

**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**

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# **The National Institute on Deafness and Other Communication Disorders Report: Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY2016 – FY2018**

## **I. Background/Overview**

### **A. Mission Statement**

The National Institute on Deafness and Other Communication Disorders (NIDCD) is one of the institutes and centers that comprise the National Institutes of Health (NIH). The NIH is the federal government's focal point for the support of biomedical research. The NIH's mission is to uncover new knowledge that will lead to better health for everyone. Simply described, the goal of NIH research is to acquire new knowledge to help prevent, detect, diagnose, and treat disease and disability. The NIH is part of the [U.S. Department of Health and Human Services](#).

Established in 1988, the NIDCD is mandated to conduct and support biomedical and behavioral research and research training in the normal and disordered processes of hearing, balance, taste, smell, voice, speech, and language. The Institute also conducts and supports research and research training related to disease prevention and health promotion; addresses special biomedical and behavioral problems associated with people who have communication impairments or disorders; and supports efforts to create devices which substitute for lost and impaired sensory and communication function.

It is estimated that more than 46 million people in the United States suffer some form of disordered communication. The NIDCD has focused national attention on disorders of human communication and has contributed to advances in biomedical and behavioral research that will improve the lives of millions of individuals with communication disorders. The NIDCD has made important contributions to the body of knowledge needed to help those who experience communication disorders and to advance research in all aspects of human communication.

The NIDCD accomplishes its mandate through its [intramural research program](#), which conducts basic and clinical research at the NIH, and through its [extramural research program](#). The NIDCD extramural program supports research grants, career development

awards, individual and institutional research training awards, center grants, and contracts to public and private research institutions and organizations. As a whole, the Institute supports and conducts more than 1,500 research projects. The Institute also conducts and supports research and research training in disease prevention and health promotion and the special biomedical and behavioral problems associated with people having communication impairments and disorders.

The NIDCD's extramural grant portfolio demonstrates a balance of basic and clinical research. The intramural research program spans a variety of topics, including, but not limited to, the identification and characterization of genes responsible for hereditary hearing impairment, genes associated with neoplasms affecting human communication, and treatment of voice disorders.

#### B. Institute Portfolio

As a whole, the Institute supports and conducts approximately 1,500 research grants, training awards, and Research & Development contracts. These programs take place within the research laboratories and clinic at the NIH campus in Bethesda, Maryland (intramural research), or in public and private institutions and organizations across the country and around the world (extramural research).

Research in the *Division of Intramural Research* includes basic and clinical research in several areas, with a primary interest in hearing and balance. The identification and characterization of genes linked to hereditary hearing impairment, stuttering, head-and-neck cancers and other conditions that affect human communication, and treatment of voice disorders, are also studied.

Extramural research and training programs are administered through the *Division of Extramural Activities* (DEA) and the *Division of Scientific Programs* (DSP). DEA staff provides grant management and processing for all of the Institute's extramural research projects and conduct initial scientific merit review of a large array of grant mechanisms. In DSP, program staff plan and direct NIDCD's extramural research grants, career development awards, individual and institutional research training awards, center grants, and contracts to public and private research institutions and organizations.

Both intramural and extramural research and training programs include the full spectrum of scientific activities including basic, clinical, and translational research. These studies answer fundamental scientific questions to prevent, screen, diagnose, and treat disorders of human communication.

## II. **Strategies for Ensuring Compliance**

### A. Peer Review

- Peer review process and how NIDCD works to resolve inclusion concerns
  - 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, 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. Applications with unacceptable inclusion plans receive a bar to funding; an award is not issued until an acceptable resolution is received.

### B. Program Monitoring and Grants Management Oversight

- The role of program and grants management in monitoring and oversight of inclusion
  - Prior to an award, program officials/program directors are responsible for reviewing the inclusion information in the application and indicating whether the plans are scientifically appropriate. Program staff monitor actual enrollment progress in annual progress reports and provide

consultation when necessary. For NIH-defined Phase III clinical trials, program officials/program directors and Data and Safety Monitoring Board members monitor the requirement for sex/gender and race/ethnicity analyses in applications and annual progress reports. Grants management staff ensure that appropriate terms and conditions of award are included in the Notice of Award, and that this information is appropriately documented in the official grant file.

#### C. Intramural

- Intramural procedures for monitoring and oversight of inclusion
  - All intramural clinical research studies require investigators to provide plans for the appropriate inclusion of women and minorities and/or a justification whenever representation is limited or absent, as part of their NIH protocol reviews. Intramural IRBs review intramural research protocols for compliance with inclusion guidelines and conduct annual monitoring. With each annual review and renewal, the investigator documents the number, gender, and race and ethnicity of those who were accrued during the past year; any issues with accrual are addressed at the annual review by the investigator and reviewed by the pertinent IRB. The Clinical Center's Office of Protocol Services (OPS) coordinates annual reporting of demographic participant data to the Office of Extramural Research (OER) and the Office of Research on Women's Health.

#### D. NIDCD training approaches

- Institute Program Officials/Program Directors and Scientific Review Officers attended the May 11, 2018 training, Ensuring Inclusion in NIH Clinical Research: Policies and Procedures for Grants and Contracts. Staff may access the archived training on the NIH staff intranet.

### III. Analysis and Interpretation of Data

- A. All inclusion tables in this report were provided by NIH Office of Extramural Research.(See Appendix, pg. 11). The following tables represent NIDCD-only enrollment data for fiscal years (FY) 2016 through 2018. All tables were generated and provided by the central NIH office charged with tracking and reporting inclusion

data. Table names and numbers were predetermined centrally. Only a subset of tables is contained in this NIDCD report for purposes of clarity.

The final Tables 5-1-1-C and 5-2-2-C contain the data in its most granular form while the earlier tables provide focused views of the data to highlight U.S. specific enrollments, Phase III Clinical Trial specific data, and specific views of the data filtered for sex/gender, race, and ethnicity. Some caveats to note about the NIDCD data are that there is only data from a single Phase III Clinical Trial grant (accruing subjects in FY 2016 through FY 2018); the intramural program had no Phase III studies during this timeframe. There were no foreign accrual sites for that clinical trial.

The following are brief comments and/or clarifications of the inclusion data for each of the tables:

#### Metrics Based on Inclusion Data Records

Table 2-1: Inclusion Data Records were renamed Inclusion Enrollment Reports (IERs) in 2018. Each IER contains inclusion data for a human subject research component of a project. Therefore, one project may have multiple IERs. "IERs without enrollment" means investigators planned to recruit human subjects but have not enrolled one yet. The NIDCD's total IERs increased from 306 to 375, i.e., 22.5% more, from FY 2016 to FY 2018.

#### Metrics Based on Aggregate Enrollment: Sex/Gender

Table 3-1-A: This table reflects combined enrollment numbers; from extramural and intramural projects. Extramural enrollment data are expected to fluctuate. Competitive grant segments generally run from three to five years. When large studies end, data associated with the studies will not be carried over to the next fiscal year, which explains a sudden decrease in the total enrollment. "Unknown" sex/gender means subjects did not report their sex/gender or investigators did not collect data. NIDCD enrollment figures fluctuate from year to year as expected. Females are well represented and slightly exceed the percentage of males during the last two years. Intramural enrollment data includes intramural clinical studies sponsored by NIDCD at the NIH Clinical Center, and studies at other U.S. and

international sites, where populations significantly affected with deafness and other communication disorders are found and studied with collaborating institutions.

Intramural data for Sex/Gender is relatively stable and comparable to extramural for percentage of females between 2016 (48.0%) and 2018 (47.4%).

#### U.S. Site Enrollment

Table 3-2-A: The U.S. sites include U.S. territories. While the total enrollment number fluctuates, the NIDCD staff monitor inclusion of females based on scientific aims for each study. The NIDCD aggregate numbers are strongly influenced by the extramural data. Combined extramural and intramural data show the percentage of females increased from 45.5% in FY 2016 to 50.1% in FY 2018. The extramural data show a similar pattern. Although not apparent from this table, U.S. Site enrollment for intramural studies decreased by nearly half between 2016 and 2018 due to completion of several Clinical Center and off-site population-based studies.

#### Total Enrollment: NIH-Defined Phase III Trials

Table 3-3: An NIH-defined Phase III clinical trial is a broadly-based prospective Phase III clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or controlled intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

All of the subjects represented in this table were enrolled in a single NIH-defined Phase III clinical trial grant accruing subjects in FY 2016 through FY 2018. That trial was performed in the U.S. The grant, DC 13995, "Efficacy of Tympanostomy Tubes for Children with Recurrent Acute Otitis Media," was active in FY 2016 through FY 2018. Valid analyses by sex/gender or race/ethnicity are required for DC 13995 when results are available. The higher percentage of males (64%) in the accrual table was anticipated and appropriate. The original grant application explained that boys are more frequently affected than girls and proposed to reflect that male preponderance in the subject accrual plans. Note, the data reported from this grant in FY2016 and

FY 2017 had clerical errors that were identified post submission. NIDCD staff worked with the grantee to rectify this problem and the FY 2018 numbers reflect the corrected cumulative numbers.

#### U.S. Site Minority Enrollment

Inclusion of minorities should reflect the prevalence of diseases and conditions. Therefore, the appropriate number of minorities varies depending on scientific aims for each project. As stated earlier, these aggregate numbers will fluctuate as completed grants no longer report enrollment numbers while new grants are only beginning enrollment.

#### Enrollment by Race

Table 4-1-1-C: Data are based on self-reporting by human subjects. Some subjects do not disclose their race, ethnicity, or sex and/or do not understand the racial and ethnic categories defined by the U.S. Office of Management and Budget. In this NIDCD data, 10 percent or more of participants often end up being categorized as Unknown.

Inclusion of minorities should reflect the prevalence of diseases and conditions. Therefore, the appropriate number of minorities varies depending on scientific aims for each project. The average percentage of minority subjects in all NIDCD clinical studies is 37.5% (averaged across three years). This number is about 8% higher than the average for NIDCD extramural studies. This difference is largely explained by the intramural's population-based studies of south Asian families with high frequency of deafness in Pakistan and India. Inclusion of these unique populations has provided these intramural studies with the statistical power to enable identification of numerous genes involved in hearing and deafness world-wide as well as in the affected international population.

#### Enrollment by Ethnicity

Table 4-1-1-D: Data are self-reported by those who identify themselves as Hispanic or Latino. Because some subjects do not understand the racial and ethnic categories defined by the U.S. Office of Management and Budget, the percentage of unknown/not reported can be higher than the percentage of Hispanic or Latino subjects enrolled in studies. In this NIDCD data, 10 percent or more of participants

often end up being categorized as Unknown. Inclusion of Hispanic and Latino subjects should reflect the prevalence of diseases and conditions. Therefore, the appropriate number of minorities varies depending on scientific aims for each project. The average enrollment of Hispanic or Latino subjects in the NIDCD studies is 5.9% (averaged across three years). Although not depicted in this table, the average for NIDCD extramural studies is 6.9%. The aggregate average percentage of enrollment by Hispanic ethnicity in intramural studies is quite low primarily due to inclusion of large population-based studies of south Asian cohorts in Pakistan and India with a high frequency of deafness.

Total Enrollment: All NIH-Defined Clinical Research, Sex/Gender, by Race and Ethnicity

Table 5-1-1-C: This master table is fairly complicated and represents a composite view of the focused points made in the prior tables. This composite view does allow one to discern that the enrolled minorities are proportionally represented in the female and male subject cohorts.

Total Enrollment: NIH-Defined Phase III Trials, Sex/Gender, by Race and Ethnicity

Table 5-2-2-C: As mentioned earlier, all of the subjects represented in this table were enrolled in a single NIH-defined Phase III clinical trial grant. Only the 2018 figures are accurate. The higher percentage of males (64%) in the accrual table was anticipated and appropriate. The original grant application explained that boys are more frequently affected than girls and proposed to reflect that male preponderance in the subject accrual plans. This more complicated presentation of the data reveals that the subjects have a fairly high minority representation both in the male (48.8%) and female (51.1%) cohorts. This was anticipated by the investigators who explained in the grant application that “the prevalence of otitis media in black lower-socioeconomic-status infants was as high as in white lower-socioeconomic-status infants, and slightly higher than in white middle-class infants.” Hence, the high percentage of minority subjects was scientifically justified.

## B. Research, Condition, and Disease Categorization

Congress requires the NIH to produce Research, Condition, and Disease Categorization (RCDC) reports. RCDC is a computerized process the NIH uses to categorize and report the amount it funded in each of the more than 280 reported categories of disease, condition, or research area. RCDC provides consistent and transparent information to the public about NIH-funded research, providing a complete list of all NIH-funded projects related to each category. Note that data on multi-disciplined studies may not reflect actual science because only one category can be assigned to a project. Of the 280 RCDC categories tracked by NIH, NIDCD is particularly engaged in the tracking/validation of the following categories: Aphasia, Assistive Technology, Autism, Dystonia, Neurofibromatosis, Otitis Media, Regenerative Medicine, Stroke, and Usher Syndrome. The link to the RCDC category reports: <https://report.nih.gov/RISR/>.

## IV. Additional information

### A. Include policy changes related to the 21<sup>st</sup> Century Cures Act

- The 21<sup>st</sup> 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 21<sup>st</sup> Century Cures Act amended the frequency of the Report of the NIH Director on the inclusion of women and minorities from biennial to triennial. Thus, this first triennial report

provides information on inclusion of participants in NIH clinical research from FY 2016 – 2018. Section IV of the [Report of the Advisory Committee on Research on Women's Health](#) includes IC reports on monitoring adherence to the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research for FY 2015 and 2016.

## **V. Summary**

The NIDCD inclusion data for FY 2016 – 2018 is on par with the trans-NIH data in terms of gender, racial, and ethnic distribution. Staff are diligent in the monitoring the enrollment projections and the accrual patterns over the life of the grants. NIDCD staff contact investigators to clarify and/or correct accrual data when necessary.

**Appendix:**

Note: The following tables represent NIDCD-only data. All tables were generated and provided by the central NIH office charged with tracking and reporting inclusion data. Table names and numbers were predetermined centrally. Only a subset of tables is contained in this NIDCD report for purposes of clarity.

**Section 2: Metrics Based on Inclusion Data Records (IERS)**

**Table 2-1. Total Inclusion Data Records (IERS) for NIH-Defined Extramural and Intramural Clinical Research Reported Between FY2016 and FY2018**

<b>Fiscal Year</b>	<b>Total IERS</b>	<b>IERS Without Enrollment</b>	<b>IERS With Enrollment</b>	<b>US Site IERS</b>	<b>Non-US Site IERS</b>	<b>Female Only IERS</b>	<b>Male Only IERS</b>	<b>IERS Excluding Male-only and Female-only*</b>
2016	306	21	285	271	14	3	6	276
2017	344	28	316	292	24	4	3	309
2018	375	47	328	296	32	5	3	320

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

### Section 3: Metrics Based on Aggregate Enrollment: Sex/Gender

Table 3-1-A. Total Enrollment for All NIH-Defined Extramural and Intramural Clinical Research Between FY2016 and FY2018

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown	Enrollment in Female-only	% Female-only	Enrollment in Male-only	% Male-only	Females, Excluding Female-only	% Females, Excluding Female-only	Males, Excluding Male-only	% Males, Excluding Male-only
2016	208,399	95,742	45.9	109,130	52.4	3,527	1.7	36	0.0	28	0.0	95,706	45.9	109,102	52.4
2017	112,109	58,491	52.2	50,337	44.9	3,281	2.9	8	0.0	45	0.0	58,483	52.2	50,292	44.9
2018	132,704	66,139	49.8	60,864	45.9	5,701	4.3	14	0.0	37	0.0	66,125	49.8	60,827	45.8

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 3-2-A. US Site Enrollment for All NIH-Defined Extramural and Intramural Clinical Research

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown	Enrollment in Female-only	% Female-only	Enrollment in Male-only	% Male-only	Females, Excluding Female-only	% Females, Excluding Female-only	Males, Excluding Male-only	% Males, Excluding Male-only
2016	181,877	82,798	45.5	96,182	52.9	2,897	1.6	36	0.0	28	0.0	82,762	45.5	96,154	52.9
2017	91,615	48,340	52.8	40,003	43.7	3,272	3.6	8	0.0	45	0.0	48,332	52.8	39,958	43.6
2018	103,465	51,812	50.1	45,968	44.4	5,685	5.5	14	0.0	29	0.0	51,798	50.1	45,939	44.4

## Total Enrollment: All NIH-Defined Phase III Trials

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

Fiscal Year	Total Enrollment	Total Females	% Females	Total Males	% Males	Total Unknown	% Unknown	Enrollment in Female-only	% Female-only	Enrollment in Male-only	% Male-only	Females, Excluding Female-only	% Females, Excluding Female-only	Males, Excluding Male-only	% Males, Excluding Male-only
2016	193	79	40.9	114	59.1	0	0.0	0	0.0	0	0.0	79	40.9	114	59.1
2017	675	294	43.6	381	56.4	0	0.0	0	0.0	0	0.0	294	43.6	381	56.4
2018	250	90	36.0	160	64.0	0	0.0	0	0.0	0	0.0	90	36.0	160	64.0

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

## Section 5: Enrollment by Race

Table 4-1-1-C. Total Enrollment of All NIH-Defined Clinical Research

Fiscal Year	Total Enrollment	No. Inclusion Data Records	Minority Enrollment	% Minority Enrollment	American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported
2016	208,399	306	68,167	32.7	418	0.2	32,590	15.6	26,491	12.7	348	0.2	120,339	57.7	2,877	1.4	25,336	12.2
2017	112,109	344	46,583	41.6	541	0.5	27,720	24.7	8,533	7.6	457	0.4	63,808	56.9	2,301	2.1	8,749	7.8
2018	132,704	375	50,616	38.1	548	0.4	30,380	22.9	9,316	7.0	287	0.2	72,553	54.7	2,577	1.9	17,043	12.8

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

## Section 6: Enrollment by Ethnicity

Table 4-1-1-D. Total Enrollment of All NIH-Defined Clinical Research

Fiscal Year	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
2016	175,752	84.3	6,704	3.2	25,943	12.4
2017	97,586	87.0	8,425	7.5	6,098	5.4
2018	107,975	81.4	9,155	6.9	15,574	11.7

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

## Total Enrollment: All NIH-Defined Clinical Research

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

Year	Sex Gender	Minority	% Minority	Total Enrollment	% Total	% American Indian Alaska Native		% Asian		% Black African American		% Native Hawaiian Islander		% White		% More Than One Race		% Unknown Not Reported	% Unknown Not Reported	Not Hispanic	% Not Hispanic	Hispanic Latino	% Hispanic Latino	Unknown Not Reported	% Unknown Not Reported
						Alaska Native	Alaska Native	Asian	Asian	African American	African American	Hawaiian Islander	Hawaiian Islander	White	White	Race	Race								
2016	Female	32,340	33.8	95,742	45.9	197	0.2	15,728	16.4	11,929	12.5	191	0.2	56,415	58.9	1,547	1.6	9,735	10.2	82,302	86.0	3,415	3.6	10,025	10.5
2016	Male	35,117	32.2	109,130	52.4	220	0.2	16,237	14.9	14,535	13.3	155	0.1	63,735	58.4	1,312	1.2	12,936	11.9	92,365	84.6	3,244	3.0	13,521	12.4
2016	Unknown	710	20.1	3,527	1.7	1	0.0	625	17.7	27	0.8	2	0.1	189	5.4	18	0.5	2,665	75.6	1,085	30.8	45	1.3	2,397	68.0
2017	Female	24,843	42.5	58,491	52.2	267	0.5	14,301	24.4	4,610	7.9	273	0.5	34,519	59.0	1,220	2.1	3,301	5.6	51,736	88.5	4,924	8.4	1,831	3.1
2017	Male	21,510	42.7	50,337	44.9	273	0.5	13,405	26.6	3,822	7.6	183	0.4	29,162	57.9	1,063	2.1	2,429	4.8	45,361	90.1	3,395	6.7	1,581	3.1
2017	Unknown	230	7.0	3,281	2.9	1	0.0	14	0.4	101	3.1	1	0.0	127	3.9	18	0.5	3,019	92.0	489	14.9	106	3.2	2,686	81.9
2018	Female	27,283	41.3	66,139	49.8	273	0.4	15,714	23.8	5,361	8.1	177	0.3	39,682	60.0	1,376	2.1	3,556	5.4	58,078	87.8	5,260	8.0	2,801	4.2
2018	Male	23,148	38.0	60,864	45.9	274	0.5	14,651	24.1	3,931	6.5	110	0.2	32,746	53.8	1,184	1.9	7,968	13.1	49,500	81.3	3,757	6.2	7,607	12.5
2018	Unknown	185	3.2	5,701	4.3	1	0.0	15	0.3	24	0.4	0	0.0	125	2.2	17	0.3	5,519	96.8	397	7.0	138	2.4	5,166	90.6

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

## US Site Enrollment: All NIH-Defined Clinical Research

Table 5-2-2-C. ALL 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	Unknown Not Reported	% Unknown Not Reported
						American Indian Alaska Native	% American Indian Alaska Native	Asian	% Asian	Black African American	% Black African American	Native Hawaiian Pacific Islander	% Native Hawaiian Pacific Islander	White	% White	More Than One Race	% More Than One Race	Unknown Not Reported	% Unknown Not Reported						
2016	Female	61	77.2	79	40.9	0	0.0	0	0.0	53	67.1	0	0.0	23	29.1	3	3.8	0	0.0	70	88.6	9	11.4	0	0.0
2016	Male	87	76.3	114	59.1	0	0.0	3	2.6	67	58.8	0	0.0	37	32.5	4	3.5	3	2.6	96	84.2	18	15.8	0	0.0
2016	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2017	Female	211	71.8	294	43.6	0	0.0	3	1.0	176	59.9	1	0.3	95	32.3	16	5.4	3	1.0	269	91.5	25	8.5	0	0.0
2017	Male	281	73.8	381	56.4	1	0.3	11	2.9	208	54.6	0	0.0	122	32.0	33	8.7	6	1.6	336	88.2	45	11.8	0	0.0
2017	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
2018	Female	46	51.1	90	36.0	0	0.0	0	0.0	33	36.7	1	1.1	49	54.4	7	7.8	0	0.0	80	88.9	10	11.1	0	0.0
2018	Male	78	48.8	160	64.0	1	0.6	5	3.1	50	31.3	0	0.0	91	56.9	11	6.9	2	1.3	141	88.1	19	11.9	0	0.0
2018	Unknown	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0