

National Institute on Minority Health and Health Disparities (NIMHD)

Triennial Report on Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY2019 – FY2021

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:

- Conducts and supports research on minority health and health disparities.
- Plans, coordinates, reviews, and evaluates NIH minority health and health disparities research and activities.
- Promotes and supports the training of a diverse research workforce.
- Translates and disseminates research information, and
- 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 with health disparities, which include the Office Management and Budget (OMB) defined racial and ethnic minority populations, people living in rural communities, individuals of less privileged socioeconomic status (SES), and sexual and gender minority (SGM) groups. The goals are to improve the health of these populations, reduce disparities in health outcomes, and promote health equity.

Minority health refers to the distinctive health characteristics and attributes of a minority racial and/or ethnic group who is socially disadvantaged due in part to being subject to potential discriminatory acts. Minority health research is a multi-disciplinary field that investigates the distinctive health characteristics and attributes of minority racial and/or ethnic groups to help understand and improve their health outcomes through tailored interventions. Minority populations are usually underrepresented in biomedical research. Racial and ethnic populations included in this definition are defined by the Office of Management and Budget Directive 15.

A health disparity is defined as a health difference that adversely affects disadvantaged populations, based on one or more of the specified health outcomes:

- Higher incidence and/or prevalence of disease and/or disorders
- Premature and/or excessive mortality in diseases where populations differ
- Greater burden of disease demonstrated with metrics such as disability-adjusted life years
- Poorer daily functioning or reduced quality of life using observed or self-reported measures, or
- Poor behavioral and/or clinical outcomes directly linked to incidence of disease or disorders

Health disparities research is a multi-disciplinary field of study devoted to gaining greater scientific knowledge about the influence of health determinants, understanding the role of different pathways leading to disparities, and determining how findings translate into interventions to reduce health disparities.

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 inclusion on the basis of sex/gender, race, ethnicity, and age when considering clinical research applications. Reviewers evaluate applications for the appropriateness of the proposed plan for inclusion by sex/gender, race, and ethnicity. For NIH-defined Phase III clinical trials, enrollment goals are further assessed for plans to conduct valid analyses of intervention effects among sex/gender, 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. Applications with unacceptable inclusion plans have their funding held; an award is not issued until an acceptable resolution to the inclusion plan is received.

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 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.

Intramural

All intramural clinical research studies require investigators to provide plans for the appropriate inclusion of women and minority groups and/or a justification whenever representation is limited or absent, as part of their NIH protocol reviews. Intramural IRBs review intramural research protocols for compliance with inclusion guidelines and conduct annual monitoring. With each annual review and renewal, the investigator documents the number, sex/gender, and race and ethnicity of those who were accrued during the past year; any issues with accrual are addressed at the annual review by the investigator and reviewed by 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).

NIMHD Training Approaches

NIMHD Program Officials/Program Directors and Scientific Review Officers, have the option of attending in-person or online training on *Ensuring Inclusion in NIH Clinical Research: Policies and Procedures for Grants and Contracts*, or accessing the archived training on the NIH staff intranet.

The enrollment of more than 60% racial and ethnic minority persons in studies supported by NIMHD underscores the staff's commitment to ensure that NIMHD-funded research is aligned with its mission to improve minority health and reduce health disparities and adheres to the NIH inclusion policy.

Analysis and Interpretation of Data

Tables 1 through 6 (see Appendix) include NIMHD aggregate inclusion data. A summary of the data is included below. NIMHD inclusion enrollment data by Research Condition and Disease Categorization (RCDC) category are available through this link: <https://report.nih.gov/RISR/>.

As evidenced by the data, NIMHD enrolled:

- More than 50% female participants across all three years for all racial and ethnic minority groups (Table 1).
- More than 60% racial and ethnic minority participants in 2019, and more than 70% racial and ethnic minority participants in 2020 and 2021 (Table 3).

Regarding Phase III clinical trials (Tables 2 and 4), in 2019, NIMHD supported 11 NIH-Defined phase III clinical trials, of which nine (or 82%) required valid analysis. In 2020 NIMHD supported 13 NIH-Defined phase III clinical trials, of which eight (or 62%) required valid analysis. In 2021 NIMHD supported 13 NIH-Defined phase III clinical trials, of which eight (or 80%) required valid analysis; however, enrollment on these trials has not begun. For phase III clinical trials, NIMHD enrolled:

- More than 50% women in 2019 and 2020.
- More than 50% racial and ethnic minority participants in 2019, and in 2020, 100% were ethnic minority participants (Table 4).

In terms of enrollment distribution by age groups, data are only available for FY 2021, following the publication of the updated *NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan*. In FY 2021, approximately 81% of participants are adults (18-64 years), 11% are children (<18 years), and 4% are older adults (65+ years) (Tables 5 and 6).

Clinical research studies fluctuate over time due to changes in actively enrolled projects. Thus, these data are cross-sectional snapshots of participants enrolled in a given year. Overall enrollment decreased from 2019 to 2021 due, in part, to phasing out of three large projects with very high enrollment or that completed their grant funding during this period. Despite this overall decrease in enrollment, the percent of racial and ethnic minority participants enrolled remained high: 65% in 2019, 72% in 2020, and 71% in 2021, Table 3. These data are consistent with NIMHD's commitment to the inclusion of racial and ethnic minority and female participants in clinical research.

Additional Information

The 21st Century Cures Act, enacted December 13, 2016, included several new requirements related to inclusion of participants in clinical research.

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/gender 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.

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 also amended the frequency of the Report of the NIH Director on the inclusion of women and minority participants from biennial to triennial. Thus, this report provides information on inclusion of participants in NIH clinical research between FY 2019 – 2021. Section IV of the [Report of the Advisory Committee on Research on Women's Health](#) includes IC reports on monitoring adherence to the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research for FY 2017 and 2018.

Appendix – Inclusion Data Tables 1-6

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 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*
2019	402	197	205	203	2	37	17	151
2020	539	295	244	243	1	44	19	181
2021	690	420	270	267	3	54	21	195

*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. Valid Analysis Requirements for NIH-Defined Phase III Extramural Grants Reported Between Fiscal Years 2019 and 2021

Fiscal Year	Total IERS	IERS Requiring Race Ethnicity Valid Analysis	% IERS Requiring Race Ethnicity Valid Analysis	IERS Requiring Sex Gender Valid Analysis	% IERS Requiring Sex Gender Valid Analysis
2019	11	9	81.8	9	81.8
2020	13	8	61.5	8	61.5
2021	10	8	80.0	8	80.0

Table 3. Enrollment for NIH-Defined Extramural Clinical Research, by Sex/Gender, Race and Ethnicity*

	2019				2020**				2021***				
	Female	Male	Unknown	Total	Female	Male	Unknown	Total	Female	Male	Unknown	Total	
Race/Ethnicity	91,661	81,833	244	173,738	51,056	39,139	189	90,384	24,146	16,478	208	40,832	
%	67.1	63.0	26.5	65.0	72.6	72.4	9.3	71.5	71.5	70.2	41.5	70.7	
Race	American Indian/Alaska Native	2,447	1,806	65	4,318	2,573	2,007	17	4,597	1,035	704	10	1,749
	%	1.8	1.4	7.0	1.6	3.7	3.7	0.8	3.6	3.1	3.0	2.0	3.0
	Asian	3,387	2,851	2	6,240	3,176	2,283	14	5,473	3,550	2,372	24	5,946
	%	2.5	2.2	0.2	2.3	4.5	4.2	0.7	4.3	10.5	10.1	4.8	10.3
	Black/African American	70,550	69,699	47	140,296	31,257	27,193	63	58,513	9,505	7,589	47	17,141
	%	51.6	53.7	5.1	52.5	44.5	50.3	3.1	46.3	28.1	32.3	9.4	29.7
	Native Hawaiian/Pacific Islander	501	335	0	836	526	368	2	896	534	361	2	897
	%	0.4	0.3	0.0	0.3	0.7	0.7	0.1	0.7	1.6	1.5	0.4	1.6
	White	53,456	51,739	111	105,306	24,147	17,223	84	41,454	12,403	8,034	167	20,604
	%	39.1	39.8	12.0	39.4	34.3	31.9	4.1	32.8	36.7	34.2	33.3	35.7
	More Than One Race	1,252	900	6	2,158	2,593	1,482	8	4,083	1,780	1,055	42	2,877
	%	0.9	0.7	0.7	0.8	3.7	2.7	0.4	3.2	5.3	4.5	8.4	5.0
	Unknown/Not Reported	5,030	2,563	691	8,284	6,027	3,514	1,840	11,381	4,979	3,371	209	8,559
%	3.7	2.0	74.9	3.1	8.6	6.5	90.7	9.0	14.7	14.4	41.7	14.8	
Ethnicity	Not Hispanic	118,664	119,957	231	238,852	53,455	44,062	268	97,785	22,165	16,110	174	38,439
	%	86.9	92.4	25.1	89.3	76.0	81.5	13.2	77.4	65.6	68.6	34.7	66.5
	Hispanic/Latino	16,132	8,367	164	24,663	14,557	8,129	110	22,796	9,972	5,827	121	15,920
	%	11.8	6.4	17.8	9.2	20.7	15.0	5.4	18.0	29.5	24.8	24.2	27.6
	Unknown/Not Reported	1,827	1,569	527	3,923	2,287	1,879	1,650	5,816	1,649	1,559	206	3,414
%	1.3	1.2	57.2	1.5	3.3	3.5	81.4	4.6	4.9	6.6	41.1	5.9	
Total Enrollment	136,623	129,893	922	267,438	70,299	54,070	2,028	126,397	33,786	23,486	501	57,773	

*NIMHD had no enrollment in its intramural research program. Numbers in the table refer to enrollment in the extramural research program.

** In FY2020, there was a reduction in overall enrollment, and, as a result, of racial and ethnic minority participant enrollment. This decline may be due to the phasing out in FY2020 of projects with very high enrollment. Examples of such projects include: [U01MD010579-04](#) (A Community based Participatory Trial to increase Stroke Treatment, University of Michigan, with PI Lesli Elizabeth Skolarus) with a total enrollment of 98,000 participants of which 61% were minority participants and [R01MD010290-05](#) (Evaluation of Racial Disparities in Access of Kidney Transplantation in New National Kidney Allocation Policy, Emory University, with PI Rachel Patzer) with a total enrollment of 66,4425 participants of which 47% were minority participants.

*** In FY2021, there was a reduction in overall enrollment, and, as a result, of racial and ethnic minority enrollment. This decline may be due to the phasing out in FY2021 of projects with very high enrollment. Examples of such projects include: [5U01MD010611-05](#) a continuation of [R01MD010290-05](#), (Reducing Racial Disparities in Access of Kidney Transplantation: The Radiant Regional Study, Emory University, with PI Rachel Patzer) with a total enrollment of 98,000 participants of which 47% were minority participants and [5R01MD011607-04](#) (Integrating Social Determinants of Health Into Risk Adjustment Models: An opportunity to Improve Care Coordination Strategies for Medicaid Beneficiaries, George Washington University, with PI Melissa McCarthy) with a total enrollment of 9,845 participants of which 98% were minority participants.

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

	Race/Ethnicity	2019				2020				2021			
		Female	Male	Unknown	Total	Female	Male	Unknown	Total	Female	Male	Unknown	Total
	Race/Ethnicity	185	83	0	268	3	2	0	5	0	0	0	0
	%	57.5	76.9	0.0	51.3	100.0	100.0	0.0	100.0	0.0	0.0	0.0	0.0
Race	American Indian/Alaska Native	133	60	0	193	0	0	0	0	0	0	0	0
	%	41.3	55.6	0.0	37.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Asian	1	0	0	1	0	0	0	0	0	0	0	0
	%	0.3	0.0	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Black/African American	1	0	0	1	0	0	0	0	0	0	0	0
	%	0.3	0.0	0.0	0.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Native Hawaiian/Pacific Islander	0	0	0	0	0	0	0	0	0	0	0	0
	%	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	White	91	27	0	118	0	0	0	0	0	0	0	0
	%	28.3	25.0	0.0	22.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	More Than One Race	45	19	0	64	0	0	0	0	0	0	0	0
	%	14.0	17.6	0.0	12.3	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Unknown/Not Reported	51	2	92	145	3	2	0	5	0	0	0	0	
%	15.8	1.9	100.0	27.8	100.0	100.0	0.0	100.0	0.0	0.0	0.0	0.0	
Ethnicity	Not Hispanic	261	100	0	361	0	0	0	0	0	0	0	0
	%	81.1	92.6	0.0	69.2	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	Hispanic/Latino	14	8	0	22	3	2	0	5	0	0	0	0
	%	4.3	7.4	0.0	4.2	100.0	100.0	0.0	100.0	0.0	0.0	0.0	0.0
Unknown/Not Reported	47	0	92	139	0	0	0	0	0	0	0	0	
%	14.6	0.0	100.0	26.6	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	
	Total Enrollment	322	108	92	522	3	2	0	5	0	0	0	0

Table 5. Age Distribution Using Broad Age Groups for NIH-Defined Extramural and Intramural Clinical Research Reported for Fiscal Year 2021.

Fiscal Year	Children (<18 years)	Adults (18-64 years)	Older Adults (65+ years)	Unknown or Not Reported	Total
2021	183	1,373	71	77	1,704
	10.7%	80.6%	4.2%	4.5%	100%

Table 6. Age Distribution Using Detailed Age Groups for NIH-Defined Extramural and Intramural Clinical Research Reported for Fiscal Year 2021.

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
2021	13	0	2	15	78	40	32	18	36	44	359	405	318	211	50	12	8	1	0	0	77	1,704
	0.8%	0.0%	0.1%	0.9%	4.6%	2.3%	1.9%	1.1%	2.1%	2.6%	21.1%	23.8%	18.7%	12.4%	2.9%	0.7%	0.5%	0.1%	0.0%	0.0%	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.