Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY2022 – FY2024

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I. Background/Overview

A. Mission Statement

NICHD's mission is to lead research and training to understand human development, improve reproductive health, enhance the lives of children and adolescents, and optimize abilities for all.

B. Description of NICHD portfolio

NICHD funds research in areas relevant to normal and abnormal human development, including contraception, fertilization, pregnancy, childbirth, prenatal and postnatal development, childhood development through adolescence, intellectual and developmental disabilities, and rehabilitation medicine. Research conducted and funded by NICHD has helped save lives, improve wellbeing, and reduce societal costs associated with illness and disability.

NICHD Structure

NICHD is organized into four primary components, the Division of Extramural Research (DER), the Division of Extramural Activities (DEA), the Division of Intramural Research (DIR) and the National Center for Medical Rehabilitation Research (NCMRR).

Division of Extramural Research (DER)

NICHD DER coordinates and funds research and training programs across the United States and globally through roughly 3,500 competing grant applications and over 450 new and competing awards each year in grants and contracts. DER advises the NICHD Director to establish scientific priorities. DER created an Office of Clinical Research (OCR) to support extramural program management and oversight, ensure research integrity and compliance with regulations and policies.

OCR provides guidance and recommendations to NICHD staff to ensure protection of the rights and safety of human study participants and leads implementation of extramural policies and procedures for NICHD. The OCR liaisons with the Inclusion Officer, Program Officials (DER), Grants Management and Scientific Review Officials, and with staff from Division of Extramural Activities. Members of OCR represent NICHD on Inclusion Operating Procedures Working Group (IOPW) and Inclusion Governance Committee (IGC).

Please visit Extramural Scientific Branches to learn more about NICHD research priorities and funding opportunities, or select a branch from the following list:

- Child Development and Behavior Branch
- Contraception Research Branch
- Developmental Biology and Congenital Anomalies Branch
- Fertility and Infertility Branch
- Gynecologic Health and Disease Branch
- Intellectual and Developmental Disabilities Branch
- Maternal and Pediatric Infectious Disease Branch
- Obstetric and Pediatric Pharmacology and Therapeutics Branch
- Pediatric Growth and Nutrition Branch
- Pediatric Trauma and Critical Illness Branch
- Population Dynamics Branch
- Pregnancy and Perinatology Branch

Division of Extramural Activities (DEA)

DEA advises NICHD leadership on policies and procedures for the implementation of the institute's research grant and training programs. DEA provides a centralized point of coordination, guidance, and implementation for policy, review, and administration. DEA contributes to inclusion monitoring through the Inclusion Service Center (ISC).

- Office of Extramural Policy (OEP)
- Scientific Review Branch (SRB)
- Grants Management Branch (GMB)

Division of Intramural Research (DIR)

By leading the institute's laboratory and clinical research programs, DIR seeks fundamental knowledge about the nature and behavior of living systems through basic, clinical, and population-based research, and determines how to apply such knowledge to illuminate developmental origins of health and disease and to 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. DIR is made up of seven divisions, including:

- Division of Developmental Biology
- Division of Translational Medicine

- Division of Molecular and Cellular Biology
- Division of Basic and Translational Biophysics
- Division of Translational Imaging and Genomic Integrity
- Division of Neurosciences and Cellular and Structural Biology
- Division of Population Health Research (DiPHR)

Basic and clinical programs are divided into 12 scientifically based affinity groups, each with a unique focus but shared research goals, objectives, and resources.

National Center for Medical Rehabilitation Research (NCMRR)

On November 16, 1990, Congress passed an amendment to the Public Health Service Act (P.L. 101-613) to establish the NCMRR within NICHD to conduct and support research and research training (including research on the development of orthotic and prosthetic devices) in medical rehabilitation.

C. History

NICHD was founded in 1962 to investigate human development throughout the entire life process, with a focus on understanding disabilities and important events that occur during pregnancy. For more than 60 years, NICHD has supported and conducted research on the processes of human development and how they affect health, from pre-pregnancy through adulthood.

> *". . . We will look to the National Institute of Child Health and Human Development for a concentrated attack on the unsolved health problems of children and of mother-infant relationships. This legislation will encourage imaginative research into the complex processes of human development from conception to old age. . . For the first time, we will have an institute to promote studies directed at the entire life process rather than toward specific diseases or illnesses."*
> *—John F. Kennedy, October 17, 1962*

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 scientific peer review panels are given specific guidance (PDF 269 KB) on reviewing the inclusion of women, racial and ethnic minorities, and participants of ages across the lifespan when considering clinical research applications. For NIH-defined Phase III clinical trials, enrollment goals are further assessed for plans

to conduct analyses of intervention effects among women and racial and ethnic groups. Unacceptable inclusion plans are considered in the determination of overall impact score of the application and are documented in the summary statements. If issues are raised in review, program staff notify principal investigators, who are required to address these issues prior to funding. The NACHHD Advisory Council performs the second level of review and makes recommendations for funding to the NICHD Director considering the overall impact score, percentile ranking, and summary statement in light of the research priorities for NICHD. Applications with unacceptable inclusion plans receive a bar to funding; an award is not issued until an acceptable resolution is received.

Effective January 2025, the new Simplified Framework for NIH Peer Review reorganizes peer review criteria into three central factors: importance, rigor and feasibility, and expertise and resources. Inclusion criteria and coding and plans for valid design and analysis of Phase III clinical trials, previously evaluated under Additional Review Criteria, will be integrated within Factor 2 (Rigor and Feasibility). This change will help to emphasize the importance of these criteria in evaluating scientific merit.

B. Program Monitoring, Grants Management, Inclusion Officer and the Office of Clinical Research Oversight

Prior to an award, program officials are responsible for reviewing the inclusion information in the application and indicating whether the plans are scientifically appropriate. Program staff monitor actual enrollment progress in annual progress reports and provide consultation when necessary. Program officials monitor requirements for plans and reporting of valid analyses by sex and race/ethnicity. The ISC supports program staff in monitoring inclusion compliance. 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. The OCR, which includes a collaboration with the Inclusion Officer, the ISC, and OEP, works with program officials, grant management specialists, and Division leadership to ensure that human subjects research complies with NIH inclusion policies.

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, race, age, and ethnicity of those who were accrued during the past year; any issues with accrual 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 (ORWH).

D. Describe IC 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 in orientation. NIH created the Inclusion Learning Path in 2024 to provide a suite of on-demand trainings on inclusion policies and procedures for program staff. NICHD staff may access these and other archived trainings live, via videocast, archived video, and/or computer-based programs.

In addition to training opportunities offered by NIH, the NICHD OEP in collaboration with the Inclusion Officer and the OCR 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 December 2023, representatives from NIH and NICHD conducted training with all Extramural Staff to review policies and procedures on the Monitoring of Inclusion in NIH Research. Tips and best practices from preventing common inclusion errors and warnings were also introduced and discussed. In April 2023, an overview of the new ISC, including structure, roles and responsibilities, and staff makeup of the service center, was reviewed with NICHD Extramural Staff. Building on this work, in June 2024 NICHD held its first “Inclusion Boot Camp”, comprising a comprehensive review of the Inclusion Across the Lifespan policy, inclusion tracking, protection of human subjects research, the need for inclusion of all races/ethnicities, sexes, and age groups in research studies. ISC and OEP staff continue to provide individualized one-on-one tutorials on the Human Subjects System (HSS) for tracking enrollment for active grants. Inclusion Office Hours, adopted in 2024, provide recurrent opportunities for more personal discussions of inclusion questions and issues and to learn from the questions of colleagues.

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 in order 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 2022 – 2024 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. While we are unable to change the formatting, table numbers, or titles of the official tables, we have included some supplement tables with similar formatting to clarify analyses.

NICHD Enrollment Tables Included in Appendix A

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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) 2022 – 2024. In 2022, 1,136 of the 1,984 IERs (57.3%) for NICHD grants, contracts, and intramural projects had enrollment data; the 848 IERs (42.7%) without enrollment represent projects for which recruitment had not yet begun or enrollment had not yet been reported (Table 2-1). Both the total number of IERs and the number of IERs with enrollment increased slightly in subsequent years, but the percentage of records with enrollment was similar: 56.7% in 2023 and 60.7% in 2024.

Table 2-2 shows the subset of those IERs that were Phase III clinical trials. Among the 2022 IERs, 93 were Phase III clinical trials, and 64 (68.8%) of those had enrollment data (Table 2-2). The numbers of Phase III trials and the percentage of studies that had begun enrollment were similar in subsequent years: 103 Phase III trials in 2023, 72.8% of which had begun enrollment, and 94 in 2024, 70.2% of which had begun enrollment.

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 studies in FYs 2022 – 2024 were domestic, with records from U.S. sites accounting for 86.9% - 88.4% of all clinical research IERs and 69.7% - 79.7% of IERs for Phase III trials.

Tables 2-1 and 2-2 also identify the annual number of records involving only one sex. Among all NICHD clinical research IERs with enrollment in FYs 2022 – 2024, between 22.0% and 24.1% involved only women ("Female-Only IERs"), compared to 3.9% - 5.1% that involved only men ("Male-Only IERs") (Table 2-1). Among Phase III clinical trials with enrollment, 0% - 3% involved only men, while 30.3% - 41.3% involved only women (Table 2-2). These sex 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 align with, and often 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. 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. The number and percentage of NICHD Phase III studies that required valid analysis by race or ethnicity was relatively stable between 2022 and 2024: 81 IERs (87.1%) in 2022, 83 (80.6%) in 2023, and 77 (81.9%) in 2024 (Table 2-3). However, the number and proportion of NICHD Phase III studies that required valid analysis by sex was more variable: 71 IERs (76.3%) in 2022, 77 (74.8%) in 2023, and 88 (93.6%) in 2024. The lower proportion of trials requiring valid analysis by sex in some years is aligned with the higher prevalence of female-only studies that is often appropriate for NICHD science.

B. Enrollment Data by Sex: Inclusion of Women

Table 3-1-A shows enrollment numbers and percentages by sex for all NICHD-supported clinical research in FYs 2022 – 2024. In all years, women were a sizable majority of participants, ranging from 63.4% - 73.3% of people enrolled (Table 3-1-A). Between 0.9% and 2.5% of individuals were unidentified with respect to sex. These 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-sex (i.e., “female-only” or “male-only”) projects were excluded. Women remained a majority of participants in studies enrolling both men and women, ranging from 59.8% - 63.4% of participants (Table 3-1-A Supplement). Supplemental analyses also revealed that the percentages of individuals in the “unknown” sex category were substantially larger at U.S. sites than at non-U.S. sites. In domestic studies, persons in the “unknown” category ranged from 1.5% - 6.2% of people enrolled, compared to a range of 0.5% - 1.1% in foreign studies (Tables 3-1-A Supplement and 3-2-A Supplement).

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, NICHD’s summary and analysis of inclusion of racial/ethnic minorities, which uses U.S.-based categories, focuses mostly on data from U.S. sites. In NIH inclusion data for FYs 2022 - 2024, 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, people identifying as more than one race, and white Hispanics/Latinos (as Hispanics/Latinos of other races would already be included).

Assessing NIH inclusion data is challenging because what is appropriate for inclusion is determined by several factors: the scientific questions of each study; the composition of the proposed target populations; what was determined acceptable in peer review; and what was approved by the study's IRB, Program, and Council. Year-to-year shifts in inclusion data, such as large increases or decreases in the number or percentage of participants in specific demographic categories, are expected, as they reflect NICHD's ever-changing scientific portfolio, and they can usually be linked to a large study beginning or ending. For example, in 2023 there was a large decrease in the number and percentage of Black/African American participants from the previous two years, dropping from 56.9% of participants in NICHD clinical research in 2022 (N=615,582) to 11.7% of participants in 2023 (N=207,120) (Table 4-1-1-D). This drop was not due to any issues or problems with inclusion, but rather to the completion in 2022 of two large studies in African countries that together included over 420,000 Black participants.

However, in 2023, there were large, unusual spikes in the numbers and percentages of participants in the "Unknown/Not Reported" categories for race, ethnicity, and age in NICHD clinical research. For example, in 2022, the percentage of participants in U.S. Clinical Research whose race was Unknown/Not Reported was 16.1% (N=81,191), but the percentage rose to 39.3% (N=262,258) in 2023, and then dropped again to 10.1% (N=38,294) in 2024 (Table 4-1-2-B). There was a similar spike in people of Unknown/Not Reported ethnicity in NICHD U.S. Extramural Clinical Research, rising from 12.5% (N=63,041) in 2022 to 38.4% (N=256,117) in 2023, and then dropping back down to 5.9% (N=22,474) in 2024 (Table 4-1-2-C). Because NIH-funded research projects are required to collect data on sex, race, ethnicity, and age at enrollment, these sudden, precipitous increases in the number and percentages of *unknown* participants were *unexpected* and suggested an error in data collection, reporting, and/or validation.

Careful analysis revealed that these precipitous increases in Unknown/Not Reported participants in 2023 were an artifact of errors in data management and validation processes that have since been corrected; they do not reflect a problem with inclusion practices in prospective NICHD clinical research. The inclusion data provided in NIH triennial reports exclude IERs from existing datasets. However, two large studies, one using electronic health records from 217,143 female hospital patients in the U.S., and another using data from 103,818 male-female couples (207,636 participants) at a foreign site, were not correctly coded as using existing data. Hence, the participant numbers from those IERs were erroneously included in NICHD's aggregated 2023 inclusion data in the official tables in this report. Moreover, for the domestic study using electronic health records, the data were only "unknown" because they had not yet been cleaned and prepared at the time the 2023 data were reported and frozen.

When the participant data from those two large studies are appropriately removed from NICHD's 2023 data, the Unknown/Not Reported values and other 2023 data are similar to those in 2022 and 2024 and previous triennial reports. NICHD has included several supplement tables with corrected values for race, ethnicity, and age for 2023 to clearly illustrate the trends without the erroneously included data. For example, once corrected,

only 10.0% of participants in NICHD domestic clinical research, rather than 39.3% as originally reported, were of Unknown/Not Reported race, nearly identical to the 10.1% of participants in 2024 (Table 4-1-2-B Supplement). Similarly, the corrected value for participants of Unknown/Not Reported ethnicity in 2023 was 8.7%, not 38.4%, and fell between the 2022 and 2024 values of 12.5% and 5.9%, respectively. (Table 4-1-2-C Supplement).

Tables 4-1-2-B, 4-1-2-B Supplement, 4-1-2-C, and 4-1-2-C Supplement show inclusion in Domestic NICHD clinical research by race and ethnicity, respectively, for FYs 2022 – 2024. Approximately half of participants in domestic NICHD clinical research studies were minorities, ranging from 48.8% - 50.5% (Table 4-1-2-B Supplement). Moreover, the proportion of minority participants, by both race and ethnicity, was remarkably consistent across years, varying by just over 1 percent for race and 2 percent for ethnicity. Between 35.1% and 36.2% of people enrolled at U.S. sites were racial minorities (Table 4-1-2-B Supplement), and 15.8% - 18.1% identified as Hispanic/Latino (Table 4-1-2-C Supplement).

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

Tables 5-1-1-C, 5-1-1-C Supplement, and 5-2-2-C provide the numbers and percentages of annual enrollment for FYs 2022 – 2024 by sex, race, and ethnicity for all NICHD clinical research and Phase III clinical trials with the original and corrected values for FY2023. These tables provide aggregated annual enrollment numbers and proportions stratified by sex and then cross tabulated by ethnicity (Hispanic and non-Hispanic), race, and being a member of any minority group (racial or ethnic).

Across fiscal years, the percent of minority women and men participating in all NICHD clinical research is similar, with only 2% - 5% more minority women than men enrolled in each year (Table 5-1-1-C Supplement). However, in Phase III Clinical Research, the sex difference in minority enrollment in NICHD is sometimes greater. For example, in 2022 minority enrollment among women (54.2%) was nearly identical to enrollment among men (54.7%) (Table 5-2-2-C). But in the subsequent two years, minority enrollment among women was notably higher. In 2023, 78.0% of women identified as a minority compared to 67.0% of men, and in 2024, 90.6% of women identified as a minority compared to 73.5% of men (Table 5-2-2-C).

When further broken down by specific racial or ethnic categories, more variability in enrollment by sex and across years is evident. For example, while the sex distributions by race in all NICHD clinical research were extremely similar in FY2022, in FY 2024, a greater proportion of female participants identified as Black/African American (35.9%) compared to men (24.2%), while a greater percentage of men identified as White (36.7%) or Asian (26.9%) compared to women (25.9% White and 19.4% Asian) (Table 5-1-1-C). In addition, the percentage of women with Unknown/Not Reported race in FY2024 (14.8%) was more than twice the percentage among men (6.6%) (Table 5-1-1-C). in FYs 2022 – 2024, there were larger sex differences by race in enrollment NICHD

Phase III Clinical Research. For example, in every year, the percentage of women enrolled in Phase III Clinical research at NICHD who identified as Black/African American (22.4%, 55.0%, 72.5%) was sizable larger than the percentage men (8.2%, 33.0%, 28.7%), while the percentage of men who identified as Asian (27.1%, 14.1%, 18.1%) was notably larger than the percentage of women (10.7%, 7.6%, 7.0%) (Table 5-2-2-C).

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 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, race, ethnicity, and age at enrollment be provided in progress reports. Fiscal year 2021 was the first year that age enrollment data were available for reporting, and age data in in FYs 2022 - 2024 are incomplete, as some projects reporting inclusion in these years were submitted as competing applications prior to 2019 and therefore not subject to the policy.

Because each year the number of studies subject to the Inclusion Across the Lifespan Policy increases, the number of participants with data on age at enrollment increased sizably with each year. In 2022, 230,539 total participants in NICHD clinical research reported age data, and by 2024, 729,958 participants reported age data (Table 1). Across all three fiscal years, approximately one-third (33.1% - 37.7%) of NICHD participants were children (<18 years) and between one-half and three-fifths (54.9% - 60.8%) were adults (18-64 years). Only a small percentage (1.5% - 3.2%) were older adults (65+ years) or of Unknown/Not Reported ages (3.5% - 6.8%) (Table 1 Supplement). 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 2022 – 2024 enrollment data by narrow age groups for NICHD clinical research, which enables a detailed analysis of the child and adult participants. In both FYs 2022 and 2023, just under 6% of NICHD participants were less than one year of age, but in FY2024 over 17% of participants were in this age range due to initiation of a large study of newborn screening. The percentages of child participants in FYs 2022 – 2024 was most concentrated among those ages 1-12 years, with participants ages 1 – 5 years ranging from 4.9% to 8.6%, ages 6 – 12 years 6.5% - 14.2%, ages 13 – 15 years 2.7% - 6.0%, and ages 16-17 years 2.3% - 3.4% (Table 2 Supplement).

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

In an effort to support reporting of human subjects research, NIH has developed a system to display enrollment data by NIH 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, endometriosis, or maternal morbidity and mortality). Inclusion enrollment data by RCDC category are published annually and are available through this link: https://report.nih.gov/RISR/.

G. Summary

The goal of the NIH inclusion policy is 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. NIH inclusion policies are not intended to satisfy any quotas for proportional representation, hence, when assessing inclusion data, enrollment figures are not meant to be comparable to national census estimates. In addition, since what constitutes ethical and appropriate science is study-specific, but enrollment data are aggregated, 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 scientists in peer review, IRBs, NICHD Council members, and NICHD program staff prior to award and annually when reviewing progress reports. Finally, it is important to remember that data on inclusion by sex, 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

Significant scientific advances across NICHD's broad mission areas occurred during FYs 2022 – 2024. These projects not only illustrate the institute's continued commitment to including women, minorities, and individuals across the lifespan in clinical research, but also to expanding inclusion policies and practices to pregnant and lactating women and people with disabilities. They include new knowledge and understanding related to human development, intellectual and developmental disabilities, reproductive health, contraception, maternal health and pregnancy, neonatal care, child development, adolescence and adolescent behavior, developing therapeutics for pregnant women, children, and people with disabilities, and rehabilitation research. Many scientific accomplishments would not be possible, or their effects would be substantially diminished, without inclusion of varied populations in research. A selection of the most notable highlights are included below, and other accomplishments by year can be found on NICHD's website:

- Selected NICHD Research Advances of 2022

- Selected NICHD Research Advances of 2023
- Selected NICHD Research Advances of 2024

The accomplishments in Appendix B align with the five scientific research themes of NICHD's Strategic Plan 2020-2025. Although each advance is organized under a single theme, many advances cut across multiple themes and illustrate the interconnectedness of several NICHD research areas. The advances also provide examples of the cross-cutting themes of NICHD's Strategic Plan, including global health, health disparities, nutrition, prevention, and infectious diseases.

Appendix A – Inclusion Data Tables

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

Inclusion Data Records (IERs)

Table 2-1. Total IERs for NIH-Defined Extramural and Intramural Clinical Research Reported Between Fiscal Years 2022 and 2024

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*
2022	1,984	848	1,136	987	149	274	44	818
2023	2,068	895	1,173	1,037	136	269	60	844
2024	2,112	830	1,282	1,132	150	282	57	943

Table 2-2. Total IERs for NIH-Defined Extramural and Intramural Phase III Trials Reported Between Fiscal Years 2022 and 2024

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*
2022	93	29	64	51	13	23	0	41
2023	103	28	75	58	17	31	1	43
2024	94	28	66	46	20	20	2	44

*Inclusion Data Records (IERs) excluding male only and female only include unknown sex and combinations of unknown and any sex.

Table 2-3. Valid Analysis Requirements for NIH-Defined Phase III Extramural Grants Reported Between Fiscal Years 2022 and 2024

Fiscal Year	Total IERs	IERs Requiring Race Ethnicity Valid Analysis	% IERs Requiring Race Ethnicity Valid Analysis	IERs Requiring Sex Valid Analysis	% IERs Requiring Sex Valid Analysis
2022	93	81	87.1	71	76.3
2023	103	83	80.6	77	74.8
2024	94	77	81.9	88	93.6

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

Table 3-1-A. Total Enrollment for All NIH-Defined Extramural (First Table) and Intramural (Second Table) Clinical Research Between Fiscal Years 2022 and 2024

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown
2022	1,176,999	745,927	63.4	401,294	34.1	29,778	2.5
2023	1,868,905	1,324,800	70.9	527,497	28.2	16,608	0.9
2024	850,057	623,494	73.3	218,578	25.7	7,985	0.9

Fiscal Year	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
2022	108,987	9.3	2,226	0.2	636,940	54.1	399,068	33.9
2023	388,182	20.8	3,778	0.2	936,618	50.1	523,719	28.0
2024	249,990	29.4	4,863	0.6	373,504	43.9	213,715	25.1

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	Females, Excluding Female-Only	% Female, Excluding Single-Sex	Males, Excluding Male-Only	% Male, Excluding Single-Sex	Total Unknown	% Unknown, Excluding Single-Sex
2022	1,065,786	636,940	59.8%	399,068	37.4%	29,778	2.8%
2023	1,476,945	936,618	63.4%	523,719	35.5%	16,608	1.1%
2024	595,204	373,504	62.8%	213,715	35.9%	7,985	1.3%

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

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown
2022	505,348	313,431	62.0	165,137	32.7	26,780	5.3
2023	666,990	506,899	76.0	148,938	22.3	11,153	1.7
2024	380,339	240,969	63.4	134,500	35.4	4,870	1.3

Fiscal Year	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
2022	71,431	14.1	2,171	0.4	242,000	47.9	162,966	32.2
2023	305,705	45.8	2,846	0.4	201,194	30.2	146,092	21.9
2024	58,908	15.5	3,363	0.9	182,061	47.9	131,137	34.5

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 Single-Sex	Females, Excluding Female-Only	% Female, Excluding Single-Sex	Males, Excluding Male-Only	% Male, Excluding Single-Sex	Total Unknown	% Unknown, Excluding Single-Sex
2022	431,746	242,000	56.1%	162,966	37.7%	26,780	6.2%
2023	358,439	201,194	56.1%	146,092	40.8%	11,153	3.1%
2024	318,068	182,061	57.2%	131,137	41.2%	4,870	1.5%

Enrollment by Race

Table 4-1-1-D. Total Enrollment of NIH-Defined Extramural 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
2022	1,082,044	1,923	844,041	78.0	3,410	0.3	119,666	11.1	615,582	56.9
2023	1,774,133	1,998	1,094,283	61.7	228,706	12.9	561,009	31.6	207,120	11.7
2024	754,956	2,041	510,881	67.7	10,338	1.4	170,426	22.6	252,796	33.5

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
2022	1,787	0.2	237,278	21.9	24,797	2.3	79,524	7.3
2023	1,197	0.1	235,656	13.3	25,555	1.4	514,890	29.0
2024	1,177	0.2	193,125	25.6	23,456	3.1	103,638	13.7

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
2022	505,348	1,738	254,978	50.5	3,300	0.7	19,448	3.8	133,641	26.4
2023	666,990	1,837	219,971	33.0	3,601	0.5	21,062	3.2	116,798	17.5
2024	380,339	1,880	185,681	48.8	3,758	1.0	18,255	4.8	90,829	23.9

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
2022	1,144	0.2	244,806	48.4	21,818	4.3	81,191	16.1
2023	1,312	0.2	241,860	36.3	20,099	3.0	262,258	39.3
2024	1,228	0.3	208,647	54.9	19,328	5.1	38,294	10.1

Table 4-1-2-B Supplement. Corrected 2023 Data: 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
2022	505,348	1,738	254,978	50.5	3,300	0.7	19,448	3.8	133,641	26.4
corrected 2023	449,847	1,836	219,971	48.9	3,601	0.8	21,062	4.7	116,798	26.0
2024	380,339	1,880	185,681	48.8	3,758	1.0	18,255	4.8	90,829	23.9

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
2022	1,144	0.2	244,806	48.4	21,818	4.3	81,191	16.1
corrected 2023	1,312	0.3	241,860	53.8	20,099	4.5	45,115	10.0
2024	1,228	0.3	208,647	54.9	19,328	5.1	38,294	10.1

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
2022	350,831	69.4	91,476	18.1	63,041	12.5
2023	339,589	50.9	71,284	10.7	256,117	38.4
2024	293,037	77.0	64,828	17.0	22,474	5.9

Table 4-1-2-C Supplement. Corrected 2023 Data: 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
2022	350,831	69.4	91,476	18.1	63,041	12.5
corrected 2023	339,589	75.5	71,284	15.8	38,974	8.7
2024	293,037	77.0	64,828	17.0	22,474	5.9

Total Enrollment

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

Fiscal Year	Sex	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported Ethnicity	% Unknown Not Reported Ethnicity	American Indian Alaska Native	% American Indian Alaska Native
2022	Female	593,445	79.6	745,927	63.4	633,909	85.0	89,811	12.0	22,207	3.0	2,720	0.4
2022	Male	312,539	77.9	401,294	34.1	344,211	85.8	36,740	9.2	20,343	5.1	1,143	0.3
2022	Unknown	2,828	9.5	29,778	2.5	3,195	10.7	329	1.1	26,254	88.2	10	0.0
2023	Female	827,661	62.5	1,324,800	70.9	819,592	61.9	254,072	19.2	251,136	19.0	171,062	12.9
2023	Male	327,444	62.1	527,497	28.2	421,942	80.0	89,854	17.0	15,701	3.0	58,081	11.0
2023	Unknown	4,009	24.1	16,608	0.9	5,178	31.2	358	2.2	11,072	66.7	26	0.2
2024	Female	427,952	68.6	623,494	73.3	530,456	85.1	76,126	12.2	16,912	2.7	7,669	1.2
2024	Male	144,791	66.2	218,578	25.7	181,532	83.1	28,243	12.9	8,803	4.0	2,991	1.4
2024	Unknown	3,080	38.6	7,985	0.9	4,062	50.9	517	6.5	3,406	42.7	144	1.8

Fiscal Year	Sex	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 Race	% Unknown Not Reported Race
2022	Female	85,053	11.4	412,472	55.3	1,179	0.2	190,581	25.5	17,893	2.4	36,029	4.8
2022	Male	44,576	11.1	226,342	56.4	748	0.2	96,149	24.0	8,466	2.1	23,870	5.9
2022	Unknown	1,031	3.5	1,359	4.6	5	0.0	935	3.1	140	0.5	26,298	88.3
2023	Female	395,780	29.9	171,223	12.9	849	0.1	189,921	14.3	19,310	1.5	376,655	28.4
2023	Male	175,774	33.3	57,473	10.9	484	0.1	94,249	17.9	7,767	1.5	133,669	25.3
2023	Unknown	438	2.6	3,093	18.6	9	0.1	1,503	9.0	193	1.2	11,346	68.3
2024	Female	120,662	19.4	224,086	35.9	779	0.1	161,724	25.9	16,248	2.6	92,326	14.8
2024	Male	58,771	26.9	52,993	24.2	532	0.2	80,178	36.7	8,707	4.0	14,406	6.6
2024	Unknown	1,988	24.9	430	5.4	11	0.1	1,373	17.2	232	2.9	3,807	47.7

Table 5-1-1-C Supplement. Corrected 2023 Data: Enrollment for All NIH-Defined Clinical Research, Sex by Race and Ethnicity

Fiscal Year	Sex	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported Ethnicity	% Unknown Not Reported Ethnicity	American Indian Alaska Native	% American Indian Alaska Native
2022	Female	593,445	79.6	745,927	63.4	633,909	85.0	89,811	12.0	22,207	3.0	2,720	0.4
2022	Male	312,539	77.9	401,294	34.1	344,211	85.8	36,740	9.2	20,343	5.1	1,143	0.3
2022	Unknown	2,828	9.5	29,778	2.5	3,195	10.7	329	1.1	26,254	88.2	10	0.0
2023c	Female	827,661	82.4	1,003,839	69.5	715,774	71.3	254,072	25.3	33,993	3.4	171,062	17.0
2023c	Male	327,444	77.3	423,679	29.3	318,124	75.1	89,854	21.2	15,701	3.7	58,081	13.7
2023c	Unknown	4,009	24.1	16,608	0.9	5,178	31.2	358	2.2	11,072	66.7	26	0.2
2024	Female	427,952	68.6	623,494	73.3	530,456	85.1	76,126	12.2	16,912	2.7	7,669	1.2
2024	Male	144,791	66.2	218,578	25.7	181,532	83.1	28,243	12.9	8,803	4.0	2,991	1.4
2024	Unknown	3,080	38.6	7,985	0.9	4,062	50.9	517	6.5	3,406	42.7	144	1.8

Fiscal Year	Sex	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 Race	% Unknown Not Reported Race
2022	Female	85,053	11.4	412,472	55.3	1,179	0.2	190,581	25.5	17,893	2.4	36,029	4.8
2022	Male	44,576	11.1	226,342	56.4	748	0.2	96,149	24.0	8,466	2.1	23,870	5.9
2022	Unknown	1,031	3.5	1,359	4.6	5	0.0	935	3.1	140	0.5	26,298	88.3
2023c	Female	395,780	39.4	171,223	17.1	849	0.1	189,921	18.9	19,310	1.9	55,694	5.5
2023c	Male	175,774	41.5	57,473	13.6	484	0.1	94,249	22.2	7,767	1.8	29,851	7.0
2023c	Unknown	438	2.6	3,093	18.6	9	0.1	1,503	9.0	193	1.2	11,346	68.3
2024	Female	120,662	19.4	224,086	35.9	779	0.1	161,724	25.9	16,248	2.6	92,326	14.8
2024	Male	58,771	26.9	52,993	24.2	532	0.2	80,178	36.7	8,707	4.0	14,406	6.6
2024	Unknown	1,988	24.9	430	5.4	11	0.1	1,373	17.2	232	2.9	3,807	47.7

2023c = 2023 corrected

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

Fiscal Year	Sex	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported Ethnicity	% Unknown Not Reported Ethnicity	American Indian Alaska Native	% American Indian Alaska Native
2022	Female	18,216	54.2	33,628	87.5	26,267	78.1	6,643	19.8	718	2.1	438	1.3
2022	Male	2,291	54.7	4,189	10.9	3,280	78.3	721	17.2	188	4.5	26	0.6
2022	Unknown	32	5.3	605	1.6	75	12.4	14	2.3	516	85.3	0	0.0
2023	Female	34,796	78.0	44,609	85.6	37,163	83.3	6,656	14.9	790	1.8	122	0.3
2023	Male	4,999	67.0	7,462	14.3	5,589	74.9	1,432	19.2	441	5.9	29	0.4
2023	Unknown	5	10.2	49	0.1	9	18.4	2	4.1	38	77.6	0	0.0
2024	Female	57,622	90.6	63,626	80.4	56,014	88.0	6,729	10.6	883	1.4	105	0.2
2024	Male	11,366	73.5	15,460	19.5	10,646	68.9	3,923	25.4	891	5.8	77	0.5
2024	Unknown	35	46.7	75	0.1	30	40.0	31	41.3	14	18.7	0	0.0

Fiscal Year	Sex	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 Race	% Unknown Not Reported Race
2022	Female	3,578	10.6	7,522	22.4	115	0.3	18,800	55.9	1,098	3.3	2,077	6.2
2022	Male	1,137	27.1	344	8.2	7	0.2	2,185	52.2	94	2.2	396	9.5
2022	Unknown	7	1.2	5	0.8	0	0.0	68	11.2	8	1.3	517	85.5
2023	Female	3,389	7.6	24,557	55.0	77	0.2	12,315	27.6	1,939	4.3	2,210	5.0
2023	Male	1,054	14.1	2,463	33.0	19	0.3	2,497	33.5	556	7.5	844	11.3
2023	Unknown	1	2.0	1	2.0	1	2.0	6	12.2	1	2.0	39	79.6
2024	Female	4,445	7.0	46,153	72.5	48	0.1	6,132	9.6	3,862	6.1	2,881	4.5
2024	Male	2,791	18.1	4,439	28.7	31	0.2	3,837	24.8	1,639	10.6	2,646	17.1
2024	Unknown	2	2.7	10	13.3	0	0.0	7	9.3	18	24.0	38	50.7

Age Tables

Table 1. Age Distribution Using Broad Age Groups for NIH-Defined Extramural and Intramural Clinical Research Reported for Fiscal Years 2022 - 2024

Fiscal Year	Children (<18 years)	Adults (18-64 years)	Older Adults (65+ years)	Unknown or Not Reported	Total
2022	86,959	126,576	3,509	13,495	230,539
	37.7%	54.9%	1.5%	5.9%	100%
2023	164,154	282,159	15,841	250,771	712,925
	23.0%	39.6%	2.2%	35.2%	100%
2024	245,019	444,090	15,432	25,417	729,958
	33.6%	60.8%	2.1%	3.5%	100%

Table 1 Supplement. Corrected 2023 Data: Age Distribution Using Broad Age Groups for NIH-Defined Extramural and Intramural Clinical Research Reported for Fiscal Years 2022 - 2024

Fiscal Year	Children (<18 years)	Adults (18-64 years)	Older Adults (65+ years)	Unknown or Not Reported	Total
2022	86,959	126,576	3,509	13,495	230,539
	37.7%	54.9%	1.5%	5.9%	100%
2023 corrected	164,154	282,159	15,841	33,628	495,782
	33.1%	56.9%	3.2%	6.8%	100%
2024	245,019	444,090	15,432	25,417	729,958
	33.6%	60.8%	2.1%	3.5%	100%

Table 2. Age Distribution Using Detailed Age Groups for NIH-Defined Extramural and Intramural Clinical Research Reported for Fiscal Years 2022 - 2024

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
2022	1,757 0.8%	3,041 1.3%	8,013 3.5%	12,811 5.6%	19,784 8.6%	32,705 14.2%	13,896 6.0%	7,763 3.4%	19,094 8.3%	20,409 8.9%	44,381 19.3%
2023	4,006 0.6%	7,978 1.1%	18,749 2.6%	30,733 4.3%	38,718 5.4%	55,041 7.7%	24,652 3.5%	15,010 2.1%	36,434 5.1%	39,377 5.5%	100,420 14.1%
2024	95,596 13.1%	14,281 2.0%	15,402 2.1%	125,279 17.2%	36,113 4.9%	47,109 6.5%	19,434 2.7%	17,084 2.3%	61,952 8.5%	84,026 11.5%	152,608 20.9%

Fiscal Year	35-44 Years	45-54 Years	55-64 Years	65-69 Years	70-74 Years	75-79 Years	80-84 Years	85-89 Years	90+ Years	Unknown or Not Reported	Total
2022	27,925 12.1%	9,528 4.1%	5,239 2.3%	1,528 0.7%	1,004 0.4%	519 0.2%	259 0.1%	133 0.1%	66 0.0%	13,495 5.9%	230,539 100%
2023	64,966 9.1%	24,816 3.5%	16,146 2.3%	6,058 0.8%	4,745 0.7%	2,607 0.4%	1,380 0.2%	630 0.1%	421 0.1%	250,771 35.2%	712,925 100%
2024	87,122 11.9%	43,267 5.9%	15,115 2.1%	5,897 0.8%	4,324 0.6%	2,622 0.4%	1,399 0.2%	738 0.1%	452 0.1%	25,417 3.5%	729,958 100%

* 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.

Table 2 Supplement. Corrected 2023 Data: Age Distribution Using Detailed Age Groups for NIH-Defined Extramural and Intramural Clinical Research Reported for Fiscal Years 2022 - 2024

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
2022	1,757 0.8%	3,041 1.3%	8,013 3.5%	12,811 5.6%	19,784 8.6%	32,705 14.2%	13,896 6.0%	7,763 3.4%	19,094 8.3%	20,409 8.9%	44,381 19.3%
2023 corrected	4,006 0.8%	7,978 1.5%	18,749 3.6%	30,733 5.8%	38,718 7.4%	55,041 10.5%	24,652 4.7%	15,010 2.9%	36,434 6.9%	39,377 7.5%	100,420 19.1%
2024	95,596 13.1%	14,281 2.0%	15,402 2.1%	125,279 17.2%	36,113 4.9%	47,109 6.5%	19,434 2.7%	17,084 2.3%	61,952 8.5%	84,026 11.5%	152,608 20.9%

Fiscal Year	35-44 Years	45-54 Years	55-64 Years	65-69 Years	70-74 Years	75-79 Years	80-84 Years	85-89 Years	90+ Years	Unknown or Not Reported	Total
2022	27,925 12.1%	9,528 4.1%	5,239 2.3%	1,528 0.7%	1,004 0.4%	519 0.2%	259 0.1%	133 0.1%	66 0.0%	13,495 5.9%	230,539 100%
2023 corrected	64,966 12.3%	24,816 4.7%	16,146 3.1%	6,058 1.2%	4,745 0.9%	2,607 0.5%	1,380 0.3%	630 0.1%	421 0.1%	33,628 6.4%	526,515 100%
2024	87,122 11.9%	43,267 5.9%	15,115 2.1%	5,897 0.8%	4,324 0.6%	2,622 0.4%	1,399 0.2%	738 0.1%	452 0.1%	25,417 3.5%	729,958 100%

* 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 – Accomplishments by the NICHD's Strategic Plan 2020 Five Scientific Research Themes

A. Understanding the Molecular, Cellular, and Structural Basis of Development

Goal: Enhance knowledge of genes and gene regulatory networks at the single- and multi-cell levels to understand typical human development and to identify periods of sensitivity in developmental processes that may lead to structural birth defects and neurodevelopmental disorders, including intellectual or developmental disabilities.

Developmental trajectories of autism

(PMID: 37615073, 2024)

Autism spectrum disorder (ASD) is a complex neurological and developmental disorder that affects how a person behaves, interacts with others, communicates, and learns. In California, all residents with ASD are offered support services, and this program incorporates regular surveys of communication and social functioning. Using records from more than 70,000 individuals with ASD born between 1992 and 2016, researchers used these surveys to look at how communication and social functioning in ASD changes over time. The scientists identified six developmental trajectories of communication skills and seven social skill trajectories. The results indicated that most individuals with ASD showed improvement as they age, with improvement in communication skills being more common than improvement in social functioning. Five percent of individuals followed a trajectory of adolescent decline, in which high social functioning in childhood declined during adolescence. Improvement was more prevalent in children from higher socioeconomic families or areas, and in children of White mothers compared to children of Hispanic, Black, Asian, or foreign-born mothers. The results show the importance of the inclusion of individuals from a variety of backgrounds in studies of people with ASD.

Using computational strategies to identify patients who should be tested for rare genetic conditions

(PMID: 35321655, 2022)

For many rare conditions, genetic testing is required for a definitive diagnosis. However, precisely because these conditions are so rare, providers often do not recognize that they are a possibility and therefore may not refer patients for the appropriate genetic testing. One example of such a rare genetic condition is PTEN hamartoma tumor syndrome (PHTS), which is associated with mutations of the PTEN tumor suppressor gene. Because PHTS affects multiple organ systems, there are established clinical criteria (based on clinical history and physical exam findings) to identify people who should be tested for PTEN mutations. In one recent study, researchers sought to determine whether a "computational phenotype" (a combination of billing codes and

diagnosis codes found in a patient's electronic health record, or EHR) could accurately identify patients who should be tested for PTEN mutations across three medical centers with different EHR and medical informatics systems. Patients identified using the computer-based strategy then had their medical records manually reviewed by clinical experts to see if they actually met the established clinical criteria for PTEN testing. Among those patients identified using the computational phenotype, between 82 and 94 percent actually met the clinical criteria for PTEN genetic testing. The results of this study suggest that computational phenotypes may help identify individuals who should be tested for certain rare genetic conditions.

Amygdala overgrowth that occurs in autism spectrum disorder may begin during infancy

(PMID: 35331012, 2022)

Autism spectrum disorder (ASD) is a complex developmental disorder that affects how a person behaves, interacts with others, communicates and learns. To assess brain differences in children with ASD, researchers studied 408 infants, 270 of whom were at higher likelihood of ASD because they had an older sibling with ASD, 109 typically developing infants, and 29 infants with Fragile X syndrome, an inherited form of developmental and intellectual disability that is also associated with ASD. The researchers conducted MRI scans of the children at 6, 12 and 24 months of age. The scientists discovered that the amygdala—a brain structure enlarged in two-year-old children diagnosed with autism spectrum disorder (ASD)—begins its accelerated growth between 6 and 12 months of age. The amygdala is involved in processing emotions, such as interpreting facial expressions or feeling afraid when exposed to a threat. The findings indicate that therapies to reduce the symptoms of ASD might have the greatest chance of success if they begin in the first year of life, before the amygdala begins its accelerated growth.

Early effects of Down syndrome in Brain Development

(PMID: 38357436, 2024)

Down syndrome (DS), also known as trisomy 21 (T21), is caused by the triplication of the 21st chromosome. This triplication has effects on development, both on the brain and throughout the body. Previous research has not addressed what happens in the early stages of the formation of the nervous system in individuals with DS. The unanswered question has been how an extra copy of human chromosome 21 contributes to the heart, brain, and other conditions that characterize individuals with DS, and how T21 affects prenatal neural development leading to neurodevelopmental disorders characterized by intellectual disability. Researchers conducted a study to present the earliest timepoint yet studied at which the effects of T21 in the brain can be detected. A key component of this study is induced pluripotent stem cells (iPSC) taken from study subjects' skin or blood and converted into neurons. The researchers examined early timepoints, day 6, 10, and 17 post neural induction (the first step of

embryonic cells becoming neurons). The study results show that at these early timepoints, T21 has already altered pathways involved in the initial stages of neural development. The researchers also found that there were dysregulated genes in other chromosomes, raising the possibility that genes in chromosome 21 are affecting the expression of genes in other chromosomes.

B. Promoting Gynecologic, Andrologic, and Reproductive Health

Goal: Enable women and men to manage fertility and minimize the impact of gynecologic and andrologic conditions in support of lifelong reproductive health.

Ethnic and racial differences in premenopausal hysterectomy

(PMID: 37473411, 2024)

Black women who have not yet gone through menopause are more likely to get a hysterectomy than premenopausal White women in the United States. While hysterectomy is an effective treatment for gynecologic conditions such as fibroids and endometriosis, it is also a sterilizing procedure, leading to infertility. Researchers wondered whether the reason why Black women have a higher rate of premenopausal hysterectomy is because they are medically overtreated, receiving more extreme treatment than warranted by severity or before trying other less invasive options. The researchers looked at health records from more than 1,700 premenopausal Black, White, and Hispanic women in North Carolina who received a hysterectomy to treat a gynecological condition. The scientists compared the average severity of gynecologic symptoms (such as bleeding and pain) across racial and ethnic groups. They reasoned that if Black patients are more likely to receive a premenopausal hysterectomy because of overtreatment, their symptom severity scores would not be higher than White patients. However, the analysis found no evidence that Black patients are overtreated. In fact, Black and Hispanic patients had higher symptom severity than White patients. When comparing the number of less invasive treatments that had been tried prior to hysterectomy, the researchers found no difference between the groups. This led them to speculate that Black and Hispanic patients may instead be undertreated for gynecological conditions, since there was no evidence that their higher symptom severity led to a corresponding higher number of treatments that were tried. While it is also possible that differences in severity reflect differences in how medical staff document symptoms across racial and ethnic groups, this study paves the way for more research into understanding disparities in treatment for gynecological conditions.

Uterine fibroids of Black women have different gene expression profiles

(PMID: 37686244, 2024)

Black women are more likely to have uterine fibroids as compared to White or Hispanic women. They are also likely to have more severe fibroids. Researchers explored how the expression of genes in the cells of uterine fibroids compared between races. They found many genes that were expressed differently in the fibroids of Black women as

compared to White or Hispanic women. This suggests that the differences in uterine fibroid presence and severity between races may be rooted in the way genes are expressed in the uterus.

Compound Could Lead to Short-term, On-Demand Male Contraceptive

(PMID: 36788210, 2023)

In a mouse study, researchers identified a potential non-hormonal contraceptive that men could take shortly before sexual activity and have fertility restored the next day. Researchers gave male mice a compound that temporarily disables soluble adenylyl cyclase, the enzyme essential for activating a sperm cell's ability to swim and mature so that it can travel through the female reproductive tract and fertilize an egg. In several tests, the researchers showed that the compound TDI-11861 rendered mouse sperm cells immobile and prevented them from maturing. The compounds did not interfere with the animals' sexual functioning. Although male mice mated with females, no pregnancies were observed. Sperm recovered from female mice remained incapacitated. The authors did not observe any side effects in the male or female mice. The compound wore off three hours later, and males recovered their fertility. The researchers say their work provides proof of concept that soluble adenylyl cyclase inhibitors may have the potential to provide a safe, on-demand, non-hormonal and reversible oral contraceptive for men.

C. Setting the Foundation for Healthy Pregnancies and Lifelong Wellness

Goal: Improve pregnancy outcomes to maximize the lifelong health of women and their children.

Birth certificate data tended to understate maternal morbidity and disparities

(PMID: 38176017, 2024)

Since 2014, all states have revised their birth certificate data collection to include information about serious conditions of pregnancy. An increasing number of studies now measure morbidity using only these data, but the quality of maternal morbidity data from birth certificates has been questioned. Researchers used data from California and Michigan to assess specific maternal morbidity measures available on birth certificates and then compared this information to hospitalization data. They also re-created the Centers for Disease Control and Prevention's severe maternal mortality (SMM) measure using hospitalization data. The analysis showed that maternal morbidity measures using birth certificate data alone were substantially underreported and had poor validity. The incidence of SMM was more than three times as large for the hospitalization data compared with birth certificate data. Moreover, Black-White disparities were smaller in the birth certificate data compared with the hospitalization data.

High Blood Pressure During Pregnancy Contributes to Racial Disparities in Health

(PMID 37678888, 2023)

People who have chronic hypertension (high blood pressure) before they become pregnant or develop it early in pregnancy face increased risks to their health and the health of their baby. Researchers examined data from nearly 8 million pregnancies in five U.S. states, and they found that pregnant Black people were more than twice as likely to have chronic hypertension as White and Latino patients. During pregnancy, Native Hawaiians and other Pacific Islanders also had rates of hypertension higher than the national average. The data showed that this disorder was linked to dangerous health conditions in the pregnant person—such as kidney failure or a buildup of fluid in the lungs—and even death. The condition was also risky for babies and linked to low birth weight, preterm birth, and stillbirth.

Rural and Urban Differences in Insurance Coverage at Pre-pregnancy, Birth, and Postpartum

(PMID: 36735410, 2023)

Compared to pregnant individuals in urban areas, those living in rural areas have a greater risk of maternal death and severe complications. To explore whether differences in health insurance coverage may contribute to this disparity, researchers looked at rates of health insurance coverage among rural and urban residents during pre-pregnancy, birth, and postpartum. They used data from the CDC's Pregnancy Risk Assessment Monitoring System (PRAMS), which collects survey data each month from a random sample of individuals who have given birth within the past 2-6 months across most of the United States. Looking at data from nearly 155,000 individuals collected between 2016 and 2019, the researchers found that rural residents were more likely to be uninsured compared to urban residents before becoming pregnant, when giving birth, and in the postpartum period. In each period, rural residents who were non-Hispanic White, married, and with intended pregnancies were more likely to be uninsured compared to their urban counterparts. English-speaking Hispanic and Indigenous individuals were more likely to be uninsured in two of the three periods compared to other rural residents.

D. Improving Child and Adolescent Health and the Transition to Adulthood

Goal: Advance understanding of typical and atypical child development in contemporary cohorts, with an emphasis on identifying sensitive time periods when prevention and treatment strategies will have the greatest impact. Improve the transition from adolescent to adult health care, especially for adolescents with disabilities or chronic health conditions.

Variations in antibiotic prescribing for North Carolina children on Medicaid

(PMID: 38287204, 2024)

Antibiotics are often prescribed to treat infections in children. However, inappropriate antibiotic use is also the primary cause of antimicrobial resistance, which in the long run makes infections more difficult to treat for everyone. In the United States, the highest rates of outpatient antibiotic use occur in the Appalachian regions. Researchers examined the rates and risk factors for inappropriate antibiotic prescription among children enrolled in Medicaid in North Carolina. The scientists found that compared to pediatricians, the risk of inappropriate antibiotic prescription was highest among other specialists and general practitioners, and lowest among nurse practitioners. Among all the study subjects, years, and counties, about 21% of antibiotic prescriptions were inappropriate in Appalachian counties, compared to 23% in counties located in other regions. Areas classified as rural had the highest rates of overall and inappropriate antibiotic prescribing. Non-Hispanic Black children were more likely to receive an inappropriate antibiotic than non-Hispanic White patients.

Free school meals associated with modest reduction in childhood obesity

(PMID: 38495019, 2024)

The Community Eligibility Provision (CEP) policy allows schools in low-income areas to provide free breakfast and lunch to all their students as opposed to requiring individual students to prove their eligibility. Using California public schools data for the 2013-19 period when CEP was adopted, researchers assessed whether this policy was associated with reductions in child obesity for children in grades 5, 7, and 9, after adjusting for other characteristics of the students and the schools. The researchers found that there was a small net decrease in obesity (a 2.4% relative reduction) after policy adoption for schools that participated in CEP, compared with similar eligible, nonparticipating schools.

Including Black and Latinx children in brain research

(PMID: 38565857, 2024)

Research scientists can use different techniques to understand how children's brains develop, including one technique known as electroencephalography or EEG. EEG works by placing a close-fitting cap or net of small sensors directly onto a child's head. Even through the scalp, these sensors can record the timing of small electrical signals sent by neurons in the brain and tell scientists about when and how the brain reacts to things that the child sees or hears. One of the challenges of using EEG, however, is trying to place each sensor as close to the scalp as possible. Most EEG caps and nets are not designed for children with more voluminous or coarse hair. Researchers highlighted that these design issues can potentially lead to the exclusion of Black and Latinx children in brain research. To ensure that brain research includes children of all races and ethnicities, researchers describe cultural differences surrounding hair that

should be considered in research laboratories and how to talk to families about the process. They also provide advice for other researchers on how to best approach specific hairstyles typically worn by Black and Latinx children. Lastly, researchers give examples of changes that can be made to the design of EEG equipment to get the best EEG recording possible. Researchers suggest that it is critical that children of all hair types be included in brain research so that scientists can learn more about how the brain develops in children of all races and ethnicities.

Improving Retention of Children with Disabilities and Their Families in Longitudinal Research

(PMID: 36807478, 2023)

In the United States, children with developmental disabilities, especially from varying backgrounds, tend to be underrepresented in research studies. This is especially the case for studies that take place over a long period of time. To identify factors supporting retainment of a range of families with children with developmental disabilities in research, researchers looked at data from an NIH-funded study that surveyed participants three times between 1995 and 2014. To compensate for their time and to provide an incentive to remain in the study, participants received $25 or $50 each time. The researchers calculated the payment amount as a proportion of participants' income and looked at the relation between this payment and retainment rates in the 9-year period between the second and third survey. Contrary to expectations, parents of children with developmental disability who were from varied racial and ethnic backgrounds were most likely to continue participation in the study between the second and third wave. Participant payment may have contributed to their retention, as the payment represented a larger proportion of income for this group.

Survival rate increases for extremely preterm infants

(PMID: 35040888, 2022)

The survival rate of extremely preterm infants born from 2013 through 2018 in a large network of U.S. research centers improved to 78.3 percent, compared to 76 percent for infants born in the network from 2008 to 2012. Their study included more than 10,000 infants born at 22 to 28 weeks of pregnancy at 19 medical centers. In the study, survival was greater for infants born later in pregnancy, with 94 percent of those born at 28 weeks surviving to hospital discharge and roughly 11 percent born at 22 weeks surviving to discharge. Survivors were assessed at 2 years corrected age—a child's chronological age, minus the number of weeks the child was born preterm. Slightly more than 8 percent had moderate to severe cerebral palsy, 1.5 percent had vision loss in both eyes, 2.5 percent needed hearing aids or cochlear implants, and 15 percent required mobility aids such as braces, walkers, or wheelchairs. Nearly 49 percent had no or only mild neurodevelopmental impairment, about 29 percent had moderate neurodevelopmental impairment and roughly 21 percent had severe neurodevelopmental impairment. The researchers noted that the infants were treated at

academic medical centers and their health outcomes may not reflect those of the whole U.S. preterm population.

E. Advancing Safe and Effective Therapeutics and Devices for Pregnant and Lactating Women, Children, and People with Disabilities

Goal: Lead efforts to develop, test, and evaluate new and existing therapeutics and devices to find safe and effective solutions that meet the unique needs of pregnant and lactating women, children, and people with intellectual and physical disabilities.

"Eat, Sleep, Console" (ESC) care approach reduces hospital stay and need for medication among opioid-exposed infants

(PMID: 37125831, 2023)

Opioid-exposed newborns may develop symptoms of neonatal opioid withdrawal syndrome (NOWS), which includes tremors; excessive crying and irritability; and problems with sleeping and feeding. For the past 50 years, the Finnegan Neonatal Abstinence Scoring Tool (FNAST) has been the traditional assessment tool for infants with NOWS. FNAST is an extensive scoring system that assesses signs of withdrawal in more than 20 areas. However, concerns have been raised about its subjectivity and overestimation of the need for opioid medication. In the randomized clinical trial, researchers assessed whether newborns cared for with the ESC approach (which prioritizes non-pharmacologic approaches to care and uses assessments based on infant sleeping, eating, and crying) would need less medication than infants cared for based on FNAST. The ESC infants were medically ready for discharge approximately nearly a week earlier and were less likely to receive medication as part of their treatment, compared to newborns cared for with FNAST.

Identifying Ways to Reduce Under-representation in Genomic Research

(PMID: 37621556, 2023)

About 70 percent of the world's 7,000 known rare disorders have a genetic basis. Diagnosis of children with such disorders, therefore, often involves whole genome sequencing. However, some people face more challenges than others when it comes to accessing genomic sequencing and getting a rare disease diagnosed. Researchers at a leading children's hospital analyzed how different racial and ethnic groups were represented in their hospital's Children's Rare Disease Cohort, and how many received genetic testing. The results showed that compared with hospital patients overall, Black or African American/African, non-Hispanic/non-Latine individuals were underrepresented in the rare disease cohort, and in the subset of that group that received whole genome sequencing. To improve equitable representation in the cohort and sequencing group, the researchers suggested incorporating inclusive racial/ethnic survey options into electronic health record data, providing cultural competence

education for medical students and health care staff, increasing community involvement, and hiring varied research staff.

New surgical procedure enables below-knee amputees to achieve more natural gait

(PMID: 38951635, 2024)

Current robotic limbs rely on algorithms to mimic a natural gait but are not under the user's full control. Researchers tested the impact of a new surgical procedure that restores the ability of muscle pairs—known as agonists and antagonists—in the severed limb to work together. They found that without relying on computer algorithms to direct the gait in the prosthetic limb, the group with the new type of surgery walked an average of 41% faster along a level surface than the group that had conventional surgery. Similarly, the group that received the new procedure performed better while walking up and down slopes and stairs, as well as avoiding obstacles while walking on a level surface.

Novel Mobility Survey Taps Prosthesis Users' Perspectives to Guide Care

(Prosthetic Limb Users Survey of Mobility (PLUS-M), 2023)

Understanding mobility challenges among individuals with lower limb prostheses can help rehabilitation providers and researchers build better protheses and devices using feedback obtained directly from prosthesis users. A team of researchers developed a brief questionnaire that allows respondents to convey their perceptions of how they complete actions at home or in daily life, such as descending a staircase or crossing a slippery floor. Clinicians and researchers use the questionnaire responses to assess individuals' mobility in clinical practice and scientific studies. The easy-to-complete survey of 7 or 12 questions allows patients to answer questions on paper or by computer. The electronic version uses an algorithm to select the next item based on a users' previous responses. For example, if a user responds "without any difficulty" to the question, "Are you able to walk a short distance in your home?" the computer will ask a tailored follow-up question such as "Are you able to walk across a parking lot?" The new tool is quickly becoming part of standard practice for assessing patients in the clinic. For example, a leading provider of orthotic and prosthetic care in the United States has integrated the survey into its more than 900 patient care clinics nationwide, and the survey tool is also part of various orthotic and prosthetic electronic health record systems.

Racial and Ethnic Variation in Studies Funded under the Best Pharmaceuticals for Children Act

(PMID: 33846237, 2022)

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.