

NINR Report

**Monitoring Adherence to the NIH Policy on the
Inclusion of Women and Minorities in Clinical
Research as Reported in FY 2019 – FY 2021**

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I. Background/Overview

The mission of the National Institute of Nursing Research (NINR) is to lead nursing research and training to solve pressing health challenges and inform practice and policy—optimizing health and advancing health equity into the future. Nursing research, with its contextualized perspective, is ideally positioned to produce evidence needed to reduce and ultimately eliminate the systemic and structural inequities that place some population groups at a disadvantage in attaining their full health potential.

NINR supports research that is innovative, applies the most rigorous methods, and has the potential for the greatest impact on individual, community, and population health. NINR-supported research advances equity, diversity, and inclusion, tackles today's pressing health challenges and stimulates discoveries to prepare for tomorrow's challenges, and discovers solutions to optimize health across clinical, community, and policy settings. NINR supports research framed through the perspectives of Health Equity; Social Determinants of Health; Population and Community Health; Prevention and Health Promotion; and Systems and Models of Care.

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/gender, 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/gender, 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/gender, 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/gender 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/gender, 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 2020 Inclusion Training for Program Staff and the 2020 Inclusion Training for Review Staff in April 2020. 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) 2019 through 2021 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/gender and race and ethnicity are shown in Table 3. Table 4 shows the enrollment data for NINR Phase III Clinical trials, sex/gender by race and ethnicity.

B. Location of data tables

Data about the inclusion of women and minorities as subjects in clinical studies during fiscal years (FY) 2019 through 2021 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 2019 and FY 2021 shows that the total IERs rose from 367 in 2019 to 434 in 2020 and then dropped back down to 410 in 2021. IERs without enrollment rose over the period from 116 in 2019 to 177 in 2021. 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 2019 to 2020 but then went back down in 2021. The percentage of minorities enrolled dropped from 44.6% in 2019 to 36.5% in 2021. Most of the reduction is due to a declining proportion of Black/African Americans, falling from 29.9% in 2019 to 21.8% in 2021.

Table 3: Total Enrollment for all NIH-defined Clinical Research, Sex/Gender by Race and Ethnicity for FYs 2019-2021 shows that the changes in the number and proportion of minority participants from 2019 to 2021 are similar for both males and females.

Table 4: All Enrollment for NIH-Defined Phase III Clinical Research, Sex/Gender by Race and Ethnicity shows that the minority enrollment rose from 2019 to 2021 in both total number and percentage. Total enrollment was lowest in 2020 but the number of minorities enrolled was still higher than in 2019. The highest percentage of participants from minority groups was in 2020 and the rise is primarily due to increased enrollment of Black/African Americans.

D. Valid analyses for Phase III clinical trials - NINR had 22 NIH-defined Phase III clinical trials that required valid analyses by sex/gender and race/ethnicity during the 2019-2021 period. There were 8 grants in 2019, 5 in 2020, and 9 in 2021 that required valid analyses by sex/gender 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 2019 and FY 2021

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

Table 3: Total Enrollment for All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity Reported Between FY 2019 and FY 2021

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

Table 1. Total Inclusion Data Records (IERS) for NIH-Defined Extramural and Intramural Clinical Research Reported Between Fiscal Years 2019 and 2021

Fiscal Year	Total IERS	IERS		US Site IERS	Non-US Site IERS	Female Only IERS	Male Only IERS	IERS Excluding Male only and Female only*
		Without Enrollment	IERS With Enrollment					
2019	367	116	251	245	6	36	9	206
2020	434	178	256	252	4	37	7	212
2021	410	177	233	228	5	40	13	180

*Inclusion Data Records (IERS) excluding male only and female only include unknown sex/gender, and combination of unknown and any sex/gender(s).

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

Fiscal Year	2019	2020	2021
Total Enrollment	28,878	48,798	35,246
Minority Enrollment	12,878	17,298	12,856
% Minority Enrollment	44.6	35.4	36.5
American Indian/Alaskan Native	438	687	811
% American Indian/Alaskan Native	1.5	1.4	2.3
Asian	796	1,151	678
% Asian	2.8	2.4	1.9
Black/African American	8,643	9,965	7,698
% Black/African American	29.9	20.4	21.8
Native Hawaiian/Pacific Islander	67	104	60
% Native Hawaiian/Pacific Islander	0.2	0.2	0.2
White	16,231	30,825	22,689
% White	56.2	63.2	64.4
More Than One Race	642	993	628
% More Than One Race	2.2	2.0	1.8
Unknown/Not Reported	2,061	5,073	2,682
% Unknown/Not Reported	7.1	10.4	7.6

Table 3. Total Enrollment for All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity Reported Between FY 2019 and FY 2021

Year	2019	2019	2019	2020	2020	2020	2021	2021	2021
Sex/Gender	Female	Male	Unknown	Female	Male	Unknown	Female	Male	Unknown
Minority	7,564	5,233	81	10,533	6,650	115	7,654	5,127	75
% Minority	46.4	44.8	9.0	38.4	35.0	4.8	37.1	35.5	37.9
Total Enrollment	16,300	11,677	901	27,418	18,985	2,395	20,616	14,432	198
% Total	56.4	40.4	3.1	56.2	38.9	4.9	58.5	40.9	0.6
American Indian/Alaska Native	260	174	4	389	296	2	343	467	1
% American Indian/Alaska Native	1.6	1.5	0.4	1.4	1.6	0.1	1.7	3.2	0.5
Asian	388	404	4	630	505	16	386	290	2
% Asian	2.4	3.5	0.4	2.3	2.7	0.7	1.9	2.0	1.0
Black/African American	5,197	3,411	35	6,304	3,613	48	4,692	2,978	28
% Black/African American	31.9	29.2	3.9	23.0	19.0	2.0	22.8	20.6	14.1
Native Hawaiian/Pacific Islander	28	39	0	54	50	0	29	31	0
% Native Hawaiian/Pacific Islander	0.2	0.3	0.0	0.2	0.3	0.0	0.1	0.2	0.0
White	9,337	6,821	73	17,884	12,875	66	13,363	9,298	28
% White	57.3	58.4	8.1	65.2	67.8	2.8	64.8	64.4	14.1
More Than One Race	387	252	3	582	404	7	365	255	8
% More Than One Race	2.4	2.2	0.3	2.1	2.1	0.3	1.8	1.8	4.0
Unknown/Not Reported	703	576	782	1,575	1,242	2,256	1,438	1,113	131
% Unknown/Not Reported	4.3	4.9	86.8	5.7	6.5	94.2	7.0	7.7	66.2
Not Hispanic	14,229	10,150	113	23,595	16,270	129	17,928	12,694	54
% Not Hispanic	87.3	86.9	12.5	86.1	85.7	5.4	87.0	88.0	27.3
Hispanic/Latino	1,613	1,220	40	2,993	2,130	46	2,092	1,333	40
% Hispanic/Latino	9.9	10.4	4.4	10.9	11.2	1.9	10.1	9.2	20.2
Unknown/Not Reported	458	307	748	830	585	2,220	596	405	104
% Unknown/Not Reported	2.8	2.6	83.0	3.0	3.1	92.7	2.9	2.8	52.5

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

Year	2019	2019	2019	2020	2020	2020	2021	2021	2021
Sex/Gender	Female	Male	Unknown	Female	Male	Unknown	Female	Male	Unknown
Minority	299	136	0	369	228	0	546	400	0
% Minority	41.6	31.1	0.0	64.6	61.6	0.0	50.5	46.7	0.0
Total Enrollment	718	438	3	571	370	4	1,081	856	3
% Total	61.9	37.8	0.3	60.4	39.2	0.4	55.7	44.1	0.2
American Indian/Alaska Native	7	2	0	4	5	0	6	4	0
% American Indian/Alaska Native	1.0	0.5	0.0	0.7	1.4	0.0	0.6	0.5	0.0
Asian	5	6	0	0	5	0	7	5	0
% Asian	0.7	1.4	0.0	0.0	1.4	0.0	0.6	0.6	0.0
Black/African American	262	121	0	346	203	0	503	369	0
% Black/African American	36.5	27.6	0.0	60.6	54.9	0.0	46.5	43.1	0.0
Native Hawaiian/Pacific Islander	0	0	0	1	2	0	0	0	0
% Native Hawaiian/Pacific Islander	0.0	0.0	0.0	0.2	0.5	0.0	0.0	0.0	0.0
White	414	293	0	186	144	0	523	465	0
% White	57.7	66.9	0.0	32.6	38.9	0.0	48.4	54.3	0.0
More Than One Race	12	3	0	8	8	0	5	4	0
% More Than One Race	1.7	0.7	0.0	1.4	2.2	0.0	0.5	0.5	0.0
Unknown/Not Reported	18	13	3	26	3	4	37	9	3
% Unknown/Not Reported	2.5	3.0	100.0	4.6	0.8	100.0	3.4	1.1	100.0
Not Hispanic	692	429	3	528	354	0	1,014	825	0
% Not Hispanic	96.4	97.9	100.0	92.5	95.7	0.0	93.8	96.4	0.0
Hispanic/Latino	25	8	0	19	13	0	31	23	0
% Hispanic/Latino	3.5	1.8	0.0	3.3	3.5	0.0	2.9	2.7	0.0
Unknown/Not Reported	1	1	0	24	3	4	36	8	3
% Unknown/Not Reported	0.1	0.2	0.0	4.2	0.8	100.0	3.3	0.9	100.0