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

I. Background/Overview

A. NHLBI Mission Statement

The National Heart, Lung, and Blood Institute (NHLBI) provides global leadership for a research, training, and education program to promote the prevention and treatment of heart, lung, and blood diseases and enhance the health of all individuals so that they can live longer and more fulfilling lives.

The NHLBI stimulates basic discoveries about the causes of disease, enables the translation of basic discoveries into clinical practice, fosters training and mentoring of emerging scientists and physicians, and communicates research advances to the public. It creates and supports a robust, collaborative research infrastructure in partnership with private and public organizations, including academic institutions, industry, and other government agencies. The Institute collaborates with patients, families, health care professionals, scientists, professional societies, patient advocacy groups, community organizations, and the media to promote the application of research results and leverage resources to address public health needs. The NHLBI also collaborates with international organizations to help reduce the burden of heart, lung, and blood diseases worldwide.

B. History of Inclusion Policy

The NIH Revitalization Act of 1993 (PL 103-43) directed the NIH to ensure that women and minorities are included as subjects in the clinical research it supports. The NIH policy on the inclusion of women and minorities as participants in clinical research was published as a notice in the *Federal Register* on March 28, 1994, (Vol. 59, No. 59) and became effective in September 1994 for all grant applications and contract proposals submitted after June 1, 1994. As stated in the notice,

> “It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.”

The law also included the following provision:

> "The advisory council of each national institute shall prepare biennial reports describing the manner in which the institute has complied with this section."

Most recently revised in January 2002, the sex, race, and ethnicity categories required by the Office of Management and Budget (OMB), are shown below. Investigators are instructed to collect these data through participant self-report and are permitted to collect more detailed information as applicable to their research topics, but are required to collapse their data into the OMB-specified categories. Also dependent upon the research topic is whether investigators choose to collect sex data from participants.

Sex	**Race**	**Ethnicity**
Female	American Indian, Alaska Native	Hispanic, Latino
Male	Asian	Not Hispanic or Latino
Unknown or Not Reported	Black, African American	Unknown or Not Reported
	Native Hawaiian, Pacific Islander	
	White	
	More than One Race	
	Unknown or Not Reported	

OMB finalized revision to Statistical Policy Directive No. 15 Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15) that includes one combined question for race and ethnicity, the addition of "Middle Eastern or North African" (MENA) as a new minimum category, required collection of detailed race and ethnicity categories by default (exceptions may be requested) and updated descriptions of minimum categories. The deadline for implementation is currently set for March 28, 2029 and as plans remain in progress, the report continues to reflect the 2002 modifications.

Other Revisions

The 21st Century Cures Act, enacted December 13, 2016, included several new requirements related to inclusion of participants in clinical research. As a result, NIH updated its policy on the Inclusion of Women and Minorities as Subjects in Clinical Research on November 28, 2017, to require studies that are both NIH-defined Phase III clinical trials and applicable clinical trials to report the results of analyses by sex and/or race/ethnicity to ClinicalTrials.gov. This requirement is effective for competing grant awards on or after December 13, 2017, as well as contract solicitations and intramural studies initiated after this date. Additionally, NIH revised its Inclusion of

Children Policy on December 19, 2017. The revised policy, now called the NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects, applies to individuals of all ages and requires reporting of participant age at enrollment in annual progress reports. The policy is effective for applications submitted on or after January 25, 2019, and contract solicitations and intramural studies initiated after this date. The 21st Century Cures Act amended the frequency of the Report of the NIH Director on the inclusion of women and minorities from biennial to triennial. Thus, this triennial report provides information on inclusion of participants in NIH clinical research from FY 2022 – 2024. Inclusion enrollment data by Research Condition and Disease Categorization (RCDC) category are published annually on the RCDC Inclusion Statistic Report website (https://report.nih.gov/RISR/).

C. National Heart, Lung, and Blood Advisory Council Review

The first mandated inclusion monitoring report was prepared for the NIH and its constituent Institutes and Centers (ICs) in 1997. As it did in each of the previous report years, the NIH has elected to prepare centrally a summary report. The report, which is to be developed by the NIH Office of Extramural Research, will include statements related to each of the national advisory councils. Because recruitment data are only required to be provided to the NIH as part of noncompeting renewal applications, there is always a lag in the data presented. The data provided as part of this report reflect enrollment of participants in NHLBI clinical research studies in fiscal years 2022, 2023, and 2024.

On April 23, 2025, the National Heart, Lung, and Blood Advisory Council (NHLBAC) reviewed:

- NHLBI's procedures for implementation of the NIH policy for inclusion of women and minorities in clinical studies and
- The results of that implementation.

The NHLBAC found that the NHLBI complied with the policy mandate. Information and data are provided herein to support this conclusion.

II. Strategies for Ensuring Compliance

A. Peer Review

The implementation of inclusion guidelines involves the participation of review, program, policy, and grants management staff. Inclusion is first addressed by peer review. Reviewers on NIH peer review panels are given specific guidance on reviewing 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 NHLBI Advisory Council performs the second level of review and makes recommendations for funding to the NHLBI Director considering the overall impact score, percentile ranking, and summary statement in light of the research priorities for NHLBI. 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.

B. Program Monitoring and Grants Management Oversight

Prior to an award, program staff 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. For NIH-defined Phase III clinical trials, program staff 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.

The NHLBI relies upon a four-step process involving its program officials (POs) for ensuring compliance with the NIH policy. Since the inception of the NIH policy, the NHLBI has examined each project—even those that were rated acceptable for inclusion of women and minorities during peer review. The NHLBI procedure is to have:

- The POs evaluate all clinical research applications for appropriate representation of women, minorities, and participants across the lifespan.

- The POs discuss any concerns regarding the extent to which an application is in compliance with the policy with senior Institute staff.
- The POs discuss those issues needing further attention and their possible solution with the applicants.
- The POs evaluate cumulative enrollment data from annual progress reports and work with investigators to develop plans for enhancing enrollment of under-represented groups.

C. Intramural Oversight

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 plan 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).

D. 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. OER provides additional training materials through their website, including the NIH Integrated Core Curriculum, with archived training sessions available on video-cast or as slide shows. In addition, the NHLBI Office of Clinical Research (OCR) conducts IC-level training sessions to address changes in policy and procedures, such as Division and Branch-level trainings on complying with Inclusion Across the Lifespan policies and Human Subjects System (HSS). One-on-one training is also available.

III. Analysis and Interpretation of Data

A. Enrollment Data for NHLBI Clinical Research

As mentioned above, the NIH Office of Extramural Research (OER) generates both NIH and IC-level data tables describing the enrollment into human subjects research studies reported during the fiscal years 2022-2024. These NHLBI tables are presented in the Appendix. These data represent only prospective enrollment and do not include secondary analyses of existing datasets. Further details describing enrollment of participants in Phase III Clinical Trials is provided below in Section B. The trends and key points illustrated in the data tables are summarized below:

- Total Number of Participants Enrolled. The total enrollment figures in Table 3-1-A show a sharp increase in participants reported from 490,840 in 2022 to 684,790 in 2023 and a small decline to 677,662 participants in 2024. This fluctuation can largely be attributed to three large foreign studies launched in 2023, adding approximately 180,000 participants. This also led to an increase in the percentage of foreign participants from 9.1% in 2022 to 33.2% and 32.2% in 2023 and 2024.

- Percentage of Women Enrolled. Table 3-1-A also illustrates NHLBI's commitment to the inclusion of women, with enrollment greater than 50% throughout the 2022-2024 reporting period. The decrease from 58.5% in 2023 to 53.9% in 2024 is largely driven by the 2023 completion of a large women-only Phase III clinical trial among a Women's Health Initiative (WHI) cohort, totaling 49,331 participants. Additional impacts of this large trial are described in several sections below.

- Percentage of Minority Participants Enrolled. Table 5-1-1-C provides a breakdown of enrollment by sex and minority status, showing in all three years across both females and males, racial and ethnic minority participation in NHLBI studies exceeded the 30% representation in the 2010 U.S census, the standard referenced in the NHLBI Policy for the Inclusion of Women, Minorities, and Participants Across the Lifespan in Clinical Research. Total minority representation rose in 2023 to 58.9% among women and 53.0% among men, then to 60.2% among women and 53.2% among men in 2024. As mentioned above, these increases are primarily attributed to the initiation of two large foreign studies focused on the implementation of hypertension management activities in Nigeria and Uganda, with the majority of participants reported as "Black or African American". When we remove these studies and review the data for domestic-only enrollment, we find that minority participants represent 35.0% of women and 34.6% of men enrolled in 2023 and 40.0% of women and 34.7% of men enrolled in 2024.

B. Enrollment Data for NHLBI-funded Phase III Clinical Trials

As mentioned above, there are additional policy requirements for Phase III Clinical Trials, requiring attention to be focused on the inclusion of women and minorities. One key provision is to ensure that each Phase III trial provides a plan to conduct valid analyses by sex, race, and ethnicity. All of the NHLBI-funded Phase III trials met this requirement. The enrollment trends and key points illustrated in Table 5-2-2-C are summarized below:

- Total Enrollment. The number of Phase III records reporting enrollment increased slightly from 61 to 68 trials across the three years; however, the total enrollment figures have dropped from 77,686 participants in 2022 to 26,682 in 2024. This drop is attributed to the 2023 completion of the large women-only trial mentioned above.

- Percentage of Women Enrolled. As a result of the completion of the WHI cohort trial, from 2022 to 2024 the inclusion of women in Phase III trials decreased from 81.8% to 44.5%. When excluding the data for this large trial, the percentage of women enrolled shifts to 48.2% in 2022, to 41.3% in 2023, and 44.1% in 2024, similar to distributions in the previous triennial reports.

- Percentage of Minority Participants Enrolled. The large, women-only trial also impacted the distribution of participants across racial and ethnic groups, as the study enrolled mostly participants self-reporting as White. As shown in Table 5-2-2C, the 2022 figures illustrate a wide disparity of minority enrollment by sex, with 23.7% women versus 44.4% of men reporting as non-White. After the completion of the trial, 2024 figures show minority enrollment by sex increasing to 68.1% in women and 58.4% in men. The proportion of Hispanic/Latino participants was significantly and consistently lower than non-Hispanic/Latino participants, with 11% in 2022, 7% in 2023, and 6% in 2024. There was a rise in the percentage of “Unknown/Not Reported” responses from 2% in 2022 to 18% in 2024, mainly attributed to a new trial with a foreign component largely reporting unknown responses for ethnicity; however, after removing that trial, the unknown figure drops to 4%.

To facilitate further improvements, the Institute will continue to share lessons learned across portfolios and encourage investigators to develop novel strategies for the recruitment of women and minorities in Phase III clinical trials.

C. New Data for Age at Enrollment

The new NIH Inclusion Across the Lifespan Policy requirement for age-at-enrollment data applies to new projects from applications or proposals submitted for 2019 due dates, with the 2022-2024 Triennial Reporting period being the first with a full three-year dataset. NHLBI staff worked closely with investigators to ensure compliance with the more complex reporting requirement and provided detailed guidance for uploading the required datasets. As a result, NHLBI shows a rate of only 4.5% “Unknown/not reported” data, significantly lower than the NIH-wide figure of 25.1%. NHLBI has steadily worked towards ensuring a broader inclusion of participants of all ages with 14.3% children, 63.3% adults and 17.8% older adult participants enrolled from applicable studies in the 2024 reporting year.

Conclusion

The mandate of the NIH Revitalization Act of 1993 was to ensure inclusion of women and minorities in all NIH-supported clinical studies. The data demonstrate that the Institute has done far more than that minimal standard. Women and minority participants are all represented in NHLBI-supported clinical studies at rates that are near or exceed their corresponding representation in the U.S. population according to the 2010 census as well as the new 2020 census.

APPENDIX 1. DATA TABLES

Table 2-1. Total Inclusion Data 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	2,632	1,037	1,595	1,518	77	95	59	1,441
2023	2,633	1,026	1,607	1,518	89	114	45	1,448
2024	2,659	982	1,677	1,574	103	133	51	1,493

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

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

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown
2022	490,840	269,404	54.9	207,197	42.2	14,239	2.9
2023	684,790	400,875	58.5	271,180	39.6	12,735	1.9
2024	677,662	365,040	53.9	300,329	44.3	12,293	1.8

Fiscal Year	Total Enrollment	Enrollment in Female only	% Female only	Enrollment in Male only	% Male only	Females, Excluding Female only	% Females, Excluding Female only	Males, Excluding Male only	% Males, Excluding Male only
2022	490,840	54,906	11.2	1,447	0.3	214,498	43.7	205,750	41.9
2023	684,790	56,787	8.3	1,875	0.3	344,088	50.2	269,305	39.3
2024	677,662	16,201	2.4	2,941	0.4	348,839	51.5	297,388	43.9

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	% Unknown Not Reported
2022	Female	106,740	39.6	269,404	54.9	221,991	82.4	33,090	12.3	14,323	5.3
2022	Male	83,981	40.5	207,197	42.2	169,648	81.9	23,748	11.5	13,801	6.7
2022	Unknown	997	7.0	14,239	2.9	1,655	11.6	568	4.0	12,016	84.4
2023	Female	235,938	58.9	400,875	58.5	353,098	88.1	31,219	7.8	16,558	4.1
2023	Male	143,758	53.0	271,180	39.6	230,703	85.1	26,109	9.6	14,368	5.3
2023	Unknown	2,962	23.3	12,735	1.9	2,338	18.4	2,249	17.7	8,148	64.0
2024	Female	219,719	60.2	365,040	53.9	310,776	85.1	38,521	10.6	15,743	4.3
2024	Male	159,842	53.2	300,329	44.3	256,002	85.2	29,170	9.7	15,157	5.0
2024	Unknown	692	5.6	12,293	1.8	2,126	17.3	230	1.9	9,937	80.8

Fiscal Year	Sex	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	1,426	0.5	8,301	3.1	63,069	23.4	433	0.2	169,514	62.9	12,634	4.7	14,027	5.2
2022	Male	1,297	0.6	7,873	3.8	50,134	24.2	499	0.2	127,609	61.6	7,730	3.7	12,055	5.8
2022	Unknown	44	0.3	74	0.5	290	2.0	6	0.0	890	6.3	55	0.4	12,880	90.5
2023	Female	1,739	0.4	8,366	2.1	193,739	48.3	382	0.1	163,978	40.9	11,576	2.9	21,095	5.3
2023	Male	1,355	0.5	7,900	2.9	107,755	39.7	452	0.2	127,688	47.1	8,112	3.0	17,918	6.6
2023	Unknown	34	0.3	189	1.5	484	3.8	6	0.0	1,428	11.2	55	0.4	10,539	82.8
2024	Female	1,925	0.5	11,558	3.2	166,268	45.5	752	0.2	146,869	40.2	15,694	4.3	21,974	6.0
2024	Male	1,365	0.5	11,352	3.8	116,518	38.8	683	0.2	141,228	47.0	10,886	3.6	18,297	6.1
2024	Unknown	27	0.2	173	1.4	196	1.6	3	0.0	1,416	11.5	88	0.7	10,390	84.5

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	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	Female	14,962	23.7	63,047	81.2	56,737	90.0	5,315	8.4	995	1.6
2022	Male	6,491	44.4	14,624	18.8	11,024	75.4	2,894	19.8	706	4.8
2022	Unknown	5	33.3	15	0.0	9	60.0	4	26.7	2	13.3
2023	Female	13,568	22.9	59,149	81.0	55,510	93.8	2,802	4.7	837	1.4
2023	Male	7,719	55.7	13,851	19.0	10,935	78.9	2,326	16.8	590	4.3
2023	Unknown	9	28.1	32	0.0	17	53.1	5	15.6	10	31.3
2024	Female	8,084	68.1	11,865	44.5	9,329	78.6	585	4.9	1,951	16.4
2024	Male	8,574	58.4	14,684	55.0	10,718	73.0	1,096	7.5	2,870	19.5
2024	Unknown	21	15.8	133	0.5	100	75.2	6	4.5	27	20.3

Fiscal Year	Sex	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	256	0.4	1,375	2.2	8,023	12.7	16	0.0	49,920	79.2	100	0.2	3,357	5.3
2022	Male	86	0.6	556	3.8	2,951	20.2	23	0.2	9,666	66.1	69	0.5	1,273	8.7
2022	Unknown	0	0.0	1	6.7	1	6.7	1	6.7	8	53.3	0	0.0	4	26.7
2023	Female	206	0.3	1,668	2.8	8,913	15.1	10	0.0	45,196	76.4	248	0.4	2,908	4.9
2023	Male	67	0.5	951	6.9	4,487	32.4	17	0.1	6,796	49.1	471	3.4	1,062	7.7
2023	Unknown	0	0.0	2	6.3	3	9.4	0	0.0	16	50.0	2	6.3	9	28.1
2024	Female	80	0.7	647	5.5	6,556	55.3	21	0.2	3,590	30.3	332	2.8	639	5.4
2024	Male	111	0.8	886	6.0	6,048	41.2	27	0.2	6,191	42.2	556	3.8	865	5.9
2024	Unknown	1	0.8	3	2.3	9	6.8	0	0.0	80	60.2	5	3.8	35	26.3

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

Table 6. Age Distribution Using Broad Age Groups for NIH-Defined Extramural and Intramural Clinical Research Reported for Fiscal Years 20222-2024

Fiscal Year	Children (<18 years)	Adults (18-64 years)	Older Adults (65+ years)	Unknown or Not Reported	Total
2022	18,298	73,619	87,856	5,618	185,391
	9.9%	39.7%	47.4%	3.0%	100%
2023	43,286	225,570	117,529	15,360	401,745
	10.8%	56.1%	29.3%	3.8%	100%
2024	82,901	366,017	103,011	26,133	578,062
	14.3%	63.3%	17.8%	4.5%	100%

Table 7. 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 or Not Reported	Total
2022	1,777	2,089	770	4,636	4,166	5,426	2,195	1,875	3,820	4,980	10,063	12,961	16,242	25,553	12,315	18,922	20,676	18,229	12,167	5,547	5,618	185,391
	1.0%	1.1%	0.4%	2.5%	2.2%	2.9%	1.2%	1.0%	2.1%	2.7%	5.4%	7.0%	8.8%	13.8%	6.6%	10.2%	11.2%	9.8%	6.6%	3.0%	3.0%	100%
2023	760	6,255	1,012	8,027	11,173	14,321	5,687	4,078	8,292	15,156	37,126	49,265	54,612	61,119	27,883	31,473	23,610	18,084	11,369	5,110	15,360	401,745
	0.2%	1.6%	0.3%	2.0%	2.8%	3.6%	1.4%	1.0%	2.1%	3.8%	9.2%	12.3%	13.6%	15.2%	6.9%	7.8%	5.9%	4.5%	2.8%	1.3%	3.8%	100%
2024	1,346	8,142	1,197	10,685	16,295	24,137	13,887	17,897	30,420	29,167	74,336	83,112	76,178	72,804	33,202	27,321	19,603	12,645	6,284	3,956	26,133	578,062
	0.2%	1.4%	0.2%	1.8%	2.8%	4.2%	2.4%	3.1%	5.3%	5.0%	12.9%	14.4%	13.2%	12.6%	5.7%	4.7%	3.4%	2.2%	1.1%	0.7%	4.5%	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.