

NIH Inclusion Update FY19-20

ACRWH | Dawn Corbett | April 14, 2021

Goals for Today

- Understand NIH policies regarding inclusion of women, racial and ethnic minorities, and individuals across the lifespan in NIH-funded clinical research
- Review status of Government Accountability Office (GAO) recommendations related to inclusion of women and minorities
- Review FY 2019FY 2020 data on the inclusion of women and minorities in NIH-funded clinical research
- Learn about NIH resources related to the inclusion of women, members of racial and ethnic minority groups, and individuals across the lifespan in NIH-funded research

Timeline of NIH Inclusion Policies

1986

- NIH establishes policy encouraging researchers to include women in studies

1993

- [PL103-43](#) requires inclusion of women and minorities in NIH clinical research

1998

- NIH issues [policy](#) requiring inclusion of children in NIH clinical research

2016

- 21st Century Cures Act includes new requirements for inclusion and reporting of participants based on sex/gender, race, ethnicity and age

2017

- NIH [requires](#) NIH-defined Phase 3 trials report results of sex/gender, race and ethnicity analyses in Clinicaltrials.gov

2019

- [Inclusion Across the Lifespan policy](#) becomes effective. First [NIH RCDC Inclusion Statistics Report](#) released.

Inclusion of Women and Minorities in NIH Research

- NIH policy requires:
 - Women and minorities be included in all NIH-funded clinical research studies unless there is a compelling rationale for exclusion
 - NIH-defined phase III clinical trials be designed to permit analysis by sex/gender, race and ethnicity and report results of analyses in Clinicaltrials.gov
 - Applicable* NIH-defined Phase III clinical trials must report results by sex/gender and/or race/ethnicity in Clinicaltrials.gov within 1 year of primary completion date
 - NIH to support outreach efforts to recruit and retain women, minorities, and their subpopulations



Inclusion Across the Lifespan

- Effective for applications submitted for due dates on or after **January 25, 2019** (and for contract solicitations issued and intramural studies initiated after that date).
 - See [NOT-OD-18-116](#)
- Requires individuals of all ages be included in NIH human subjects research unless there are scientific or ethical reasons not to do so
- Requires submission of individual-level data on participant age at enrollment in progress reports





United States Government Accountability Office

Report to Congressional Requesters

October 2015

NATIONAL INSTITUTES OF HEALTH

Better Oversight
Needed to Help
Ensure Continued
Progress Including
Women in Health
Research

GAO Recommendations

1. Make IC-level enrollment data readily available through public means **CLOSED**
2. Examine approaches for aggregating more detailed enrollment data at the disease and condition level **CLOSED**
3. Ensure that program officers have a means of recording their monitoring of awardees plans for and progress in conducting analysis of potential sex differences **CLOSED**
4. On a regular basis, systematically collect and analyze summary data regarding awardees' plans for analysis of potential sex differences **CLOSED**
5. Report on this summary data and analysis in its regular report to Congress on the inclusion of women in research **OPEN**

Summary of FY 2019 and FY 2020 NIH Clinical Research Inclusion Records

Table 2-1. Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Clinical Research

| Fiscal Year | Total Inclusion Records | Inclusion Records with Enrollment | US Site Inclusion Records | Non-US Site Inclusion Records | Female Only Inclusion Records | Male Only Inclusion Records |
|-------------|-------------------------|-----------------------------------|---------------------------|-------------------------------|-------------------------------|-----------------------------|
| 2019 | 20,976 | 14,225 | 12,819 | 1,406 | 1,542 | 738 |
| 2020 | 23,856 | 14,260 | 12,759 | 1,501 | 1,545 | 659 |

Table 2-2. Total Inclusion Data Records (IERs) for NIH-Defined Extramural and Intramural Phase III Trials

| Fiscal Year | Total Inclusion Records | Inclusion Records with Enrollment | US Site Inclusion Records | Non-US Site Inclusion Records | Female Only Inclusion Records | Male Only Inclusion Records |
|-------------|-------------------------|-----------------------------------|---------------------------|-------------------------------|-------------------------------|-----------------------------|
| 2019 | 664 | 404 | 335 | 69 | 41 | 12 |
| 2020 | 907 | 489 | 373 | 116 | 84 | 32 |

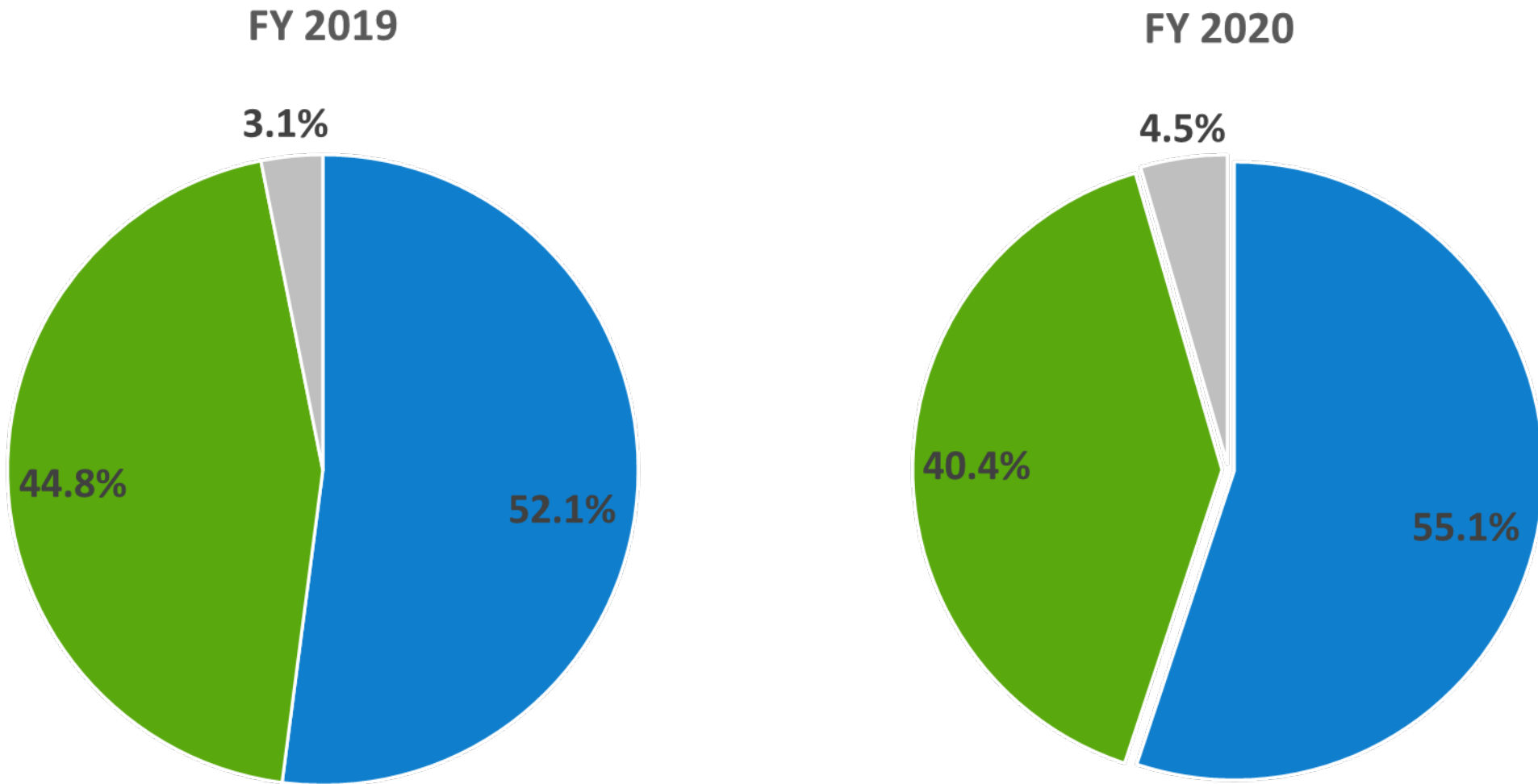
NIH-defined Phase 3 Sex/Gender, Race, and Ethnicity Analysis Requirements

Table 2-3. Valid Analysis Requirements for NIH-Defined Phase III Extramural Grants Reported Between Fiscal Years 2019 and 2020

| Fiscal Year | Total IERs | IERs Requiring Race Ethnicity Valid Analysis | % IERs Requiring Race Ethnicity Valid Analysis | IERs Requiring Sex Gender Valid Analysis | % IERs Requiring Sex Gender Valid Analysis |
|-------------|------------|--|--|--|--|
| 2019 | 664 | 622 | 93.7 | 625 | 94.1 |
| 2020 | 907 | 853 | 94.0 | 800 | 88.2 |

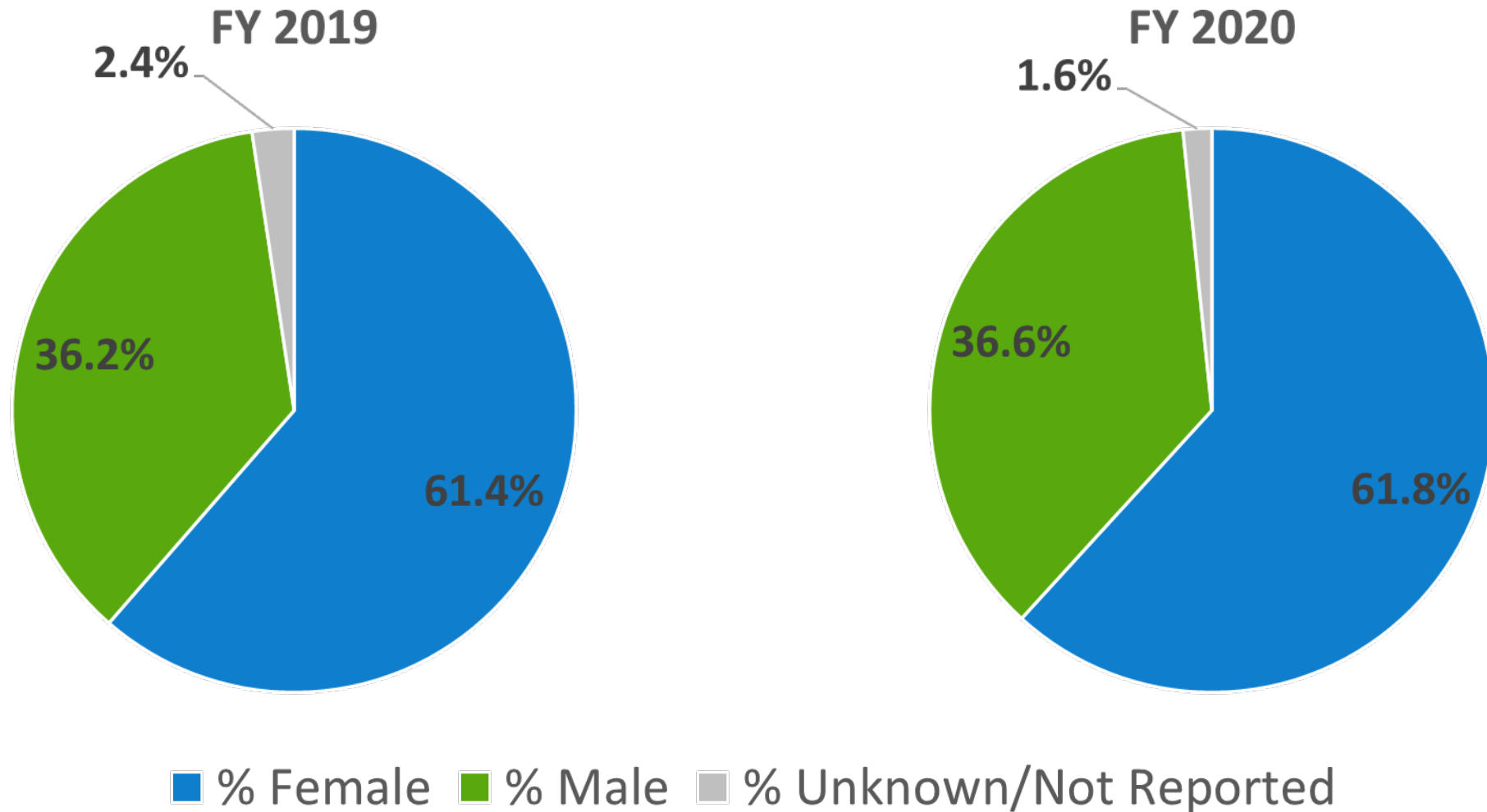
Plans for valid analysis methodologies specified in the project application are reported for all Inclusion Enrollment Records (IERs) , including IERs that have no reported actual enrollment at the time of reporting.

All Clinical Research Enrollment by Sex/Gender

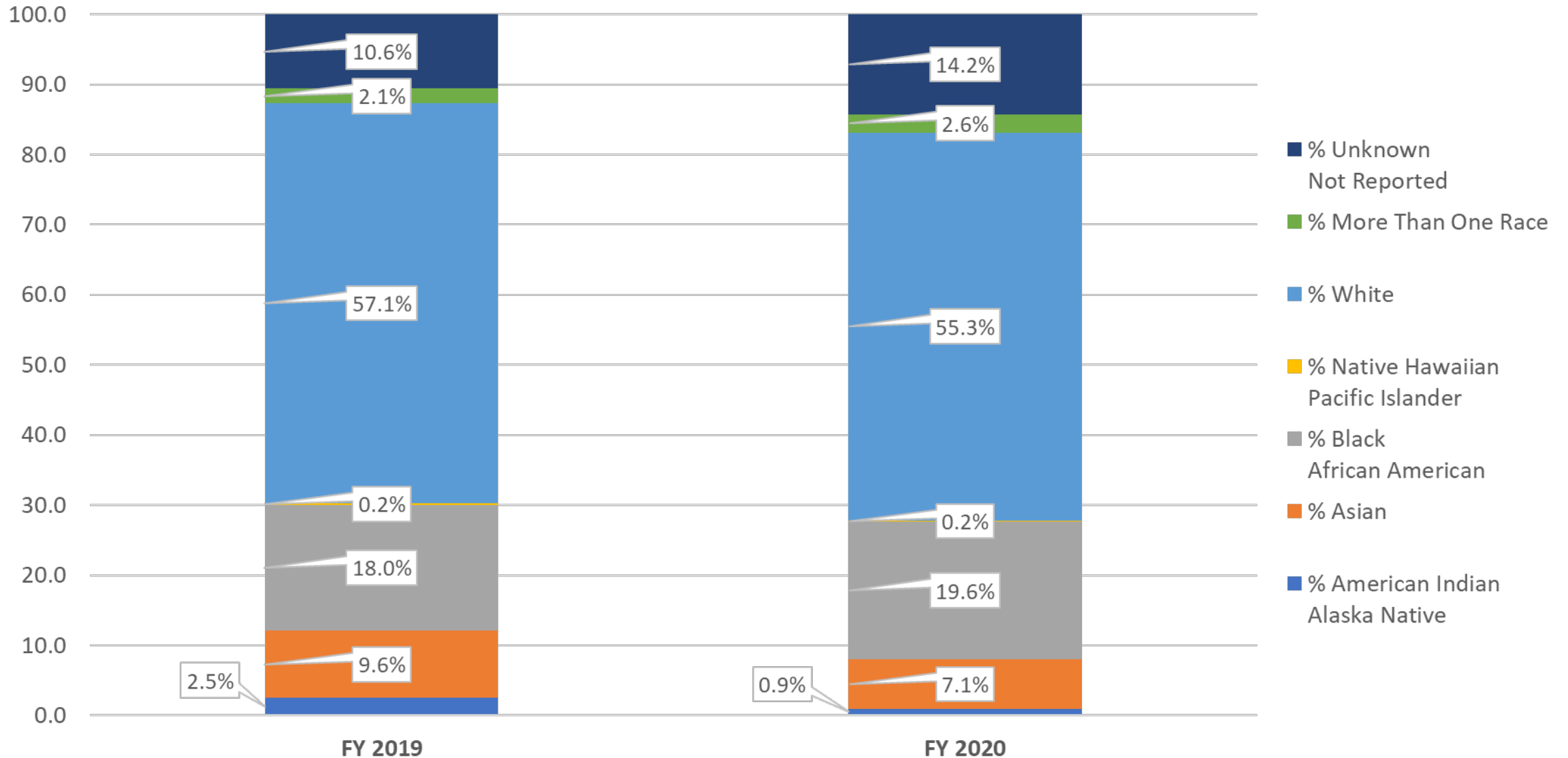


■ % Female ■ % Male ■ % Unknown/Not Reported

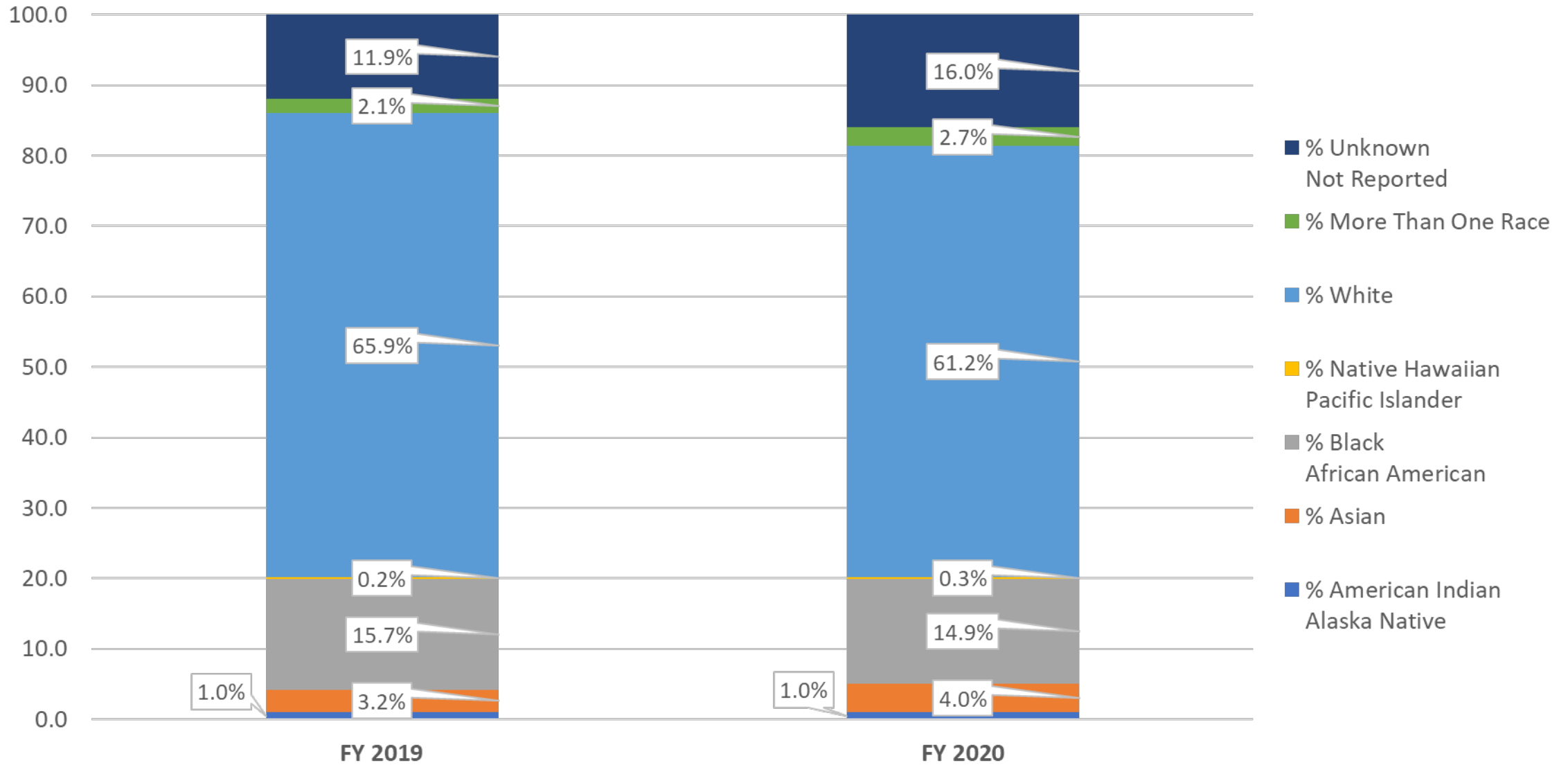
NIH-Defined Phase 3 Enrollment by Sex/Gender



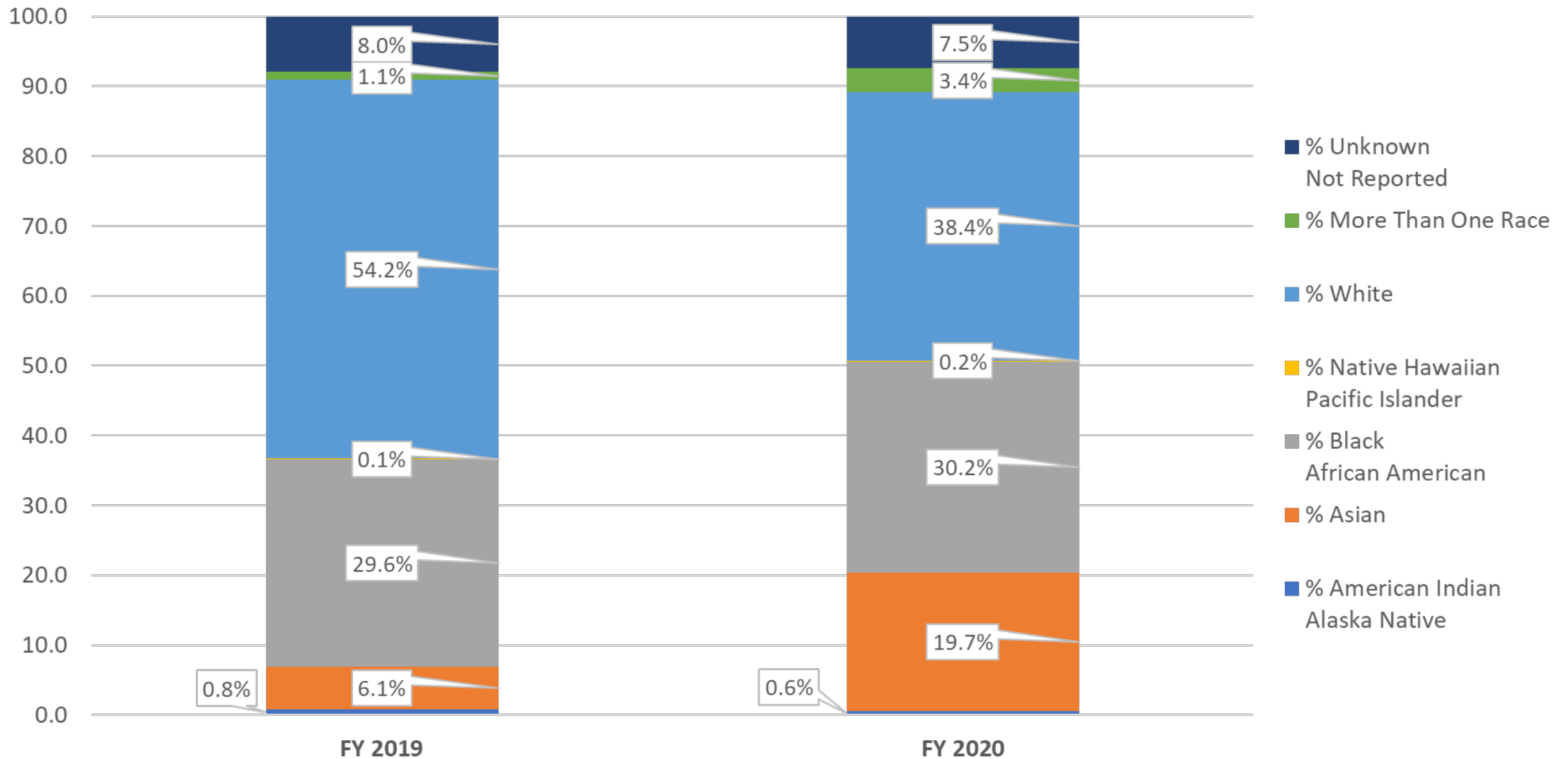
All Clinical Research Enrollment by Race



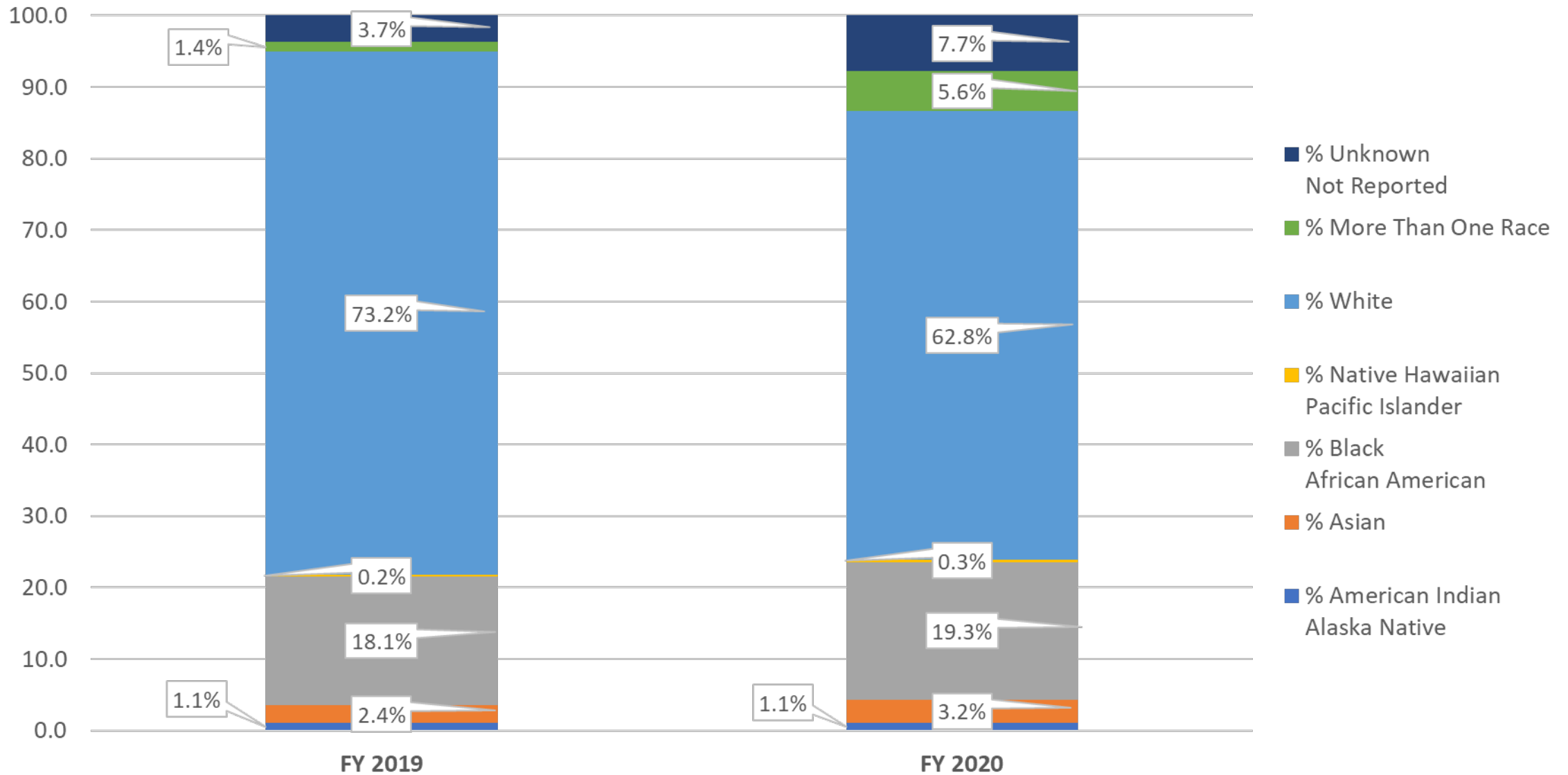
U.S. Only Clinical Research Enrollment by Race



NIH-Defined Phase 3 Enrollment by Race

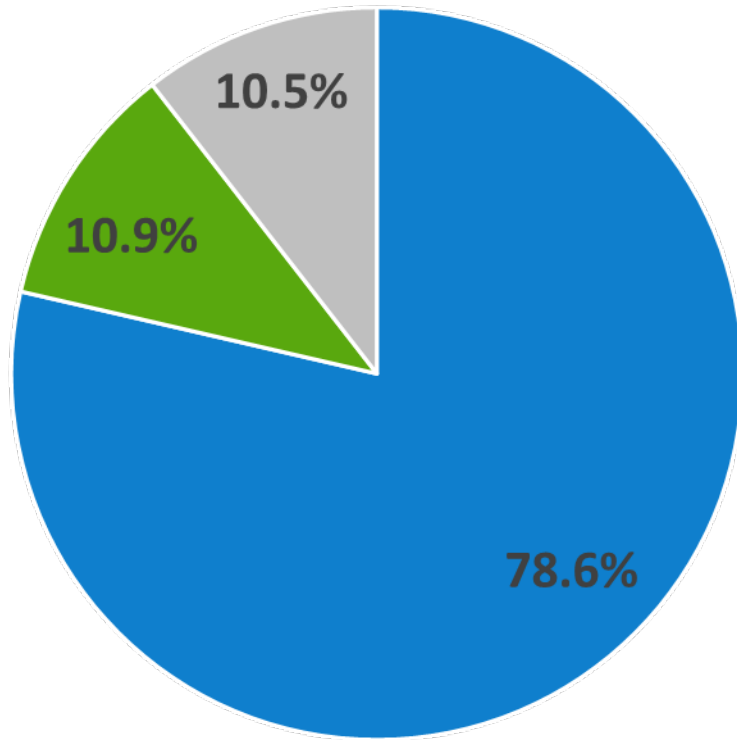


U.S. Only NIH-Defined Phase 3 Enrollment by Race

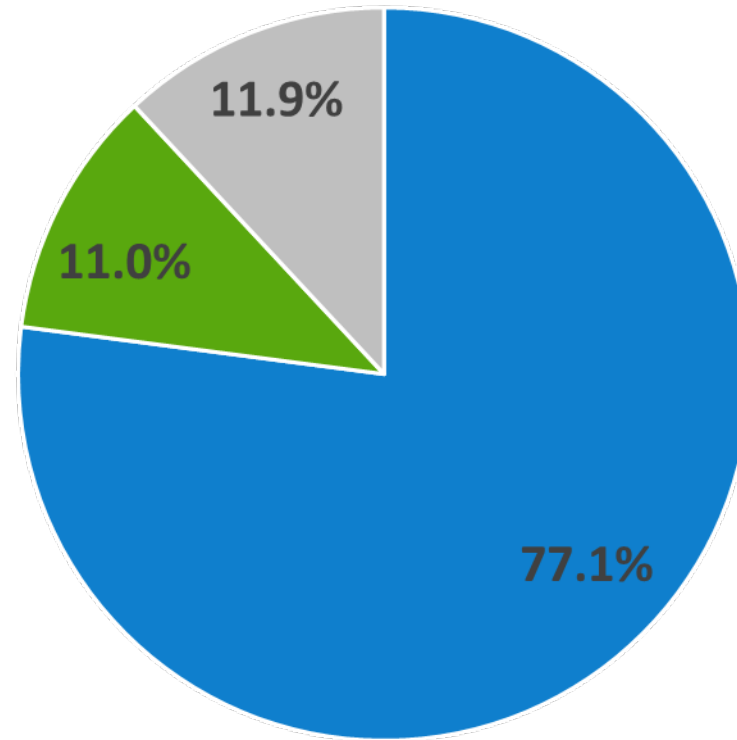


All Clinical Research Enrollment by Ethnicity

FY 2019



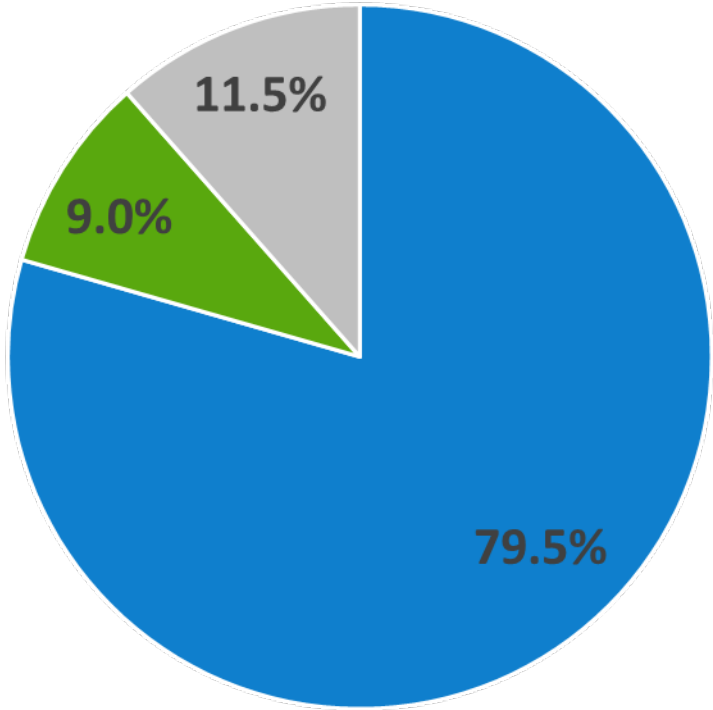
FY 2020



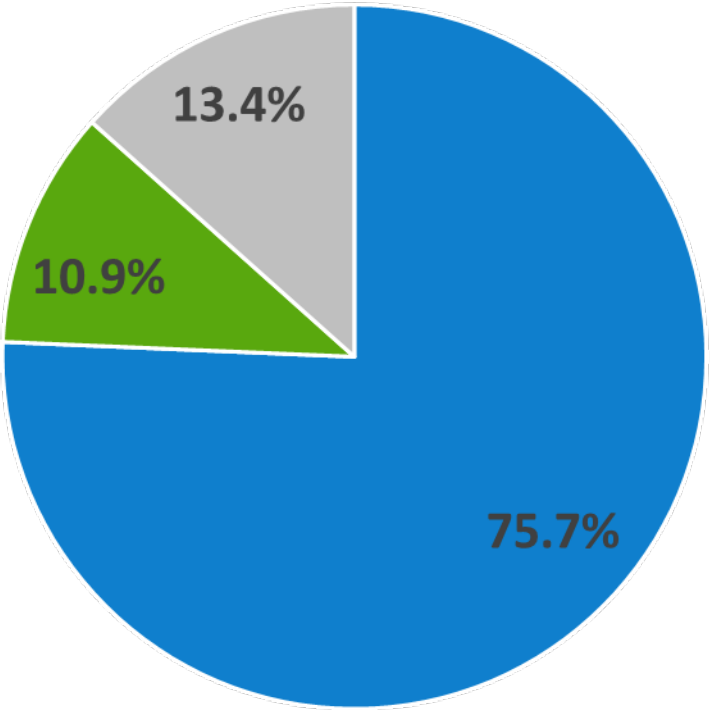
■ % Not Hispanic ■ % Hispanic or Latino ■ % Unknown/Not Reported

U.S. Only Clinical Research Enrollment by Ethnicity

FY 2019

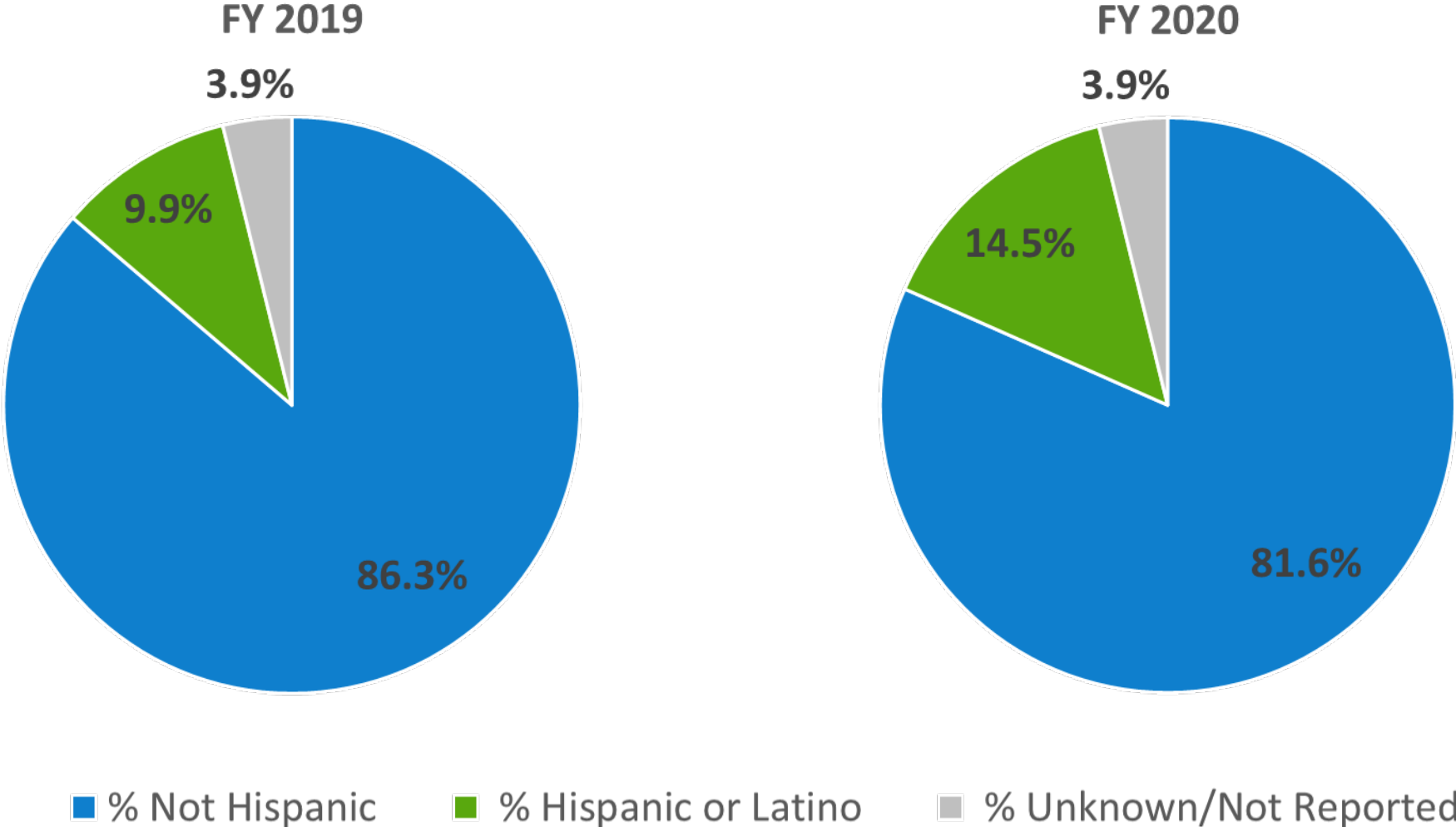


FY 2020

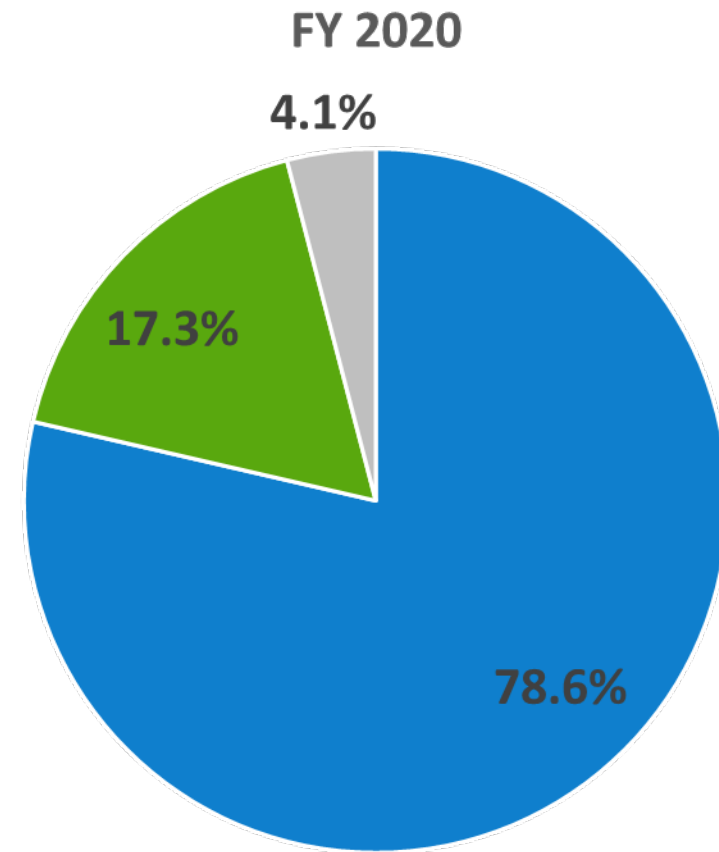
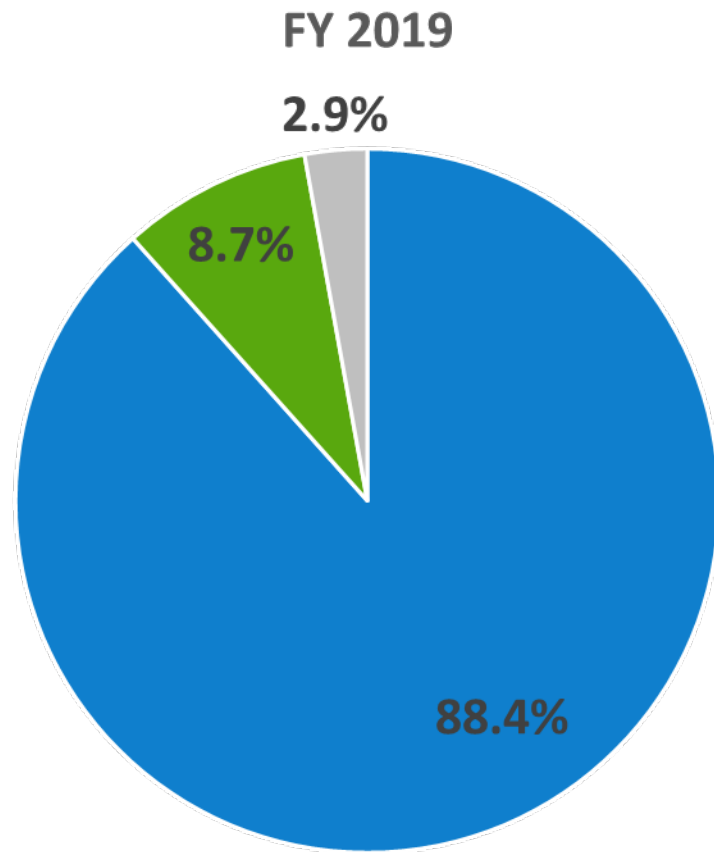


■ % Not Hispanic ■ % Hispanic or Latino ■ % Unknown/Not Reported

NIH-Defined Phase III Enrollment by Ethnicity



U.S. Only NIH-Defined Phase III Enrollment by Ethnicity



■ % Not Hispanic ■ % Hispanic or Latino ■ % Unknown/Not Reported

NIH Inclusion Statistics Report

This report displays the typical representation of participants in human subject studies enrolled in FY2018 projects associated with the listed research, condition, or disease category. Median percent participation is presented for each demographic variable.

Adjust the filters to view characteristics by race or ethnicity or to exclude single population studies. Drill down to explore more detailed statistics.

****Notes:** Research, condition, and disease categories are not mutually exclusive, so the same projects may appear in more than one category. All participants enrolled in a project's studies are included in all categories associated with that project. Individual research projects can be included in multiple categories so amounts depicted within each column of this table do not add up to the total participants enrolled in NIH-funded research.

Example: R01 IC12345 enrolled 300 participants and is associated with the Basic Behavioral and Social Science and Prevention categories. All 300 participants will appear in both the Basic Behavioral and Social Science and Prevention category totals for that IC.

| RCDC Category | Median % Female Participants | Median % Male Participants | Median % Participants of Unknown or Unreported Sex/Gender |
|-------------------------------------|------------------------------|----------------------------|---|
| ALS | 45% | 55% | <1% |
| Acquired Cognitive Impairment | 55% | 44% | <1% |
| Acute Respiratory Distress Syndrome | 45% | 55% | <1% |
| Adolescent Sexual Activity | 52% | 48% | <1% |
| Agent Orange & Dioxin | 76% | 24% | <1% |
| Aging | 56% | 43% | <1% |
| Alcoholism, Alcohol Use and Health | 44% | 54% | <1% |
| Allergic Rhinitis (Hay Fever) | 49% | 50% | <1% |
| Alzheimer's Disease | 50% | 49% | <1% |

Available at <https://report.nih.gov/risr/#/>

Training

Entering Inclusion Data Using the Participant Level Data Template

February 26, 2020

| | White | More than One Race | Total |
|--|-------|--------------------|-------|
| | 2 | 3 | 3 |
| | 6 | | 14 |

| Racial Categories | Not Hispanic or Latino | | Hispanic or Latino | | | Unknown/Not Reported Ethnicity | | | Total |
|---|------------------------|------|----------------------|--------|------|--------------------------------|--------|------|-------|
| | Female | Male | Unknown/Not Reported | Female | Male | Unknown/Not Reported | Female | Male | |
| American Indian/Alaska Native | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Asian | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Black or African American | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| White | 0 | 0 | 0 | 4 | 0 | 0 | 0 | 0 | 4 |
| More than One Race | 0 | 4 | 0 | 0 | 0 | 0 | 0 | 0 | 4 |
| Unknown or Not Reported | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 4 |
| Total | 0 | 12 | 0 | 4 | 0 | 0 | 0 | 0 | 20 |

Need Help?
Participant level data file (CSV):
[Download Participant Level Data Template](#) [Upload Participant Level Data Attachment](#) [Download Current Participant Level Data](#)

To enter data using the template, scroll to the bottom of the screen.

<https://youtu.be/IHYrdIPfKVo>

Including Diverse Populations in NIH-funded Clinical Research

October 30, 2020

Including Diverse Populations in NIH-funded Clinical Research

Dawn Corbett, MPH
NIH Inclusion Policy Officer
Division of Human Subjects Research, Office of Extramural Research

NIH Virtual Seminar
October 30, 2020

https://youtu.be/fYoNnIt_f1o

Resources

- NIH Office of Extramural Research Inclusion of Women and Minorities Website
 - https://grants.nih.gov/policy/inclusion/women_and-minorities.htm
- NIH Office of Extramural Research Inclusion Across the Lifespan Website
 - <https://grants.nih.gov/grants/funding/lifespan/lifespan.htm>
- Inclusion RePORT page
 - https://report.nih.gov/research/inclusion_women-and-minorities-clinical-research#/
- Human Subjects System (HSS) Training Page
 - <https://era.nih.gov/help-tutorials/era-training-hss.htm>