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

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 16 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 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 analyses of intervention effects among sex/gender, 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/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. 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, 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.

D. Training

NLM extramural staff are required to attend inclusion and monitoring training. Institute program officials 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. 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 Appendix 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 2019 - 2021.

B. Interpretation of Data

Table 2.1 (see Appendix A) reports IERs between FY 2019 and FY 2021. In FY 2019, NLM had 55 IERs for NIH-Defined Extramural and Intramural Clinical Research with 18 clinical studies in enrollment status, and 2 involving women only. In FY 2020, 61 IERs were reported, with 24 clinical studies in enrollment status, and 3 involving women only. In FY 2021, 75 IERs were reported, with 25 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/ Gender, Race and Ethnicity. In FY 2019, NLM-funded clinical research enrolled 1,181 participants, 48.6% female and 45.7% male. In FY 2019, NLM-funded studies enrolled 317 African-American/Black participants (27%), 89 Asian participants (8%), 94 American Indian/Alaska Native participants (8%), 4 Native Hawaiian/Pacific Islander participants (0.3%), 508 White participants (43%), 27 participants reporting more than one race (2%), and 284 Hispanic/Latino participants (24%). In FY 2020, NLM clinical research enrolled 1,945 participants, 54% female and 45% male. Data for FY 2020 show that 741 African American/Black participants (38%), 156 Asian participants (8%), 46 American Indian/Alaska Native participants (2.4%), 27 Native Hawaiian/Pacific Islander participants (1.4%), 831 White participants (43%), 39 participants reporting more than one race (2%) and 643 Hispanic/Latino participants (33%) were included in NLM funded clinical studies. In FY 2021, 7,730 participants were enrolled into NLM funded clinical studies, 57.3% female and 41.5% male. Study enrollment in 2021 included 1,640 African American/ Black participants (21%), 571 Asian participants (7.4%), 45 American Indian/Alaska Native participants (0.6%), 24 Native Hawaiian/Pacific Islander participants (0.3%), 4,359 White participants (56%), 430 participants reporting more than one race (6%) and 2,099 Hispanic/Latino participants (27%).

NLM did not fund any NIH-defined Phase III clinical trials in FY 2019 – 2021. A 2019 study was marked as an NIH-defined Phase III clinical trial in error and was corrected in 2020.

Inclusion enrollment data by Research, Condition, and Disease Categorization (RCDC) is available at https://report.nih.gov/RISR/. For more information about RCDC, please visit the RCDC categorization process website.

IV. **Additional Information**

Policy changes related to the 21st Century Cures Act

The 21st Century Cures Act, enacted December 13, 2016, included several new requirements related to inclusion of participants in clinical research. As a result, 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. Additionally, 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 amended the frequency of the Report of the NIH Director on the inclusion of women and minorities from biennial to triennial. Section V 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 2019 and 2020.

V. Appendices

Appendix A: Table 2-1. Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Clinical Research Reported Between Fiscal Years 2019 and 2021

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

Appendix A.

Table 2-1. Total Inclusion Data/Enrollment 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	55	37	18	18	0	2	0	16
2020	61	37	24	24	0	3	0	21
2021	75	50	25	25	0	2	0	23

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

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

Fiscal Year	Sex Gender	Minority	% Minority	Total Enrollment	% Total	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	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	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2019	Female	348	60.6	574	48.6	37	6.4	52	9.1	148	25.8	4	0.7	272	47.4	13	2.3	48	8.4	439	76.5	129	22.5	6	1.0
2019	Male	390	72.2	540	45.7	57	10.6	37	6.9	167	30.9	0	0.0	234	43.3	14	2.6	31	5.7	387	71.7	153	28.3	0	0.0
2019	Unknown	3	4.5	67	5.7	0	0.0	0	0.0	2	3.0	0	0.0	2	3.0	0	0.0	63	94.0	63	94.0	2	3.0	2	3.0
2020	Female	794	76.3	1,040	53.5	25	2.4	91	8.8	390	37.5	17	1.6	434	41.7	24	2.3	59	5.7	628	60.4	310	29.8	102	9.8
2020	Male	702	81.1	866	44.5	21	2.4	65	7.5	341	39.4	10	1.2	388	44.8	13	1.5	28	3.2	466	53.8	319	36.8	81	9.4
2020	Unknown	20	51.3	39	2.0	0	0.0	0	0.0	10	25.6	0	0.0	9	23.1	2	5.1	18	46.2	7	17.9	14	35.9	18	46.2
2021	Female	2,539	57.4	4,426	57.3	22	0.5	367	8.3	935	21.1	19	0.4	2,445	55.2	224	5.1	414	9.4	2,997	67.7	1,236	27.9	193	4.4
2021	Male	1,799	56.1	3,209	41.5	21	0.7	203	6.3	695	21.7	5	0.2	1,893	59.0	199	6.2	193	6.0	2,221	69.2	840	26.2	148	4.6
2021	Unknown	32	33.7	95	1.2	2	2.1	1	1.1	10	10.5	0	0.0	21	22.1	7	7.4	54	56.8	26	27.4	23	24.2	46	48.4

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