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CERTIFYING COMPLIANCE WITH THE

NIH POLICY ON INCLUSION GUIDELINES



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# **NINR Report**

**Monitoring Adherence to the NIH Policy on the  
Inclusion of Women and Minorities in Clinical  
Research as Reported in FY 2016 – FY 2018**

## NINR Report

### Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities in Clinical Research as Reported in FY 2016 – FY 2018

#### I. Background/Overview

The mission of the National Institute of Nursing Research (NINR) is to promote and improve the health of individuals, families, communities, and populations. NINR supports clinical, basic, and translational research to build the scientific foundation for clinical practice, prevent disease and disability, manage and eliminate symptoms caused by illness, enhance palliative and end-of-life care, and train the next generation of scientists.

Scientific focus areas to implement NINR's Strategic Plan include symptom science, wellness, self-management, and end-of-life and palliative care. NINR also supports the development of innovative strategies and new technologies and invests in training strategies and programs that support ongoing development of investigators at all career stages, including those from underrepresented communities. The focal areas of science help to inform health policy, develop best practices, and promote innovation in all areas of nursing science. NINR's Strategic Plan seeks to harness the strengths of nursing science to power an ambitious research agenda that will meet current and future healthcare needs and anticipate future health challenges and priorities.

**II. Strategies for Ensuring Compliance** - The implementation of inclusion guidelines involves the participation of review, program, policy, and grants management staff.

##### A. Peer Review

NINR Scientific Review Officers use [inclusion reviewer guidelines](#) to instruct reviewers to focus on the scientific acceptability of plans for inclusion on the basis of sex/gender, race, ethnicity, and age (i.e., whether the proposed composition of the study population is scientifically appropriate and/or justified) while preparing critiques of clinical research applications. Scientific acceptability is specifically addressed during review meeting discussions. 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. The NIH scientific peer review regulations (42 CFR Part 52h) specify that reviewers will assess the overall impact that the proposed project could have on the research field in light of the assessment of individual review criteria, and additional review criteria regarding planned inclusion on the basis of sex/gender, race, ethnicity, and age.

Unacceptable inclusion plans must be reflected in the priority score of the application and documented in the summary statement. In addition, the initial review groups make recommendations as to the acceptability of the proposed study population with respect to the inclusion policies. If issues are raised by the initial review group, NINR Program Officials work with principal investigators to ensure that the concerns are appropriately resolved 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

Prior to an award, Program Officials are responsible for reviewing the inclusion information in the application and indicating whether the plans are scientifically appropriate. Program Officials monitor actual enrollment progress in annual progress reports and provide consultation when necessary. For NIH-defined Phase III clinical trials, program officials/program directors 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

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. Describe IC training approaches

Institute Program Officials 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. In addition, NINR Program Officials and Grants Management Staff attended training on May 17, 2018 on the use of the new electronic system (HSS) designed to record data about inclusion.

## III. **Analysis and Interpretation of Data**

### A. Narrative summary

Data about the inclusion of women and minorities as subjects in clinical studies during fiscal years (FY) 2016 through 2018 are shown in appended tables. All the data were generated by an NIH reporting system. The total number of Inclusion Data Records, reflecting the number of clinical studies, is shown in Table 1. The total number of enrolled participants is shown in Table 2, and aggregate enrollment data with gender, race and ethnicity is shown in Table 3.

Tables 4-6 present NINR enrollment data broken down by sex/gender, race and ethnicity, respectively.

The overwhelming majority of NINR-funded clinical research is carried out by researchers funded through the NINR extramural program. The specific enrollment data for the extramural program are shown in Tables 7-9, and the corresponding data for intramural research protocols are presented in Tables 10-12. The enrollment data for NINR Phase III clinical trials are shown in Table 13. All of the small number of NINR-funded Phase III clinical trials were supported by the extramural program; there were no intramural Phase III research protocols during this time period.

B. Location of data tables - Data about the inclusion of women and minorities as subjects in clinical studies during fiscal years (FY) 2016 through 2018 are shown in appended tables

### C. Summary of the inclusion data presented in tables

#### *Aggregate data*

Table 1: Total Inclusion Data Records (IERs) for All NIH-Defined Clinical Research Reported Between FY 2016 and FY 2018 shows that the number of NINR protocols has increased steadily from 172 in FY 2016 to 289 in FY 2018 during this three-year period, the vast majority of which are enrolling participants at U.S. sites.

Table 2: Total Enrollment in All NIH-Defined Clinical Research Reported Between FY 2016 and FY 2018 shows the total number of participants in all NINR protocols for FYs 2016-2018. The enrollment has increased from 79,618 in FY 2016 to 279,760 in FY 2018. Most of the sharp increase between FY 2017 and FY 2018 is due to a single grant that is studying nursing documentation in large Electronic Health Record systems and enrolled nearly 200,000 participants in FY 2018 (R01 NR016941-02).

Table 3: Total Enrollment for All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity Reported Between FY 2016 and FY 2018, shows enrollment in all NINR protocols for FYs 2016-2018. This is aggregate annual data on the inclusion of women and minorities as subjects in clinical studies/research for all NINR-supported studies.

#### *Enrollment by Sex/Gender, Race or Ethnicity*

Table 4: Total Enrollment for All NIH-Defined Clinical Research Reported Between FY 2016 and FY 2018: Sex/Gender. NINR extramural studies consistently enroll substantially more females than males. However, from FY 2016 to FY 2018, the proportion of female participants has dropped from 82.4% to 63%. The proportion of single gender studies has declined dramatically since FY 2016, falling from 11.2% of studies in FY 2016 to 0.9% of studies in FY 2018. This likely reflects NIH's increased focus on "Sex as a Biological Variable" throughout the grant review process (see <https://grants.nih.gov/grants/guide/notice-files/not-od-15-102.html>). The proportion of female participants is higher than that of NIH funded studies overall, where 52.4% of participants were female in FY 2018.

Table 5: Total Enrollment of All NIH-Defined Clinical Research Reported Between FY 2016 and FY 2018; Race. The percent of minority enrollment in extramurally funded clinical studies has not varied substantially over the past three years, rising from 32.7% in FY 2016 to 36.0% in FY 2017 and then dipping to 34.2% in FY 2018. For the past two years, the overall minority participation has been higher than that of NIH-funded studies overall, where the proportion of minority participants was 28.3% in FY 2017 and 29.2% in FY 2018.

Table 6: Total Enrollment of All NIH-Defined Clinical Research Reported Between FY 2016 and FY 2018: Ethnicity. The percent of Hispanic enrollment in NINR-funded clinical studies has risen more than 25% over the past three years, from 7.0% in FY 2016 to 9.7% in FY 2018. The overall Hispanic participation is comparable to that of NIH-funded studies overall, where the proportion of Hispanic participants was 9.3% in FY 2018.

#### *Extramural program*

More than 99% of reported participants in NINR-funded clinical studies were enrolled in extramurally funded studies. The sex/gender, race and ethnicity data for extramural clinical research participants are shown in Tables 7, 8 and 9, respectively.

#### *Intramural program*

Fewer than 1000 individuals participated in clinical studies carried out by the NINR intramural program. The sex/gender, race and ethnicity data for extramural clinical research participants are shown in Tables 10, 11 and 12, respectively.

#### *Phase III Clinical Trial Data*

Table 13: Total Enrollment for All NIH-Defined Phase III Clinical Research, Sex/Gender by Race and Ethnicity Reported Between FY 2016 and FY 2018. NINR has funded a small number of Phase III Clinical Trials in the past three years, with 2 in FY 2016, 1 in FY 2017 and 4 in FY 2018. All were funded through the extramural program. The aggregate enrollment data for Phase III studies is shown in Table 16, broken down by gender, race and ethnicity.

D. Valid analyses for Phase III clinical trials - In FY 2018, NINR awarded one NIH-defined Phase III clinical trial, and it required valid analyses by sex/gender and race/ethnicity.

E. Participation by Disease/Condition category - This year, NIH began reporting participant enrollment data within the NIH-defined Reporting Categories in the RCDC system. The Research, Condition, and Disease Categorization (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. The data are available at <https://report.nih.gov/RISR/>.

#### **IV. Additional information**

##### 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.

## Appendices

**Table 1:** Total Inclusion Data Records (IERS) for All NIH-Defined Clinical Research Reported Between FY 2016 and FY 2018

**Table 2:** Total Enrollment in All NIH-Defined Clinical Research Reported Between FY 2016 and FY 2018

**Table 3:** Total Enrollment for All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity Reported Between FY 2016 and FY 2018

**Table 4:** Total Enrollment for All NIH-Defined Clinical Research Reported Between FY 2016 and FY 2018: Sex/Gender

**Table 5:** Total Enrollment of All NIH-Defined Clinical Research Reported Between FY 2016 and FY 2018; Race

**Table 6:** Total Enrollment of All NIH-Defined Clinical Research Reported Between FY 2016 and FY 2018: Ethnicity

**Table 7:** Total Enrollment for Extramural NIH-Defined Clinical Research Reported Between FY 2016 and FY 2018; Sex/Gender

**Table 8:** Total Enrollment for Extramural NIH-Defined Clinical Research Reported Between FY 2016 and FY 2018; Race

**Table 9:** Total Enrollment for Extramural NIH-Defined Clinical Research Reported Between FY 2016 and FY 2018; Ethnicity

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**Table 11:** Total Enrollment for Intramural NIH-Defined Clinical Research Reported Between FY 2016 and FY 2018; Race

**Table 12:** Total Enrollment for Intramural NIH-Defined Clinical Research Reported Between FY 2016 and FY 2018; Ethnicity

**Table 13:** Total Enrollment for All NIH-Defined Phase III Clinical Research, Sex/Gender by Race and Ethnicity Reported Between FY 2016 and FY 2018

**Table 1. Total Inclusion Data Records (IERs) for All NIH-Defined Clinical Research Reported Between FY 2016 and FY 2018**

<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	172	22	150	150	0	27	14	109
2017	250	34	216	211	5	33	11	172
2018	289	55	234	229	5	22	9	203

\*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. Total Enrollment for All NIH-Defined Clinical Research Reported Between FY 2016 and FY 2018**

<b>Fiscal Year</b>	<b>Total Enrollment</b>
2016	79,618
2017	91,157
2018	279,760

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. Total Enrollment for All NIH-Defined Clinical Research, Sex/Gender by Race and Ethnicity Reported Between FY 2016 and FY 2018**

Year Sex/Gender	2016 Female	2016 Male	2016 U	2017 Female	2017 Male	2017 U	2018 Female	2018 Male	2018 U
Minority	18,200	7,802	10	22,643	11,493	18	59,201	38,173	97
% Minority	27.7	56.9	3.9	31.3	62.6	5.4	33.6	37.0	21.1
Total Enrollment	65,639	13,722	257	72,452	18,371	334	176,170	103,131	459
% Total	82.4	17.2	0.3	79.5	20.2	0.4	63.0	36.9	0.2
American Indian/Alaska Native	218	52	0	323	105	0	490	215	0
% American Indian/Alaska Native	0.3	0.4	0.0	0.4	0.6	0.0	0.3	0.2	0.0
Asian	5,346	859	1	5,599	1,095	3	15,402	9,009	3
% Asian	8.1	6.3	0.4	7.7	6.0	0.9	8.7	8.7	0.7
Black/African American	7,897	5,625	1	10,955	8,745	7	30,239	21,291	51
% Black/African American	12.0	41.0	0.4	15.1	47.6	2.1	17.2	20.6	11.1
Native Hawaiian/Pacific Islander	91	34	0	112	55	0	157	82	0
% Native Hawaiian/Pacific Islander	0.1	0.2	0.0	0.2	0.3	0.0	0.1	0.1	0.0
White	49,398	6,583	3	52,062	7,719	9	116,621	63,187	12
% White	75.3	48.0	1.2	71.9	42.0	2.7	66.2	61.3	2.6
More Than One Race	1,123	181	4	1,658	264	0	1,351	271	3
% More Than One Race	1.7	1.3	1.6	2.3	1.4	0.0	0.8	0.3	0.7
Unknown/Not Reported	1,566	388	248	1,743	388	315	11,910	9,076	390
% Unknown/Not Reported	2.4	2.8	96.5	2.4	2.1	94.3	6.8	8.8	85.0
Not Hispanic	61,240	12,260	16	67,050	16,586	36	149,490	84,122	54
% Not Hispanic	93.3	89.3	6.2	92.5	90.3	10.8	84.9	81.6	11.8
Hispanic/Latino	4,233	1,342	8	5,182	1,629	8	16,022	11,158	88
% Hispanic/Latino	6.4	9.8	3.1	7.2	8.9	2.4	9.1	10.8	19.2
Unknown/Not Reported	166	120	233	220	156	290	10,658	7,851	317
% Unknown/Not Reported	0.3	0.9	90.7	0.3	0.8	86.8	6.0	7.6	69.1

Abbreviation: U - Unknown

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 4. Total Enrollment for All NIH-Defined Clinical Research Reported Between FY 2016 and FY 2018: Sex/Gender**

<b>Fiscal Year</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>Total Enrollment</b>	79,618	91,157	279,760
<b>Total Females</b>	65,639	72,452	176,170
<b>% Females</b>	82.4	79.5	63.0
<b>Total Males</b>	13,722	18,371	103,131
<b>% Males</b>	17.2	20.2	36.9
<b>Total Unknown</b>	257	334	459
<b>% Unknown</b>	0.3	0.4	0.2
<b>Enrollment in Female-only</b>	5,115	6,030	2,325
<b>% Female-only</b>	6.4	6.6	0.8
<b>Enrollment in Male-only</b>	3,857	5,357	348
<b>% Male-only</b>	4.8	5.9	0.1
<b>Females, Excluding Female-only</b>	60,524	66,422	173,845
<b>% Females, Excluding Female-only</b>	76.0	72.9	62.1
<b>Males, Excluding Male-only</b>	9,865	13,014	102,783
<b>% Males, Excluding Male-only</b>	12.4	14.3	36.7

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

**Table 5. Total Enrollment of All NIH-Defined Clinical Research Reported Between FY 2016 and FY 2018; Race.**

<b>Fiscal Year</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>Total Enrollment</b>	79,618	91,157	279,760
<b>No. Inclusion Data Records</b>	172	250	289
<b>Minority Enrollment</b>	26,012	34,154	97,471
<b>% Minority Enrollment</b>	32.7	37.5	34.8
<b>American Indian/Alaska Native</b>	270	428	705
<b>% American Indian/Alaska Native</b>	0.3	0.5	0.3
<b>Asian</b>	6,206	6,697	24,414
<b>% Asian</b>	7.8	7.3	8.7
<b>Black/African American</b>	13,523	19,707	51,581
<b>% Black/African American</b>	17.0	21.6	18.4
<b>Native Hawaiian/Pacific Islander</b>	125	167	239
<b>% Native Hawaiian/Pacific Islander</b>	0.2	0.2	0.1
<b>White</b>	55,984	59,790	179,820
<b>% White</b>	70.3	65.6	64.3
<b>More Than One Race</b>	1,308	1,922	1,625
<b>% More Than One Race</b>	1.6	2.1	0.6
<b>Unknown/Not Reported</b>	2,202	2,446	21,376
<b>% Unknown/Not Reported</b>	2.8	2.7	7.6

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

**Table 6. Total Enrollment of All NIH-Defined Clinical Research Reported Between FY 2016 and FY 2018: Ethnicity.**

<b>Fiscal Year</b>	<b>Not Hispanic</b>	<b>% Not Hispanic</b>	<b>Hispanic Latino</b>	<b>% Hispanic Latino</b>	<b>Unknown Not Reported</b>	<b>% Unknown Not Reported</b>
2016	73,516	92.3	5,583	7.0	519	0.7
2017	83,672	91.8	6,819	7.5	666	0.7
2018	233,666	83.5	27,268	9.7	18,826	6.7

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

**Table 7. Total Enrollment for Extramural NIH-Defined Clinical Research Reported Between FY 2016 and FY 2018; Sex/Gender**

<b>Fiscal Year</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>Total Enrollment</b>	78,938	90,373	278,799
<b>Total Females</b>	65,370	72,123	175,744
<b>% Females</b>	82.8	79.8	63.0
<b>Total Males</b>	13,400	18,005	102,685
<b>% Males</b>	17.0	19.9	36.8
<b>Total Unknown</b>	168	245	370
<b>% Unknown</b>	0.2	0.3	0.1
<b>Enrollment in Female-only</b>	5,060	5,974	2,270
<b>% Female-only</b>	6.4	6.6	0.8
<b>Enrollment in Male-only</b>	3,721	5,210	224
<b>% Male-only</b>	4.7	5.8	0.1
<b>Females, Excluding Female-only</b>	60,310	66,149	173,474
<b>% Females, Excluding Female-only</b>	76.4	73.2	62.2
<b>Males, Excluding Male-only</b>	9,679	12,795	102,461
<b>% Males, Excluding Male-only</b>	12.3	14.2	36.8

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 8. Total Enrollment for Extramural NIH-Defined Clinical Research Reported Between FY 2016 and FY 2018; Race.**

<b>Fiscal Year</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>Total Enrollment</b>	78,938	90,373	278,799
<b>No. Inclusion Data Records</b>	159	235	274
<b>Minority Enrollment</b>	25,805	33,924	97,220
<b>% Minority Enrollment</b>	32.7	37.5	34.9
<b>American Indian/Alaska Native</b>	270	428	705
<b>% American Indian/Alaska Native</b>	0.3	0.5	0.3
<b>Asian</b>	6,168	6,655	24,368
<b>% Asian</b>	7.8	7.4	8.7
<b>Black/African American</b>	13,400	19,574	51,438
<b>% Black/African American</b>	17.0	21.7	18.4
<b>Native Hawaiian/Pacific Islander</b>	125	167	239
<b>% Native Hawaiian/Pacific Islander</b>	0.2	0.2	0.1
<b>White</b>	55,591	59,309	179,187
<b>% White</b>	70.4	65.6	64.3
<b>More Than One Race</b>	1,286	1,902	1,598
<b>% More Than One Race</b>	1.6	2.1	0.6
<b>Unknown/Not Reported</b>	2,098	2,338	21,264
<b>% Unknown/Not Reported</b>	2.7	2.6	7.6

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

**Table 9. Total Enrollment for Extramural NIH-Defined Clinical Research Reported Between FY 2016 and FY 2018; Ethnicity**

<b>Fiscal Year</b>	<b>Not Hispanic</b>	<b>% Not Hispanic</b>	<b>Hispanic Latino</b>	<b>% Hispanic Latino</b>	<b>Unknown Not Reported</b>	<b>% Unknown Not Reported</b>
2016	72,969	92.4	5,546	7.0	423	0.5
2017	83,026	91.9	6,776	7.5	571	0.6
2018	232,855	83.5	27,219	9.8	18,725	6.7

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

**Table 10. Total Enrollment for Intramural NIH-Defined Clinical Research Reported Between FY 2016 and FY 2018; Sex/Gender**

<b>Fiscal Year</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>Total Enrollment</b>	680	784	961
<b>Total Females</b>	269	329	426
<b>% Females</b>	39.6	42.0	44.3
<b>Total Males</b>	322	366	446
<b>% Males</b>	47.4	46.7	46.4
<b>Total Unknown</b>	89	89	89
<b>% Unknown</b>	13.1	11.4	9.3
<b>Enrollment in Female-only</b>	55	56	55
<b>% Female-only</b>	8.1	7.1	5.7
<b>Enrollment in Male-only</b>	136	147	124
<b>% Male-only</b>	20.0	18.8	12.9
<b>Females, Excluding Female-only</b>	214	273	371
<b>% Females, Excluding Female-only</b>	31.5	34.8	38.6
<b>Males, Excluding Male-only</b>	186	219	322
<b>% Males, Excluding Male-only</b>	27.4	27.9	33.5

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 11. Total Enrollment for Intramural NIH-Defined Clinical Research Reported Between FY 2016 and FY 2018; Race**

<b>Fiscal Year</b>	<b>2016</b>	<b>2017</b>	<b>2018</b>
<b>Total Enrollment</b>	680	784	961
<b>No. Inclusion Data Records</b>	13	15	15
<b>Minority Enrollment</b>	207	230	251
<b>% Minority Enrollment</b>	30.4	29.3	26.1
<b>American Indian/Alaska Native</b>	0	0	0
<b>% American Indian/Alaska Native</b>	0.0	0.0	0.0
<b>Asian</b>	38	42	46
<b>% Asian</b>	5.6	5.4	4.8
<b>Black/African American</b>	123	133	143
<b>% Black/African American</b>	18.1	17.0	14.9
<b>Native Hawaiian/Pacific Islander</b>	0	0	0
<b>% Native Hawaiian/Pacific Islander</b>	0.0	0.0	0.0
<b>White</b>	393	481	633
<b>% White</b>	57.8	61.4	65.9
<b>More Than One Race</b>	22	20	27
<b>% More Than One Race</b>	3.2	2.6	2.8
<b>Unknown/Not Reported</b>	104	108	112
<b>% Unknown/Not Reported</b>	15.3	13.8	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.

**Table 12. Enrollment by Ethnicity: Total Enrollment of All NIH-Defined Intramural Clinical Research**

<b>Fiscal Year</b>	<b>Not Hispanic</b>	<b>% Not Hispanic</b>	<b>Hispanic Latino</b>	<b>% Hispanic Latino</b>	<b>Unknown Not Reported</b>	<b>% Unknown Not Reported</b>
2016	547	80.4	37	5.4	96	14.1
2017	646	82.4	43	5.5	95	12.1
2018	811	84.4	49	5.1	101	10.5

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 13. Total Enrollment for All NIH-Defined Phase III Clinical Research, Sex/Gender by Race and Ethnicity Reported Between FY 2016 and FY 2018**

Year Sex/Gender	2016			2017			2018		
	Female	Male	U	Female	Male	U	Female	Male	U
Minority	222	1	0	0	0	0	52	29	0
% Minority	79.6	14.3	0.0	0.0	0.0	0.0	22.6	16.6	0.0
Total Enrollment	279	7	0	0	0	0	230	175	0
% Total	97.6	2.4	0.0	0.0	0.0	0.0	56.8	43.2	0.0
American Indian/Alaska Native	7	0	0	0	0	0	0	1	0
% American Indian/Alaska Native	2.5	0.0	0.0	0.0	0.0	0.0	0.0	0.6	0.0
Asian	5	1	0	0	0	0	5	7	0
% Asian	1.8	14.3	0.0	0.0	0.0	0.0	2.2	4.0	0.0
Black/African American	208	0	0	0	0	0	37	15	0
% Black/African American	74.6	0.0	0.0	0.0	0.0	0.0	16.1	8.6	0.0
Native Hawaiian/Pacific Islander	0	0	0	0	0	0	0	0	0
% Native Hawaiian/Pacific Islander	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
White	51	6	0	0	0	0	179	145	0
% White	18.3	85.7	0.0	0.0	0.0	0.0	77.8	82.9	0.0
More Than One Race	1	0	0	0	0	0	3	2	0
% More Than One Race	0.4	0.0	0.0	0.0	0.0	0.0	1.3	1.1	0.0
Unknown/Not Reported	7	0	0	0	0	0	6	5	0
% Unknown/Not Reported	2.5	0.0	0.0	0.0	0.0	0.0	2.6	2.9	0.0
Not Hispanic	278	7	0	0	0	0	221	169	0
% Not Hispanic	99.6	100.0	0.0	0.0	0.0	0.0	96.1	96.6	0.0
Hispanic/Latino	1	0	0	0	0	0	9	4	0
% Hispanic/Latino	0.4	0.0	0.0	0.0	0.0	0.0	3.9	2.3	0.0
Unknown/Not Reported	0	0	0	0	0	0	0	2	0
% Unknown/Not Reported	0.0	0.0	0.0	0.0	0.0	0.0	0.0	1.1	0.0

Abbreviation: U - Unknown

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