DEPARTMENT OF HEALTH AND HUMAN SERVICES
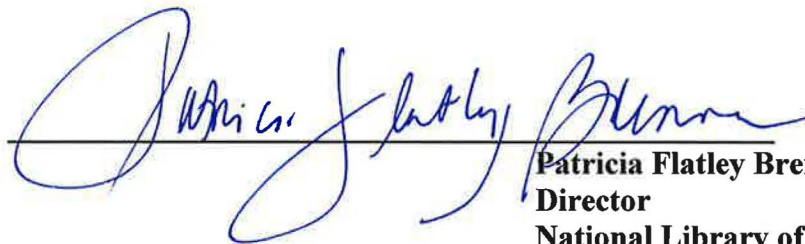
National Institutes of Health

Office of the Director

2019 TRIENNIAL ADVISORY COUNCIL REPORTS CERTIFYING COMPLIANCE WITH THE NIH POLICY ON INCLUSION GUIDELINES

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NLM Report on Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY2016 – FY2018

I. Background/Overview

A. Mission Statement

The National Library of Medicine (NLM) is a global leader and trusted agent in the collection, organization and dissemination of biomedical information. Tracing its roots to the library of the U.S. Army Surgeon General in 1836, its 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 this 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 support 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. The home institutions of these programs make certain that research undertaken by NLM-funded trainees meets inclusion requirements.

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 Program Officials and Scientific Review Officers attended the May 11, 2018 training, "Ensuring Inclusion in NIH Clinical Research: Policies and Procedures for Grants and Contracts". Staff may access the archived training on the NIH staff intranet.

III. **Analysis and Interpretation of Data**
A. The following inclusion tables provided by OER are included in the appendix.

NLM aggregate inclusion data tables:

o Table 2-1. Total Inclusion Enrollment Reports (IERs) for NIH-Defined Extramural and Intramural Clinical Research

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

B. The appended tables show enrollment data for fiscal years (FY) 2016 through 2018.

C. As shown in Table 2-1, NLM supported clinical research studies with a total of 14 IERs in FY 2016, a total of 15 IERs in FY 2017 and a total of 25 IERs in FY 2018. As shown in Table 5-1-1-C, the total enrollment in NLM funded clinical research for FY 2016 was 4,041. Total enrollment in NLM funded clinical research for FY 2017 was 4,571. Total enrollment in FY 2018 was 5,430.

D. NLM does not support NIH-defined Phase III clinical trials.

E. FY 2018 inclusion 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 process website.

IV. Additional information

A. 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. Thus, this first triennial report provides information on inclusion of participants in NIH clinical research from FY

2016 – 2018. 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 2015 and 2016.

V.   Appendix

Table 2-1. Total Inclusion Enrollment Reports (IERs) for NIH-Defined Extramural and Intramural Clinical Research Reported Between FY2016 and

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*
2016	14	2	12	12	0	0	0	12
2017	15	2	13	13	0	0	0	13
2018	25	7	18	18	0	0	1	17

*Inclusion Enrollment Reports (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

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
2016	Female	735	36.8	3,995	49.4	31	1.6	176	8.8	240	12.0	23	1.2	1,479	74.1	22	1.1	24	1.2	1,669	84.7	306	15.5	0	0.0
2016	Male	745	36.4	2,046	50.6	38	1.9	194	9.5	234	11.4	22	1.1	1,526	74.6	16	0.8	16	0.8	1,738	84.9	308	15.1	0	0.0
2016	Unknown	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
2017	Female	780	35.7	2,187	47.8	36	1.6	147	6.7	251	11.5	28	1.3	1,699	77.7	23	1.1	3	0.1	1,809	82.7	378	17.3	0	0.0
2017	Male	806	34.7	2,320	50.8	44	1.9	191	8.2	216	9.3	25	1.1	1,820	78.4	18	0.8	6	0.3	1,938	83.5	382	16.5	0	0.0
2017	Unknown	0	0.0	64	1.4	0	0.0	0	0.0	0	0.0	0	0.0	3	4.7	0	0.0	61	95.3	3	4.7	0	0.0	61	95.3
2018	Female	754	34.1	2,212	40.7	48	2.2	113	5.1	250	11.3	23	1.0	1,731	78.3	23	1.0	24	1.1	1,830	82.7	377	17.0	5	0.2
2018	Male	1,547	48.1	3,217	59.2	57	1.8	175	5.4	624	19.4	21	0.7	2,028	63.0	294	9.1	18	0.6	2,532	78.7	680	21.1	5	0.2
2018	Unknown	1	100.0	1	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	100.0	0	0.0	1	100.0	0	0.0

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