

NATIONAL ADVISORY DENTAL AND CRANIOFACIAL RESEARCH COUNCIL
REPORT MONITORING ADHERENCE TO THE NIH POLICY ON THE INCLUSION
OF WOMEN AND MINORITIES IN CLINICAL RESEARCH
AS REPORTED IN FY 2019 THROUGH FY 2021
January 25, 2022

I. BACKGROUND/OVERVIEW

The mission of the National Institute for Dental and Craniofacial Research (NIDCR) is to advance fundamental knowledge about dental, oral, and craniofacial (DOC) health and disease and translate these findings into prevention, early detection, and treatment strategies that improve overall health for all individuals and communities across the lifespan. We accomplish our mission through five strategic priorities:

- Advance cross-disciplinary fundamental research in the biomedical, behavioral, social, and environmental sciences and drive its translation into innovations for the early diagnosis, prevention, and treatment of DOC diseases and conditions across the lifespan.
- Develop more precise and individualized ways of managing and preventing DOC diseases.
- Accelerate the translation of research and the uptake of new discoveries into oral and general healthcare practices that reduce health inequities and disparities and improve oral health outcomes for individuals and communities worldwide.
- Nurture future generations of DOC researchers and oral health professional scholars who can address existing and emerging challenges driven by personalized and public health needs and a continually evolving landscape of science and technology advances.
- Expand already existing partnerships and create new ones to advance the NIDCR research enterprise and increase its reach and impact.

The NIDCR aspires to transform human lives through scientific discoveries and innovations that advance DOC health and overall well-being for all.

The NIH Revitalization Act of 1993 directed the NIH to establish guidelines for inclusion of women and minorities in NIH-funded clinical research. 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 in Clinical Research](#) on November 28, 2017, to require studies that are NIH-defined Phase III clinical trials and/or applicable clinical trials to report the results of analyses by sex/gender and/or race/ethnicity to ClinicalTrials.gov. This requirement is in effect 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](#), addresses

consideration of individuals of all ages in NIH-funded clinical research and requires reporting of participant age at enrollment in annual progress reports. The policy is in effect for applications submitted on or after January 25, 2019, and contract solicitations and Intramural studies initiated after this date.

The 21st Century Cures Act also amended the frequency from biennial to triennial for reporting inclusion activities to advisory councils and providing the Report of the NIH Director on the Inclusion of Women and Minorities. The triennial report provides information from each NIH Institute and Center (IC) on inclusion of participants in NIH-defined clinical research from Fiscal Year (FY) 2019 through FY 2022. This report of monitoring adherence to inclusion policies being presented to the National Advisory Dental and Craniofacial Research Council (NADCRC) presents the NIDCR's activities related to fulfilling its responsibilities under these statutes.

II. STRATEGIES FOR ENSURING POLICY COMPLIANCE

The implementation of inclusion guidelines involves the participation of NIH Review, Program, Policy, and Grants Management staff. Inclusion is first addressed by peer review. Reviewers on NIH peer review panels are given specific [Guidelines for the Review of Inclusion on the Basis of Sex/Gender, Race, Ethnicity and Age in Clinical Research](#) 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. Review groups make initial recommendations as to the acceptability of the proposed study population with respect to the inclusion policies. The NADCRC performs the second level of review.

Applications with unacceptable inclusion plans receive a bar to funding; an award is not issued until an acceptable resolution is received. If issues are raised in review, Program and/or Grants Management staff notify Principal Investigators, who are required to address these issues prior to funding. Prior to funding a new award, Program staff are responsible for reviewing the inclusion information in the application and indicating whether the plans are scientifically appropriate. For NIH-defined Phase III clinical trials, Program staff review applications for the requirement that sex/gender and race/ethnicity analyses are planned. Grants Management staff ensure that applications with unacceptable inclusion plans are resolved prior to issuing an award. Further, for awards that require inclusion monitoring, Program staff monitor actual enrollment progress in annual and final progress reports and provide consultation when necessary. For NIH-defined Phase III clinical trials, Program staff monitor annual and final progress reports for the requirement to conduct analyses by sex/gender and race/ethnicity. Grants Management staff ensure that appropriate terms and conditions of award are included

in the Notice of Award, and that inclusion 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. These plans are considered during the scientific review process. With the annual scientific review and IRB review renewal, the Intramural investigator documents the number, sex/gender, 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. Dr. Janice Lee, Clinical Director of the Intramural Program at NIDCR, is responsible for overseeing protocol recruitment efforts of NIDCR Intramural investigators and ensuring they make efforts to include appropriate representation of sex/gender, race, and ethnicity in their studies. 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.

The NIH Revitalization Act of 1993 and subsequent statutes have stipulated that NIH staff and Extramural investigators understand the requirement of the statutes and their impact on the conduct of clinical research. Dr. Dena Fischer, Director for the Center for Clinical Research, Division of Extramural Research, NIDCR, has provided guidance to NIDCR's Extramural Program Officials/Directors about the inclusion guidelines. Dr. Fischer is a member of the NIH Inclusion Operating Procedures Workgroup, which reviews the tracking system used by NIH to capture inclusion data and recommends changes as needed. NIDCR Extramural Program Officials/Directors provide assistance to investigators to ensure that target and current enrollment information for the inclusion of human subjects on the basis of sex/gender, race, ethnicity, and age are included in grant applications and provided in progress reports. Further, NIDCR Program Officials/Directors, Scientific Review Officers, and Grants Management staff attended the 2020 Inclusion Training for Program Staff and the 2020 Inclusion Training for Review Staff in April 2020. Staff may access the archived training on the NIH staff intranet.

III. ANALYSIS AND INTERPRETATION OF DATA

All NIDCR Extramural and Intramural Clinical Research Studies

In FY 2019, 27,594 participants were enrolled in 123 of 181 NIDCR-supported Extramural and Intramural studies that required enrollment monitoring. In FY 2020, 17,874 participants were enrolled in 128 of 212 NIDCR-supported Extramural and Intramural studies that required enrollment monitoring, and in FY 2021, 21,790 participants were enrolled in 141 of 272 NIDCR-supported clinical studies that required enrollment monitoring. The decreased enrollment with increased IERs in FY 2020 and 2021 compared to FY 2019 is likely due to COVID-related impacts upon clinical research activities.

Aggregate FY 2019 data (Table 2) revealed 54.2% of enrolled participants were female, 43.2% were male, and sex/gender was unknown for 2.6%. Similar patterns were present in the aggregate FY 2020 (Table 3) and FY 2021 (Table 4) data in that 54.9% (2020) and 54.2% (2021) of participants were female, 43.0% (2020) and 43.1% (2021) were male, and sex/gender was unknown for 2.1% in 2020 and 2.7% in 2021.

In FY 2019 through FY 2021 (Tables 2 through 4), Whites had the highest rates of participation (48.7% in FY 2019, 51.6% in FY 2020, 50.0% in FY 2021). Black / African American participation was 26.5% in FY 2019, 23.6% in FY 2020, and 23.2% in FY 2021. In FY 2019, Asian participation was 3.3%; it was 3.0% in FY 2020 and 4.3% in FY 2021. American Indian / Alaska Native participation was 1.3% in FY 2019, 2.7% in FY 2020, and 2.5% in FY 2021. Race was unknown / not reported or refused identification for 12.0% of participants in FY 2019, 14.5% FY 2020, and 10.5% in FY 2021. The racial distribution of research participants remained consistent between FY 2019 and FY 2021. Hispanics represented 20.6% of enrolled participants in FY 2019, 17.7% in FY 2020, and 16.0% in FY 2021. Ethnicity was unknown / not reported for 7.3% in FY 2019, 12.5% in FY 2020, and 9.8% in FY 2021. Hispanic participation decreased during the reporting timeframe from FY 2019 to FY 2021.

Tables 5 through 7 display the total number of participants enrolled in NIDCR-supported Phase III clinical trials between FY 2019 and FY 2021. In FY 2019, 4469 participants were enrolled in seven Phase III clinical trials (Table 5); 4486 participants were enrolled in eight Phase III trials in FY 2020 (Table 6), and 3981 participants were enrolled in eight Phase III trials in FY 2021 (Table 7). All NIDCR-supported Phase III clinical trials are required to report the results of analyses by sex/gender and/or race/ethnicity to ClinicalTrials.gov. The majority of participants enrolled in these Phase III trials were female (65.3% in FY 2019, 65.0% in FY 2020, and 69.0% in FY 2021). In FY 2019, 48.1% of Phase III clinical trial participants were White, and White participation decreased to 38.0% in FY 2020 and 32.0% in FY 2021. Black / African Americans represented 35.7% of Phase III clinical trial participants in FY 2019. In FY 2020 and FY 2021, Black / African American participation in Phase III clinical trials increased and exceeded White Phase III trial participation. In FY 2020, 40.2% of Phase III trial participants were Black / African American, and participation increased to 47.5% of Phase III trial participants in FY 2021. Race was unknown or not reported by 6.2% of Phase III clinical trial participants in FY 2019, 11.0% in FY 2020, and 9.0% in FY 2021. Black / African American participation was higher in Phase III trials than in the aggregate clinical studies in FYs 2019 through 2021. Hispanic enrollment in Phase III trials was 10.4% in FY 2019, 13.1% in FY 2020, and 16.3% in FY 2021, representing an increase over the reporting timeframe; in FY 2021, Hispanic participation in Phase III trials was similar to Hispanic enrollment for all clinical research. Ethnicity was unknown or not reported by 28.3% of Phase III clinical trial participants in FY 2019, 9.7% in FY 2020, and 4.6% in FY 2021.

Inclusion enrollment data by Research, Condition, and Disease Categorization (RCDC) categories are available at the following link: <https://report.nih.gov/RISR/>.

Summary

- The number of NIDCR-supported clinical studies requiring enrollment monitoring has increased substantially from FY 2019 to FY 2021 (increase from 181 to 272), while the number of cumulative participants enrolled has decreased over the reporting timeframe. This discrepancy is likely due to COVID-related impacts upon clinical research activities.
- Substantial numbers of women were enrolled in NIDCR-supported clinical research studies (>54%), and this number was consistent over the reporting timeframe.
- The number of study participants identifying as Hispanic decreased somewhat from FY 2019 to FY 2021, while the number of individuals for whom ethnicity was unknown or not reported slightly increased. It is possible that COVID-related impacts have affected participation of Hispanic individuals in clinical research activities.
- The participation of study participants identifying as White has remained relatively stable from FY 2019 to FY 2021, with an increase in White participation relative to other racial categories occurring in FY 2020. Further, participation of Blacks / African Americans and those reporting more than one race decreased in FY 2020. These aberrations may represent racial differences in COVID issues impacting clinical research study participation.
- NIDCR supported 7-8 Phase III clinical trials on a variety of topical areas, including dental caries prevention and treatment, acute post-surgical pain management, timing of cleft lip/palate primary surgery, tobacco cessation, and reduction of dental anxiety.
- The majority of NIDCR-supported Phase III clinical trial participants were women (>65%), and this number increased over the reporting timeframe.
- Hispanic participation in NIDCR-supported Phase III trials increased over the reporting timeframe from approximately 10% to greater than 16%.
- Phase III clinical trial participants identifying as White decreased from FY 2019 to FY 2021, while Black / African American participation in Phase III clinical trials increased and exceeded White Phase III trial participation (FY 2021: 32% White vs 47.5% Black / African American).

Conclusions

- The FY 2019 through FY 2022 NIDCR inclusion data shows that substantial numbers of women were enrolled in NIDCR-supported clinical studies requiring enrollment monitoring. The racial and ethnic distribution of study participants reflects the US population in certain categories, but more work needs to be done to increase enrollment in other categories.
- Phase III clinical trial participation in FY 2019 through FY 2022 shows that NIDCR-supported Phase III trials have improved the racial and ethnic distribution of trial participants over the reporting timeframe.

Table 1. Total Inclusion Enrollment Reports (IERs) for Research Studies Receiving Funding between FY 2019 and FY 2021

Extramural and Intramural NIH-Defined Clinical Research
NATIONAL INSTITUTE OF DENTAL & CRANIOFACIAL RESEARCH

	FY 2019		FY 2020		FY 2021	
	Phase III trials*	Other Clinical studies**	Phase III trials*	Other Clinical studies**	Phase III trials*	Other Clinical studies**
Domestic site IERs	5	114	8	118	8	125
Foreign site IERs	2	2	0	2	0	8
IERs reporting combination of females, males, and/or unknown sex/gender	7	104	8	111	8	122
Female-only IERs	0	7	0	7	0	8
Male-only IERs	0	5	0	2	0	3
Total IERs with enrollment data	7	116	8	120	8	133
Total IERs without enrollment data	2	56	5	79	4	127
Total IERs	9	172	13	199	12	260

IER = Inclusion Enrollment Report, as reported by grantee institution

* An NIH-Defined Phase III Clinical Trial “usually involves several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with standard or control intervention or comparing two or more existing treatments.”

** Human subjects studies that are not a NIH-Defined Phase III Clinical Trial

**Table 2: FY2019 Aggregate Enrollment Data for Extramural and Intramural NIH-Defined Clinical Research
NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH
All Domestic and Foreign Sites, Total Reported Enrollment ***

	Total Enrollment by Race								Total Enrollment by Ethnicity			
	American Indian/ Alaska Native	Asian	Black/ African American	Hawaiian/ Pacific Islander	White	More than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	169	467	4,276	28	7,031	1,229	1,766	14,966	10,752	3,266	948	14,966
	0.6%	1.7%	15.5%	0.1%	25.5%	4.5%	6.4%	54.2%	39.0%	11.8%	3.4%	54.2%
Male	195	333	3,035	19	6,265	959	1,111	11,917	8,900	2,359	658	11,917
	0.7%	1.2%	11.0%	0.1%	22.7%	3.5%	4.0%	43.2%	32.3%	8.5%	2.4%	43.2%
Unknown	1	113	10	0	149	9	429	711	241	57	413	711
	0.0%	0.4%	0.0%	0.0%	0.5%	0.0%	1.6%	2.6%	0.9%	0.2%	1.5%	2.6%
Total	365	913	7,321	47	13,445	2,197	3,306	27,594	19,893	5,682	2,019	27,594
	1.3%	3.3%	26.5%	0.2%	48.7%	8.0%	12.0%	100.0%	72.1%	20.6%	7.3%	100.0%

* Number of Inclusion Enrollment Reports (IERs) with Enrollment Data: 123 of 181 total IERs in FY2019

**Table 3: FY2020 Aggregate Enrollment Data for Extramural and Intramural NIH-Defined Clinical Research
NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH
All Domestic and Foreign Sites, Total Reported Enrollment***

	Total Enrollment by Race								Total Enrollment by Ethnicity			
	American Indian/ Alaska Native	Asian	Black/ African American	Hawaiian/ Pacific Islander	White	More than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	291	292	2,689	25	4,686	472	1,357	9,812	6,808	1,935	1,069	9,812
	1.6%	1.6%	15.0%	0.1%	26.2%	2.6%	7.6%	54.9%	38.1%	10.8%	6.0%	54.9%
Male	197	241	1,518	12	4,523	308	892	7,691	5,652	1,210	829	7,691
	1.1%	1.3%	8.5%	0.1%	25.3%	1.7%	5.0%	43.0%	31.6%	6.8%	4.6%	43.0%
Unknown	1	2	11	0	18	2	337	371	25	11	335	371
	0.0%	0.0%	0.1%	0.0%	0.1%	0.0%	1.9%	2.1%	0.1%	0.1%	1.9%	2.1%
Total	489	535	4,218	37	9,227	782	2,586	17,874	12,485	3,156	2,233	17,874
	2.7%	3.0%	23.6%	0.2%	51.6%	4.4%	14.5%	100.0%	69.9%	17.7%	12.5%	100.0%

* Number of Inclusion Enrollment Reports (IERs) with Enrollment Data: 128 of 212 total IERs in FY2020

**Table 4: FY2021 Aggregate Enrollment Data for Extramural and Intramural NIH-Defined Clinical Research
NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH
All Domestic and Foreign Sites, Total Reported Enrollment***

Total Enrollment by Race									Total Enrollment by Ethnicity			
	American Indian/ Alaska Native	Asian	Black/ African American	Hawaiian/ Pacific Islander	White	More than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	304	516	3,205	29	5,511	1,176	1,071	11,812	8,982	1,898	932	11,812
	1.4%	2.4%	14.7%	0.1%	25.3%	5.4%	4.9%	54.2%	41.2%	8.7%	4.3%	54.2%
Male	219	406	1,819	21	5,352	818	757	9,392	7,100	1,564	728	9,392
	1.0%	1.9%	8.3%	0.1%	24.6%	3.8%	3.5%	43.1%	32.6%	7.2%	3.3%	43.1%
Unknown	12	11	34	6	38	20	465	586	92	25	469	586
	0.1%	0.1%	0.2%	0.0%	0.2%	0.1%	2.1%	2.7%	0.4%	0.1%	2.2%	2.7%
Total	535	933	5,058	56	10,901	2,014	2,293	21,790	16,174	3,487	2,129	21,790
	2.5%	4.3%	23.2%	0.3%	50.0%	9.2%	10.5%	100.0%	74.2%	16.0%	9.8%	100.0%

* Number of Inclusion Enrollment Reports (IERs) with Enrollment Data: 141 of 272 total IERs in FY2021

**Table 5: FY2019 Aggregate Enrollment Data for Extramural and Intramural NIH-Defined Phase III Clinical Trials
NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH
All Domestic and Foreign Sites, Total Reported Enrollment ***

Total Enrollment by Race									Total Enrollment by Ethnicity			
	American Indian/ Alaska Native	Asian	Black/ African American	Hawaiian/ Pacific Islander	White	More than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	5	49	1,112	3	1,354	222	172	2,917	1,895	281	741	2,917
	0.1%	1.1%	24.9%	0.1%	30.3%	5.0%	3.8%	65.3%	42.4%	6.3%	16.6%	65.3%
Male	3	26	481	1	787	132	87	1,517	844	155	518	1,517
	0.1%	0.6%	10.8%	0.0%	17.6%	3.0%	1.9%	33.9%	18.9%	3.5%	11.6%	33.9%
Unknown	1	0	1	0	10	3	20	35	0	31	4	35
	0.0%	0.0%	0.0%	0.0%	0.2%	0.1%	0.4%	0.8%	0.0%	0.7%	0.1%	0.8%
Total	9	75	1,594	4	2,151	357	279	4,469	2,739	467	1,263	4,469
	0.2%	1.7%	35.7%	0.1%	48.1%	8.0%	6.2%	100.0%	61.3%	10.4%	28.3%	100.0%

* Number of Inclusion Enrollment Records (IERs) with Enrollment Data: 7 of 9 total IERs in FY2019

**Table 6: FY2020 Aggregate Enrollment Data for Extramural and Intramural NIH-Defined Phase III Clinical Trials
NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH
All Domestic and Foreign Sites, Total Reported Enrollment***

Total Enrollment by Race									Total Enrollment by Ethnicity			
	American Indian/ Alaska Native	Asian	Black/ African American	Hawaiian/ Pacific Islander	White	More than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	9 0.2%	77 1.7%	1,248 27.8%	17 0.4%	1,072 23.9%	195 4.3%	296 6.6%	2,914 65.0%	2,294 51.1%	382 8.5%	238 5.3%	2,914 65.0%
Male	5 0.1%	57 1.3%	554 12.3%	5 0.1%	633 14.1%	119 2.7%	195 4.3%	1,568 35.0%	1,166 26.0%	207 4.6%	195 4.3%	1,568 35.0%
Unknown	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	0 0.0%	4 0.1%	4 0.1%	0 0.0%	0 0.0%	4 0.1%	4 0.1%
Total	14 0.3%	134 3.0%	1,802 40.2%	22 0.5%	1,705 38.0%	314 7.0%	495 11.0%	4,486 100.0%	3,460 77.1%	589 13.1%	437 9.7%	4,486 100.0%

* Number of Inclusion Enrollment Reports (IERs) with Enrollment Data: 8 of 13 total IERs in FY2020

**Table 7: FY2021 Aggregate Enrollment Data for Extramural and Intramural NIH-Defined Phase III Clinical Trials
NATIONAL INSTITUTE OF DENTAL AND CRANIOFACIAL RESEARCH
All Domestic and Foreign Sites, Total Reported Enrollment***

Total Enrollment by Race									Total Enrollment by Ethnicity			
	American Indian/ Alaska Native	Asian	Black/ African American	Hawaiian/ Pacific Islander	White	More than One Race	Unknown/ Not Reported	Total	Not Hispanic	Hispanic or Latino	Unknown/ Not Reported	Total
Female	9 0.2%	49 1.2%	1,327 33.3%	6 0.2%	867 21.8%	233 5.9%	256 6.4%	2,747 69.0%	2,186 54.9%	459 11.5%	102 2.6%	2,747 69.0%
Male	7 0.2%	29 0.7%	562 14.1%	2 0.1%	406 10.2%	123 3.1%	100 2.5%	1,229 30.9%	961 24.1%	190 4.8%	78 2.0%	1,229 30.9%
Unknown	0 0.0%	0 0.0%	0 0.0%	0 0.0%	1 0.0%	0 0.0%	4 0.1%	5 0.1%	1 0.0%	0 0.0%	4 0.1%	5 0.1%
Total	16 0.4%	78 2.0%	1,889 47.5%	8 0.2%	1,274 32.0%	356 8.9%	360 9.0%	3,981 100.0%	3,148 79.1%	649 16.3%	184 4.6%	3,981 100.0%

* Number of Inclusion Enrollment Reports (IERs) with Enrollment Data: 8 of 12 total IERs in FY2021

APPENDIX – ADDITIONAL TABLES

Appendix Table A: NIDCR 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	181	58	123	119	4	7	5	111
2020	212	84	128	126	2	7	2	119
2021	272	131	141	133	8	8	3	130

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

Appendix Table B1: NIDCR Enrollment for All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity

Fiscal Year	Sex Gender	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2019	Female	8,769	58.6	14,966	54.2	10,752	71.8	3,266	21.8	948	6.3
2019	Male	6,401	53.7	11,917	43.2	8,900	74.7	2,359	19.8	658	5.5
2019	Unknown	183	25.7	711	2.6	241	33.9	57	8.0	413	58.1
2020	Female	5,285	53.9	9,812	54.9	6,808	69.4	1,935	19.7	1,069	10.9
2020	Male	3,257	42.3	7,691	43.0	5,652	73.5	1,210	15.7	829	10.8
2020	Unknown	25	6.7	371	2.1	25	6.7	11	3.0	335	90.3
2021	Female	6,180	52.3	11,812	54.2	8,982	76.0	1,898	16.1	932	7.9
2021	Male	4,276	45.5	9,392	43.1	7,100	75.6	1,564	16.7	728	7.8
2021	Unknown	87	14.8	586	2.7	92	15.7	25	4.3	469	80.0

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

Appendix Table B2: NIDCR Enrollment for All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity (continued)

Fiscal Year	Sex Gender	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
2019	Female	169	1.1	467	3.1	4,276	28.6	28	0.2	7,031	47.0	1,229	8.2	1,766	11.8
2019	Male	195	1.6	333	2.8	3,035	25.5	19	0.2	6,265	52.6	959	8.0	1,111	9.3
2019	Unknown	1	0.1	113	15.9	10	1.4	0	0.0	149	21.0	9	1.3	429	60.3
2020	Female	291	3.0	292	3.0	2,689	27.4	25	0.3	4,686	47.8	472	4.8	1,357	13.8
2020	Male	197	2.6	241	3.1	1,518	19.7	12	0.2	4,523	58.8	308	4.0	892	11.6
2020	Unknown	1	0.3	2	0.5	11	3.0	0	0.0	18	4.9	2	0.5	337	90.8
2021	Female	304	2.6	516	4.4	3,205	27.1	29	0.2	5,511	46.7	1,176	10.0	1,071	9.1
2021	Male	219	2.3	406	4.3	1,819	19.4	21	0.2	5,352	57.0	818	8.7	757	8.1
2021	Unknown	12	2.0	11	1.9	34	5.8	6	1.0	38	6.5	20	3.4	465	79.4

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

Appendix Table C1: NIDCR Enrollment for All NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity

Fiscal Year	Sex Gender	Minority	% Minority	Total Enrollment	% Total	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2019	Female	1,555	53.3	2,917	65.3	1,895	65.0	281	9.6	741	25.4
2019	Male	731	48.2	1,517	33.9	844	55.6	155	10.2	518	34.1
2019	Unknown	31	88.6	35	0.8	0	0.0	31	88.6	4	11.4
2020	Female	1,794	61.6	2,914	65.0	2,294	78.7	382	13.1	238	8.2
2020	Male	875	55.8	1,568	35.0	1,166	74.4	207	13.2	195	12.4
2020	Unknown	0	0.0	4	0.1	0	0.0	0	0.0	4	100.0
2021	Female	1,898	69.1	2,747	69.0	2,186	79.6	459	16.7	102	3.7
2021	Male	827	67.3	1,229	30.9	961	78.2	190	15.5	78	6.3
2021	Unknown	0	0.0	5	0.1	1	20.0	0	0.0	4	80.0

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Appendix Table C2: NIDCR Enrollment for All NIH-Defined Extramural and Intramural Phase III Clinical Research, Sex/Gender by Race and Ethnicity (continued)

Fiscal Year	Sex Gender	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
2019	Female	5	0.2	49	1.7	1,112	38.1	3	0.1	1,354	46.4	222	7.6	172	5.9
2019	Male	3	0.2	26	1.7	481	31.7	1	0.1	787	51.9	132	8.7	87	5.7
2019	Unknown	1	2.9	0	0.0	1	2.9	0	0.0	10	28.6	3	8.6	20	57.1
2020	Female	9	0.3	77	2.6	1,248	42.8	17	0.6	1,072	36.8	195	6.7	296	10.2
2020	Male	5	0.3	57	3.6	554	35.3	5	0.3	633	40.4	119	7.6	195	12.4
2020	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	4	100.0
2021	Female	9	0.3	49	1.8	1,327	48.3	6	0.2	867	31.6	233	8.5	256	9.3
2021	Male	7	0.6	29	2.4	562	45.7	2	0.2	406	33.0	123	10.0	100	8.1
2021	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	1	20.0	0	0.0	4	80.0

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