

National Institute on Minority Health and Health Disparities 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

The mission of the National Institute on Minority Health and Health Disparities (NIMHD) is to lead scientific research to improve minority health and to reduce health disparities. To accomplish its mission, NIMHD: 1) Conducts and supports research on minority health and health disparities; 2) Plans, coordinates, reviews, and evaluates NIH minority health and health disparities research and activities; 3) Promotes and supports the training of a competent research workforce; 4) Translates and disseminates research information; and 5) Fosters innovative collaborations and partnerships. NIMHD supports research through its extramural research program and conducts intramural research. NIMHD works to advance the fields of minority health and health disparities science by building on evidence-based advances in promising areas such as social epigenomics, social determinants of health, and health information technology that could be beneficial in improving the health of NIH-designated populations that experience health disparities. The goals are to improve the health of these populations and reduce disparities in health outcomes.

II. Strategies for Ensuring Compliance (Required)

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 NIMHD Advisory Council performs the second level of review and makes recommendations for funding to the NIMHD Director considering the overall impact score, percentile ranking, and summary statement in light of the research priorities for NIMHD. 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 officials/program directors 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 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.

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 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. *NIMHD's 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.

III. Analysis and Interpretation of Data

A. *NIMHD Clinical Research*

Aggregate data for FY 2022–2024 were provided by the NIH Office of Extramural Research (OER) through the Human Subjects System (HSS). The HSS database is the centralized repository for collecting and storing data for all NIH Institutes and Centers on human subjects and clinical trials. Study and enrollment data by sex, race, and ethnicity for clinical research studies are shown in the attached tables (see Appendix A-C).

Table 2-1 shows the number of IERs for NIMHD extramural and Intramural clinical research projects that reported inclusion data between FY 2022 and FY 2024. IERs without enrollment

indicate studies that have not yet recruited any participants. Female only or male only IERs indicate studies that were scientifically justified to recruit only a single sex. Essentially all (99%) of enrollment is from U.S. sites. The total number of IERs reporting inclusion data increased over the 3-year period of the report with a 17.8% increase from FY 2022 to FY 2024 (see Appendix A).

The total enrollment for all NIMHD extramural and intramural clinical research by sex, race, and ethnicity is displayed in Table 5-1-1-C (see Appendix B). The NIMHD total enrollment counts for females and males in FY 2022 (66,407) and FY 2024 (164,978) represents a significant increase in the number of participants enrolled. This 148% increase in the number of participants may be attributed to more inclusion records as a result of the increase in the NIMHD appropriations and/or larger cohorts enrolled. The number of participants with unknown information was relatively high in FY 2024 (23%). This significant increase may be due to internet-based studies or studies using electronic health records.

The percentage of females (56.1%) enrolled in clinical research in FY 2022 increased somewhat in FY 2023 (62.1%), but then decreased to 50.6% in FY 2024. The drop have been due to a significant increase in the number of IERs with unknown sex. With the exception of FY 2022, the enrollment of females was almost twice that of males (35.4% in FY 2023 and 26.4% in FY 2024). The percentage of minority enrollment for NIMHD clinical research studies has remained steady in the 60-70% range. Hispanic/Latino and Black/African American represent the largest number of enrollees (25.4% and 24.2%, respectively). The number of individuals from American Indian/Alaska Native and Native Hawaiian/Pacific Islander increased 2-3 times the previous level over the 3-year period. The percentage of Asian participants remained approximately in the 6-8% participant range.

B. NIMHD NIH-Defined Phase III Trials

NIMHD supported several extramural NIH-defined Phase III clinical trials. Table 2-2 shows the number of IERs fluctuated from a low of 9 in FY 2022 to a high of 23 in FY 2023 (See Appendix A). The total number of NIMHD Phase Trials III requiring valid analyses by race and ethnicity was 8 (88.9%) in FY 2022; 17 (73.9%) in FY 2023; and 13 (100%) in FY 2024. The total number of NIMHD Phase III trials requiring valid analyses by sex indicated in Table 2-3 was 8 (88.9%) in FY 2022; 17 (73.9%) in FY 2023; and 13 (100%) in FY 2024. (See Appendix A).

The total enrollment for all NIMHD supported NIH-Defined Phase III Clinical Trials by sex, race, and ethnicity is displayed in Table 5-2-2-C (see Appendix C). Total enrollment decreased from 690 in FY 2023 to 535 in FY 2024. However, the percentage of females enrolled increased significantly from 57.2% in FY 2023 to 83.9% in 2024. The percentage of minorities enrolled in NIMHD Phase III trials averaged over 90% during the 3-year timeframe with Black/African Americans the most common participant. It was noted that the enrollment of Hispanic/Latino dramatically increased from 41 in FY 2023 to 119 in FY 2024.(See Appendix C).

C. Research, Condition, and Disease Categorization (RCDC) Report

The Research Condition and Disease Categorization (RCDC) Report is a computerized process used by NIH to categorize expenditures by the Institutes and Centers to support biomedical research by diseases, conditions, or research areas. Inclusion enrollment data by 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.

Appendix A

Table 2-1. Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Clinical Research

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	768	524	244	241	3	46	20	178
2023	894	543	351	348	3	67	19	265
2024	905	507	398	395	3	74	15	309

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

Total Inclusion Data Records (IERs): All NIH-Defined Phase III Trials

Table 2-2. Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Phase III Trials

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	9	9	0	0	0	0	0	0
2023	23	19	4	4	0	0	0	4
2024	13	7	6	6	0	1	1	4

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

Total Inclusion Data Records (IERs): All NIH Phase III Clinical Trials

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

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	9	8	88.9	8	88.9
2023	23	17	73.9	17	73.9
2024	13	13	100.0	13	100.0

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.

Appendix B

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	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	Female	22,836	61.2	37,286	56.1	26,553	71.2	9,880	26.5	853	2.3
2022	Male	17,031	59.6	28,554	43.0	20,148	70.6	7,647	26.8	759	2.7
2022	Unknown	189	33.3	567	0.9	229	40.4	103	18.2	235	41.4
2023	Female	56,304	64.4	87,458	62.1	60,540	69.2	25,406	29.0	1,512	1.7
2023	Male	30,884	61.9	49,888	35.4	34,285	68.7	14,537	29.1	1,066	2.1
2023	Unknown	1,077	30.2	3,563	2.5	1,054	29.6	442	12.4	2,067	58.0
2024	Female	59,169	70.9	83,474	50.6	60,845	72.9	21,685	26.0	944	1.1
2024	Male	31,048	71.2	43,635	26.4	29,821	68.3	13,029	29.9	785	1.8
2024	Unknown	955	2.5	37,869	23.0	838	2.2	223	0.6	36,808	97.2

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

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	771	2.1	2,270	6.1	9,168	24.6	294	0.8	15,075	40.4	2,642	7.1	7,066	19.0
2022	Male	715	2.5	1,508	5.3	6,452	22.6	296	1.0	11,284	39.5	2,398	8.4	5,901	20.7
2022	Unknown	15	2.6	8	1.4	55	9.7	2	0.4	152	26.8	22	3.9	313	55.2
2023	Female	2,174	2.5	4,911	5.6	23,008	26.3	539	0.6	40,624	46.4	6,617	7.6	9,585	11.0
2023	Male	1,287	2.6	3,351	6.7	11,348	22.7	340	0.7	23,371	46.8	3,449	6.9	6,742	13.5
2023	Unknown	142	4.0	77	2.2	344	9.7	13	0.4	531	14.9	139	3.9	2,317	65.0
2024	Female	2,298	2.8	5,935	7.1	28,087	33.6	1,217	1.5	31,013	37.2	3,822	4.6	11,102	13.3
2024	Male	1,552	3.6	3,752	8.6	11,688	26.8	894	2.0	16,832	38.6	2,317	5.3	6,600	15.1
2024	Unknown	280	0.7	70	0.2	327	0.9	12	0.0	309	0.8	125	0.3	36,746	97.0

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

Appendix C

All Enrollment: All NIH-Defined Clinical Research

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	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2022	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2022	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2023	Female	378	95.7	395	57.2	346	87.6	41	10.4	8	2.0
2023	Male	134	99.3	135	19.6	135	100.0	0	0.0	0	0.0
2023	Unknown	65	40.6	160	23.2	65	40.6	0	0.0	95	59.4
2024	Female	375	83.5	449	83.9	354	78.8	93	20.7	2	0.4
2024	Male	45	81.8	55	10.3	29	52.7	26	47.3	0	0.0
2024	Unknown	31	100.0	31	5.8	31	100.0	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.

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	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2022	Male	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2022	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2023	Female	0	0.0	1	0.3	335	84.8	1	0.3	9	2.3	37	9.4	12	3.0
2023	Male	0	0.0	0	0.0	122	90.4	0	0.0	1	0.7	12	8.9	0	0.0
2023	Unknown	0	0.0	0	0.0	45	28.1	0	0.0	0	0.0	20	12.5	95	59.4
2024	Female	4	0.9	13	2.9	265	59.0	1	0.2	78	17.4	11	2.4	77	17.1
2024	Male	0	0.0	8	14.5	11	20.0	0	0.0	12	21.8	2	3.6	22	40.0
2024	Unknown	0	0.0	0	0.0	31	100.0	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.