National Institute of Environmental Health Sciences (NIEHS) Report Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY2022 – FY2024

I. Background/Overview

Among the 27 research institutes and centers that comprise the National Institutes of Health (NIH), the National Institute of Environmental Health Sciences (NIEHS) is the institute most focused on prevention rather than diagnosis or treatment of health issues. The mission of the National Institute of Environmental Health Sciences is to research how the environment affects biological systems across the lifespan and to translate this knowledge to reduce disease and promote human health. Our vision is to provide global leadership for innovative research that improves the health of people and communities.

The NIEHS research agenda is based on the concept that all complex diseases have both an environmental and a genetic component, and the Institute focuses on understanding the environmental component and the interaction of environment with genetics. Research programs cover the effects of environmental exposures throughout the lifespan, from preconception to old age. Funded studies range from computational and cell-based models to epidemiological studies with human subjects. The more we know about environmental exposures and how they affect health outcomes, the greater our ability to create healthy environments by reducing or preventing hazardous exposures. To this end, NIEHS investments are significant and measurable.

The Extramural Division (DERT) includes review, grants management, program analysis and five program branches with a focus on different aspects of the grant portfolio. DERT staff plans, reviews, approves, directs, fiscally administers, and evaluates performance of the Institute's grants, cooperative agreements, and contract programs, all of which support research and training in environmental health science. In addition, the Extramural review staff review the research contracts that support the Intramural human studies.

The Intramural Division conducts a broad range of human studies primarily through research contracts. In addition, NIEHS has an on-site Clinical Research Program with the primary goals of translating basic laboratory findings to humans, studying interactions between genetic susceptibility (host factors) and environment factors in the

pathogenesis of complex human traits and diseases, identifying populations at increased risk, and developing novel preventative and therapeutic strategies to combat human diseases. NIEHS also has a clinical program on autoimmune diseases, in particular myositis, at the NIH Clinical Center in Bethesda, Maryland.

II. Strategies for Ensuring Compliance

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 the inclusion of women, racial and ethnic minorities, and participants across the lifespan when considering clinical research applications.

Reviewers evaluate applications for the appropriateness of the proposed plan for inclusion. 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 must be reflected in the priority score of the application and documented in the minutes of the review session. Initial review groups make recommendations as to the acceptability of the proposed study population with respect to the inclusion policies. If issues are raised in review, program staff notify principal investigators, who are required to address these issues prior to funding.

The NIEHS Advisory Council performs the second level of review and makes recommendations for funding to the NIEHS Director considering the overall impact score, percentile ranking, and summary statement in light of the research priorities for NIEHS. 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 Criteria 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.

Program Monitoring and Grants Management Oversight

Prior to an award, program staff including a human subjects specialist are responsible for reviewing the inclusion information in the application and makes recommendations to the program officer who determines whether the plans are scientifically appropriate. Program staff monitor actual enrollment progress in annual progress reports and provide consultation when necessary. For NIH-defined Phase III clinical trials, program officials/program directors monitor requirements for plans and reporting of sex and race/ethnicity 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.

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, and ethnicity of those who were accrued during the past year; any issues with accrual are addressed and planned to increase recruitment 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).

IC Training Approaches

NIH created the Inclusion Learning Path in 2024 to provide a suite of on-demand trainings on inclusion policies and procedures for program staff. Staff may access the training on the NIH staff intranet. Trainings include "Overview of Inclusion Policies" and "PO Oversight and Inclusion Monitoring". Good Clinical Practice training for new staff or as a refresher was completed by all staff required to take the course. In addition, the DERT human subjects specialist gave trainings to staff on the "Review of the Human

Subjects System" and "Human Subject Common Issues & Case Studies". In addition, the specialist is available to staff to answer human subjects' inclusion, clinical trial, and systems related questions. The NIH Office of Human Subjects Research Protections (OHSRP) provides a monthly training series for Intramural staff who work with human subjects.

Compliance

To ensure compliance with policies, program staff, grants management and the DERT human subjects specialist are responsible for reviewing the Research Performance Progress Reports (RPPRs) of awarded grants for accuracy of inclusion data reporting. In addition, the human subjects specialist performs a discrepancy report on all human study records and a reconciliation of the inclusion data at year's end. The specialist also maintains the Good Clinical Practice Training records, reminding staff when it is time for refresher training and recording completion.

III. Analysis and Interpretation of Data

NIEHS tables of inclusion data, provided by NIH, covering the three-year period of this report are provided in the Appendix. All data tables include combined Extramural, Intramural and contract data for fiscal years (FY) 2022-2024.

As shown in Table 2-1, the number of Inclusion Enrollment Records (IERs) varies over the three-year period, decreasing by 8.7% between 2022 and 2023 and recovering 8% in 2024 back to 2022 levels. While the data may fluctuate somewhat over the three years, the majority (82-84%) of the IERs are enrolling from US sites. Foreign countries in which NIEHS supported research have taken place during the past three years include Mexico, Guatemala, Cambodia, Bangladesh, Ecuador, Seychelles, Nicaragua, Rwanda, and Kenya.

For single sex studies, it is important to note that many of our studies include mothers or caregivers which is usually the mother/child pairs in recruiting studies, the NIEHS Extramural Division reports adults separately from children. Reporting adults separately from children ensures staff know the number of adults who have been recruited are adult women/men or girls/boys. For this reason, a significant percentage of the IERs are female only. The male only studies include research of environmental

factors on male reproductive development or fertility.

Table 5-1-1-C displays the total number of participants enrolled by year and sex in all prospective studies funded by the Institute. There were 14.6% fewer participants reported between 2022 and 2023, but total enrollment recovered by 5.5% between 2023 and 2024. Four awards which ended in 2022 accounted for majority of the reduction. While the number of females decreased from 63.7% in 2022 to 56.1% in 2024, the number of minority women increased from 22.9% in 2022 to 35.9% in 2024. Male enrolled participants increased from 35.5% to 40.5%, as well as the male minority participation (20.3% to 27.9%), over the three-year period. Minority data categories include those who identify as American Indian/Alaska Natives, Asian, Black/African American, Native Hawaiian/Pacific Islander, More Than One Race, White Hispanics, and those that identify as Hispanic Unknown for race. Between 2022 and 2024, the percentage of participants identifying as Hispanic rose from 7.1% to 12.8%.

The data between 2022 and 2024 distributed by race categories showed participation increased among American Indian/Alaska Native and Asian and remained relatively level among Black/African America and More Than One Race.

Table 5-2-2-C shows the accrual of participants of all Phase III clinical trials supported by NIEHS. NIEHS rarely funds Phase III trials so this table includes the enrollment of participants in the sole Phase III clinical trial which was awarded in 2021 and ended funding in 2023. This is a random controlled trial of exercise on per- and polyfluoroalkyl substances (PFAS) in obese pregnant sedentary women in Arkansas and the development of their infants until the age of 2 years old. While this is a small NIH-defined Phase III trial, it is not considered to be an applicable clinical trial under 42 CFR Part 11 and does not require reporting of valid analysis in ClinicalTrials.gov. However, the grant awardee does plan to do all race/ethnicity and sex analyses where applicable.

Table 1 displays the NIEHS combined portfolio of Intramural and Extramural research enrolled participants by broad age categories: Children (Under 18 years of age); Adults (18-64 years); and Older Adults (65 years and over). The number of participants with age of enrollment data has increased significantly from approximately 30,000 to almost 96,000 though the distribution has stayed level among the broad age

groups. For example, the 2024 data is comprised of 24.4% Children, 62.1% Adults, and 5.3% Older Adults. The number of Unknown stayed relatively stable over the three-year period. The slight increase (14.1%) in unreported age for 2023 was due to one pilot award in an Environmental Health Science Core Center that updated their records in the 2024 reporting period.

Table 2 shows the NIEHS participants enrolled in studies by narrow age groups. All age ranges saw an increase in the total enrollment over the three-year period which is also shown in the graph (Chart A-1) below. Chart A-1 displays the age data from Table 2 in a bar graph using the narrow age groups over the three-year period. Due to privacy rules in the narrow age categories, participants aged 90 and over are reported as one group. While the majority (52.3%) of participants range in age between 26-64, NIEHS supported research does include a significant number of older adults (7.2%) ages 65-79 years, children (14.9%) ages 1-12 years, and infants (4%) less than one year old. While the numbers are much smaller in the older age ranges, 4.1% fall between ages 70-89 and 0.1% are 90 or older, it is encouraging that we do see people in these range groups represented in our supported research.

Research, Condition, and Disease Categorization (RCDC)

Inclusion enrollment data by Research Condition and Disease Categorization (RCDC) category will be available on the RCDC Inclusion Statistics Report website (https://report.nih.gov/risr/#/) at a later date but are available by request. These data will now be published annually at this website. Using the dropdown boxes at the top, the data can be viewed for all of NIH or broken out by the individual Institutes.

Please note that the inclusion categories are not mutually exclusive, so the same projects may appear in more than one category. All participants enrolled in a project's studies are included in all categories associated with that project. Individual research projects can be included in multiple categories so amounts depicted within each column of this table do not add up to the total participants enrolled in NIH-funded research.

Appendix

Section 2: Metrics Based on Inclusion Enrollment Records (IERs)

Table 2-1. Total Inclusion Enrollment Records (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	492	217	275	232	43	60	11	204
2023	449	149	300	247	53	63	7	230
2024	488	161	327	267	60	71	8	248

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

Section 5: Total Enrollment: All NIH-Defined Clinical Research

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

Fiscal Year	Sex	Total Enrollment	% Total	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
2022	Female	222,679	63.7	2,184	1.0	4,304	1.9	24,781	11.1	314	0.1	176,943	79.5	5,764	2.6	8,389	3.8
2022	Male	124,219	35.5	1,246	1.0	2,405	1.9	14,036	11.3	107	0.1	99,110	79.8	2,060	1.7	5,255	4.2
2022	Unknown	2,671	0.8	16	0.6	60	2.2	647	24.2	0	0.0	743	27.8	24	0.9	1,181	44.2
2023	Female	161,934	54.3	1,945	1.2	3,567	2.2	22,618	14.0	128	0.1	114,130	70.5	3,612	2.2	15,934	9.8
2023	Male	126,275	42.3	1,068	0.8	3,416	2.7	13,873	11.0	128	0.1	94,351	74.7	2,055	1.6	11,384	9.0
2023	Unknown	10,281	3.4	13	0.1	7	0.1	247	2.4	0	0.0	174	1.7	5	0.0	9,835	95.7
2024	Female	177,207	56.1	3,408	1.9	6,597	3.7	26,958	15.2	128	0.1	117,605	66.4	4,794	2.7	17,717	10.0
2024	Male	127,861	40.5	1,685	1.3	5,088	4.0	14,833	11.6	121	0.1	92,359	72.2	2,242	1.8	11,533	9.0
2024	Unknown	10,739	3.4	268	2.5	6	0.1	225	2.1	2	0.0	233	2.2	21	0.2	9,984	93.0

Fiscal Year	Sex	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	Female	51,013	22.9	222,679	63.7	201,221	90.4	18,201	8.2	3,257	1.5
2022	Male	25,225	20.3	124,219	35.5	112,941	90.9	6,642	5.3	4,636	3.7
2022	Unknown	825	30.9	2,671	0.8	744	27.9	81	3.0	1,846	69.1
2023	Female	49,978	30.9	161,934	54.3	135,480	83.7	22,144	13.7	4,310	2.7
2023	Male	31,878	25.2	126,275	42.3	108,225	85.7	12,858	10.2	5,192	4.1
2023	Unknown	394	3.8	10,281	3.4	421	4.1	127	1.2	9,733	94.7
2024	Female	63,701	35.9	177,207	56.1	144,644	81.6	26,985	15.2	5,578	3.1
2024	Male	35,666	27.9	127,861	40.5	108,821	85.1	13,197	10.3	5,843	4.6
2024	Unknown	653	6.1	10,739	3.4	493	4.6	341	3.2	9,905	92.2

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

Fiscal Year	Sex	Total Enrollment	% Total	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
2022	Female	331	77.3	1	0.3	1	0.3	119	36.0	0	0.0	195	58.9	12	3.6	3	0.9
2022	Male	97	22.7	0	0.0	0	0.0	33	34.0	0	0.0	57	58.8	6	6.2	1	1.0
2022	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2023	Female	351	76.8	1	0.3	1	0.3	122	34.8	0	0.0	210	59.8	14	4.0	3	0.9
2023	Male	106	23.2	0	0.0	0	0.0	35	33.0	0	0.0	62	58.5	8	7.5	1	0.9
2023	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2024	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2024	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2024	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Fiscal Year	Sex	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	Female	146	44.1	331	77.3	316	95.5	15	4.5	0	0.0
2022	Male	45	46.4	97	22.7	90	92.8	7	7.2	0	0.0
2022	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2023	Female	152	43.3	351	76.8	333	94.9	18	5.1	0	0.0
2023	Male	49	46.2	106	23.2	98	92.5	8	7.5	0	0.0
2023	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2024	Female	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2024	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2024	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

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 Data Based on Inclusion Data Records (IERs)

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

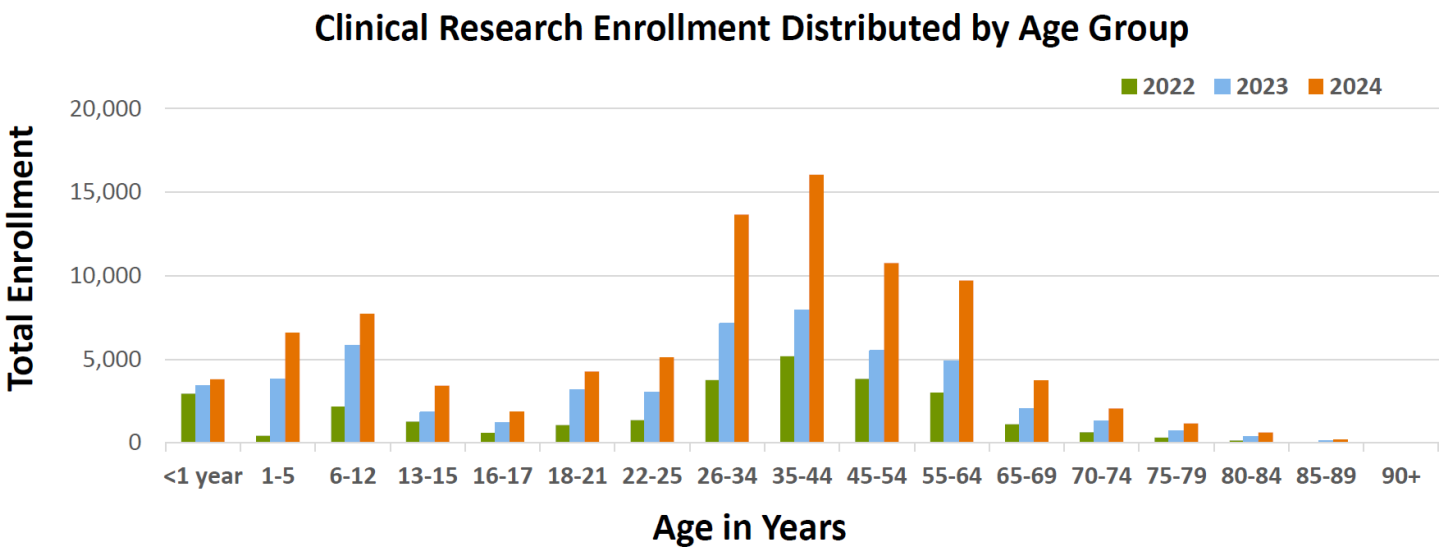
Fiscal Year	Children (<18 years)	Adults (18-64 years)	Older Adults (65+ years)	Unknown/Not Reported	Total
2022	7,399 (24.6%)	18,183 (60.6%)	2,267 (7.6%)	2,173 (7.2%)	30,022
2023	16,053 (26.4%)	31,661 (52.1%)	4,493 (7.4%)	8,546 (14.1%)	60,753
2024	23,434 (24.4%)	59,582 (62.1%)	7,830 (8.2%)	5,087 (5.3%)	95,933

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	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/ Not Reported	Total
2022	846	89	2,012	2,947	423	2,163	1,268	598	1,062	1,355	3,752	5,191	3,823	3,000	1,108	634	320	144	48	13	2,173	30,022
	2.8%	0.3%	6.7%	9.8%	1.4%	7.2%	4.2%	2.0%	3.5%	4.5%	12.5%	17.3%	12.7%	10.0%	3.7%	2.1%	1.1%	0.5%	0.2%	0.0%	7.2%	100%
2023	1,840	400	1,184	3,424	3,791	5,822	1,814	1,202	3,174	3,032	7,135	7,926	5,500	4,894	2,006	1,298	697	354	107	31	8,546	60,753
	3.0%	0.7%	1.9%	5.6%	6.2%	9.6%	3.0%	2.0%	5.2%	5.0%	11.7%	13.0%	9.1%	8.1%	3.3%	2.1%	1.1%	0.6%	0.2%	0.1%	14.1%	100%
2024	2,331	378	1,101	3,810	6,598	7,722	3,432	1,872	4,275	5,119	13,669	16,045	10,754	9,720	3,739	2,060	1,163	621	197	50	5,087	95,933
	2.4%	0.4%	1.1%	4.0%	6.9%	8.0%	3.6%	2.0%	4.5%	5.3%	14.2%	16.7%	11.2%	10.1%	3.9%	2.1%	1.2%	0.6%	0.2%	0.1%	5.3%	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.

Chart A-1



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