NLM Report Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY2022 – FY2024

I. Background/Overview

A. Mission Statement

The National Library of Medicine (NLM) is the world's largest biomedical library and a leader in biomedical informatics research. NLM plays a pivotal role in translating biomedical research into practice. NLM's research and information services support scientific discovery, health care, and public health. Tracing its roots to the library of the U.S. Army Surgeon General in 1836, NLM's statutory mission is "…to assist with the advancement of medical and related sciences and to aid in the dissemination and exchange of scientific and other information important to the progress of medicine and to the public health."

NLM fulfills its mission by collecting, organizing, and providing access to the biomedical literature, as well as the growing volumes of molecular biology and clinical research data; engaging with users to discern and meet their information needs; advancing research and development in biomedical informatics and data science; and serving as the primary supporter of pre- and post-doctoral research training in biomedical informatics and data science in the United States.

B. Description of NLM Portfolio

The Extramural Programs (EP) Division of NLM offers grants for research projects, small business development, career transition and research training in biomedical informatics and data science. Biomedical informatics and data science research applies computer and information sciences to improve the access, storage, retrieval, management, dissemination, and use of biomedical information. NLM also offers special resource grant programs in history/philosophy of biomedicine and information resources for health disparity populations. Career transition awards assist recent PhDs and MDs who are establishing their research careers in informatics and data science.

Research, career transition and small business grants are available for a wide range of innovative basic and applied biomedical informatics and data science research projects. Fields of interest include: computational representation of biomedical knowledge; integration, organization and retrieval in very large databases, disparate forms of knowledge, and multiple datasets; enhancement of human intellectual capacities through virtual reality, artificial intelligence, and machine learning; support for health decisions; in silico science; natural language understanding; investigations of topics relevant to health information science, computational modeling, and management of information during disasters. NLM places priority on research that is novel, significant, and of high impact.

To assure an adequate national pool of informaticians and data scientists, NLM supports research training in biomedical informatics and data science at 26 educational institutions in the United States. These programs offer graduate education and postdoctoral research experiences in a wide range of areas including: health care informatics, bioinformatics and computational biology, clinical research translational informatics, and public health informatics.

II. Strategies for Ensuring Compliance

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 the inclusion of women, racial and ethnic minorities, and participants across the lifespan when considering clinical research applications. Reviewers evaluate applications for the appropriateness of the proposed plan for inclusion. For NIH-defined Phase III clinical trials, enrollment goals are further assessed for plans to conduct analyses of intervention effects among women, and racial and ethnic groups. Unacceptable inclusion plans must be reflected in the impact score of the application. 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 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 staff monitor actual enrollment progress in annual progress reports and provide consultation when necessary. For NIH-defined Phase III clinical trials, program officials 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. 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, 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.

D. Training

NLM extramural staff are required to attend inclusion and monitoring training. 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. Staff may access the archived training on the NIH staff intranet. Within NLM, training requirements are disseminated to all health scientist administrators (program officials and scientific review officers), grants management specialists, and other extramural program professional staff via email. Program officials and scientific review officers are required to accrue two policy and administrative credits per year and must attend all mandatory training courses.

III. Analysis and Interpretation of Data

A. Data Tables

The appended tables (see Appendices A and B) show detailed information on the total number of studies/protocols, referred to as inclusion enrollment records (IERs) in the NIH Human Subjects System and detailed enrollment data for FY 2022 - 2024.

B. Interpretation of Data

Table 2.1 (see Appendix A) reports IERs between FY 2022 and FY 2024. In FY 2022, NLM had 65 IERs for NIH-Defined Extramural and Intramural Clinical Research with 26 clinical studies in enrollment status, and 4 involving women only. In FY 2023, 71 IERs were reported, with 34 clinical studies in enrollment status, and 1 involving women only. In FY 2024, 65 IERs were reported, with 37 clinical studies in enrollment status, and 2 involving women only.

Table 5-1-1-C (see Appendix B) reports total enrollment for all NIH-defined Clinical Research by Sex, Race and Ethnicity.

In FY 2022, NLM-funded clinical research enrolled 8,704 participants, 62.3% female, 36.6% male, and 1.4% unknown. In FY 2022, NLM-funded studies enrolled 994 African-American/Black participants (11.4%), 243 Asian participants (2.8%), 82 American Indian/Alaska Native participants (0.9%), 14 Native Hawaiian/Pacific Islander participants (0.05%), 6,424 White participants (73.8%), 232 participants reporting more than one race (2.7%), and 714 unknown/not reported (8.2%). 947 participants (10.9%) identified as Hispanic/Latino.

In FY 2023, NLM-funded clinical research enrolled 6,912 participants, 62.4% female, 34.3% male, and 3.3% unknown. In FY 2023, NLM-funded studies enrolled 1,188 African-American/Black participants (17.2%), 421 Asian participants (6.1%), 143 American Indian/Alaska Native participants (2.1%), 36 Native Hawaiian/Pacific Islander participants (0.5%), 3,909 White participants (56.6%), 262 participants reporting more than one race (3.8%), and 953 unknown/not reported (13.8%). 1,083 participants (15.7%) identified as Hispanic/Latino.

In FY 2024, NLM-funded clinical research enrolled 18,069 participants, 23.4% female, 11.6% male, and 65% unknown. In FY 2024, NLM-funded studies enrolled 1,011 African-American/Black participants (5.6%), 624 Asian participants (3.5%), 122 American Indian/Alaska Native participants (0.7%), 14 Native Hawaiian/Pacific Islander participants (0.08%), 3,511 White participants (19.4%), 200 participants reporting more than one race (1.1%), and 12,587 unknown/not reported (70%). 848 participants (4.7%) identified as Hispanic/Latino.

NLM did not fund any NIH-defined Phase III clinical trials in FY 2022 – 2024.

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

The variations in NLM's FY 2024 enrollment data are due to a fourth-year grant that did enroll a larger number of participants (n=11,445), where the data was collected through their routine clinical practice and has been de-identified.

IV. Appendices

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

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

Appendix A.

Table 2-1. Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural 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	65	39	26	26	0	4	1	21
2023	71	37	34	33	1	1	1	32
2024	65	28	37	36	1	2	0	35

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

Appendix B.

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

Fiscal Year	Sex	Minority	% Minority	Total Enrollment	% Total	American Indian Alaska Native	% American Indian Alaska	Asian	% Asian	Black African American	% Black African American	Native Hawaiian Pacific Islande	% Native Hawaiian Pacific	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reporte	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reporte
2022	Female	1,588	29.3	5,424	62.3	62	1.1	176	3.2	711	13.1	13	0.2	3,743	69.0	153	2.8	566	10.4	4,388	80.9	535	9.9	501	9.2
2022	Male	750	23.8	3,156	36.3	16	0.5	59	1.9	269	8.5	0	0.0	2,639	83.6	73	2.3	100	3.2	2,755	87.3	392	12.4	9	0.3
2022	Unknown	44	35.5	124	1.4	5	4.0	8	6.5	14	11.3	1	0.8	42	33.9	6	4.8	48	38.7	65	52.4	20	16.1	39	31.5
2023	Female	1,748	40.5	4,316	62.4	97	2.2	254	5.9	821	19.0	22	0.5	2,463	57.1	150	3.5	509	11.8	3,604	83.5	506	11.7	206	4.8
2023	Male	1,116	47.1	2,371	34.3	40	1.7	159	6.7	345	14.6	13	0.5	1,368	57.7	106	4.5	340	14.3	1,641	69.2	551	23.2	179	7.5
2023	Unknown	59	26.2	225	3.3	6	2.7	8	3.6	22	9.8	1	0.4	78	34.7	6	2.7	104	46.2	120	53.3	26	11.6	79	35.1
2024	Female	1,709	40.4	4,235	23.4	86	2.0	506	11.9	709	16.7	10	0.2	2,229	52.6	118	2.8	577	13.6	3,558	84.0	339	8.0	338	8.0
2024	Male	927	44.3	2,092	11.6	31	1.5	114	5.4	286	13.7	4	0.2	1,216	58.1	76	3.6	365	17.4	1,348	64.4	492	23.5	252	12.0
2024	Unknown	44	0.4	11,742	65.0	5	0.0	4	0.0	16	0.1	0	0.0	66	0.6	6	0.1	11,645	99.2	102	0.9	17	0.1	11,623	99.0

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