2025 NIMH TRIENNIAL REPORT CERTIFYING ADHERENCE TO THE NIH POLICY ON THE INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH AS REPORTED FOR FISCAL YEARS 2022 - 2024

Background/Overview

The National Institutes of Health (NIH) Revitalization Act of 1993 (P.L. 103-43) mandated that the advisory council of each Institute prepare a biennial report describing the manner in which the Institute has complied with requirements regarding the inclusion of women and minorities in clinical research. Enacted December 13, 2016, the 21st Century Cures Act (P.L. 114-255) contained measures to assess, report, and improve inclusion of key demographic groups (groups that reflect diversity of sex, age, and racial and ethnic minority status) to advance understanding of health disparities between different demographic groups. The 21st Century Cures Act also amended the frequency of the Report of the NIH Director on the inclusion of women and minorities from biennial to triennial. NIH is mandated (NIH Revitalization Act of 1993, P.L. 103-43 (Public Health Service Act sec. 492B, 42 U.S.C. sec. 289a-2)) to ensure that women and minorities are included in NIH-funded clinical research in a manner that is appropriate to the scientific question under study, and that NIH-defined Phase III clinical trials are designed in a manner sufficient to examine differential effects of interventions on both women and men, as well as diverse racial and ethnic groups. As a result, NIH established policies and guidelines for inclusion of women and minorities in clinical research.[1]

This report details the National Institute of Mental Health's (NIMH) strategies for maintaining compliance with these inclusion policies and guidelines and provides data on extramural and intramural clinical research and NIH-defined Phase III clinical trials. As the NIH inclusion guidelines apply to studies both within and outside the United States, data are presented for all NIMH-funded and -conducted studies (domestic and foreign). The data reflect the breadth of the clinical research supported by NIMH to fulfill its mission to transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for prevention, recovery, and cure. The NIMH clinical research portfolio includes large-scale clinical trials and observational studies, as well as smaller studies in basic, translational, and services research. NIMH-funded and -conducted research has significantly advanced understanding of mental health and has contributed to improving the lives of individuals affected by mental illnesses. Priority research areas include suicide prevention, genomics, and global mental health.

Strategies for Ensuring Compliance

Extramural Processes

NIMH follows several steps to ensure compliance with the NIH inclusion policy and guidelines. NIH policies and changes to the policies are disseminated via NIH Guide Notices. In grant applications involving human subjects research[2], applicants are required to include plans for the inclusion of women and minorities and individuals across the lifespan. Applicants can seek assistance from program officials in developing inclusion plans. Once the grant application is

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[1] For further information about the guidelines, please see https://grants.nih.gov/grants/funding/women_min/guidelines.htm

[2] Refer to the Public Health Service (PHS) Human Subjects and Clinical Trial Information Form Instructions for complete guidance on what should be addressed (https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#top).

received by NIMH, the implementation of inclusion guidelines involves the participation of review, program, policy, and grants management staff.

Upon receipt of the grant application, inclusion is first addressed by peer review.[3] Individuals serving on NIH scientific review groups are given specific guidance[4] for evaluating applications for the appropriateness of the proposed plan for inclusion by age, sex, and racial and ethnic minority enrollment goals, as well as the recruitment plans that explain how the applicant will meet these goals. For NIH-defined Phase III clinical trials, reviewers further assess enrollment goals for plans to conduct analyses of intervention effects by sex and racial and ethnic minority groups. Scientific review groups make recommendations as to the acceptability of the proposed study population with respect to the inclusion policies. Unacceptable inclusion plans must be reflected in the priority score of the application and documented in the summary statement. Applications with unacceptable inclusion plans receive a bar to funding which must be resolved prior to award of the grant or cooperative agreement. In the case of a bar to funding, the program official associated with the grant application notifies the grant applicant. The program official reviews the revised inclusion plan (and if applicable, the inclusion enrollment report) and works with the NIMH Office of Clinical Research (OCR) to ensure the revisions adequately address the inclusion concerns. Once satisfactory, the inclusion plan is returned to the NIMH program official and the Division of Extramural Activities Grants Management Branch, and the bar to funding is lifted. This response is kept in the official grant file, along with a record of administrative actions taken.

As noted above, program officials are also involved in the implementation of the NIH inclusion policies and/or guidelines. For all grants that include participation of human subjects, program officials review the inclusion plan in the application and indicate whether it is scientifically appropriate. NIMH program officials monitor actual enrollment progress in annual progress reports and provide consultation to investigators when necessary. For NIH-defined Phase III clinical trials, program officials monitor the requirement for sex, race, and ethnicity analyses in applications and annual progress reports. In addition to program officials' activities over the life of the grant, 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.

For NIMH extramural clinical research studies, OCR monitors the entry of inclusion data within the Human Subjects System (HSS), performs quality assurance tasks, and prepares aggregate reports for the National Advisory Mental Health Council and the NIH Office of Research on Women's Health (ORWH). OCR and the NIH Office of Extramural Research (OER) also provide support on procedures for ensuring the accuracy of inclusion data, as well as on the use of HSS. OCR delivers this support by providing training materials to staff and individual assistance calls. NIH created the Inclusion Learning Path in 2024 to provide a suite of on-demand trainings on inclusion policies and procedures for program staff. NIMH staff may access the training on the NIH staff intranet. There are additional training opportunities facilitated by NIH OER for NIMH staff, such as the NIH Integrated Core Curriculum series, to learn about inclusion policies and reporting procedures.

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[3] 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.

[4] For further information about the guidelines, please see https://grants.nih.gov/grants/peer/guidelines_general/Review_Human_subjects_Inclusion.pdf

Intramural Processes

All intramural clinical research studies require investigators to provide plans for the appropriate inclusion of women, racial and ethnic minorities, and individuals across the lifespan, and/or a justification whenever representation is limited or absent, as part of their NIH protocol reviews. The Intramural Institutional Review Board (IRB) reviews research protocols for compliance with inclusion guidelines and conducts annual monitoring. With each annual review and renewal, the investigator documents the number, sex, race, and ethnicity of participants accrued during the past year; any issues with accrual are addressed by the investigator at the IRB annual review and evaluated by the IRB. The NIH Clinical Center's Office of Protocol Services (OPS) renamed Protocol Support Services (PSS) maintains centralized systems for capturing accrual data including sex, race, and ethnicity. OPS coordinates annual reporting of participants' demographic data to the NIH OER and the NIH ORWH.

Analysis and Interpretation of Data

The appended tables show enrollment data for Fiscal Year 2022 (FY22) to FY24. Included in the tables are enrollment data for extramural and intramural clinical research, including all clinical research and data specific to NIH-defined Phase III clinical trials. Inclusion data are reported using the Office of Management and Budget's (OMB) revised 1997 racial and ethnic categories, which are required for the collection, tabulation, and presentation of race and ethnicity data within the Federal Statistical System.[5] When assessing inclusion data, it is important to keep in mind that the number of individuals in sex and racial and ethnic minority groups included in a particular study depends upon the scientific questions addressed in the study and the prevalence or incidence of the disease, disorder, or condition under investigation among these groups.

As context for the trends in the inclusion data for FY22 to FY24 described in this report, there was a significant overall increase in participant enrollment in all NIMH-funded and -conducted extramural and intramural clinical research over this three-year period. This trend also included an increase in participant enrollment in NIH-defined Phase III clinical trials across the fiscal years, aligning with gradual increases in percentages of female enrollment in these trials. The rise in participant enrollment over this period impacted the overall percentages discussed below. While there were increases in the number of participants enrolled within various racial and ethnic groups, the percentages for some of these groups decreased during this period. As detailed below, the noted trends can largely be attributed to an extramural study utilizing two digital mental health platforms to optimize engagement with digital mental health treatment which enrolled ~2,676,000 participants across FY23 and FY24.

Other notable trends focused on the enrollment by sex and racial and ethnic minority groups. For example, decreased percentages in male enrollment and increases in percentages of unknown/not reported sex between FY22 to FY23. Also, percentages for racial and ethnic minority groups decreased from FY22 to FY23. More specifically, there was a decrease in the percentage of enrollment for African American or Black participants for all clinical research, with

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[5] For more information about revised racial and ethnic categories required by OMB revisions to Statistical Policy Directive 15, see https://nces.ed.gov/programs/handbook/data/pdf/Appendix_A.pdf. OMB recently announced on March 28, 2024, an update of Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity. For more information, please see https://www.federalregister.gov/documents/2024/03/29/2024-06469/revisions-to-ombs-statistical-policy-directive-no-15-standards-for-maintaining-collecting-and.

a decline across fiscal years. For NIH-defined Phase III clinical trials, there was a gradual decline in enrollment percentages for African American or Black participants and increases in percentages of unknown/not reported race across the fiscal years.

Table 1 displays the total inclusion enrollment records[6] (IERs) for NIH-defined extramural and intramural clinical research for FY22, FY23, and FY24. The total number of IERs was relatively consistent across the fiscal years with a slight increase each year. On average, 56 percent of the IERs had enrollment. Within the IERs with enrollment, on average, 88 percent of those IERs were from domestic sites across the fiscal years. IERs without enrollment slightly increased across the fiscal years. IERs without enrollment include studies that were not yet recruiting participants during the given fiscal year.

Table 2 displays the sex by racial and ethnic distribution of participants in NIH-defined extramural and intramural clinical research in FY22, FY23, and FY24. From FY22 to FY24, NIH-defined extramural and intramural studies saw a significant increase in participant enrollment. The large increase in enrollment from FY22 to both FY23 and FY24 can be accounted for, in large part, by an extramural study utilizing two digital mental health platforms to optimize engagement with digital mental health treatment which enrolled ~2,676,000 participants. Enrollment percentages for females remained relatively consistent across the fiscal years. However, there was a stark decrease in the percentage of males enrolled in FY23 and FY24. Although the overall number of male participants increased from FY22 to FY24, due to the overall participant enrollment increase, the percentage of male participants decreased. Also, there was an increase in percentages of unknown/not reported sex from FY22 to both FY23 and FY24. The aforementioned digital study also significantly contributed to the increase in number of participants with unknown/not reported sex in FY23 (N= ~543,290) and FY24 (N= ~699,300).

From FY22 to FY23, total racial and ethnic minority enrollment percentages decreased, with FY24 remaining relatively consistent with FY23. The largest racial minority group was Black or African American followed by Asian, and more than one race. Although the total number of Black or African American participants increased across the fiscal years, percentages for this group declined as a proportion of total enrolled participants. Similarly, the total number of Asian participants increased substantially across the fiscal years, but the percentages decreased from FY22 to FY23 and slightly increased in FY24, given the increase in total enrolled participants across the fiscal years. The decreases in racial minority percentages may, in part, be explained by the significant increase in percentages for participants of unknown/not reported race from FY22 to both FY23 and FY24. The increase in percentages for unknown/not reported race are accounted for by the previously mentioned extramural study utilizing digital mental health platforms. The percentage of participants who reported Hispanic ethnicity remained relatively consistent across the fiscal years. Percentages for unknown/not reported ethnicity increased from FY22 to both FY23 and FY24 and are accounted for by both the previously mentioned digital study and an additional extramural study piloting use of suicide risk prediction algorithms in primary care (total enrollment N = ~687,900).

Table 3 displays the sex by racial and ethnic distribution of participants in NIH-defined Phase III clinical trials (extramural and intramural) for FY22, FY23, and FY24. Participant enrollment in NIH-defined Phase III clinical trials notably increased across the fiscal years as the number of NIMH-supported Phase III clinical trials increased from 70, 72 and 93 in FY22, FY23, and FY24, respectively. In addition to the impact of the growing number of Phase III trials during this

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[6] The inclusion enrollment report is used to report both planned and cumulative (or actual) enrollment, and the sex, race, ethnicity, and age of enrollment of the study participants.

period, the large increase from FY22 to both FY23 and FY24 can be accounted for by an extramural study identifying effective approaches and implementation strategies in a sample of women at high risk for HIV. Given that this study exclusively enrolled women (N= 13,320 for FY23; N= 27,269 for FY24), the substantial increase in female percentages across fiscal years can largely be attributed to this study. Conversely, the percentages for males decreased across the fiscal years. Although there were slight increases in the total number of male participants from FY22 to FY23 (and holding in FY24), due to the overall participant enrollment increase, the percentage of male participants decreased. From FY22 to FY24, Black or African American participants accounted for an average of 33 percent of enrollment into NIH-defined Phase III clinical trials, the largest racial minority group. Percentages for more than one race enrollment increased from FY22 to FY23 and held steady in FY24. This can be attributed to an extramural study evaluating an internet-based cognitive behavioral therapy in college students in Colombia and Mexico. Conversely, there was a gradual decrease in percentages for Asian participants across the fiscal years. There was a substantial increase in the percentages for unknown/not reported race across the fiscal years. This significant increase may, in part, be accounted for by the aforementioned extramural study utilizing digital mental health platforms. Percentages for individuals who reported Hispanic ethnicity held steady from FY22 to FY23 and slightly decreased from FY23 to FY24. Notably, there was a gradual decrease in percentages for unknown/not reported ethnicity. This decrease can be attributed, in part, to the overall increase in the total number of participants enrolled in NIH-defined Phase III clinical trials across the fiscal years.

As noted above, NIH-defined Phase III clinical trials should be designed in a manner sufficient to allow for valid analyses of whether the variables being studied affect women or members of racial and ethnic minority groups differently than other trial participants. Recipients conducting applicable[7] NIH-defined Phase III clinical trials must ensure results of valid analyses[8] by sex, race, and/or ethnicity are submitted to Clinicaltrials.gov. NIH-defined Phase III clinical trials that required valid analyses by sex for FY22, FY23 and FY24 were 99 percent, 76 percent, and 83 percent, respectively; and valid analyses by race and/or ethnicity were 99 percent, 64 percent, and 67 percent, respectively. (Of note, a NIH-defined Phase III clinical trial would not complete valid analyses if the trial is only enrolling one sex, or one race and/or ethnicity.)

An alternative way to review inclusion data is by Research, Condition, and Disease Categorization (RCDC). The total number of participants enrolled in projects associated with listed research, condition, or disease category can be displayed by sex, race, and ethnicity. RCDC category reports for inclusion data for NIMH are available upon request. These data are now published annually, and the reports can be found at https://report.nih.gov/RISR/.

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[7] Applicable clinical trial is the term used in Title VIII of the Food and Drug Administration Amendments Act (FDAAA) of 2007 (P.L. 110-85) to designate the scope of clinical trials that may be subject to the registration and results reporting requirements in FDAAA. Clinical trials that are subject to the regulation are, in general, clinical trials of drug, biological, and device products regulated by the Food and Drug Administration (FDA). A pediatric post-market surveillance study of a device product required by the FDA is also subject to the regulation.

[8] Valid analyses mean an unbiased assessment. Such an assessment will, on average, yield the correct estimate of the difference in outcomes between two groups of subjects. Valid analysis can and should be conducted for both small and large studies. A valid analysis does not need to have a high statistical power for detecting a stated effect. The principal requirements for ensuring a valid analysis of the question of interest are: allocation of study participants of both sexes (males and females) and from different racial and/or ethnic groups to the intervention and control groups by an unbiased process such as randomization; unbiased evaluation of the outcome(s) of study participants; and use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects by sex, race, and/or ethnicity.

Tables

1. Table 1. FY22-24 Total Inclusion Enrollment Records (IERs) for NIH-Defined Extramural and Intramural Clinical Research
2. Table 2. FY22-24 Enrollment for All NIH-Defined Clinical Research, Sex by Race and Ethnicity
3. Table 3. FY22-24 Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex by Race and Ethnicity

Table 1. FY22-24 Total Inclusion Enrollment 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	2,442	1,106	1,336	1,184	152	130	73	1,133
2023	2,582	1,131	1,451	1,262	189	157	52	1,242
2024	2,595	1,147	1,448	1,267	181	138	55	1,255

** IERs excluding male only and female only include unknown sex, and combination of unknown and any sex.*

*Table 2. FY22-24 Enrollment for All NIH-Defined Clinical Research, Sex by Race and Ethnicity****

****Tables 2 and 3 below are both one continuous table that includes both the first and second set of rows below to include all racial and ethnic minority categories.***

Fiscal Year	Sex	Total Enrollment	% Total	Minority	% Minority	AI/AN	% AI/AN	Asian	% Asian	AA	% AA	PI	% PI	White	% White
2022	Female	208,541	53.6	101,721	48.8	2,190	1.1	20,548	9.9	52,235	25.0	472	0.2	96,984	46.5
2022	Male	157,427	40.4	76,760	48.8	1,458	0.9	19,550	12.4	34,739	22.1	333	0.2	72,346	46.0
2022	Unknown	23,361	6.0	6,463	27.7	40	0.2	5,495	23.5	438	1.9	58	0.2	1,377	5.9
2023	Female	1,110,451	49.6	438,596	39.5	13,692	1.2	93,785	8.4	149,637	13.5	3,536	0.3	502,080	45.2
2023	Male	562,761	25.1	224,985	40.0	6,902	1.2	50,749	9.0	73,209	13.0	1,793	0.3	276,611	49.2
2023	Unknown	564,630	25.2	34,938	6.2	1,947	0.3	6,653	1.2	7,966	1.4	367	0.1	38,154	6.8
2024	Female	2,140,772	52.6	835,989	39.1	25,332	1.2	266,085	12.4	228,173	10.7	9,621	0.4	945,267	44.2
2024	Male	1,210,477	29.7	429,347	35.5	13,819	1.1	134,371	11.1	108,381	9.0	6,062	0.5	588,623	48.6
2024	Unknown	718,286	17.7	48,956	6.8	2,698	0.4	11,124	1.5	10,429	1.5	539	0.1	57,441	8.0

Fiscal Year	Sex	MTOR	% MTOR	U/NR	% U/NR	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	U/NR	% U/NR
2022	Female	11,105	5.3	25,007	12.0	163,089	78.2	21,642	10.4	23,810	11.4
2022	Male	7,978	5.1	21,023	13.4	118,959	75.6	18,089	11.5	20,379	12.9
2022	Unknown	257	1.1	15,696	67.2	9,076	38.9	278	1.2	14,007	60.0
2023	Female	57,973	5.2	289,748	26.1	672,267	60.5	134,520	12.1	303,664	27.3
2023	Male	28,780	5.1	124,717	22.2	355,212	63.1	74,131	13.2	133,418	23.7
2023	Unknown	6,543	1.2	503,000	89.1	49,353	8.7	11,801	2.1	503,476	89.2
2024	Female	115,597	5.4	550,697	25.7	1,145,260	53.5	249,026	11.6	746,486	34.9
2024	Male	61,451	5.1	297,770	24.6	659,217	54.5	141,001	11.6	410,259	33.9
2024	Unknown	9,107	1.3	626,948	87.3	69,371	9.7	15,453	2.2	633,462	88.2

The data presented in this report show only IERs labeled as prospective data. Inclusion data records labeled as existing data are excluded. [Abbreviations: American Indian/Alaska Native = AI/AN; Black/African American = AA; Native Hawaiian/Pacific Islander = PI; More Than One Race= MTOR; Unknown/Not Reported = U/NR]

Table 3. FY22-24 Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex by Race and Ethnicity

Fiscal Year	Sex	Total Enrollment	% Total	Minority	% Minority	AI/ AN	% AI/AN	Asian	% Asian	AA	% AA	PI	% PI	White	% White
2022	Female	11,807	55.6	8,730	73.9	67	0.6	792	6.7	5,426	46.0	15	0.1	4,137	35.0
2022	Male	8,630	40.7	6,487	75.2	72	0.8	690	8.0	4,011	46.5	17	0.2	3,090	35.8
2022	Unknown	792	3.7	765	96.6	0	0.0	750	94.7	3	0.4	0	0.0	27	3.4
2023	Female	27,032	73.0	13,080	48.4	27	0.1	2,108	7.8	6,282	23.2	6	0.0	1,385	5.1
2023	Male	9,995	27.0	9,764	97.7	17	0.2	1,436	14.4	6,094	61.0	2	0.0	1,154	11.5
2023	Unknown	20	0.1	16	80.0	0	0.0	0	0.0	16	80.0	0	0.0	4	20.0
2024	Female	43,505	81.2	14,345	33.0	82	0.2	1,202	2.8	6,760	15.5	20	0.0	2,676	6.2
2024	Male	9,982	18.6	9,269	92.9	27	0.3	1,815	18.2	4,871	48.8	3	0.0	1,036	10.4
2024	Unknown	75	0.1	46	61.3	0	0.0	20	26.7	24	32.0	0	0.0	9	12.0

Fiscal Year	Sex	MTOR	% MTOR	U/NR	% U/NR	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	U/NR	% U/NR
2022	Female	983	8.3	387	3.3	7,520	63.7	2,297	19.5	1,990	16.9
2022	Male	421	4.9	329	3.8	5,162	59.8	1,610	18.7	1,858	21.5
2022	Unknown	2	0.3	10	1.3	774	97.7	12	1.5	6	0.8
2023	Female	3,493	12.9	13,731	50.8	20,555	76.0	4,776	17.7	1,701	6.3
2023	Male	1,236	12.4	56	0.6	6,126	61.3	2,226	22.3	1,643	16.4
2023	Unknown	0	0.0	0	0.0	20	100.0	0	0.0	0	0.0
2024	Female	4,804	11.0	27,961	64.3	36,871	84.8	6,296	14.5	338	0.8
2024	Male	1,965	19.7	265	2.7	7,380	73.9	2,502	25.1	100	1.0
2024	Unknown	1	1.3	21	28.0	57	76.0	2	2.7	16	21.3

The data presented in this report show only IERs labeled as prospective data. Inclusion data records labeled as existing data are excluded. [Abbreviations: American Indian/Alaska Native = AI/AN; Black/African American = AA; Native Hawaiian/Pacific Islander = PI; More Than One Race= MTOR; Unknown/Not Reported = U/NR]