

DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health Office of the Director

NATIONAL INSTITUTE ON AGING FY2016 - 2018 INCLUSION
REPORT
(Inclusion of Women and Minorities)

National Advisory Council on Aging Meeting
(January 2019)

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

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January, 2019

NIA Report of FY2016 - 2018 Inclusion Data

I. Background/Overview

NIA, one of the 27 Institutes and Centers of NIH, leads the federal government in conducting and supporting research on aging and the health and well-being of older people. The Institute seeks to understand the nature of aging and the aging process, and diseases and conditions associated with growing older, in order to extend the healthy, active years of life.

In 1974, Congress granted authority to form NIA to provide leadership in aging research, training, health information dissemination, and other programs relevant to aging and older people. Subsequent amendments to this legislation designated NIA as the primary Federal agency on Alzheimer's disease research.

NIA's mission is to support and conduct genetic, biological, clinical, behavioral, social, and economic research on aging; to foster the development of research and clinician scientists in aging; to provide research resources for research on aging; and to disseminate information about aging and advances in research to the public, health care professionals, and the scientific community, among a variety of audiences.

NIA pursues this mission by funding extramural research and training at universities and medical centers across the United States and around the world; maintaining an active communications and outreach program; and conducting a vibrant intramural research program at NIA laboratories in Baltimore and Bethesda, Maryland.

Strategic Directions.

Ageing Well in the 21st Century: Strategic Directions for Research on Aging, most recently updated in 2016, is NIA's "road map" for progress in aging research and outlines our goals and vision. It provides a point of reference for setting priorities and a framework for systematically analyzing the Institute's scientific portfolio and assessing progress.

NIA sponsors research on aging through extramural and intramural programs. The extramural program funds research and training at universities, hospitals, medical centers, and other public and private organizations nationwide. The intramural program conducts basic and clinical research in Baltimore, MD, and on the NIH campus in Bethesda, MD.

II. Strategies for Ensuring Compliance

The National Institute on Aging (NIA) as a component of the National Institutes of Health is mandated by the U.S. Congress under the NIH Revitalization Act of 1993, Public Law 103-43, Section 492B(2)(f), to report on the inclusion of women and minorities in clinical research studies. This act requires that each clinical research trial be designed and

carried out in a manner sufficient to provide for valid analysis of variables that may affect women or minority groups. As interventions or therapies may affect women and /or men or members of minority groups and their subpopulations differently, it is, therefore, recognized that scientific evidence can be very important in leading to a change in health policy or standard of care. The NIA, consequently, pursues scientific evidence for these purposes and complies with NIH guidelines and other requirements of this law. This report provides a comparison of FY2016 through FY2018, inclusion of both genders and all racial and ethnic minority groups in clinical studies at NIA.

A. Peer Review

The Scientific Review Branch (SRB) at the National Institute on Aging (NIA) is responsible for the initial peer review of specific research grant applications assigned to NIA. These include contract proposals, applications for Research Centers, Program Projects, scientific meetings, and training and career development, and applications responding to funding opportunity announcements (FOAs) published by NIA.

External peer reviewers selected from the grant community participate in the reviews, and an overall impact/priority score is given for each grant application. Scores range from 10 (best) to 90 (worst). We produce an official document (Summary Statement) for each reviewed application. Scores and Summary Statements are used by Program Division Staff and NIA Council in making final funding decisions.

Most investigator-initiated research projects (R01), exploratory/developmental research grants (R21), and small research projects (R03), submitted in response to parent announcements (PA, PAR, PAS) are reviewed at the Center for Scientific review, NIH.

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

B. 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 officials consider the guidance provided by reviewers and request modifications to inclusion plans needed prior to award. 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.

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 (ORWH).

D. NIA Training Approaches

NIA Program Officials/Program Directors and Scientific Review Officers attended the May 11, 2018 training, ensuring inclusion in NIH Clinical Research: Policies and Procedures for Grants and Contracts. Staff are able to access the archived training on the NIH intranet.

III. Analysis and Interpretation of Data

NIA's Aggregate Extramural Enrollment Data: Analysis and Interpretation: The enrollment data for all Extramural Research Protocols for FY2016 was 2,043,512, for FY2017 was 2,759,957 and for FY2018 was 2,318,091. These numbers are shown in Table 2. These inclusion enrollment numbers were reported on 657 Inclusion Data Records for FY2016, 867 Inclusion Data Records for FY2017 and 960 Inclusion Data Records for FY2018 (Table 2) showing an increasing trend of inclusion enrollment records. Phase III clinical trial Enrollment data (Table 3) as well as Inclusion data records (Table 2) increased significantly in FY2018 compared to FY2016 and FY2017.

Minority Enrollment: NIA had a consistent decrease in total Minority enrollees from FY2016 to FY2018 (Table 4-1). For detailed prospective enrollment by race, please see Table 5: Prospective enrollment numbers were within acceptable US population trends. However, on Phase III trials prospective minority enrollees showed an increasing trend from FY2016 to FY2018. Nevertheless, the detailed data on Phase III trials for All or US sites alone shows higher numbers for White US population than US population trends.

Note: Most of the NIA Inclusion Enrollees from FY2016-FY2018 were on epidemiological studies or surveys (see examples below).

	FY2016	FY2017	FY2018
5R01AG052527, ENHANCING THE COMPARABILITY OF SHARE WITH HRS AND ELSA	80,505	3,740	80,505
2R01AG041794, ESTIMATING RETURNS TO MEDICAL CARE	1,159,745	371,816	371,816
5R01AG030146, GENETIC EPIDEMIOLOGY OF COGNITIVE DECLINE IN AN AGING POPULATION SAMPLE	29,448	29,448	29,448

NIA HSS Enrollment Tables

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IV. 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.

Section 1: Metrics Based on Inclusion Data Records

Table 1-1. Total Inclusion Data Records 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	657	47	610	596	14	21	18	571
2017	867	93	774	761	13	32	33	709
2018	960	175	785	768	17	26	24	735

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

Total Inclusion Data Records: All NIH-Defined Phase III Trials

Table 1-2. Total Inclusion Data Records for NIH-Defined Extramural and Intramural Phase III Trials 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	7	0	7	6	1	0	0	7
2017	6	0	6	6	0	0	0	6
2018	21	9	12	12	0	0	0	12

*Inclusion Data Records excluding male-only and female-only include unknown sex/gender, and combination of unknown and any sex/gender(s). The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

Section 2: Metrics Based on Aggregate Enrollment: Sex/Gender

Table 2. Total Enrollment for All NIH-Defined Extramural Clinical Research Between FY2016 and FY2018

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown	Enrollment in Female-only	% Female-only	Enrollment in Male-only	% Male-only	Females, Excluding Female-only	% Females, Excluding Female-only	Males, Excluding Male-only	% Males, Excluding Male-only
2016	2,043,512	1,028,665	50.3	1,006,532	49.3	8,315	0.4	1,502	0.1	6,602	0.3	1,027,163	50.3	999,930	48.9
2017	2,759,957	1,030,874	37.4	1,725,254	62.5	3,829	0.1	2,030	0.1	720,094	26.1	1,028,844	37.27*	1005160.00	36.42*
2018	2,318,091	937,011	40.4	1,376,996	59.4	4,084	0.2	2,523	0.1	714,701	30.8	934,488	40.31*	662295.00	28.57*

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

*Percent total were significantly less than 100% for FY2017 and FY2018 due to substantial numbers enrolled in Male or Female only studies.

Section 3: Total Enrollment: All NIH-Defined Phase III Trials

Table 3. Total Enrollment for All NIH-Defined Phase III Trials Reporting Between FY2016 and FY2018

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown	Enrollment in Female-only	% Female-only	Enrollment in Male-only	% Male-only	Females, Excluding Female-only	% Females, Excluding Female-only	Males, Excluding Male-only	% Males, Excluding Male-only
2016	19,399	10,996	56.7	8,403	43.3	0	0.0	0	0.0	0	0.0	10,996	56.7	8,403	43.3
2017	13,251	7,545	56.9	5,706	43.1	0	0.0	0	0.0	0	0.0	7,545	56.9	5,706	43.1
2018	29,015	16,408	56.6	12,595	43.4	12	0.0	0	0.0	0	0.0	16,408	56.6	12,595	43.4

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

Section 4: US Site Minority Enrollment

Table 4-1. Total US Site Enrollment of NIH-Defined Clinical Research

Fiscal Year	Total Enrollees	Minority Enrollees	% Minority Enrollees
2016	1,984,918	677,186	34.1
2017	2,672,418	685,262	25.6
2018	2,130,259	342,020	16.1

Table 4-2. US Site Enrollment of NIH-Defined Phase III Trials

Fiscal Year	Total Enrollees	Minority Enrollees	% Minority Enrollees
2016	285	42	14.7
2017	13,251	2,581	19.5
2018	29,015	6,152	21.2

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

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

Year	Sex Gender	Minority	% Minority	Total Enrollment	% Total	%														Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
						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						
2016	Female	364,758	35.2	1,035,478	50.3	3,598	0.3	103,468	10.0	141,757	13.7	906	0.1	675,495	65.2	82,537	8.0	27,717	2.7	915,228	88.4	71,355	6.9	48,895	4.7
2016	Male	362,420	35.7	1,014,136	49.3	3,633	0.4	102,251	10.1	121,468	12.0	895	0.1	655,002	64.6	101,145	10.0	29,742	2.9	880,293	86.8	77,144	7.6	56,699	5.6
2016	Unknown	201	2.4	8,315	0.4	4	0.0	30	0.4	32	0.4	0	0.0	157	1.9	27	0.3	8,065	97.0	1,444	17.4	115	1.4	6,756	81.3
2017	Female	340,319	32.8	1,036,978	37.4	5,175	0.5	62,773	6.1	147,787	14.3	1,200	0.1	705,827	68.1	84,444	8.1	29,772	2.9	906,135	87.4	79,978	7.7	50,865	4.9
2017	Male	420,676	24.3	1,732,329	62.5	5,318	0.3	63,572	3.7	182,797	10.6	1,077	0.1	1,199,656	69.3	103,216	6.0	176,693	10.2	1,443,681	83.3	111,239	6.4	177,409	10.2
2017	Unknown	162	4.2	3,829	0.1	4	0.1	15	0.4	16	0.4	0	0.0	141	3.7	25	0.7	3,628	94.8	2,677	69.9	108	2.8	1,044	27.3
2018	Female	174,157	18.5	939,348	40.4	4,977	0.5	38,577	4.1	80,689	8.6	1,084	0.1	761,057	81.0	11,023	1.2	41,941	4.3	851,970	90.7	44,845	4.8	42,533	4.9
2018	Male	206,754	15.0	1,380,589	59.4	4,272	0.3	30,836	2.2	106,349	7.7	861	0.1	1,044,865	75.7	10,344	0.7	183,062	13.3	1,162,061	84.2	60,633	4.4	157,895	11.4
2018	Unknown	124	3.0	4,084	0.2	1	0.0	17	0.4	29	0.7	1	0.0	449	11.0	10	0.2	3,577	87.6	2,841	69.6	74	1.8	1,169	28.4

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

Section 5: All Enrollment for NIH-Defined Phase III Clinical Research

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

Year	Sex Gender	Minority	% Minority	Total		%														Not		% Not		Hispanic		% Hispanic		Unknown		% Unknown	
				Enrollment	% Total	American Indian Alaska Native	American Indian Alaska Native	Asian	% Asian	Black American	% Black 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	Hispanic	% Hispanic	Latino	% Latino	Not Reported	% Not Reported						
2016	Female	1,039	9.4	10,996	56.7	16	0.1	78	0.7	614	5.6	8	0.1	10,082	91.7	52	0.5	146	1.3	10,703	97.3	293	2.7	0	0.0						
2016	Male	653	7.8	8,403	43.3	14	0.2	88	1.0	313	3.7	4	0.0	7,845	93.4	37	0.4	102	1.2	8,192	97.5	206	2.5	5	0.1						
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	1,595	21.1	7,545	56.9	8	0.1	55	0.7	1,200	15.9	13	0.2	6,178	81.9	27	0.4	64	0.8	7,148	94.7	323	4.3	74	1.0						
2017	Male	986	17.3	5,706	43.1	9	0.2	44	0.8	784	13.7	9	0.2	4,809	84.3	11	0.2	40	0.7	5,510	96.6	150	2.6	46	0.8						
2017	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						
2018	Female	3,698	22.5	16,408	56.6	17	0.1	152	0.9	2,570	15.7	26	0.2	13,427	81.8	41	0.2	175	1.1	15,292	93.2	938	5.7	178	1.1						
2018	Male	2,452	19.5	12,595	43.4	13	0.1	111	0.9	1,784	14.2	18	0.1	10,530	83.6	33	0.3	106	0.8	11,937	94.8	533	4.2	125	1.0						
2018	Unknown	2	16.7	12	0.0	0	0.0	0	0.0	0	0.0	0	0.0	8	66.7	0	0.0	4	33.3	5	41.7	2	16.7	5	41.7						

Section 5: US Site Prospective Enrollment: All NIH-Defined Phase III Clinical Research

Table 5-3. US Site Enrollment for NIH-Defined Extramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity

Year	Sex Gender	Minority	% Minority	American	%	Asian	%	Black	%	Native	%	White	%	More Than	%	Unknown	%	Not Hispanic	%	Hispanic	%	Unknown	%
				Indian Alaska Native	American Indian Alaska Native		African American	African American	Hawaiian Pacific Islander	Hawaiian Pacific Islander	One Race		Than One Race	Not Reported	Not Reported	Hispanic	Hispanic		Latino	Latino	Not Reported	Not Reported	
2016	Female	32	14.8	2	0.9	2	0.9	15	6.9	0	0.0	187	86.6	8	3.7	2	0.9	210	97.2	6	2.8	0	0.0
2016	Male	10	14.5	0	0.0	3	4.3	3	4.3	0	0.0	57	82.6	0	0.0	6	8.7	61	88.4	4	5.8	4	5.8
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
2017	Female	1,595	21.1	8	0.1	55	0.7	1,200	15.9	13	0.2	6,178	81.9	27	0.4	64	0.8	7,148	94.7	323	4.3	74	1.0
2017	Male	986	17.3	9	0.2	44	0.8	784	13.7	9	0.2	4,809	84.3	11	0.2	40	0.7	5,510	96.6	150	2.6	46	0.8
2017	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
2018	Female	3,698	22.5	17	0.1	152	0.9	2,570	15.7	26	0.2	13,427	81.8	41	0.2	175	1.1	15,292	93.2	938	5.7	178	1.1
2018	Male	2,452	19.5	13	0.1	111	0.9	1,784	14.2	18	0.1	10,530	83.6	33	0.3	106	0.8	11,937	94.8	533	4.2	125	1.0
2018	Unknown	2	16.7	0	0.0	0	0.0	0	0.0	0	0.0	8	66.7	0	0.0	4	33.3	5	41.7	2	16.7	5	41.7

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