

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

**2022 TRIENNIAL ADVISORY COUNCIL REPORTS CERTIFYING
COMPLIANCE WITH THE
NIH POLICY ON INCLUSION GUIDELINES
Fiscal Years 2019 - 2021**

Eric Green, MD, PhD
Director
National Human Genome
Research Institute

[February, 2022]

NATIONAL HUMAN GENOME RESEARCH INSTITUTE

FY2019-FY2021 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. The broader scope includes funding research that strives to unravel the complexities of the human genome, identify the genomic underpinnings of human health and disease, and ensure that genomics is applied responsibly to improve patient care and benefit society. NHGRI's Intramural Research Program plans and conducts a broad program of laboratory and clinical research, and these efforts have elucidated and explored the biology and management of multiple genetic and other health conditions, including cancer; diabetes; premature aging; hereditary deafness; and various neurological, developmental, metabolic, and immunological disorders. The work of NHGRI Intramural Investigators also integrates social and behavioral research and genomics together with public health.

The NIH is mandated by the Public Health Service Act to ensure the inclusion of women and minority groups in all NIH-funded clinical research in a manner that is appropriate to the scientific question under study. The primary goal of this law is to ensure that research findings can be generalizable to the entire population. Additionally, the statute requires clinical trials to be designed to provide information about differences by sex/gender, race and/or ethnicity. Clinical research is defined as research with human subjects, including:

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.

Not all studies involving human participants must be tracked. Most training, fellowship and career development awards do not require inclusion tracking. In addition, certain types of grants can be coded as exempt from tracking. This includes human subjects research that involves the collection or study of data or specimens that are publicly available, or recorded in such a way that subjects cannot be identified.

Inclusion coding and information is initially collected on the grant application using the PHS Human Subjects and Clinical Trials Information form. This form requires an Inclusion Enrollment Report (IER) for each study in the grant application. The IER table contains the planned distribution of subjects by sex/gender, race, and ethnicity. Applicants also describe the rationale for selection of sex/gender, racial, and ethnic group members in terms of the scientific objectives and proposed study design, as well as the proposed outreach for recruitment. Over the course of the grant as progress reports are submitted, the grantee submits IERs containing cumulative enrollment data, which is based on the actual number of participants recruited and examined in the course of the study.

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 sex/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 FY2019 to FY2021 from the Extramural Research Program (ERP), including the Divisions of Genome Sciences, Genomic Medicine, and Genomics and Society, as well as 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 7-8, 2022, 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. 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

(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, program staff notify principal investigators, who are required to address these issues prior to funding. The NHGRI Advisory Council performs the second level of review and makes recommendations for funding considering the overall impact score, percentile ranking, and summary statement in light of the research priorities for NHGRI. Applications with unacceptable inclusion plans receive a bar to funding; 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 monitor actual enrollment progress by reviewing annual research performance progress reports (RPPR) or 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 FY2019 to FY2021 reporting period, Ms. Christine Chang and Dr. Rongling Li served as the Institute's inclusion monitoring officers. They also provided guidance to extramural on inclusion policies and procedures. Staff have access to archived IC-specific training and NIH-wide training (e.g., NIH Core Curriculum and Human Subjects System training at <https://era.nih.gov/help-tutorials/era-training-hss.htm>).

Intramural Research Program

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. These plans are considered during the initial scientific review process and subsequent IRB approval. With the submission of the annual review for IRB renewal and quadrennial scientific reviews, the investigator documents the number, sex/gender, race and ethnicity of those who were accrued during the past year; any issues with accrual are addressed and plan to increase recruitment reviewed by both the Institute and 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. Demographic participant data from NHGRI's Division of Intramural Research (DIR) for this period were submitted by the NIH IRB office to OPS for processing, and then reviewed by Ms. Mindy Perilla, Protocol Coordinator for the Office of the Clinical Director (OCD)/DIR for the preparation of this report.

III. Analysis and Interpretation of Data from FY2019 to FY2022

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 always be 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.

Inclusion enrollment data by Research Condition and Disease Categorization (RCDC) category are available through this link: <https://report.nih.gov/RISR/>.

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 for different sites, and each study can also have multiple IERs to separate participants. 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 1 shows the total IERs for clinical research across NHGRI between FY2019 and FY2021. About a third of IERs did not have enrollment (29% in FY 2019, 34% in FY2020 and 35% in FY2021) 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 (91% in FY2019, 90% in FY2020 and 91% in FY2021). IERs with non-US Sites included the countries Botswana, Cameroon, Ghana, India, Mali, Nigeria, Senegal, Sierra Leone, South Africa, Thailand, and Uganda. A few studies include only female participants because of the nature of studies, e.g. pregnant women’s views on prenatal sequencing.

Table 2 shows actual enrollment and IERs by Extramural and Intramural Research Programs. The number of IERs is lower in Intramural compared to Extramural across all years. Participant enrollment in Intramural was steady across years, whereas enrollment in Extramural noticeably dropped in FY2019 to FY2021. In the Extramural, the enrollment decreased from 165,799 in FY2019 to 42,336 in FY2020 largely due to the end of eMERGE III consortium. Whereas in FY2019 actual enrollment was similar to typical enrollment numbers, FY2020 and FY2021 enrollment dropped significantly. This is consistent with many grantees having reported difficulty reaching target enrollment due to the onset of the COVID-19 pandemic and related restrictions in spring of 2020. Even after academic research and health centers resumed business, understandably patients were hesitant to participate in research and low recruitment rates continued. Participation in intramural studies was not affected in this manner.

Sex/Gender Distribution

NIH uses sex/gender to indicate that either sex or gender may be reported for inclusion enrollment purposes. “Sex” refers to biological differences between females and males, including chromosomes, sex organs, and endogenous hormonal profiles. “Gender” refers to socially constructed and enacted roles and behaviors which occur in a historical and cultural context. The NIH encourages investigators to design their data collection instruments in a way that allows the participants to self-identify their sex or gender in a way that is meaningful within the study’s context.

Table 3 shows the overall and sex/gender distribution including Extramural and Intramural Research Programs. Overall, the sex/gender distribution was balanced for FY2019 to FY2021. The slightly higher proportion of females is largely due to having some female-only studies but no male-only studies (Table 1). Comparing across years, there is a doubling of unknown sex/gender participants in FY2020 and FY2021 vs FY2019. This is largely due to an intramural study on the “Genetic Analysis of Brain Disorders” (1Z01HG900002-20 and 1ZIAHG000209-19) with about 4,000 Unknown or Not Reported sex/gender. This study was active in all three reporting years, but because of the smaller overall actual enrollment numbers, the proportion of unknowns is higher in FY2020 and FY2021. This dataset includes historic participant samples for which some identifiers had been removed.

Race/Ethnic Minority Distribution

Race/Ethnic minority distribution is shown in Table 4 with the following US Census-designated race 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). When enrolling research participants, researchers ask participants to self-identify both their ethnicity and their race, with the option to select more than one racial category, or to decline providing race and ethnicity. Minority enrollment in this report includes all races except White and Unknown race, plus Hispanic enrollment (Table 4) not already identified in another race category that fits the minority definition. The total proportion of minority enrollment gradually increased between FY2019 (28.3%) to FY2020 (31.5%) to FY2021 (35.6%). This is a modest increase over previous years: FY2017 (25.0%) and FY2018 (26.6%) (<https://report.nih.gov/catalog/DisplayRePORT.aspx?rid=909>). The increased minority enrollment is due to efforts in Extramural to recruit minority participants. For example, increases in the proportion of Black/African American participants in FY2021 include the H3Africa study titled, “Genomic Characterization and Surveillance of Microbial Threats in West Africa” (U54HG077480) with 5,958 Black/African American participants.

Table 5 shows enrollment stratified by ethnicity, defined as Hispanic/Latino versus not Hispanic/Latino participants. Following the U.S. Office of Management and Budget’s definition, Hispanic and Latino participants may be of any race. The proportion identifying as Hispanic/Latino was generally steady across FY2019 through FY2021, with small variations due to the decreased overall enrollment numbers in FY2020 and FY2021.

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

Table 6 shows enrollment for NHGRI clinical research parsed by sex/gender, race, and ethnicity. The trends across the three years are generally stable. It was noted above that the total proportion of minority enrollment increased between FY2019 and FY2021. When stratified by sex/gender, the increase in minority enrollment is greater among female participants: FY2019 (30.5% minority among females vs 25.8% among males), FY2020 (35.0% vs 26.1%), and FY2021 (39.7% vs 30.7%). There were no differences by sex/gender in proportions identifying as Hispanic/Latino.

NHGRI Data Compared to Overall NIH Data and 2021 US Census Data

Table 7 provides a comparison of NHGRI enrollment data with overall NIH enrollment from FY2019 through FY2021. Most demographic category proportions are similar for NHGRI and overall NIH, except for Asian participants and Hispanic/Latino participants. Asian and Hispanic/Latino participant proportions across NIH was higher than NHGRI.

Table 8 provides a comparison of the trend of the NHGRI actual enrollments in FY2017 through FY2021 with the demographic breakdown of the 2021 US Census Population Estimate. Comparing trends across FY2017 through FY2021, NHGRI improved enrollment of Black/African American participants for clinical research. The proportion of Black/African American participants was notably higher than the 2021 US Census estimate. Most other categories were fairly consistent with US Census proportions, although enrollment of Hispanic/Latino participants was markedly lower than the US Census estimate (18.1%).

IV. Inclusion Across the Lifespan

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.

Table 9 shows the age distribution for enrolled participants for studies falling under this policy in FY2021. The data should be interpreted with caution given the very low enrollment numbers overall. The overall enrollment numbers are low because the policy applies only to the very small portion of studies recently funded (15 out of 260 studies in FY2021), and most of NHGRI's research does not fall under the policy yet.

V. Concluding Remarks

The deleterious effect of COVID-19 on NHGRI participant enrollment is substantial. While academic research centers and other study sites quickly adapted and resumed recruitment efforts, there are residual delays and difficulty in reaching initial target enrollment numbers.

Since the last triennial report, the proportion of race/ethnic minority participants has remained generally stable. Of note, however, there is a steady increase in Black/African American participant enrollment. This is due to continued 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 (IGNITE2) consortia. In addition, language encouraging applications that include diverse participants is standard for all applicable NHGRI funding opportunity announcements.

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 NIH overall enrollment (Table 7) and US Census 2021 population estimates (Table 8). 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 in NHGRI studies. Successful strategies in enrolling Hispanic/Latino participants in studies at other NIH institutes/centers could be also be adapted for NHGRI studies.

Table 1. Total Inclusion Data Records (IERS) for NIH-Defined Extramural and Intramural Clinical Research Reported Between Fiscal Years 2019 and 2021

Fiscal Year	Total IERS	IERS		US Site IERS	Non-US Site IERS	Female Only IERS	Male Only IERS	IERS Excluding Male only and Female only*	
		Without Enrollment	IERS With Enrollment						
2019	237	68	169	154	15	12	0		157
2020	235	79	156	140	16	10	0		146
2021	260	91	169	154	15	8	0		161

*Inclusion Data Records (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 FY2019 and FY2021

Fiscal Year	Total		Extramural		Intramural	
	Actual Enrollment	No. of IERS	Actual Enrollment	No. of IERS	Actual Enrollment	No. of IERS
2019	250,151	237	165,799	148	84,352	89
2020	130,043	235	42,336	154	87,707	81
2021	118,460	260	27,533	178	90,927	82

Table 3. Total Enrollment for All NIH-Defined Extramural and Intramural Clinical Research Between Fiscal Years 2019 and 2021

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown
2019	250,151	124,704	49.9	117,604	47.0	7,843	3.1
2020	130,043	60,554	46.6	59,966	46.1	9,523	7.3
2021	118,460	55,412	46.8	54,107	45.7	8,941	7.5

Table 4. Minority Distribution of All NIH-Defined Extramural and Intramural Clinical Research Between FY2019 and FY2021

Fiscal Year	Total Enrollment	Minority	% Minority	% AI/AN	% AI/AN	% Asian	% Asian	% B/AA	% B/AA	% NH/PI	% NH/PI	% White	% White	MR	MR	UK	UK
2019	250,151	70,900	28.3	1,366	0.5	8,302	3.3	45,613	18.2	193	0.1	171,409	68.5	6,562	2.6	16,706	6.7
2020	130,043	40,949	31.5	1,263	1.0	5,347	4.1	26,083	20.1	92	0.1	79,854	61.4	2,100	1.6	15,304	11.8
2021	118,460	42,122	35.6	416	0.4	5,294	4.5	29,792	25.1	91	0.1	70,453	59.5	1,569	1.3	10,845	9.2

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

Table 5. Ethnic Distribution of All NIH-Defined Extramural and Intramural Clinical Research Between FY2019 and FY2021

Fiscal Year	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2019	224,383	89.7	10,833	4.3	14,935	6.0
2020	106,955	82.2	6,761	5.2	16,327	12.6
2021	101,818	86.0	5,617	4.7	11,025	9.3

Table 6. Enrollment for All NIH-Defined Clinical Research, by Sex/Gender, Race, and Ethnicity

Fiscal Year	Sex/Gender	Minority	% Minority	Total Enrollment	% Total	AI/AN	% AI/AN	Asian	% Asian	B/AA	% B/AA	NH/PI	% NH/PI	White	% White	MR	% MR	UK	% UK
2019	Female	38,017	30.5	124,704	49.9	752	0.6	4,500	3.6	24,305	19.5	112	0.1	85,492	68.6	3,378	2.7	6,165	4.9
2019	Male	30,399	25.8	117,604	47.0	611	0.5	3,788	3.2	18,892	16.1	81	0.1	85,713	72.9	3,173	2.7	5,346	4.5
2019	Unknown	2,484	31.7	7,843	3.1	3	0.0	14	0.2	2,416	30.8	0	0.0	204	2.6	11	0.1	5,195	66.2
2020	Female	21,170	35.0	60,554	46.6	755	1.2	2,728	4.5	13,159	21.7	55	0.1	37,442	61.8	1,085	1.8	5,330	8.8
2020	Male	15,666	26.1	59,966	46.1	471	0.8	2,604	4.3	8,898	14.8	37	0.1	42,211	70.4	1,005	1.7	4,740	7.9
2020	Unknown	4,113	43.2	9,523	7.3	37	0.4	15	0.2	4,026	42.3	0	0.0	201	2.1	10	0.1	5,234	55.0
2021	Female	21,981	39.7	55,412	46.8	228	0.4	2,713	4.9	15,398	27.8	42	0.1	33,019	59.6	875	1.6	3,137	5.7
2021	Male	16,606	30.7	54,107	45.7	182	0.3	2,565	4.7	10,938	20.2	48	0.1	37,231	68.8	679	1.3	2,464	4.6
2021	Unknown	3,535	39.5	8,941	7.5	6	0.1	16	0.2	3,456	38.7	1	0.0	203	2.3	15	0.2	5,244	58.7

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

Fiscal Year	Sex/Gender	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2019	Female	113,532	91.0	6,095	4.9	5,077	4.1
2019	Male	107,916	91.8	4,692	4.0	4,996	4.2
2019	Unknown	2,935	37.4	46	0.6	4,862	62.0
2020	Female	51,018	84.3	3,741	6.2	5,795	9.6
2020	Male	51,391	85.7	2,993	5.0	5,582	9.3
2020	Unknown	4,546	47.7	27	0.3	4,950	52.0
2021	Female	49,085	88.6	3,034	5.5	3,293	5.9
2021	Male	48,812	90.2	2,537	4.7	2,758	5.1
2021	Unknown	3,921	43.9	46	0.5	4,974	55.6

Table 7. Comparison of NHGRI with NIH Enrollment Data

Category	<u>2019</u>		<u>2020</u>		<u>2021</u>	
	NHGRI	NIH	NHGRI	NIH	NHGRI	NIH
American Indian/ Alaska Native (%)	0.5	2.5	1.0	0.9	0.4	0.7
Asian (%)	3.3	9.6	4.1	7.1	4.5	12.0
Black/African American (%)	18.2	18.0	20.1	19.6	25.1	17.7
Hawaiian/Pacific Islander (%)	0.1	0.2	0.1	0.2	0.1	0.6
White (%)	68.5	57.1	61.4	55.3	59.5	53.4
>1 Race (%)	2.6	2.1	1.6	2.6	1.3	2.0
Unknown (%)	6.7	10.6	11.8	14.2	9.2	13.6
Not Hispanic (%)	89.7	78.6	82.2	77.1	86.0	79.6
Hispanic/Latino (%)	4.3	10.9	5.2	11.0	4.7	10.2
Unknown (%)	6.0	10.5	12.6	11.9	9.3	10.1
Female (%)	49.9	52.1	46.6	55.1	46.8	58.5
Male (%)	47.0	44.8	46.1	40.4	45.7	39.0
Unknown (%)	3.1	3.1	7.3	4.5	7.5	2.5
Total	250,151	13,241,413	130,043	13,705,659	118,460	1,2937,156

Table 8. Comparison of NHGRI Enrollment Data with 2021 US Census Estimates

Category	NHGRI					US Census 2021 Population Estimate*
	2017	2018	2019	2020	2021	
American Indian/ Alaska Native (%)	0.2	0.2	0.5	1.0	0.4	1.3
Asian (%)	2.9	2.2	3.3	4.1	4.5	5.9
Black/African American (%)	16.1	18.6	18.2	20.1	25.1	13.4
Hawaiian/Pacific Islander (%)	0.1	0.1	0.1	0.1	0.1	0.2
White (%)	66.3	71.8	68.5	61.4	59.5	76.3
>1 Race (%)	2.0	2.7	2.6	1.6	1.3	2.8
Unknown (%)	12.4	4.4	6.7	11.8	9.2	-
Not Hispanic (%)	90.7	91.4	89.7	82.2	86.0	60.1
Hispanic/Latino (%)	5.1	4.3	4.3	5.2	4.7	18.5
Unknown (%)	4.2	4.2	6.0	12.6	9.3	-
Female (%)	48.9	51.3	49.9	46.6	46.8	50.8
Male (%)	48.6	47.8	47.0	46.1	45.7	49.2
Unknown (%)	2.5	0.8	3.1	7.3	7.5	-
Total	258,605	192,255	250,151	130,043	118,460	331,893,745

* Data from <https://www.census.gov/quickfacts/fact/table/US/PST045221>

Table 9. Age Distribution Using Broad Age Groups for NIH-Defined Extramural and Intramural Clinical Research

Fiscal Year	Children (<18 years)	Adults (18-64 years)	Older Adults (65+ years)	Unknown or Not Reported	Total
2021	115 16.3%	519 73.4%	53 7.5%	20 2.8%	707 100%