: 33612898; PMCID: PMC7882465.

Peters SU, Fu C, Marsh ED, Benke TA, Suter B, Skinner SA, Lieberman DN, Standridge S, Jones M, Beisang A, Feyma T, Heydeman P, Ryther R, Glaze DG, Percy AK, Neul JL. Phenotypic features in MECP2 duplication syndrome: Effects of age. American journal of medical genetics. Part A. 2021 February;185(2):362-369. PubMed PMID: 33170557; PubMed Central PMCID: PMC8000774; DOI: 10.1002/ajmg.a.61956.

Polos J, Koning S, McDade T. Do intersecting identities structure social contexts to influence life course health? The case of school peer economic disadvantage and obesity. Soc Sci Med. 2021 Nov; 289:114424. doi: 10.1016/j.socscimed.2021.114424. Epub 2021 Sep 29. PMID: 34649177; PMCID: PMC8631455.

Pravata VM, Omelková M, Stavridis MP, Desbiens CM, Stephen HM, Lefeber DJ, Gecz J, Gundogdu M, Õunap K, Joss S, Schwartz CE, Wells L, van Aalten DMF. An intellectual disability syndrome with single-nucleotide variants in O-GlcNAc transferase. European journal of human genetics: EJHG. 2020 June;28(6):706-714. PubMed PMID: 32080367; PubMed Central PMCID: PMC7253464; DOI: 10.1038/s41431-020-0589-9.

Puls HT, Hall M, Anderst JD, Leventhal JM, Chung PJ. Insurance Coverage for Children Impacts Reporting of Child Maltreatment by Healthcare Professionals. J Pediatr. 2020 Jan; 216:181-188.e1. doi: 10.1016/j.jpeds.2019.09.073. Epub 2019 Nov 1.

Quandt SA, Arnold TJ, Mora DC, Arcury TA, Talton JW, Daniel SS. Hired Latinx Child Farmworkers in North Carolina: Educational Status and Experience Through a Social Justice Lens. *New Solut*. 2021;30(4):282-293. doi:10.1177/1048291120970207.

Raspa M, Bann CM, Gwaltney A, Benke TA, Fu C, Glaze DG, Haas R, Heydemann P, Jones M, Kaufmann WE, Lieberman D, Marsh E, Peters S, Ryther R, Standridge S, Skinner SA, Percy AK, Neul JL. A Psychometric Evaluation of the Motor-Behavioral Assessment Scale for Use as an Outcome Measure in Rett Syndrome Clinical Trials. American journal on intellectual and developmental disabilities. 2020 November 1;125(6):493-509. PubMed PMID: 33211820; PubMed Central PMCID: PMC7778880; DOI: 10.1352/1944-7558-125.6.493.

Rosengard JL, Donato J, Ferastraoaru V, Zhao D, Molinero I, Boro A, Gursky J, Correa DJ, Galanopoulou AS, Hung C, Legatt AD, Patel P, Rubens E, Moshé SL, Haut S. Seizure control, stress, and access to care during the COVID-19 pandemic in New York City: The patient perspective. Epilepsia. 2021 January;62(1):41-50. PubMed PMID: 33258109; PubMed Central PMCID: PMC7753328; DOI: 10.1111/epi.16779.

Saby JN, Benke TA, Peters SU, Standridge SM, Matsuzaki J, Cutri-French C, Swanson LC, Lieberman DN, Key AP, Percy AK, Neul JL, Nelson CA, Roberts TPL, Marsh ED. Multisite Study of Evoked Potentials in Rett Syndrome. Annals of neurology. 2021 April;89(4):790-802. PubMed PMID: 33480039; DOI: 10.1002/ana.26029.

Sattler KMP, Font SA. Predictors of Adoption and Guardianship Dissolution: The Role of Race, Age, and Gender Among Children in Foster Care. Child Maltreat. 2021 May;26(2):216-227. doi: 10.1177/1077559520952171. Epub 2020 Sep 10. PMID: 32909825; PMCID: PMC8127608.

Schuster MA, Osherov A, Chung PJ. Why Counting Black Lives Matters - The 2020 Census. N Engl J Med. 2020 Aug 27;383(9): e60. doi: 10.1056/NEJMp2022162. Epub 2020 Aug 11.

Schwartz GL, Leifheit KM, Berkman LF, Chen JT, Arcaya MC. Health Selection into Eviction: Adverse Birth Outcomes and Children's Risk of Eviction Through Age 5 Years. Am J Epidemiol. 2021 Jul 1;190(7):1260-1269. doi: 10.1093/aje/kwab007. PMID: 33454765; PMCID: PMC8484772.

Smith JP, Hardy ST, Hale LE, Gazmararian JA. Racial disparities and sleep among preschool aged children: a systematic review. Sleep Health. 2019 Feb;5(1):49-57. doi: 10.1016/j.sleh.2018.09.010. Epub 2018 Oct 15. PMID: 30670165; PMCID: PMC6519123.

Spencer RA, Livingston MD, Woods-Jaeger B, Rentmeester ST, Sroczynski N, Komro KA. The impact of temporary assistance for needy families, minimum wage, and Earned Income Tax Credit on Women's well-being and intimate partner violence victimization. Soc Sci Med. 2020 Dec; 266:113355. doi: 10.1016/j.socscimed.2020.113355. Epub 2020 Sep 8. PMID: 32947076.

Stephen HM, Adams TM, Wells L. Regulating the Regulators: Mechanisms of Substrate Selection of the O-GlcNAc Cycling Enzymes OGT and OGA. Glycobiology. 2021 August 7;31(7):724-733. PubMed PMID: 33498085; PubMed Central PMCID: PMC8351506; DOI: 10.1093/glycob/cwab005.

Stephen HM, Praissman JL, Wells L. Generation of an Interactome for the Tetratricopeptide Repeat Domain of O-GlcNAc Transferase Indicates a Role for the Enzyme in Intellectual Disability. Journal of proteome research. 2021 February 5;20(2):1229-1242. PubMed PMID: 33356293; DOI: 10.1021/acs.jproteome.0c00604.

Sudhinaraset M, Vilda D, Gipson JD, Bornstein M, Wallace ME. Women's Reproductive Rights Policies and Adverse Birth Outcomes: A State-Level Analysis to Assess the Role of Race and Nativity Status. Am J Prev Med. 2020 Dec;59(6):787-795. doi: 10.1016/j.amepre.2020.07.025. Epub 2020 Oct 13. PMID: 33067070; PMCID: PMC7683369.

Suglia SF, Appleton AA, Bleil ME, Campo RA, Dube SR, Fagundes CP, Heard- Garris NJ, Johnson SB, Slopen N, Stoney CM, Watamura SE. Timing, duration, and differential susceptibility to early life adversities and cardiovascular disease risk across the lifespan: Implications for future research. Prev Med. 2021 Dec; 153:106736. doi: 10.1016/j.ypmed.2021.106736. Epub 2021 Jul 19. PMID: 34293381; PMCID: PMC8595689.

Surkar SM, Bland MD, Mattlage AE, et al. Effects of remote limb ischemic conditioning on muscle strength in healthy young adults: A randomized controlled trial. *PLoS One*. 2020;15(2): e0227263. Published 2020 Feb 4. doi: 10.1371/journal.pone.0227263.

Sutter EN, Mattlage AE, Bland MD, et al. Remote Limb Ischemic Conditioning and Motor Learning: Evaluation of Factors Influencing Response in Older Adults. *Transl Stroke Res*. 2019;10(4):362-371. doi:10.1007/s12975-018-0653-8.

Tartaglia N, Howell S, Davis S, Kowal K, Tanda T, Brown M, Boada C, Alston A, Crawford L, Thompson T, van Rijn S, Wilson R, Janusz J, Ross J. Early neurodevelopmental and medical profile in children with sex chromosome trisomies: Background for the prospective eXtraordinarY babies' study to identify early risk factors and targets for intervention. American journal of medical genetics. Part C, Seminars in medical genetics. 2020 June;184(2):428-443. PubMed PMID: 32506668; PubMed Central PMCID: MC7413625; DOI: 10.1002/ajmg.c.31807.

Teitler JO, Plaza R, Hegyi T, Kruse L, Reichman NE. Elective Deliveries and Neonatal Outcomes in Full-Term Pregnancies. Am J Epidemiol. 2019 Apr 1;188(4):674-683. doi: 10.1093/aje/kwz014. PMID: 30698621; PMCID: PMC6438816.

Teresi JA, Ocepek-Welikson K, Kleinman M, Cheville A, Ramirez M. Challenges in Measuring Applied Cognition: Measurement Properties and Equivalence of the Functional Assessment in Acute Care Multidimensional Computerized Adaptive Test (FAMCAT) Applied Cognition Item Bank [published online ahead of print, 2021 Feb 5]. *Arch Phys Med Rehabil*. 2021; S0003-9993(21)00136-2. doi: 10.1016/j.apmr.2020.12.029.

Teresi JA, Wang C, Kleinman M, Jones RN, Weiss DJ. Differential Item Functioning Analyses of the Patient-Reported Outcomes Measurement Information System (PROMIS®) Measures: Methods, Challenges, Advances, and Future Directions. *Psychometrika*. 2021;86(3):674-711. doi:10.1007/s11336-021-09775-0.

Thomas AS, Osbourne M, Appelhans BM, Roisman GI, Booth-LaForce C, Bleil ME. Disparities in COVID-19-related stressful life events in the United States: Understanding who is most impacted. Health Soc Care Community. 2021 Dec 1. doi: 10.1111/hsc.13671. Epub ahead of print. PMID: 34854149.

Thompson T, Howell S, Davis S, Wilson R, Janusz J, Boada R, Pyle L, Tartaglia N. Current survey of early childhood intervention services in infants and young children with sex chromosome aneuploidies. American journal of medical genetics. Part C, Seminars in medical genetics. 2020 June;184(2):414-427. PubMed PMID: 32449585; PubMed Central PMCID: PMC7413639; DOI: 10.1002/ajmg.c.31785.

Urbanus E, Swaab H, Tartaglia N, Cordeiro L, van Rijn S. The behavioral profile of children aged 1-5years with sex chromosome trisomy (47, XXX, 47, XXY, 47, XYY). American journal of medical genetics. Part C, Seminars in medical genetics. 2020 June;184(2):444-455. PubMed PMID: 32432413; PubMed Central PMCID: PMC7384033; DOI: 10.1002/ajmg.c.31788.

Varnell RR, Arnold TJ, Quandt SA, Talton JW, Chen H, Miles CM, Daniel SS, Sandberg JC, Anderson KA, Arcury TA. Menstrual Cycle Patterns and Irregularities in Hired Latinx Child Farmworkers. J Occup Environ Med. 2021 Jan 1;63(1):38-43. doi: 10.1097/JOM.0000000000002065. PMID: 33105405.

Veatch OJ, Malow BA, Lee HS, Knight A, Barrish JO, Neul JL, Lane JB, Skinner SA, Kaufmann WE, Miller JL, Driscoll DJ, Bird LM, Butler MG, Dykens EM, Gold JA, Kimonis V, Bacino CA, Tan WH, Kothare SV, Peters SU, Percy AK, Glaze DG. Evaluating Sleep Disturbances in Children with Rare Genetic Neurodevelopmental Syndromes. Pediatric neurology. 2021 October; 123:30-37. PubMed PMID: 34388423; PubMed Central PMCID: PMC8429141; DOI: 10.1016/j.pediatrneurol.2021.07.009.

Vilda D, Hardeman R, Dyer L, Theall KP, Wallace M. Structural racism, racial inequities and urban-rural differences in infant mortality in the US. J Epidemiol Community Health. 2021 Aug;75(8):788-793. doi: 10.1136/jech-2020-214260. Epub 2021 Jan 27. PMID: 33504545; PMCID: PMC8273079.

Vilda D, Wallace ME, Daniel C, Evans MG, Stoecker C, Theall KP. State Abortion Policies and Maternal Death in the United States, 2015–2018. Am J Public Health. 2021 Sep;111(9):1696-1704. doi: 10.2105/AJPH.2021.306396. Epub 2021 Aug 19. PMID: 34410825; PMCID: PMC8589072.

Vilda D, Wallace M, Dyer L, Harville E, Theall K. Income inequality and racial disparities in pregnancy-related mortality in the US. SSM Popul Health. 2019 Aug 28; 9:100477. doi: 10.1016/j.ssmph.2019.100477. Erratum in: SSM Popul Health. 2020 Dec 10; 12:100714. PMID: 31517017; PMCID: PMC6734101.

Wallace ME, Crear-Perry J, Mehta PK, Theall KP. Homicide During Pregnancy and the Postpartum Period in Louisiana, 2016-2017. JAMA Pediatr. 2020 Apr 1;174(4):387-388. doi: 10.1001/jamapediatrics.2019.5853. Erratum in: JAMA Pediatr. 2020 Apr 1;174(4):393. PMID: 32011644; PMCID: PMC7042931.

Wallace ME, Friar N, Herwehe J, Theall KP. Violence As a Direct Cause of and Indirect Contributor to Maternal Death. J Womens Health (Larchmt). 2020 Aug;29(8):1032-1038. doi: 10.1089/jwh.2019.8072. Epub 2020 Mar 23. PMID: 32202951; PMCID: PMC7462032.

Wallace M, Dyer L, Felker-Kantor E, Benno J, Vilda D, Harville E, Theall K. Maternity Care Deserts and Pregnancy-Associated Mortality in Louisiana. Womens Health Issues. 2021 Mar-Apr;31(2):122-129. doi: 10.1016/j.whi.2020.09.004. Epub 2020 Oct 14. PMID: 33069560; PMCID: PMC8005403.

Wang C, Chen P, Huebner A. Stopping rules for multi-category computerized classification testing. *Br J Math Stat Psychol*. 2021;74(2):184-202. doi:10.1111/bmsp.12202

Wang C, Weiss DJ, Shang Z. Variable-Length Stopping Rules for Multidimensional Computerized Adaptive Testing. *Psychometrika*. 2019;84(3):749-771. doi:10.1007/s11336-018-9644-7.

Ward KP, Lee SJ, Limb GE, Grogan-Kaylor AC. Physical Punishment and Child Externalizing Behavior: Comparing American Indian, White, and African American Children. J Interpers Violence. 2021 Sep;36(17-18):NP9885-NP9907. doi: 10.1177/0886260519861678. Epub 2019 Jul 13. PMID: 31303101.

Webb L, Musci R, Mendelson T. Co-Occurring Mental Health Symptoms in Urban Adolescents: Comorbidity Profiles and Correlates. J Clin Child Adolesc Psychol. 2021 Apr 5:1-13. doi: 10.1080/15374416.2021.1901228. Epub ahead of print. PMID: 33819113; PMCID: PMC8490478.

Webb L, Sibinga E, Musci R, Clary LK, Mendelson T. Confirming Profiles of Comorbid Psychological Symptoms in Urban Youth: Exploring Gender Differences and Trait Mindfulness. J Youth Adolesc. 2021 Nov;50(11):2249-2261. doi: 10.1007/s10964-021-01509-w. Epub 2021 Oct 6. PMID: 34613544; PMCID: PMC8607347.

Weiss NH, Walsh K, DiLillo DD, Messman-Moore TL, Gratz KL. A Longitudinal Examination of Posttraumatic Stress Disorder Symptoms and Risky Sexual Behavior: Evaluating Emotion Dysregulation Dimensions as Mediators. Arch Sex Behav. 2019 Apr;48(3):975-986. doi: 10.1007/s10508-019-1392-y. Epub 2019 Feb 15. PMID: 30771054; PMCID: PMC6474756.

Wigby K, Cordeiro L, Wilson R, Angkustsiri K, Simon TJ, Tartaglia N. Adaptive functioning in children and adolescents with Trisomy X: An exploratory analysis. American journal of medical genetics. Part C, Seminars in medical genetics. 2020 June;184(2):456-468. PubMed PMID: 32548885; DOI: 10.1002/ajmg.c.31803.

Wu B, Arslanian KJ, Nyhan K, Taylor S, Shabanova V, Muasau-Howard B, Hawley NL. Preterm birth among Pacific Islander women and related perinatal outcomes: a scoping review protocol. BMJ Open. 2021 Nov 2;11(11): e050483. doi: 10.1136/bmjopen-2021-050483. PMID: 34728448; PMCID: PMC8565552.

Younce JR, Campbell MC, Hershey T, et al. Resting-State Functional Connectivity Predicts STN DBS Clinical Response. *Mov Disord*. 2021;36(3):662-671. doi:10.1002/mds.28376.

Youssef AM, Peng K, Kim PK, et al. Pain stickiness in pediatric complex regional pain syndrome: A role for the nucleus accumbens. *Neurobiol Pain*. 2021; 9:100062. Published 2021 Feb 19. doi: 10.1016/j.ynpai.2021.100062.

Zito RC. Relative Employment, Gender Beliefs, and Intimate Partner Coercion and Violence Against New Mothers Across Marital and Residential Contexts. J Interpers Violence. 2020 Nov;35(21-22):4492-4516. doi: 10.1177/0886260517715603. Epub 2017 Jun 22. PMID: 29294804.