National Institute of General Medical Sciences (NIGMS) Report for Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY2022 – FY2024

I. Background/Overview (Required)

The NIH Revitalization Act of 1993 (PL 103-43) included a provision that women and minorities must be included in all NIH-funded clinical research, unless a clear and compelling rationale and justification that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Included in this Act was a statement indicating that "The advisory council of each national research institute shall prepare biennial reports describing the manner in which the Institute has complied with this section." The 21st Century Cures Act amended the frequency of the Report of the NIH Director on the inclusion of women and minorities from biennial to triennial. This triennial report provides information on inclusion of participants in NIGMS clinical research from FY2022 – FY2024 and serves to document how NIGMS has continued to comply with this policy requirement.

NIGMS' research mission is aimed at understanding the principles, mechanisms, and processes that underlie living organisms, often using research organisms. NIGMS also supports the development of fundamental methods and new technologies to achieve its mission. NIGMS- supported research may utilize specific cells or organ systems if they serve as models for understanding general principles. Research with the overall goal to gain knowledge about a specific organ or organ system or the pathophysiology, treatment, or cure of a specific disease or condition will, in most cases, be supported by other Institutes or Centers. NIGMS does support research in specific clinical areas that affect multiple organ systems: anesthesiology and peri-operative pain; sepsis; clinical pharmacology that is common to multiple drugs and treatments; and trauma, burn injury, and wound healing. In addition, many NIGMS IDeA state capacity building programs contain clinical research components.

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 inclusion on the basis of sex, race, ethnicity, and age when considering clinical research applications. Reviewers evaluate applications for the appropriateness of the proposed plan for inclusion by sex, race, ethnicity, and age. 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. 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 NIGMS Advisory Council provides oversight to ensure that the initial review for scientific and technical merit conducted by the study section was expert, fair, objective and in compliance with policy. Council review complements—rather than duplicates—study section review. 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/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

NIGMS does not have an Intramural Division.

D. Describe IC 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. In 2021 NIGMS created the position of Clinical Research Strategy Coordinator (CRSC). The CRSC advises the Institute on clinical research priorities within the NIGMS scope and provides central oversight of NIH human subjects, inclusion, and clinical research policy, including clinical trials policy. The CRSC chairs the NIGMS Human Subjects and Clinical Trials Oversight Committee (HSCT Committee). The HSCT Committee is composed of a liaison from each Programmatic Division, liaisons from the Scientific Review and Grants Management branches, and a representative from the Division of Extramural Activities. The CRSC is the IC point of contact for the NIH Office of Extramural Research (OER) and attends relevant NIH-wide meetings and educational seminars. Information provided from OER is presented at the HSCT meetings, then the liaisons inform their Division or Branch. In 2024 NIGMS established the NIGMS Extramural Research Administration Training Program. A working group as part of this initiative is developing additional trainings for NIGMS staff related to human subjects and inclusion policies.

E. Additional NIGMS Actions to Ensure Compliance with the Inclusion Policy

The CRSC with support from the HSCT ensures compliance with NIH Human Subjects and Inclusion policies using the following strategies:

- Create and maintain Standard Operating Procedures and guidance for NIGMS staff.
- Disseminate information from OER to NIGMS staff.
- Identify applications that are non-compliant with the Human Subjects/Inclusion policy and resolve the compliance issue.
- Provide training for using the eRA HSS Module to NIGMS staff.

III. Analysis and Interpretation of Data

Tables of NIGMS inclusion enrollment data are provided in the appendix to this report.

As shown in Table 2-1, the total number of NIGMS Inclusion Enrollment Records (IERs) decreased from 875 in FY2022 to 790 in FY2024. In each year, the majority of IERs were records for studies that had started enrollment. Of the IERs with enrollment, the majority of IERs (98%-99%) were for enrollment at sites in the United States in each of the three fiscal years. The composition and number of enrollees in studies is driven by the scope of projects active during the reporting period.

Table 4-1-1-C shows minority enrollment decreased during the reporting period. Minority enrollment was 39.0% in FY2022, 38.3% in FY2023, and 30.5% in FY2024. The majority of participants accounting for minority enrollment across all years were those who reported Black/African American race. Multiple studies with a high enrollment of individuals reporting Black/African American race ended recruitment over the course of the reporting period.

Table 5-1-1-C displays the enrollment of sex by race and ethnicity. The table is separated into multiple portions for viewing. In FY2022 females accounted for 53.2% of total enrollment. Female enrollment decreased to 52.2% in FY2023 and 50.5% in FY2024. The percentages of American Indian/Alaska Native, Asian and Black/African American enrollment all decreased from FY2022 to 2024 for female and male participants. Native Hawaiian Pacific Islander enrollment increased from FY2022 to FY2024 for both female and male participants. The percentage of White enrollment increased from FY2022 to FY2024 for both female and male participants.

There was a decrease in Hispanic/Latino enrollment among female participants from FY2022 to FY2023 (12.5%, 10.3%, respectively). The percentage of Hispanic/Latino enrollment among female participants slightly increased from FY2023 to FY2024 (10.3%, 10.8%, respectively). There was also a decrease in Hispanic/Latino enrollment among male participants from FY2022 to FY2023 (11.7%, 8.4%, respectively). However, the was a significant increase in percentage of Hispanic/Latino enrollment among male participants from FY2023 to FY2024 (8.4%; 15.3%, respectively).

NIGMS did not support any NIH-Defined Phase III clinical trials during this reporting period

Inclusion enrollment data by Research Condition and Disease Categorization (RCDC) category will be available on the RCDC Inclusion Statistics Report website at a later date, but are available by request. These data will now be published annually at this website.

IV. Additional information

NIGMS is committed to promoting inclusion in human subjects research through targeted notices of funding opportunities. One example is the program announcement "Native American Research Centers for Health (NARCH) (S06 – Clinical Trial Optional)". The purpose of NARCH is to work toward reducing health disparities and promoting wellness in AI/AN populations by allowing the AI/AN communities to select, control and prioritize health-related research and research career enhancement opportunities.

Appendix

Table 2-1. Total Inclusion Data Records (IERs) for NIH-Defined Extramural Clinical Research Reported Between Fiscal Years 2022 and 2024

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	875	364	511	505	6	45	19	447
2023	802	384	418	411	7	28	14	376
2024	790	357	433	429	4	45	6	382

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

Table 4-1-1-C. Total Enrollment of NIH-Defined Extramural Clinical Research

Fiscal Year	Total Enrollment	No. Inclusion Data Records	Minority Enrollment	% Minority Enrollment	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian
2022	132,330	875	51,549	39.0	4,425	3.3	6,826	5.2
2023	120,618	802	46,151	38.3	2,337	1.9	6,031	5.0
2024	140,513	790	42,800	30.5	3,218	2.3	5,278	3.8

Fiscal Year	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	24,688	18.7	698	0.5	80,696	61.0	5,457	4.1	9,540	7.2
2023	26,918	22.3	764	0.6	74,596	61.8	2,918	2.4	7,054	5.8
2024	13,604	9.7	1,930	1.4	96,940	69.0	3,102	2.2	16,441	11.7

Note: 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 5-1-1-C. Enrollment for All NIH-Defined Clinical Research, Sex by Race and Ethnicity

Note: This table has been separated into multiple portions for viewing. Below each table is a summary of notable trends or changes.

Table 5-1-1-C: Enrollment for All NIH-Defined Clinical Research, Sex by Race and Ethnicity– **Section I**

Fiscal Year	Sex	Minority	% Minority	Total Enrollment	% Total
2022	Female	28,865	41.0	70,358	53.2
2022	Male	22,295	37.5	59,471	44.9
2022	Unknown	389	15.6	2,501	1.9
2023	Female	25,688	40.8	62,933	52.2
2023	Male	19,760	35.6	55,564	46.1
2023	Unknown	703	33.1	2,121	1.8
2024	Female	21,173	29.8	70,970	50.5
2024	Male	21,415	31.7	67,582	48.1
2024	Unknown	212	10.8	1,961	1.4

Table 5-1-1-C: Enrollment for All NIH-Defined Clinical Research, Sex by Race and Ethnicity– **Section II**

Fiscal Year	Sex	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian
2022	Female	3,268	4.6	3,732	5.3
2022	Male	1,116	1.9	3,062	5.1
2022	Unknown	41	1.6	32	1.3
2023	Female	1,427	2.3	3,549	5.6
2023	Male	844	1.5	2,431	4.4
2023	Unknown	66	3.1	51	2.4
2024	Female	1,951	2.7	2,969	4.2
2024	Male	1,223	1.8	2,289	3.4
2024	Unknown	44	2.2	20	1.0

Table 5-1-1-C: Enrollment for All NIH-Defined Clinical Research, Sex by Race and Ethnicity– **Section III**

Fiscal Year	Sex	Black African American	% Black African American	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander
2022	Female	13,071	18.6	369	0.5
2022	Male	11,542	19.4	323	0.5
2022	Unknown	75	3.0	6	0.2
2023	Female	14,470	23.0	379	0.6
2023	Male	12,190	21.9	366	0.7
2023	Unknown	258	12.2	19	0.9
2024	Female	7,279	10.3	982	1.4
2024	Male	6,288	9.3	944	1.4
2024	Unknown	37	1.9	4	0.2

Table 5-1-1-C: Enrollment for All NIH-Defined Clinical Research, Sex by Race and Ethnicity– **Section IV**

Fiscal Year	Sex	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
2022	Female	42,310	60.1	3,096	4.4	4,512	6.4
2022	Male	37,923	63.8	2,269	3.8	3,236	5.4
2022	Unknown	463	18.5	92	3.7	1,792	71.7
2023	Female	37,727	59.9	1,783	2.8	3,598	5.7
2023	Male	35,930	64.7	937	1.7	2,866	5.2
2023	Unknown	939	44.3	198	9.3	590	27.8
2024	Female	49,887	70.3	1,788	2.5	6,114	8.6
2024	Male	46,922	69.4	1,250	1.8	8,666	12.8
2024	Unknown	131	6.7	64	3.3	1,661	84.7

Table 5-1-1-C: Enrollment for All NIH-Defined Clinical Research, Sex by Race and Ethnicity– **Section V**

Fiscal Year	Sex	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2022	Female	57,336	81.5	8,783	12.5	4,239	6.0
2022	Male	48,011	80.7	6,962	11.7	4,498	7.6
2022	Unknown	541	21.6	176	7.0	1,784	71.3
2023	Female	54,197	86.1	6,477	10.3	2,259	3.6
2023	Male	49,004	88.2	4,692	8.4	1,868	3.4
2023	Unknown	454	21.4	159	7.5	1,508	71.1
2024	Female	60,570	85.3	7,639	10.8	2,761	3.9
2024	Male	55,281	81.8	10,335	15.3	1,966	2.9
2024	Unknown	224	11.4	56	2.9	1,681	85.7