

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**

A handwritten signature in black ink, reading "Paul Sieving M.D. Ph.D.", is written over a horizontal line.

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The National Eye Institute (NEI) Report Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY2016 – FY2018

Background/Overview

Mission Statement of the NEI: As part of the Federal Government's National Institutes of Health (NIH), the National Eye Institute (NEI) was established to protect and prolong the vision of the American people. The National Eye Institute's mission is to conduct and support research, training, health information dissemination, and other programs with respect to blinding eye diseases, visual disorders, and mechanisms of visual function. NEI research leads to sight-saving treatments, reduces visual impairment and blindness, and improves the quality of life for people of all ages. NEI-supported research has advanced our knowledge of how the visual system functions in health and disease.

Description of the NEI Portfolio: The NEI supports a significant numbers of clinical research projects on potentially blinding eye diseases and other visual disorders. Examples include diabetic retinopathy, amblyopia, age-related macular degeneration, glaucoma, retinopathy of prematurity, corneal stromal keratitis, uveitis, retinitis pigmentosa, Leber's congenital amaurosis and myopia (nearsightedness).

NEI Strategies for Ensuring Compliance

The Director, Division of Extramural Scientific Programs (DESP), NEI, is the official with responsibility for ensuring compliance. To educate the vision research community, inclusion policies are highlighted on the NEI extramural research website. The policy is also explicitly detailed in all NEI Funding Opportunity Announcements, Requests for Applications, and Requests for Proposals.

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 receive a bar to funding; an award is not issued until an acceptable resolution is received.

Program Monitoring and Grants Management Oversight: Prior to an award, 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 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.

NEI Training Approaches: NEI staff are required to participate in the NIH Training on Gender, Race and Ethnicity. The Director, DESP, routinely distributes policy updates to all staff. NEI staff members participate in several trans-NIH committees regularly involved with compliance and policy issues. All NEI-funded Phase III clinical trials are supported through the cooperative agreement mechanism. NEI Clinical Program Directors collaborate with the study team to ensure that all protocols are designed with appropriate inclusion goals before funding. Most Phase III trials are multicenter, which permits broader sampling of minority

subpopulations. NEI staff monitor enrollment in all Phase III trials routinely and document inclusion in the grant file. NEI staff work collaboratively with study biostatisticians to ensure that appropriate valid analyses of differences in intervention effect are performed.

Analysis and Interpretation of Data: The National Advisory Eye Council (NAEC) reviewed NIH policy documents and NEI-specific inclusion data for FY2016-18 at their January 11, 2019, meeting. Data for all clinical research, NIH-defined Phase III clinical trials, extramural and intramural research was reviewed. The appended tables show enrollment data for fiscal years (FY) 2016-2018. Table 2-1 includes Total Inclusion Data Records (IDRs) for NIH-Defined Extramural and Intramural Clinical Research. Approximately 95 percent of NEI studies include both females and males. The NEI has few female-only or male-only studies and most of these are studies that include samples derived from existing data sources. Table 5-1-1-C includes Enrollment for All NIH-Defined Clinical Research, by Sex/Gender, Race, and Ethnicity. The NAEC noted that the NEI data show good representation of women and minority populations in NEI clinical research studies. The data tables for FY 2016 and FY 2017 included one very large international study resulting in the NEI having a large percentage of minority representation. Without this study, the data appear more like the 2018 results. Commenting specifically on 2018 inclusion data, the NAEC noted that women represented approximately 62 percent of enrolled participants. This figure included one large study that collected samples from an existing data source. Without this study, the representation of women would be 55.6 percent. The NEI data shows good representation of racial inclusion. In 2018, approximately 30 percent of the NEI data were from minority participants; 18 percent of participants were African-American and 4 percent were Asian-American. The percentages of other racial groups included in the NEI data appropriately reflect the make-up of the U.S. population.

Table 5-2-2-C presents Enrollment for NIH-Defined Extramural and Intramural Phase III Trials by Sex/Gender, Race, and Ethnicity. In NEI-sponsored Phase III clinical trials, women and men study participants were well represented with a slight preponderance of women. Inclusion of minority groups in Phase III clinical trials was commensurate with United States population averages. Inclusion of Hispanic participants in Phase III clinical trials was commensurate with United States population averages as well. The NEI currently supports 38 Phase III clinical trials. All NEI-funded Phase III clinical trials are designed with enrollment targets for gender, race, and ethnicity which result in sufficient power for valid subgroup analyses as required by policy. Inclusion data broken out by Research, Condition, and Disease Categorization (RCDC) can be found at: <https://report.nih.gov/RISR/>.

The NEI supports a large portfolio of clinical research. The NAEC reviewed the inclusion data and concluded that the NEI has complied with the NIH Policy on Inclusion of Women & Minorities in Clinical Research. Overall, inclusion of minority groups in NEI clinical research was commensurate with United States population averages.

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 2-1. Total Inclusion Data Records (IDRs) for NIH-Defined Extramural and Intramural Clinical Research Reported Between FY2016 and FY2018

Fiscal Year	Total IDRs	IDRs Without Enrollment	IDRs With Enrollment	US Site IDRs	Non-US Site IDRs	Female Only IDRs	Male Only IDRs	IDRs Excluding Male-only and Female-only*
2016	266	26	240	224	16	1	3	236
2017	326	31	295	279	16	3	8	284
2018	335	18	317	303	14	5	12	300

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

Total Enrollment: All NIH-Defined Clinical Research

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	% by Race and Ethnicity														% Not Reported	% Not Reported	% Not Reported	% Not Reported		
						American Indian Alaska Native	American Indian Alaska Native	Asian % Asian	Black African American % Black African American	Black African American % Black African American	Native Hawaiian Pacific Islander % Native Hawaiian Pacific Islander	Native Hawaiian Pacific Islander % Native Hawaiian Pacific Islander	White % White	White % White	More Than One Race % More Than One Race	More Than One Race % More Than One Race	Unknown Not Reported % Unknown Not Reported	Unknown Not Reported % Unknown Not Reported							
2016	Female	162,952	72.2	225,628	56.7	207	0.1	122,633	54.4	35,966	15.9	93	0.0	59,423	26.3	637	0.3	6,669	3.0	217,054	96.2	3,864	1.7	4,710	2.1
2016	Male	132,341	79.6	166,311	41.8	191	0.1	95,198	57.2	32,924	19.8	62	0.0	31,816	19.1	565	0.3	5,555	3.3	158,691	95.4	3,801	2.3	3,819	2.3
2016	Unknown	1,675	29.5	5,680	1.4	1	0.0	16	0.3	1,640	28.9	2	0.0	534	9.4	7	0.1	3,480	61.3	992	17.5	10	0.2	4,678	82.4
2017	Female	184,731	73.5	251,275	58.3	211	0.1	151,140	60.1	28,594	11.4	106	0.0	63,801	25.4	748	0.3	6,675	2.7	242,331	96.4	4,524	1.8	4,420	1.8
2017	Male	140,216	78.9	177,752	41.2	172	0.1	110,004	61.9	25,432	14.3	72	0.0	35,825	20.2	684	0.4	5,563	3.1	169,861	95.6	4,357	2.5	3,534	2.0
2017	Unknown	204	10.0	2,030	0.5	0	0.0	26	1.3	114	5.6	2	0.1	777	38.3	9	0.4	1,102	54.3	1,417	69.8	66	3.3	547	26.9
2018	Female	27,924	28.6	97,647	61.5	210	0.2	5,871	6.0	16,786	17.2	127	0.1	65,302	66.9	887	0.9	8,464	8.7	84,729	86.8	4,570	4.7	8,348	8.5
2018	Male	20,246	33.6	60,233	37.9	188	0.3	4,510	7.5	10,642	17.7	107	0.2	36,765	61.0	789	1.3	7,232	12.0	49,107	81.5	4,446	7.4	6,680	11.1
2018	Unknown	123	12.5	982	0.6	1	0.1	18	1.8	25	2.5	0	0.0	62	6.3	21	2.1	855	87.1	159	16.2	60	6.1	763	77.7

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

US Site Enrollment: All NIH-Defined Clinical Research

Table 5-2-2-C. ALL Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity

Year	Sex Gender	Minority	% Minority	Total Enrollment		% American Indian Alaska Native American Indian Alaska Native Black African American % Black African American Hawaiian Pacific Islander % Hawaiian Pacific Islander More Than One Race % More Than One Race Unknown Reported % Unknown Reported												% Not Reported % Not Reported Hispanic Latino % Hispanic Latino Unknown Reported % Unknown Reported							
				t	% Total	Native	Native	Asian	% Asian	American African	American African	Islander	Islander	White	% White	Race	Race	Reported	Reported	Hispanic	Hispanic	Latino	Latino	Reported	Reported
2016	Female	148,779	97.8	152,139	55.0	30	0.0	119,220	78.4	28,625	18.8	25	0.0	3,919	2.6	90	0.1	230	0.1	151,214	99.4	851	0.1	74	0.1
2016	Male	120,851	97.1	124,457	45.0	26	0.0	92,092	74.0	27,860	22.4	19	0.0	4,164	3.3	99	0.1	197	0.1	123,566	99.3	819	0.1	74	0.1
2016	Unknown	1	12.5	8	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	12.5	7	87.1	1	12.5	0	0.0	7	87.1
2017	Female	164,719	97.8	168,354	56.7	34	0.0	145,459	86.4	18,267	10.9	25	0.0	4,227	2.5	112	0.1	230	0.1	167,376	99.4	902	0.1	74	0.1
2017	Male	124,753	97.0	128,608	43.3	31	0.0	105,401	82.0	18,387	14.3	20	0.0	4,445	3.5	110	0.1	214	0.1	127,659	99.3	872	0.1	74	0.1
2017	Unknown	15	78.9	19	0.0	0	0.0	0	0.0	15	78.9	0	0.0	0	0.0	0	0.0	4	21.1	15	78.9	0	0.0	4	21.1
2018	Female	3,249	43.2	7,514	52.7	41	0.5	148	2.0	1,956	26.0	25	0.3	4,930	65.6	134	1.8	280	3.1	6,395	85.1	1,037	13.1	84	1.1
2018	Male	2,451	36.4	6,734	47.3	35	0.5	179	2.7	1,147	17.0	22	0.3	4,957	73.6	126	1.9	268	4.1	5,629	83.6	1,017	15.1	84	1.1
2018	Unknown	0	0.0	2	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	2	100.0	0	0.0	0	0.0	2	100.0