DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director

National Institute on Minority Health and Health Disparities

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

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Background/Overview

The mission of the National Institute on Minority Health and Health Disparities (NIMHD) is to lead scientific research to improve minority health and to reduce health disparities. To accomplish its mission, NIMHD:

- Conducts and supports research on minority health and health disparities;
- Plans, coordinates, reviews, and evaluates NIH minority health and health disparities research and activities;
- Promotes and supports the training of a diverse research workforce;
- Translates and disseminates research information, and
- Fosters innovative collaborations and partnerships.

NIMHD supports research through its extramural research program and conducts intramural research. Currently, NIMHD does not support or conduct phase III clinical trials. NIMHD works to transform the field of minority health and health disparities by building on evidence-based advances in promising areas such as social epigenomics, social determinants of health, and health information technology that could be beneficial in improving the health of racial and ethnic minority populations, people living in rural communities, individuals of less privileged socioeconomic status, and sexual and gender minorities. All disparity populations often experience poorer health and greater disparities in health outcomes.

Minority health refers to the distinctive health characteristics and attributes of a minority racial and/or ethnic group who is socially disadvantaged due in part to being subject to potential discriminatory acts. Minority health research is the scientific investigation of distinctive health characteristics and attributes of minority racial and/or ethnic groups to help understand their health outcomes. Minority populations are usually underrepresented in biomedical research. Racial and ethnic populations included in this definition are defined by the Office of Management and Budget Directive 15.

A health disparity is defined as a health difference that adversely affects disadvantaged populations, based on one or more of the specified health outcomes:

- Higher incidence and/or prevalence of disease and/or disorders;
- Premature and/or excessive mortality in diseases where populations differ;
- Greater burden of disease demonstrated with metrics such as disability-adjusted life years
- Poorer daily functioning or reduced quality of life using observed or self-reported measures, or
- Poor behavioral and/or clinical outcomes directly linked to incidence of disease or disorders

Health disparities research is a multi-disciplinary field of study devoted to gaining greater scientific knowledge about the influence of health determinants, understanding the role of different pathways leading to disparities, and determining how findings translate into interventions to reduce health disparities. Health disparity populations include OMB defined racial and ethnic minorities, rural residents, persons of less privileged socioeconomic status (SES), and sexual/gender minorities (SGM).

Strategies for Ensuring Compliance

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 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. Applications with unacceptable inclusion plans have their funding held; an award is not issued until an acceptable resolution to the inclusion plan is received.

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 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.

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.

NIMHD Training Approaches

NIMHD Program Officials/Program Directors and Scientific Review Officers, have the option of attending in-person training on *Ensuring Inclusion in NIH Clinical Research: Policies and Procedures for Grants and Contracts*, or accessing the archived training on the NIH staff intranet.

The enrollment of more than 60 percent racial and ethnic minorities in studies supported by NIMHD, underscores the commitment of NIMHD's staff in ensuring that NIMHD-funded research is aligned with its mission to improve minority health and reduce health disparities, and adheres to the NIH inclusion policy.

Analysis and Interpretation of Data

Tables 1 and 2 (see Appendix) include NIMHD aggregate inclusion data. A summary of the data is included below. NIMHD inclusion enrollment data by Research Condition and Disease Categorization (RCDC) category for FY 2018 are available through this link: https://report.nih.gov/RISR/.

As evidenced by the data, NIMHD enrolled:

- More than 50% women across all three years for all racial and ethnic minority groups, except Asians for 2016 and 2018. For these groups, women had similar rates of enrollment as men.
- More than 60% racial and ethnic minorities across all three years.

These enrollments meet or exceed the distribution of women and all minorities combined in the U.S. population. Whites, Asians and Hispanics/Latinos were proportionately underrepresented in NIMHD-funded studies.

Clinical studies fluctuate over time in the continuum of conducting the best science and these data are cross-sectional snapshots of participants enrolled in a given year. Although the total numbers enrolled decreased from 2016 to 2017, an increase was observed in 2018, and the percent of racial and ethnic minorities and women remained stable. These data are consistent with NIMHD's commitment to the inclusion of minorities and women in clinical research.

Studies enrolling men rightly included only men as their purpose precluded the inclusion of women. These studies focused on prostate cancer and on HIV among men having sex with men.

Additional Information

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.

Table 1. Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Clinical Research Reported Between FY2016 and FY2018

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	364	27	337	336	1	67	36	234
2017	378	55	323	322	1	62	41	220
2018	551	107	444	443	1	88	47	309

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

Table 2. Enrollment for NIH-Defined Extramural Clinical Research, Sex/Gender by Race and Ethnicity

			2016				**2017**				**2018**		
Sex/Gender		**Female**	**Male**	**Unknown**	**Total**	**Female**	**Male**	**Unknown**	**Total**	**Female**	**Male**	**Unknown**	**Total**
	Minority	97,457	90,919	1,219	189,595	65,424	62,730	3,393	131,547	85,113	72,493	568	158,174
	%	***66.7***	***62.8***	***57.1***	***64.7***	***67.9***	***65.7***	***85.2***	***67.1***	***69.5***	***63.7***	***38.1***	***66.6***
	American Indian/Alaska Native	5,911	5,469	165	11,545	379	341	3	723	1,238	897	9	2,144
	%	***4.0***	***3.8***	***7.7***	***3.9***	***0.4***	***0.4***	***0.1***	***0.4***	***1.0***	***0.8***	***0.6***	***0.9***
	Asian	3,710	4,030	144	7,884	2,600	2,556	130	5,286	2,404	2,552	134	5,090
	%	***2.5***	***2.8***	***6.7***	***2.7***	***2.7***	***2.7***	***3.3***	***2.7***	***2.0***	***2.2***	***9.0***	***2.1***
	Black/African American	60,931	58,345	273	119,549	46,551	45,974	119	92,644	55,572	53,916	96	109,584
	%	***41.7***	***40.3***	***12.8***	***40.8***	***48.3***	***48.1***	***3.0***	***47.3***	***45.4***	***47.4***	***6.4***	***46.1***
	Native Hawaiian/Pacific Islander	1,010	787	21	1,818	924	695	1	1,620	1,106	863	1	1,970
Race	**%**	***0.7***	***0.5***	***1.0***	***0.6***	***1.0***	***0.7***	***0.0***	***0.8***	***0.9***	***0.8***	***0.1***	***0.8***
	White	49,648	53,452	707	103,807	34,897	38,348	3,490	76,735	46,021	45,765	629	92,415
	%	***34.0***	***36.9***	***33.1***	***35.4***	***36.2***	***40.1***	***87.6***	***39.2***	***37.6***	***40.2***	***42.2***	***38.9***
	More Than One Race	9,475	8,264	257	17,996	5,627	3,235	40	8,902	8,577	4,277	35	12,889
	%	***6.5***	***5.7***	***12.0***	***6.1***	***5.8***	***3.4***	***1.0***	***4.5***	***7.0***	***3.8***	***2.3***	***5.4***
	Unknown/Not Reported	15,518	14,361	568	30,447	5,432	4,389	199	10,020	7,508	5,468	587	13,563
	%	***10.6***	***9.9***	***26.6***	***10.4***	***5.6***	***4.6***	***5.0***	***5.1***	***6.1***	***4.8***	***39.4***	***5.7***
	Not Hispanic	116,398	120,215	895	237,508	80,211	81,130	695	162,036	95,199	97,551	794	193,544
	%	***79.6***	***83.1***	***41.9***	***81.0***	***83.2***	***84.9***	***17.5***	***82.7***	***77.8***	***85.8***	***53.3***	***81.4***
	Hispanic/Latino	21,943	17,784	635	40,362	15,097	13,403	3,130	31,630	25,001	14,587	317	39,905
Ethnicity	**%**	***15.0***	***12.3***	***29.7***	***13.8***	***15.7***	***14.0***	***78.6***	***16.1***	***20.4***	***12.8***	***21.3***	***16.8***
	Unknown/Not Reported	7,862	6,709	605	15,176	1,102	1,005	157	2,264	2,226	1,600	380	4,206
	%	***5.4***	***4.6***	***28.3***	***5.2***	***1.1***	***1.1***	***3.9***	***1.2***	***1.8***	***1.4***	***25.5***	***1.8***
Total (US Sites)		**146,203**	**144,708**	**2,135**	**293,046**	**96,410**	**95,538**	**3,982**	**195,930**	**122,426**	**113,738**	**1,491**	**237,655**
		146,212	**144,708**	**2,135**	**293,055**	**97,239**	**95,538**	**3,982**	**196,759**	**123,615**	**113,738**	**1,491**	**238,844**

Notes:

*****Total Enrollment (US and non-US sites)

*Non-US sites included China, Namibia, Brazil, Barbados, and Trinidad & Tobago

*NIMHD does not have any phase 3 Clinical Trials

*NIMHD had no enrollment in its intramural research program. Numbers in the table refer to enrollment in the extramural research program.