

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director

**FY2016-FY2018 TRIENNIAL ADVISORY COUNCIL REPORT CERTIFYING
COMPLIANCE WITH THE NIH POLICY ON INCLUSION GUIDELINES**



Eric D. Green, M.D., Ph.D.

Director

National Human Genome Research Institute

February 2019

NATIONAL HUMAN GENOME RESEARCH INSTITUTE

FY2016-FY2018 TRIENNIAL ADVISORY COUNCIL REPORT CERTIFYING COMPLIANCE WITH THE NIH POLICY ON INCLUSION GUIDELINES

I. Background and Overview

The mission of the National Human Genome Research Institute (NHGRI) is to accelerate scientific and medical breakthroughs that improve human health by driving cutting-edge research, developing new technologies, and studying the impact of genomics on society. Since its inception in leading the Human Genome Project and completing the entire reference human genome in 2003, NHGRI has expanded its research portfolio from a narrow focus on studying the structure of the human genome to a widening array of programs that range from basic research to elucidate how the genome functions to high-powered discovery projects to discern the genomic bases of health and disease to innovative programs piloting the implementation of genomic medicine. NHGRI's Intramural Research Program plans and conducts a broad program of laboratory and clinical research, and these efforts have elucidated potential disease genes, including those implicated in cancer, diabetes, premature aging, hereditary deafness, various neurological, developmental, metabolic, and immunological disorders, and others.

NIH mandates that women and members of minority groups and their subpopulations be included in all NIH-funded clinical research, unless a clear and compelling rationale and justification establishes, to the satisfaction of the relevant Institute/Center Director, that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. Clinical research is defined as research with human subjects that is:

1. Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are *in vitro* studies that utilize human tissues that cannot be linked to a living individual. It includes:
 - Mechanisms of human disease
 - Therapeutic interventions
 - Clinical trials
 - Development of new technologies
2. Epidemiological and behavioral studies.
3. Outcomes research and health services research.

Studies falling under 45 CFR part 46.101(b) (4) (Exemption 4) are not considered clinical research by this definition.

Not all studies involving human participants must be tracked. Most training, fellowship and career development awards do not require tracking. In addition, certain types of grants can be coded as exempt from tracking when the grant checklist is completed. Tracking data are collected in two forms: planned enrollment as described in an investigator's grant application and cumulative (actual) enrollment based on participants recruited and examined in the course of the study. This information is saved in the Human Subjects System in the form of Inclusion Enrollment Records (IERS).

Every two to three years, each NIH Institutional Advisory Council is required to review the aggregate data on the cumulative enrollment of participants in research supported by the Institute to ensure that the Institute: 1) is in compliance with the mandate for appropriate gender and minority inclusion; and 2) has in place adequate procedures to ensure these inclusion levels are monitored and maintained.

The following report discusses the aggregate enrollment data reported from FY2016 to FY2018 from the Extramural Research Programs (ERP) including the Divisions of Genome Sciences, Genomic Medicine, and Genomics and Society; and the Intramural Research Program (IRP). This report also describes the procedures followed by NHGRI staff to ensure appropriate gender and minority inclusion in all NHGRI research. The information contained in this report was discussed at the February 11-12, 2019, meeting of the National Advisory Council on Human Genome Research (NACHGR).

II. Strategies for Ensuring Compliance

Extramural Research Program

The implementation of inclusion guidelines involves the participation of review, program, policy, and grants management staff.

Inclusion is first addressed by peer review. Scientific Review Officers (SROs) read all applications and note if clinical research is being proposed, and if the application is in compliance with the NIH policy on the Inclusion of Women and Minorities. SROs provide reviewers on NIH peer review panels specific guidance on reviewing inclusion on the basis of sex/gender, race, ethnicity, and age when considering clinical research applications

(https://grants.nih.gov/grants/peer/guidelines_general/Review_Human_Subjects_Inclusion.pdf).

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 and it is determined that a study is not in compliance or the applicant has not addressed the requirements in the application, a code is placed in the system that bars funding. If an award is to be made, the bar must be lifted, and documentation for the grounds on which the bar was lifted must be included in the official grant file. Grants Management staff will detect the bar and refer the issue to the Program Director. It is the responsibility of the Program Director to work with the applicant and her/his institution to comply with the NIH regulations. An award is not issued until an acceptable resolution is received. Grants management staff also 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.

Program Directors also review non-competing renewal applications (Type 5s) to determine recruitment status. If a Program Director determines that the recruitment is behind schedule, s/he will contact the grantee to determine what measures can be taken to ensure that the recruitment goals are met within the specified time.

Lastly, the ERP conducts an annual review of NHGRI's inclusion efforts and provides data to the NIH Office of Research on Women's Health. During the FY2016 to FY2018 reporting period, Ms. Christine Chang and Dr. Rongling Li served as the Institute's inclusion monitoring officers. They also provided

extramural staff guidance on inclusion policies and procedures, as well as organized annual refresher trainings. Staff have access to archived IC-specific trainings and NIH-wide trainings (e.g., NIH Core Curriculum and Human Subjects System training at https://era.nih.gov/hss_training.htm).

Intramural Research Program

The "Standards for Clinical Research within the NIH Intramural Program" found at <http://www.cc.nih.gov/ccc/clinicalresearch/index.html> states: "All clinical investigators are required to take an overview training course, or equivalent, on the roles and responsibilities of clinical investigators." The Clinical Center web site <http://www.cc.nih.gov/researchers/training.html> describes the general and degree training programs in clinical research that are available. The "Introduction to the Principles and Practice of Clinical Research" is part of the core curriculum in clinical research training, and is required of all principal investigators before they can submit a protocol for review by an NIH Institutional Review Board (<https://prevention.nih.gov/education-training/training-prevention-research-methods/introduction-principles-and-practice-clinical-research-ippcr>). All new clinical fellows are oriented as to the clinical research training programs that are available shortly after they arrive at NIH.

In addition, as established in Standard Operating Procedures Chapter 25 (SOP25), Training Requirements for the NIH Human Research Protection Program [HRPP] (https://ohsr.od.nih.gov/public/SOP_25_v4_2-29-16_508.pdf), "all incoming Intramural Research Program (IRP) scientists are required to complete training in order to assure that they understand when research activities involve human subjects research and what is required when they conduct this type of research." All investigators and non-investigator research staff for the FY2016-FY2018 protocols covered in this report were required to complete the training requirements established in SOP 25.

The Intramural scientists who conduct clinical studies with human subjects submit their research protocols to the Intramural Institutional Review Board (IRB) for review. Only protocols that ensure the health and safety of human participants and that meet the NIH standards for appropriate inclusion of women and racial/ethnic minorities are approved. Specifically, investigators submit to the IRB a detailed description of their recruitment strategy for each protocol, including efforts to include under-represented minorities. In addition, investigators project their planned enrollment, with anticipated numbers of participants in gender, racial, and ethnic categories. Continuing review applications that include ongoing gender and minority enrollment forms are reviewed by the IRB at least annually to ensure ongoing compliance. Enrollment data are submitted annually to the Clinical Center Office of Protocol Services (OPS), which coordinates annual reporting of demographic participant data to the Office of Extramural Research (OER) and the Office of Research on Women's Health.

Dr. Sara Hull, Co-Chair of NIH General Medicine IRB Panel #1 and appointed member of the newly centralized NIH intramural IRB, coordinates with IRB staff and OPS on behalf of the NHGRI Division of Intramural Research for the receipt and review of these data in preparation of inclusion reports.

III. Analysis and Interpretation of Data from FY2016 to FY2018

The clinical research studies funded by NHGRI tend to fall into a few basic categories: 1) qualitative studies that include a small number of research participants in focus group or structured interview settings; 2) phone, paper, or internet-based studies that survey the attitudes, beliefs or practices of either discrete populations (e.g. health professionals, genomic researchers, IRB chairs, individuals who have undergone genetic testing, disease/disability communities, minority communities) or the general population; 3) studies that utilize existing or prospectively identified cohorts for statistical analysis,

prospective linkage/gene identification, or genome-wide associations; and 4) genomic medicine implementation studies that apply genetic testing/sequencing for clinical care. Some of the qualitative, survey, and genetic testing studies are limited to discrete target populations that may not be always racially or ethnically diverse. As a result, the demographic breakdown of NHGRI research enrollment may differ slightly from the US population, depending on the types of studies active in a given year.

The FY2018 NHGRI Research, Condition, and Disease Categorization (RCDC) Inclusion Statistics Report (<https://report.nih.gov/RISR/#/home?ic=NHGRI>) shows the percentage of participants in each RCDC category by sex/gender, race, and ethnicity. For example, Genetic Testing studies have a median of 51% female participants.

Inclusion Enrollment Reports (IERs) contain study participant information for each grant or project. Because a single grant or project can have multiple studies, and each study can have multiple IERs, there can be multiple IERs per grant or project. For example, an extramural multicenter project will have multiple studies, and each study can also have multiple IERs to separate participants from existing datasets and participants that will be newly enrolled.

There is a small amount of overlap in participants that are included in both Extramural and Intramural enrollment data because of funding and participation in the Undiagnosed Diseases Network (n=572), which includes the intramural Undiagnosed Diseases Program (UDP).

Table 1 shows the total IERs for clinical research across NHGRI between FY2016 and FY2018. A small number of IERs did not have enrollment (17/175 in FY2016, 17/178 in FY2017 and 30/102 in FY2018) because of delayed onset of recruitment or active studies that completed enrollment in previous years so that they no longer need to recruit participants in that report year. Among the IERs with enrollment, the majority are associated with US sites (145/158 in FY2016, 148/161 in FY2017 and 64/72 in FY2018). IERs with non-US Sites included the countries Cameroon, Ghana, Mali, Nigeria, South Africa, United Kingdom, and Zimbabwe. A few studies include only female or only male participants because of the nature of studies, e.g. HPV and cervical cancer in women and prostate cancer in men.

Table 2 shows the enrollment and IERs by Extramural and Intramural Research Programs. The number of IERs is greater in Intramural compared to Extramural, except for 2018, whereas the number of enrolled participants is greater in Extramural compared to Intramural. This suggests that on average, the sample size in Extramural studies is bigger than that in Intramural studies. In FY2016, a grant to 23andMe, “A New Reference Panel to Boost African American Genotype Imputation” (R44HG009460, PI Adam Auton) aimed to create a new reference panel to boost African-American genotype imputation. This grant had a cumulative enrollment of 1,283,141 participants in FY2016, roughly five times the total enrollment in FY2017 and FY2018, and constituting 83% of the total number of enrolled participants (1,545,412) in that year. Because this one study substantially distorts overall trends, we have analyzed the data with and without this grant. The moderate increase in the number of IERs in Extramural in FY2018 can be attributed to an increase in new clinical research awards as well as supplements with participants different from the parent award. The decrease in reported Intramural IERs in FY2018 is due to closure of studies that were no longer active and exclusion of studies using existing data. Prior to FY2018, there was not a flag to identify Intramural records with existing data so FY2016 and FY2017 Intramural data have IERs that by default are labeled as “prospective data”. Existing data were correctly excluded for FY2018, during which NHGRI also had a change in and centralization of the IT system used to manage Intramural protocols. The IER data continue to be collected with each protocol’s continuing review by the new centralized IRB for Intramural studies.

Sex/Gender Distribution

Table 3 shows the overall and sex/gender distribution by Extramural and Intramural Research Programs. Overall the sex/gender distribution was generally balanced for FY2016 to FY2018. In the Extramural Research Program after excluding the 23andMe study in FY2016, the proportion female is slightly higher than the proportion male (53.3% vs. 44.8% in FY2016, 50.6% vs. 48.9% in FY2017 and 54.4% vs. 45.1% in FY2018). However, the Intramural Research Program enrolled slightly higher proportion of male participants than female participants. The high proportion of unknown sex/gender (24.5%) in the Intramural Research Program in FY2016 can be attributed to failure to self-report in online/mail surveys. The apparently high proportion of males (60.5%) relative to females (37.1%) in the Intramural Research Program in FY2018 is likely due to skewing from one large study among a small total number of studies (n=9). The largest study, “Genetic Analysis of Type II Diabetes in Finnish Population” (ZIAHG000024-24, PI Francis Collins) had 20,277 males and 12,014 females.

Race/Ethnic Minority Distribution

Race/Ethnic minority distribution is shown in Table 4. Minority enrollment in this report includes all races except White and Unknown race plus Hispanic enrollment. The number used for Hispanic enrollment excludes participants who also identified in another race category that fits the minority definition to avoid double counting. The total proportion of minority enrollment approximately doubled from FY2016 (13.2%) to FY2017 (25.0%) and FY2018 (26.6%). After excluding the 23andMe study, the proportion of minority enrollment increased for FY2016 (41.4%), which is due to the low proportion of minority (8.8%) and high proportion of unknown race and unknown or non-Hispanic/Latino ethnicity (56.0%) in the 23andMe study. The increased minority enrollment in Extramural resulted from specific targeting of minority participants in Extramural (more details in narrative text for Tables 5 and 6 below). The decrease in FY2018 Intramural minority enrollment is likely due to skewing from one large study among the small total number of studies, the largest of which was “Genetic Analysis of Type II Diabetes in Finnish Population” (ZIAHG000024-24, PI Francis Collins) with 30,114 Non-Hispanic White participants.

Ethnicity and Race Distributions

Table 5 shows enrollment stratified by ethnicity, defined as Hispanic/Latino versus not Hispanic/Latino. Extramural had increased Hispanic/Latino enrollment during the FY2016 to FY2018 (FY2016: 2.7%; FY2017: 5.1%; FY2018: 4.3%). The largest contributor in FY2017 was from an ELSI study (R21HG009205, PI Alexandra Stern), “Demographic Patterns of Eugenic Sterilization in California,” which had 2,865 Hispanic/Latino participants. The largest contributor in FY2018 to the increase of Hispanic/Latino came from John Harley’s grant (U01HG8666). In that grant, they enrolled 2,350 Hispanic/Latino participants for the biorepository in their project “Establishment of a General Repository of Remnant Clinical Specimens (Biorepository)”. Intramural had a relatively high percentage of Unknown or Not Reported ethnicity data in FY2016 due to a high amount of Unknown or Not Reported ethnicity in “Advanced Genetic Analyses of dbGaP Datasets for the Study of Complex Diseases” (Z01HG900002-15, Center for Research on Genomics and Global Health (CRGGH)). Because this study contributed 61% to the total Unknown or Not Reported ethnicity in FY2016, Table 5 excludes this outlier study.

Table 6 shows the racial distribution by the following categories: American Indian/Alaska Native (AI/AN), Asian, Black/African American (B/AA), Native Hawaiian/Pacific Islander (AH/PI), White, More than One

Race (MR), and Unknown/Not Reported (UK/NR) with and without the 23andMe and CRGGH studies. The enrollment of B/AA (FY2016: 5.7%, FY2017: 16.1%, FY2018: 18.6%) and Asian (FY2016: 1.8%, FY2017: 2.9%, FY2018: 2.2%) increased from FY2016 to FY2018. The proportion of UK/NR (FY2016: 49.5%, FY2017: 12.4% and FY2018: 4.4%) steadily decreased. However, in analysis excluding outlier studies, these trends are more stable. Excluding the 23andMe study, there is instead a decrease in the percentage of Extramural B/AA enrollment from FY2016 (33.9%) to FY2017 (13.7%) that is largely attributed to H3Africa grants ending in FY2016. They account for more than half of the B/AA enrollment in FY2016. The increase in the percentage of B/AA enrollment from FY2017 (13.7%) to FY2018 (20.5%) is mostly due to an H3Africa supplement in FY2018. Intramural had a relatively high percentage of Unknown or Not Reported race data in FY2016 due to a high amount of Unknown or Not Reported race in “Advanced Genetic Analyses of dbGaP Datasets for the Study of Complex Diseases” (Z01HG900002-15, Center for Research on Genomics and Global Health (CRGGH)), so data is also shown excluding that record. The increase in FY2017 UN/NR enrollment is largely due to an ELSI study (R21HG009205, PI Alexandra Stern), “Demographic Patterns of Eugenic Sterilization in California.” This study used eugenic sterilization records from 1921 to 1952, many of which did not have information about the individual’s racial background.

Enrollment Distribution of Ethnicity by Sex/Gender and Race by Sex/Gender

Table 7 shows cumulative enrollment for NHGRI clinical research parsed out by sex/gender, race, and ethnicity. NHGRI clinical research enrolled more females than males among Hispanic/Latino and Black/African-American participants, contributing to an overall higher proportion of minority females than minority males (FY2016: 15.0% vs 11.5%, FY2017: 27.6% vs 23.2%, and FY2018: 31.0% vs 21.5%).

Phase III Clinical Trials Distribution

NHGRI has very few Phase III clinical trials (Table 8), and all of the participants in Phase III trials during the FY2016 to FY2018 reporting period was in the Intramural Research Program. The Intramural Research Program enrolled 2 Asian males in FY2016 for a study to conduct the “International Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study of the Efficacy and Safety of KIACTA in Preventing Renal Function Decline in Patients with AA Amyloidosis.”

NHGRI Data Compared to 2010 US Census Data

Table 9 provides a comparison among: (1) the NHGRI actual enrollments in FY2016, FY2017 and FY2018, excluding and including the 23andMe study; and (2) the demographic breakdown from the 2018 US Census Population Estimate.

Comparing trends across FY2016 through FY2018, NHGRI improved enrollment of Black/African American participants for clinical research. The proportion of Black/African American was notably higher than the 2018 US Census estimate. Although Hispanic/Latino enrollment was markedly lower than the US Census estimate (18.1%), there were incremental improvements during this time period from 2.7% to 4.3%.

I. 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 FY2016 – 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 FY2015 and FY2016.

II. Concluding Remarks

Since previous the last reporting period, there was a general increase in the diversity of participants, particularly of Black/African Americans. Recent focused efforts by NHGRI to increase the number of studies with diverse participants through programs such as the Human Heredity and Health in Africa (H3Africa), Clinical Sequencing Evidence-Generating Research (CSER2) and Implementing Genomics in Practice (IGNITE) consortia. The H3Africa program aims to develop large-scale population studies including genomic studies by African research on African populations. CSER2 and IGNITE programs in their most recent round of solicitations required grant applicants to include a minimum percentage of diverse participants in their proposed studies.

Although the goal of NIH's inclusion policy is not to endorse or enforce quotas for proportional representation based on census data, but rather to support biomedical and behavioral research that produces scientific knowledge that is generalizable to the population under study and ultimately applicable to the entire population of the United States, comparisons show that certain racial groups fall below the US Census 2018 population estimates. It is possible that some of the strategies used to increase enrollment of Black/African American participants could be applied to increase the enrollment of Hispanic/Latino participants and other race/ethnic groups.

Table 1 (Official Table 2-1). 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	175	17	158	145	13	8	6	144
2017	178	17	161	148	13	6	4	151
2018	102	30	72	64	8	5	0	67

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

Table 2. Participants and IERs by Extramural and Intramural for NIH-Defined Clinical Research Reported Between FY2016 and FY2018

Fiscal Year	Total Enrolled Participants	Total No. of IERs	Enrolled Participants (Extramural)	No. of IERs (Extramural)	Enrolled Participants (Intramural)	No. of IERs (Intramural)
2016	1,545,412	175	1,445,917	68	99,495	107
2016*	262,271	174	162,776	67	99,495	107
2017	258,605	178	173,244	69	85,361	109
2018	192,255	102	157,767	93	34,505	9

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

* Extramural data excluding 1,283,141 participants in the 23andMe study.

Table 3. Sex/Gender Distribution for All NIH-Defined Extramural and Intramural Clinical Research Between FY2016 and FY2018

Fiscal Year		Total Enrolled Participants	Females	% Females	Males	% Males	Unknown Not Reported	% Unknown Not Reported
2016	Total	1,545,412	751,120	48.6	755,124	48.9	39,168	2.5
2016	Extramural	1,445,917	715,125	49.5	715,967	49.5	14,825	1.0
2016	Intramural	99,495	35,995	36.2	39,157	39.4	24,343	24.5
2016*	Total	262,271	122,701	46.8	112,106	42.7	27,464	10.5
2016*	Extramural	162,776	86,706	53.3	72,949	44.8	3,121	1.9
2016*	Intramural	99,495	35,995	36.2	39,157	39.4	24,343	24.5
2017	Total	258,605	126,550	48.9	125,586	48.6	6,469	2.5
2017	Extramural	173,244	87,606	50.6	84,747	48.9	891	0.5
2017	Intramural	85,361	38,944	45.6	40,839	47.8	5,578	6.5
2018	Total	192,255	98,680	51.3	91,964	47.8	1,611	0.8
2018	Extramural	157,750	85,878	54.4	71,085	45.1	787	0.5
2018	Intramural	34,505	12,802	37.1	20,879	60.5	824	2.4

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

* Extramural data excluding 1,283,141 participants in the 23andMe study.

Table 4. Minority Distribution of All NIH-Defined Extramural and Intramural Clinical Research Between FY2016 and FY2018

Fiscal Year		Total	Minority	% Minority
2016	Total	1,545,412	204,324	13.2
2016	Extramural	1,445,917	178,213	12.3
2016	Intramural	99,495	26,111	26.2
2016*	Total	262,271	91,738	35.0
2016*	Extramural	162,776	65,627	40.3
2016*	Intramural	99,495	26,111	26.2
2017	Total	258,605	64,695	25.0
2017	Extramural	173,244	39,984	23.1
2017	Intramural	85,361	24,711	28.9
2018	Total	192,255	51,134	26.6
2018	Extramural	157,750	47,277	30.0
2018	Intramural	34,505	3,857	11.2

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

* Extramural data excluding 1,283,141 participants in the 23andMe study.

Table 5. Ethnic Distribution of All NIH-Defined Extramural and Intramural Clinical Research Between FY2016 and FY2018

Fiscal Year		Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2016	Total	1,472,187	95.3	41,669	2.7	31,556	2.0
2016	Extramural	1,402,064	97.0	39,401	2.7	4,452	0.3
2016	Intramural	70,123	70.5	2,268	2.3	27,104	27.2
2016*†	Total	223,978	92.1	6,737	2.8	12,384	5.1
2016*†	Extramural	153,855	94.5	4,469	2.7	4,452	2.7
2016*†	Intramural	70,123	87.3	2,268	2.8	7,932	9.9
2017	Total	231,195	89.4	11,176	4.3	16,234	6.3
2017	Extramural	157,128	90.7	8,756	5.1	7,360	4.2
2017	Intramural	74,067	86.8	2,420	2.8	8,874	10.4
2018	Total	178,671	92.9	6,892	3.6	6,692	3.5
2018	Extramural	144,262	91.4	6,798	4.3	6,690	4.2
2018	Intramural	34,409	99.7	94	0.3	2	0.0

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

* Extramural data excluding 1,283,141 participants in the 23andMe study

† Intramural data excluding 19,172 participants in CRGGH study

Table 6. Racial Distribution of All NIH-Defined Extramural and Intramural Clinical Research Between FY2016 and FY2018

Fiscal Year		AI/AN	% AI /AN	Asian	% Asian	B/AA	% B/A A	NH /PI	% NH /PI	White	% White	MR	% MR	UK/NR	% UK /NR
2016	Total	3,926	0.3	27,795	1.8	88,112	5.7	988	0.1	610,425	39.5	49,269	3.2	764,897	49.5
2016	Extramural	3,826	0.3	24,670	1.7	68,033	4.7	940	0.1	558,527	38.6	48,610	3.4	741,311	51.3
2016	Intramural	100	0.1	3,125	3.1	20,079	20.2	48	0.0	51,898	52.2	659	0.7	23,586	23.7
2016*†	Total	345	0.1	6,551	2.7	71,628	29.5	152	0.1	146,681	60.3	3,867	1.6	13,875	5.7
2016*†	Extramural	245	0.2	3,426	2.1	55,146	33.9	104	0.1	94,783	58.2	3,208	2.0	5,864	3.6
2016*†	Intramural	100	0.1	3,125	3.9	16,482	20.5	48	0.1	51,898	64.6	659	0.8	8,011	10.0
2017	Total	475	0.2	7,613	2.9	41,736	16.1	242	0.1	171,381	66.3	5,098	2.0	32,060	12.4
2017	Extramural	374	0.2	3,824	2.2	23,795	13.7	126	0.1	116,680	67.4	4,578	2.6	23,867	13.8
2017	Intramural	101	0.1	3,789	4.4	17,941	21.0	116	0.1	54,701	64.1	520	0.6	8,193	9.6
2018	Total	414	0.2	4,159	2.2	35,848	18.6	145	0.1	138,045	71.8	5,226	2.7	8,418	4.4
2018	Extramural	414	0.3	3,845	2.4	32,400	20.5	145	0.1	107,394	68.1	5,225	3.3	8,327	5.3
2018	Intramural	0	0.0	314	0.9	3,448	10.0	0	0.0	30,651	88.8	1	0.0	91	0.3

AI/AN: American Indian/Alaska Native, B/AA: Black/African American, NH/PI: Native Hawaiian/Pacific Islander, MR: More than One Race, UK: Unknown/Not Report

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

* Extramural data excluding 1,283,141 participants in the 23andMe study

† Intramural data excluding 19,172 participants in the CRGGH study

Table 7 (Official Table 5-1-1-C). Enrollment for All NIH-Defined Clinical Research, by Sex/Gender, Race, and Ethnicity

Fiscal Year	Sex/Gender	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	UK	% UK
2016	Female	112,422	15.0	751,120	48.6	725,926	96.6	21,342	2.8	3,852	0.5
2016	Male	87,103	11.5	755,124	48.9	731,061	96.8	19,972	2.6	4,091	0.5
2016	Unknown	4,799	12.3	39,168	2.5	15,200	38.8	355	0.9	23,613	60.3
2017	Female	34,962	27.6	126,550	48.9	114,895	90.8	6,035	4.8	5,620	4.4
2017	Male	29,118	23.2	125,586	48.6	114,258	91.0	5,096	4.1	6,232	5.0
2017	Unknown	615	9.5	6,469	2.5	2,042	31.6	45	0.7	4,382	67.7
2018	Female	30,602	31.0	98,680	51.3	91,947	93.2	3,810	3.9	2,923	3.0
2018	Male	19,738	21.5	91,964	47.8	85,845	93.3	3,075	3.3	3,044	3.3
2018	Unknown	794	49.3	1,611	0.8	879	54.6	7	0.4	725	45.0

Fiscal Year	Sex/Gender	AI/AN	% AI/AN	Asian	% Asian	B/AA	% B/AA	NH/PI	% NH/PI	White	% White	MR	% MR	UK	% UK
2016	Female	2,185	0.3	14,354	1.9	50,227	6.7	527	0.1	307,781	41.0	27,826	3.7	348,220	46.4
2016	Male	1,732	0.2	13,389	1.8	33,540	4.4	455	0.1	299,686	39.7	21,359	2.8	384,963	51.0
2016	Unknown	9	0.0	52	0.1	4,345	11.1	6	0.0	2,958	7.6	84	0.2	31,714	81.0
2017	Female	235	0.2	3,974	3.1	22,907	18.1	128	0.1	82,291	65.0	2,620	2.1	14,395	11.4
2017	Male	216	0.2	3,626	2.9	18,284	14.6	113	0.1	88,076	70.1	2,473	2.0	12,798	10.2
2017	Unknown	24	0.4	13	0.2	545	8.4	1	0.0	1,014	15.7	5	0.1	4,867	75.2
2018	Female	213	0.2	2,397	2.4	22,336	22.6	86	0.1	67,066	68.0	2,662	2.7	3,920	4.0
2018	Male	201	0.2	1,762	1.9	12,727	13.8	59	0.1	70,927	77.1	2,559	2.8	3,729	4.1
2018	Unknown	0	0.0	0	0.0	785	48.7	0	0.0	52	3.2	5	0.3	769	47.7

AI/AN: American Indian/Alaska Native, B/AA: Black/African American, NH/PI: Native Hawaiian/Pacific Islander, MR: More than One Race, UK: Unknown/Not Reported. The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded

Table 8 (Official Table 5-2-2-C). Enrollment for NIH-Defined Extramural and Intramural Phase III Trials by Sex/Gender, Race, and Ethnicity

Fiscal Year	Sex/Gender	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	UK	% UK
2016	Female	0	0	0	0	0	0	0	0	0	0
2016	Male	1	100	1	100	1	100	0	0	0	0
2016	Unknown	0	0	0	0	0	0	0	0	0	0
2017	Female	0	0	0	0	0	0	0	0	0	0
2017	Male	2	100	2	100	2	100	0	0	0	0
2017	Unknown	0	0	0	0	0	0	0	0	0	0
2018	Female	0	0	0	0	0	0	0	0	0	0
2018	Male	0	0	0	0	0	0	0	0	0	0
2018	Unknown	0	0	0	0	0	0	0	0	0	0

Fiscal Year	Sex/Gender	AI/AN	% AI/AN	Asian	% Asian	B/AA	% B/AA	NH/PI	% NH/PI	White	% White	MR	% MR	UK	% UK
2016	Female	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2016	Male	0	0	1	100	0	0	0	0	0	0	0	0	0	0
2016	Unknown	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2017	Female	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2017	Male	0	0	2	100	0	0	0	0	0	0	0	0	0	0
2017	Unknown	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2018	Female	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2018	Male	0	0	0	0	0	0	0	0	0	0	0	0	0	0
2018	Unknown	0	0	0	0	0	0	0	0	0	0	0	0	0	0

AI/AN: American Indian/Alaska Native, B/AA: Black/African American, NH/PI: Native Hawaiian/Pacific Islander, MR: More than One Race, UK: Unknown/Not Report. The data presented in this report show only inclusion data records labeled as prospective data. Inclusion data records labeled as existing data are excluded.

Table 9. Comparison with 2018 US Census Estimates

Category	NHGRI (2016)	NHGRI (2016*)	NHGRI (2017)	NHGRI (2018)	US Census (2018 Population Estimate**)
American Indian/ Alaska Native (%)	0.3	0.1	0.2	0.2	1.3
Asian (%)	1.8	2.5	2.9	2.2	5.8
Black/African American (%)	5.7	28.7	16.1	18.6	13.4
Hawaiian/Pacific Islander (%)	0.1	0.1	0.1	0.1	0.2
White (%)	39.5	55.9	66.3	71.8	76.6
>1 Race (%)	3.2	1.5	2.0	2.7	2.7
Unknown (%)	49.5	11.2	12.4	4.4	0.0
Not Hispanic (%)	95.3	97.0	90.7	91.4	81.9
Hispanic/Latino (%)	2.7	2.7	5.1	4.3	18.1
Unknown (%)	2.0	0.3	4.2	4.2	0.0
Female (%)	48.6	46.8	48.9	51.3	50.8
Male (%)	48.9	42.7	48.6	47.8	49.2
Unknown (%)	2.5	10.5	2.5	0.8	0.0
Total	1,545,412	262,271	258,605	192,255	327,167,434

* Extramural data excluding 1,283,141 participants in the 23andMe study

** Data from <https://www.census.gov/quickfacts/fact/table/US/PST045218>