

NINR Report

**Monitoring Adherence to the NIH Policy on the
Inclusion of Women and Minorities in Clinical
Research as Reported in FY 2022 – FY 2024**

NINR Report

Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY 2022 – FY 2024

I. Background/Overview

The National Institute of Nursing Research (NINR) leads nursing research to solve pressing health challenges and inform practice and policy, optimizing health for all.

NINR prioritizes research that:

- tackles today's pressing health challenges and stimulates discoveries to prepare for, prevent, or address tomorrow's challenges;
- discovers solutions across clinical, community, and policy settings to optimize health for individuals, families, communities, and populations;
- is innovative, develops or applies the most rigorous methods, and has the potential for the greatest impact on health.

NINR supports research framed through five complementary and synergistic research lenses that best leverage the strengths of nursing research and promote multilevel approaches, cross-disciplinary and -sectoral collaboration, and community engagement in research. The research lenses are health disparities, social determinants of health, population and community health, prevention and health promotion, and systems and models of care. Nursing research is well positioned to address each of these research lenses because of nursing's expertise in biological, behavioral, social, and public health sciences.

II. Strategies for Ensuring Compliance - The implementation of inclusion guidelines involves the participation of review, program, policy, and grants management staff.

A. Peer Review

NINR Scientific Review Officers use [inclusion reviewer guidelines](#) to instruct reviewers to focus on the scientific acceptability of plans for inclusion on the basis of sex, race, ethnicity, and age (i.e., whether the proposed composition of the study population is scientifically appropriate and/or justified) while preparing critiques of clinical research applications. Scientific acceptability is specifically addressed during review meeting discussions. For NIH-defined Phase III clinical trials, enrollment goals are further assessed for plans to conduct analyses of intervention effects among sex, racial, and ethnic groups. The NIH scientific peer review regulations specify that reviewers will assess the overall impact that the proposed project could have on the research field in light of the assessment of individual review criteria, and additional review criteria regarding planned inclusion on the basis of sex, race, ethnicity, and age.

Unacceptable inclusion plans must be reflected in the priority score of the application and documented in the summary statement. In addition, the initial review groups make recommendations as to the acceptability of the proposed study population with respect to the inclusion policies. If issues are raised by the initial review group, NINR Program Officials work with principal investigators to ensure that the concerns are appropriately resolved prior to funding. The National Advisory Council for Nursing Research performs the second level of review and makes recommendations for funding to the NINR Director considering the overall impact score, percentile

ranking, and summary statement in light of the research priorities for NINR. Applications with unacceptable inclusion plans receive a bar to funding; an award is not issued until an acceptable resolution is received.

B. Program Monitoring and Grants Management 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 Officials 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 the requirement for 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, as part of their NIH protocol reviews. These plans are considered during the scientific review process. Intramural IRBs review intramural research protocols for compliance with inclusion guidelines and conduct annual monitoring. With each annual 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 plans 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.

D. Describe IC training approaches

Institute Program Officials/Program Directors and Scientific Review Officers attended the 2024 Inclusion Training for Program Staff and the 2024 Inclusion Training for Review Staff in April 2024. Staff may access the archived training on the NIH staff intranet.

III. Analysis and Interpretation of Data

A. Narrative summary

Data about the inclusion of women and minorities as subjects in clinical studies during fiscal years (FY) 2022 through 2024 are shown in appended tables. All the data were generated by an NIH reporting system. The total number of Inclusion Data Records, reflecting the number of clinical studies, is shown in Table 1. Total enrollment numbers for NINR's Clinical Research and minority representation are shown in Table 2. Enrollment data broken out by sex and race and ethnicity are shown in Table 3. Table 4 shows the enrollment data for NINR Phase III Clinical trials, sex by race and ethnicity.

B. Location of data tables

Data about the inclusion of women and minorities as subjects in clinical studies during FY 2022 through 2024 are shown in appended tables.

C. Summary of the inclusion data presented in tables

Table 1: Total Inclusion Data Records (IERs) for All NIH-Defined Clinical Research Reported Between FY 2022 and FY 2024 shows that the total IERs declined from 424 in 2022 to 388 in 2023

and then to 382 in 2024. IERs without enrollment declined from 177 in 2022 to 156 in 2023 and slightly rose to 160 in 2024. The vast majority of IERs come from US sites.

Table 2: Total Enrollment of All NIH-Defined Clinical Research shows that the number of minority participants rose from 2022 to 2024. The percentage of minorities enrolled increased from 42.8% in 2022 to 49.9% in 2023 before falling back down to 41.0% in 2024. Most of the fluctuation is due to the proportion of Black/African Americans enrolled, increasing from 26.5% in 2022 to 33.1% in 2023 before falling to 22.8% in 2024.

Table 3: Total Enrollment for all NIH-defined Clinical Research, Sex by Race and Ethnicity for FYs 2022-2024 shows that the changes in the number and proportion of minority participants from 2022 to 2024 are similar for both males and females.

Table 4: All Enrollment for NIH-Defined Phase III Clinical Research, Sex by Race and Ethnicity shows that the minority enrollment initially increased from 2022 to 2023 but then declined in 2024 in terms of total number while the proportion of minority enrollment initially decreased before increasing by 2024. Total enrollment was lowest in 2024 and this was the year with the lowest number of minorities enrolled. However, the highest percentage of participants from minority groups was in 2024 and the rise is primarily due to increased enrollment of Black/African Americans.

D. Valid analyses for Phase III clinical trials - NINR had 40 NIH-defined Phase III clinical trials that required valid analyses by sex and race/ethnicity during the 2022–2024 period. There were 12 grants in 2022, 15 in 2023, and 13 in 2024 that required valid analyses by sex and race/ethnicity.

E. Participation by Disease/Condition category - Inclusion enrollment data by Research Condition and Disease Categorization (RCDC) category are available through this link: <https://report.nih.gov/RISR/>.

Appendices

Table 1: Total Inclusion Data Records (IERs) for All NIH-Defined Clinical Research Reported Between FY 2022 and FY 2024

Table 2. Total Enrollment of All NIH-Defined Clinical Research

Table 3: Total Enrollment for All NIH-Defined Clinical Research, Sex by Race and Ethnicity Reported Between FY 2022 and FY 2024

Table 4: All Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex by Race and Ethnicity

Table 1. Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Clinical Research Reported Between Fiscal Years 2022 and 2024

Fiscal Year	IERs							IERs Excluding Male only and Female only*
	Total IERs	Without Enrollment	IERs With Enrollment	US Site IERs	Non-US Site IERs	Female Only IERs	Male Only IERs	
2022	424	177	247	236	11	38	14	195
2023	388	156	232	219	13	49	11	172
2024	382	160	222	215	7	38	8	176

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

Table 2. Total Enrollment of All NIH-Defined Clinical Research

Fiscal Year	2022	2023	2024
Total Enrollment	53,591	54,449	90,217
Minority Enrollment	22,963	27,151	37,019
% Minority Enrollment	42.8	49.9	41.0
American Indian/Alaskan Native	657	410	844
% American Indian/Alaskan Native	1.2	0.8	0.9
Asian	1,785	1,486	4,142
% Asian	3.3	2.7	4.6
Black/African American	14,183	17,998	20,612
% Black/African American	26.5	33.1	22.8
Native Hawaiian/Pacific Islander	118	100	213
% Native Hawaiian/Pacific Islander	0.2	0.2	0.2
White	30,992	27,383	48,216
% White	57.8	50.3	53.4
More Than One Race	1,504	1,758	2,758
% More Than One Race	2.8	3.2	3.1
Unknown/Not Reported	4,352	5,314	13,432
% Unknown/Not Reported	8.1	9.8	14.9

Table 3. Total Enrollment for All NIH-Defined Clinical Research, Sex by Race and Ethnicity Reported Between FY 2022 and FY 2024

Year	2022	2022	2022	2023	2023	2023	2024	2024	2024
Sex	Female	Male	Unknown	Female	Male	Unknown	Female	Male	Unknown
Minority	14,002	8,786	175	17,348	9,686	117	22,981	13,053	985
% Minority	44.0	41.0	45.3	52.9	45.8	23.2	40.4	47.1	17.3
Total Enrollment	31,789	21,416	386	32,791	21,154	504	56,832	27,697	5,688
% Total	59.3	40.0	0.7	60.2	38.9	0.9	63.0	30.7	6.3
American Indian/Alaska Native	273	380	4	267	136	7	463	338	43
% American Indian/Alaska Native	0.9	1.8	1.0	0.8	0.6	1.4	0.8	1.2	0.8
Asian	1,027	754	4	848	633	5	2,922	1,089	131
% Asian	3.2	3.5	1.0	2.6	3.0	1.0	5.1	3.9	2.3
Black/African American	8,651	5,417	115	11,356	6,614	28	12,354	8,141	117
% Black/African American	27.2	25.3	29.8	34.6	31.3	5.6	21.7	29.4	2.1
Native Hawaiian/Pacific Islander	70	44	4	65	35	0	153	57	3
% Native Hawaiian/Pacific Islander	0.2	0.2	1.0	0.2	0.2	0.0	0.3	0.2	0.1
White	18,213	12,649	130	15,902	11,374	107	32,879	11,951	3,386
% White	57.3	59.1	33.7	48.5	53.8	21.2	57.9	43.1	59.5
More Than One Race	971	511	22	1,067	656	35	1,562	742	454
% More Than One Race	3.1	2.4	5.7	3.3	3.1	6.9	2.7	2.7	8.0
Unknown/Not Reported	2,584	1,661	107	3,286	1,706	322	6,499	5,379	1,554
% Unknown/Not Reported	8.1	7.8	27.7	10.0	8.1	63.9	11.4	19.4	27.3
Not Hispanic	26,735	18,473	250	26,045	18,038	147	45,137	20,735	3,545
% Not Hispanic	84.1	86.3	64.8	79.4	85.3	29.2	79.4	74.9	62.3
Hispanic/Latino	3,652	2,070	47	5,100	1,896	72	7,115	3,077	283
% Hispanic/Latino	11.5	9.7	12.2	15.6	9.0	14.3	12.5	11.1	5.0
Unknown/Not Reported	1,402	873	89	1,646	1,220	285	4,580	3,885	1,860
% Unknown/Not Reported	4.4	4.1	23.1	5.0	5.8	56.5	8.1	14.0	32.7

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

Table 4. ALL Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex by Race and Ethnicity

Year	2022	2022	2022	2023	2023	2023	2024	2024	2024
Sex	Female	Male	Unknown	Female	Male	Unknown	Female	Male	Unknown
Minority	445	1,465	0	639	1,677	0	439	1,433	4
% Minority	31.9	63.6	0.0	29.3	55.1	0.0	60.4	87.9	57.1
Total Enrollment	1,395	2,305	3	2,178	3,045	3	727	1,631	7
% Total	37.7	62.2	0.1	41.7	58.3	0.1	30.7	69.0	0.3
American Indian/Alaska Native	4	7	0	6	8	0	9	6	0
% American Indian/Alaska Native	0.3	0.3	0.0	0.3	0.3	0.0	1.2	0.4	0.0
Asian	10	6	0	15	10	0	3	11	0
% Asian	0.7	0.3	0.0	0.7	0.3	0.0	0.4	0.7	0.0
Black/African American	382	1,410	0	535	1,582	0	275	1,288	2
% Black/African American	27.4	61.2	0.0	24.6	52.0	0.0	37.8	79.0	28.6
Native Hawaiian/Pacific Islander	0	0	0	0	0	0	0	1	0
% Native Hawaiian/Pacific Islander	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.0
White	976	863	0	1,576	1,404	0	395	296	2
% White	70.0	37.4	0.0	72.4	46.1	0.0	54.3	18.1	28.6
More Than One Race	10	11	0	28	32	0	12	18	0
% More Than One Race	0.7	0.5	0.0	1.3	1.1	0.0	1.7	1.1	0.0
Unknown/Not Reported	13	8	3	18	9	3	33	11	3
% Unknown/Not Reported	0.9	0.3	100.0	0.8	0.3	100.0	4.5	0.7	42.9
Not Hispanic	1,324	2,250	0	2,085	2,970	0	539	1,472	4
% Not Hispanic	94.9	97.6	0.0	95.7	97.5	0.0	74.1	90.3	57.1
Hispanic/Latino	56	45	0	75	62	0	167	142	2
% Hispanic/Latino	4.0	2.0	0.0	3.4	2.0	0.0	23.0	8.7	28.6
Unknown/Not Reported	15	10	3	18	13	3	21	17	1
% Unknown/Not Reported	1.1	0.4	100.0	0.8	0.4	100.0	2.9	1.0	14.3