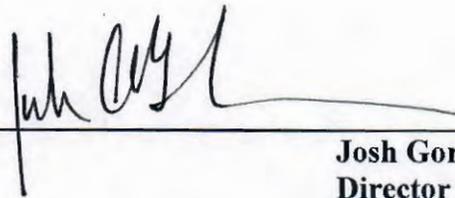


DEPARTMENT OF HEALTH AND HUMAN SERVICES

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, appearing to read "Josh Gordon", is written over a horizontal line.

**Josh Gordon, MD
Director
National Institute of Mental
Health**

January 31, 2019

2019 NIMH TRIENNIAL REPORT CERTIFYING ADHERENCE TO THE NIH POLICY ON THE INCLUSION OF WOMEN AND MINORITIES IN CLINICAL RESEARCH AS REPORTED FOR FY2016 – FY2018

Background/Overview

The National Institutes of Health (NIH) Revitalization Act of 1993 (PL 103-43) mandated that the advisory council of each Institute prepare a biennial report describing the manner in which the Institute has complied with requirements regarding the inclusion of women and minorities in clinical research. Most recently, the 21st Century Cures Act requires inclusion to be reported in the NIH Director's Report triennially. NIH guidelines ensure that women and minorities are included in NIH-funded clinical research in a manner that is appropriate to the scientific question under study, and that NIH-defined Phase III clinical trials are designed in a manner sufficient to examine differential effects of interventions on both women and men, as well as individuals of diverse racial and ethnic groups.¹

This report details the National Institute of Mental Health's (NIMH) strategies for maintaining compliance with the inclusion guidelines and includes data on extramural and intramural clinical research, and Phase III clinical trials. As the NIH inclusion guidelines apply to studies both within and outside the U.S., data are presented for all NIMH studies (both domestic and foreign). The data reflect the breadth of the clinical research supported by NIMH to fulfill its mission to transform the understanding and treatment of mental illnesses through basic and clinical research, paving the way for prevention, recovery, and cure. The NIMH clinical research portfolio includes large-scale clinical trials and observational studies, as well as smaller studies in basic, translational and services research.

Strategies for Ensuring Compliance

NIMH follows several steps to ensure compliance with the inclusion guidelines. 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, racial and ethnic minority enrollment goals; and recruitment plans that demonstrate how the investigator will meet these goals. 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 will notify principal investigators, who are required to address these issues prior to funding. Applications with unacceptable inclusion plans receive a bar to funding, which must be resolved prior to award of the grant or cooperative agreement. In the case of a bar to funding, the program official forwards the revised enrollment plan to the Office of Clinical Research (OCR), for review. If satisfactory, the enrollment plan is returned to the program official and the grants management branch and the bar to funding is then lifted. This response is kept in the official grant file along with a record of administrative actions taken.

¹ For further information about the guidelines, please see https://grants.nih.gov/grants/funding/women_min/guidelines.htm

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.

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 NIH Clinical Center's Office of Protocol Services (OPS) maintains centralized systems for capturing accrual data including sex/gender, ethnic, and racial status. OPS coordinates annual reporting of demographic participant data to the Office of Extramural Research (OER) and the Office of Research on Women's Health.

For extramural clinical research studies, OCR monitors the entry of inclusion data, performs quality assurance tasks, prepares aggregate reports for the National Advisory Mental Health Council and the NIH Office of Research on Women's Health and provides up-to-date training on procedures for ensuring the accuracy of inclusion data, as well as on the use of the electronic Human Subjects System (HSS). OCR provides this training through individual assistance, workshops for staff, and the provision of training materials to employees. Institute program officials and scientific review officers recently had the opportunity to attend 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. Other training opportunities that institute staff have participated in include the NIH Integrated Core Curriculum series and the training on HSS facilitated by OER staff.

Analysis and Interpretation of Data

The appended tables show enrollment data for fiscal years (FYs) 2016-2018.² Included in the tables are enrollment data for all extramural and intramural clinical research. Inclusion data are reported using the Office of Management and Budget's (OMB) revised 1997 racial and ethnic categories, which are required for the collection, tabulation, and presentation of race and ethnicity data within the Federal statistical system.³ When assessing inclusion data, it is important to keep in mind that the number of individuals in sex/gender, racial, and ethnic subgroups included in a particular study depends upon the scientific questions addressed in the study and the prevalence or incidence among these subgroups of the disease, disorder, or condition under investigation.

Table 1 displays the total inclusion data records (IDRs) for NIH-defined extramural and intramural clinical research for FY2016, FY2017 and FY2018. The total number of IDRs was relatively consistent across the fiscal years with a slight increase in FY 2018 (1,060, 1,076 and 1,245, respectively). On average, 91% of the IDRs had enrollment; IDRs without enrollment in

² The next triennial report will include FYs 2019-2021.

³ For more information about revised racial and ethnic categories required by OMB revisions to Statistical Policy Directive 15, see https://nces.ed.gov/programs/handbook/data/pdf/Appendix_A.pdf

FY2016 and FY2017 are studies that never enrolled participants and in FY2018 are studies that have yet to enroll participants. On average, 83% of the IDRs are from domestic sites across the FYs.

Table 2 displays the sex/gender by racial, and ethnic distribution of participants in NIH-defined extramural and intramural clinical research in FY2016, FY2017, and FY2018. In FY2016, NIH-defined extramural and intramural studies enrolled 1,384,838 participants; 64% of participants identified as female and 34% identified as male, and less than 2% did not identify a sex or gender. In FY2017, NIH-defined extramural and intramural studies enrolled 414,963 participants; 47% and 44% of participants identified as female and male, respectively, and about 9% did not identify a sex or gender. In FY2018, NIH-defined extramural and intramural studies enrolled 470,993 participants; 48% and 41% of participants identified as female and male, respectively, and about 11% did not identify a sex or gender. The large decrease in enrollment in clinical research from FY2016 to FY2017 can be accounted for by the 'Mental Health Research Network II' (U mechanism that has multiple projects with the goal to establish research centers based in integrated health care systems to conduct rapid and efficient effectiveness trials in mental health.) as one of the large projects completed enrollment in FY2017. Increases in unknown/not reported sex/gender across the FYs are due in part to the 'Detection of ASD [Autism Spectrum Disorder] at the 1st Birthday as Standard of Care: The get set early model' study. This study reported 18,565 in FY2016, 29,379 in FY2017 and 41,537 in FY2018 as unknown/not reported sex/gender.

Across FYs 2016-2018, the majority of participants identified as White (58% in FY2016, 53% in FY2017 and 51% in FY2018) and the largest racial minority groups were Black or African American (11% in FY2016, 20% in FY2017 and 23% in FY2018) and Asian (6% in FY2016, 11% in FY2017 and 8% in FY2018) followed by Hawaiian/Pacific Islander (1.1% in FY2016 to 0.3% in FY2017 and FY2018) and American Indian/Alaska Native (1% in FY2016 to 0.6% in FY2017 and FY2018). More Than One Race accounted for 1% in FY2016, 4.2% in FY2017 and 4.6% in FY2018. Total minority enrollment slowly increased across FY2016, FY2017 and FY2018 (40%, 43% and 44%, respectively). The percentage of participants who reported Hispanic ethnicity decreased from 21% in FY2016 to 10% in FY2017 and the percentage remained consistent in FY 2018 (10%). This decrease from FY2016 to FY2017 is accounted for by the 'Mental Health Research Network II' which enrolled about 263,000 participants in FY2016 who identified as Hispanic ethnicity. [In 2015, this study enrolled about 65,100 participants who identified as Hispanic ethnicity.] Percentages for Unknown race and ethnicity decreased from FY2016 to FY2017 (Unknown race: 22% to 11%; Unknown ethnicity: 19% to 14%) and slightly increased in FY2018 (12% and 18%, respectively). These decreases from FY2016 to FY2017 for unknown race and ethnicity are again accounted for by the 'Mental Health Research Network II' which enrolled over 267,000 and 221,000 participants in FY2016 of unknown race and ethnicity, respectively. FY2017 had less of a decrease in unknown ethnicity due to the 'Detection of ASD at the 1st Birthday as Standard of Care: The get set early model' study which reported 39,046 participants as unknown ethnicity.

Tables 3 displays the sex/gender by racial, and ethnic distribution of participants in NIH-defined extramural and intramural Phase III clinical trials for FY2016, FY2017, and FY2018. Participant enrollment into Phase III clinical trials steadily increased from FYs 2016-2018 (1,294 in FY2016, 3,185 in FY2017 and 8,005 in FY2018). On average 58% of participants were females with slight fluctuations in female representation from FY2016 (58%), FY2017 (63%) and FY2018 (53%). In FYs 2016-2018, the largest racial minority group in Phase III clinical trials was Black or African American (30% in FY2016, 51% in FY2017 and 34% in FY2018), followed by More Than One Race (6% in FY2016, 3% in FY2017 and 4% in FY2018) and Asian (2% in FY2016,

1% in FY2017 and 2% in FY2018). In FY2017, Black or African American enrollment accounted for over 50% of enrollment into Phase III clinical trials. Across the FYs, participants who reported American Indian/Alaska Native increased from 0.7% (FY2016) to 1.0% (FY2017) then decreased to 0.4% in FY2018. Similarly, across FYs 2016-2018, on average 5.7% of participants identified their ethnicity as Hispanic with declines in Hispanic participation (7.9% in FY2016, 5.5% in FY2017 and 3.8% in FY2018). For FY2018, NIMH only had one competing Phase III clinical trial that requires valid analyses by sex/gender and/or race/ethnicity. An alternative way to review inclusion data is by RCDC (Research, Condition, and Disease Categorization). The total number of participants enrolled in projects associated with listed research, condition, or disease category can be displayed by sex/gender, race and ethnicity. RCDC category reports for inclusion data for NIMH can be found at <https://report.nih.gov/RISR/>.

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 FYs 2015 and 2016.

Appendices

1. Table 1. FYs 2016-2018 Total Inclusion Data Records (IDRs) for NIH-Defined Extramural and Intramural Clinical Research
2. Table 2: FYs 2016-2018 Enrollment for All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity
3. Table 3. FYs 2016-2018 Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity

Appendices

Table 1. FYs 2016-2018 Total Inclusion Data Records (IDRs) for NIH-Defined Extramural and Intramural Clinical Research

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	1,060	74	986	913	73	84	49	853
2017	1,076	70	1,006	912	94	88	48	870
2018	1,245	153	1,092	966	126	101	49	942

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

Table 2: FYs 2016-2018 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	U/NR	% U/NR
2016	Female	376,199	42.3	888,712	64.2	525,631	59.1	211,334	23.8	151,747	17.1
2016	Male	169,626	36.0	471,207	34.0	296,109	62.8	81,535	17.3	93,563	19.9
2016	Unknown	5,272	21.2	24,919	1.8	6,609	26.5	1,365	5.5	16,945	68.0
2017	Female	89,287	45.5	196,449	47.4	161,384	82.2	20,885	10.6	14,180	7.2
2017	Male	82,227	45.0	182,635	44.0	148,379	81.2	18,191	10.0	16,065	8.8
2017	Unknown	5,913	16.6	35,609	8.6	6,381	17.9	1,221	3.4	28,007	78.7
2018	Female	108,226	48.0	225,414	47.9	176,372	78.2	25,940	11.5	23,102	10.2
2018	Male	91,055	46.9	194,282	41.2	154,369	79.5	21,031	10.8	18,882	9.7
2018	Unknown	9,359	18.2	51,297	10.9	7,468	14.6	1,638	3.2	42,191	82.2

Year	Sex/ Gender	AI/AN	% AI/AN	Asian	% Asian	AA	% AA	PI	% PI	White	% White	MTOR	% MTOR	U/NR	% U/NR
2016	Female	9,449	1.1	56,222	6.3	96,290	10.8	10,592	1.2	523,696	58.9	7,544	0.8	184,919	20.8
2016	Male	4,181	0.9	29,435	6.2	50,444	10.7	4,634	1.0	271,137	57.5	5,306	1.1	106,070	22.5
2016	Unknown	244	1.0	907	3.6	1,833	7.4	98	0.4	10,306	41.4	1,048	4.2	10,483	42.1
2017	Female	1,009	0.5	23,870	12.2	39,088	19.9	522	0.3	105,333	53.6	9,361	4.8	17,266	8.8
2017	Male	900	0.5	18,579	10.2	40,909	22.4	443	0.2	98,163	53.7	7,571	4.1	16,070	8.8
2017	Unknown	425	1.2	1,420	4.0	2,321	6.5	161	0.5	16,856	47.3	597	1.7	13,829	38.8
2018	Female	1,164	0.5	19,448	8.6	56,804	25.2	770	0.3	116,108	51.5	10,275	4.6	20,845	9.2
2018	Male	976	0.5	15,649	8.1	49,399	25.4	638	0.3	101,831	52.4	8,822	4.5	16,967	8.7
2018	Unknown	571	1.1	1,922	3.7	2,843	5.5	213	0.4	22,786	44.4	2,510	4.9	20,452	39.9

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded. [Abbreviations: American Indian/Alaska Native = AI/AN; Black/African American = AA; Native Hawaiian/Pacific Islander = PI; More Than One Race= MTOR; Unknown/Not Reported = U/NR]

Table 3. FYs 2016-2018 Enrollment for NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity

Year	Sex/ Gender	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	U/NR	% U/NR
2016	Female	287	38.6	744	57.5	698	93.8	40	5.4	6	0.8
2016	Male	287	52.3	549	42.4	484	88.2	62	11.3	3	0.5
2016	Unknown	1	100.0	1	0.1	1	100.0	0	0.0	0	0.0
2017	Female	1,132	56.8	1,992	62.5	1,873	94.0	103	5.2	16	0.8
2017	Male	793	66.8	1,187	37.3	1,110	93.5	71	6.0	6	0.5
2017	Unknown	4	66.7	6	0.2	5	83.3	0	0.0	1	16.7
2018	Female	1,955	46.1	4,245	53.0	4,079	96.1	162	3.8	4	0.1
2018	Male	1,587	42.4	3,743	46.8	3,595	96.0	145	3.9	3	0.1
2018	Unknown	1	5.9	17	0.2	1	5.9	0	0.0	16	94.1

Year	Sex/ Gender	AI/AN	% AI/AN	Asian	% Asian	AA	% AA	PI	% PI	White	% White	MTOR	% MTOR	U/NR	% U/NR
2016	Female	4	0.5	16	2.2	200	26.9	0	0.0	476	64.0	38	5.1	10	1.3
2016	Male	5	0.9	12	2.2	185	33.7	0	0.0	257	46.8	33	6.0	57	10.4
2016	Unknown	0	0.0	0	0.0	1	100.0	0	0.0	0	0.0	0	0.0	0	0.0
2017	Female	20	1.0	25	1.3	946	47.5	3	0.2	886	44.5	66	3.3	46	2.3
2017	Male	11	0.9	11	0.9	686	57.8	1	0.1	399	33.6	30	2.5	49	4.1
2017	Unknown	1	16.7	1	16.7	1	16.7	0	0.0	1	16.7	1	16.7	1	16.7
2018	Female	20	0.5	104	2.4	1,516	35.7	4	0.1	2,333	55.0	174	4.1	94	2.2
2018	Male	15	0.4	94	2.5	1,221	32.6	2	0.1	2,173	58.1	136	3.6	102	2.7
2018	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	1	5.9	16	94.1

The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded. [Abbreviations: American Indian/Alaska Native = AI/AN; Black/African American = AA; Native Hawaiian/Pacific Islander = PI; More Than One Race= MTOR; Unknown/Not Reported = U/NR]