

NIH Inclusion Updates

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ACRWH

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Inclusion of Women and Minorities in NIH Research

- Women and members of racial and ethnic minority groups must be included in all NIH-funded clinical research studies unless there is a compelling rationale for exclusion ([NOT-OD-18-014](#))
- NIH-defined phase 3 clinical trials must be designed to permit analysis by sex/gender, race and ethnicity
 - Applicable NIH-defined phase 3 clinical trials must report results of analyses in Clinicaltrials.gov



Inclusion Across the Lifespan



- Individuals of all ages must be included in NIH human subjects research unless there are scientific or ethical reasons not to do so ([NOT-OD-18-116](#))
 - 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)
- Submission of individual-level data on participant sex/gender, race, ethnicity and age at enrollment in progress reports required



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

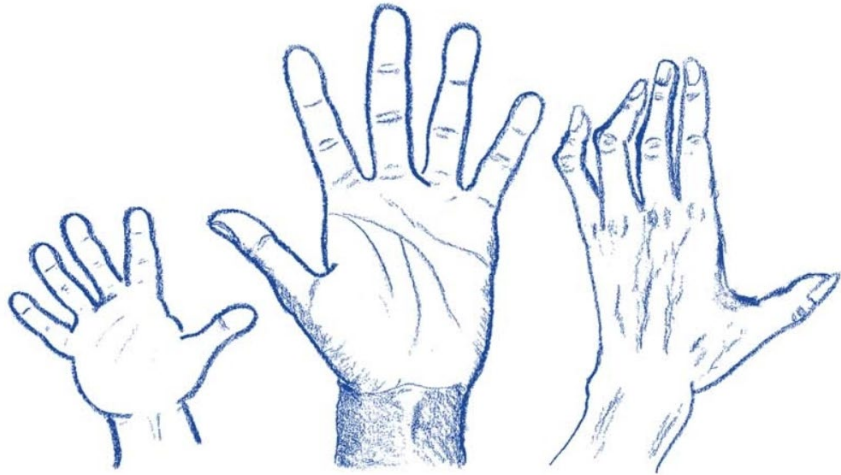


National Institutes of Health
Office of Extramural Research

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 **CLOSED**

NIH Inclusion Across the Lifespan II Workshop, September 2, 2020

NIH Inclusion Across the Lifespan II



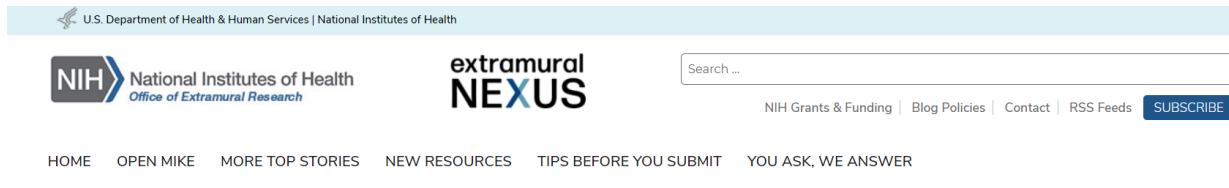
Report available on Inclusion Across the Lifespan website

<https://grants.nih.gov/policy/inclusion/lifespan.htm>

Recurrent Themes

- Select **trial outcomes** that reflect participant concerns
- Limit use of unnecessary **inclusion/exclusion criteria**
- Adequately weigh **risks of excluding** groups—like pregnant women and children—with that of their participation
- **Minimize** participant and caregiver **burden**
- Consider the **diversity** of individuals within a given group (e.g. size, comorbidities, diet, cognitive status)
- Regularly **assess recruitment and retention** and make modifications as needed

Communications and Training



Some Thoughts Following the NIH Inclusion Across the Lifespan 2 Workshop

By Mike Lauer

Posted December 10, 2020

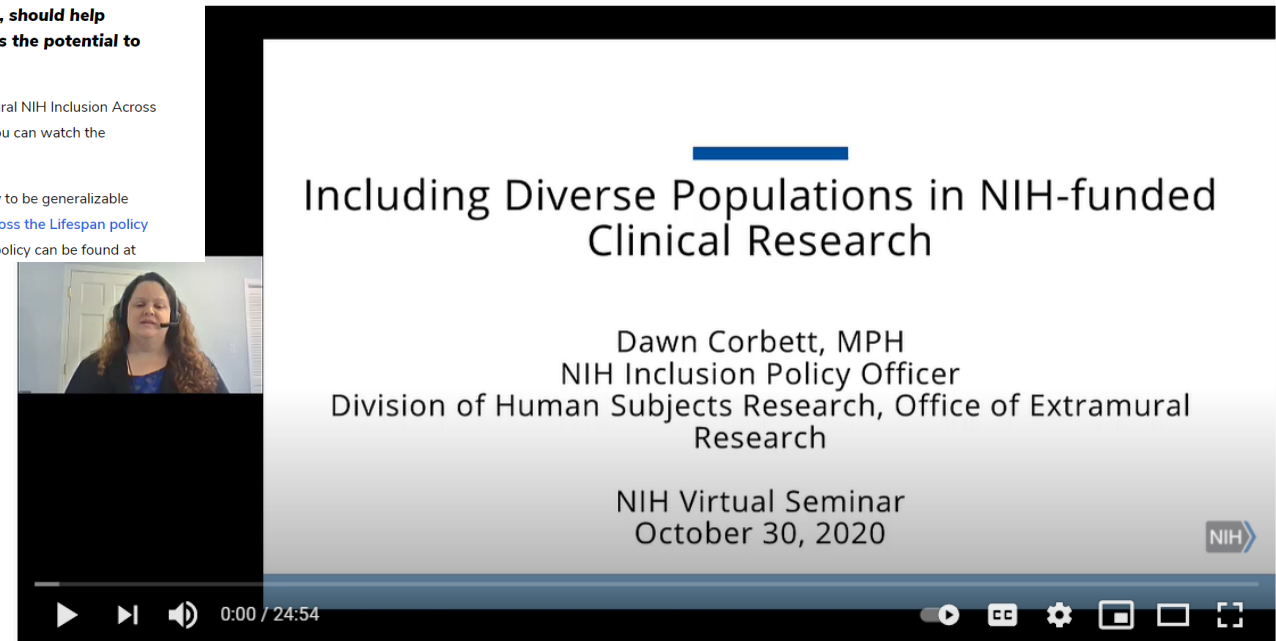


"The [NIH Inclusion Across the Lifespan] policy, and the review and reporting requirements associated with it, should help ensure that children and older adults are not inappropriately excluded from clinical studies. The policy also has the potential to provide a more robust understanding of the full spectrum of participants recruited into clinical studies."

Together with my NIH colleagues Drs. Marie Bernard and Janine Clayton, we made this point in a [2018 JAMA opinion piece](#) following the inaugural NIH Inclusion Across the Lifespan workshop. Fast forward, we revisited this issue at the [NIH's Inclusion Across the Lifespan 2 workshop](#) held this past September. You can watch the [videocast here](#). The [report](#) covering the event was posted today, and I wanted to share some of my takeaways.

Including appropriate participants in research leads to sound science that informs clinical practice. It also means that study results are more likely to be generalizable across populations. We remain [committed](#) to these inclusion principles, including as it comes to persons of different ages. The [NIH Inclusion Across the Lifespan policy](#) requires individuals of all ages be included in clinical research studies unless there are scientific or ethical reasons to exclude them. More on the policy can be found at

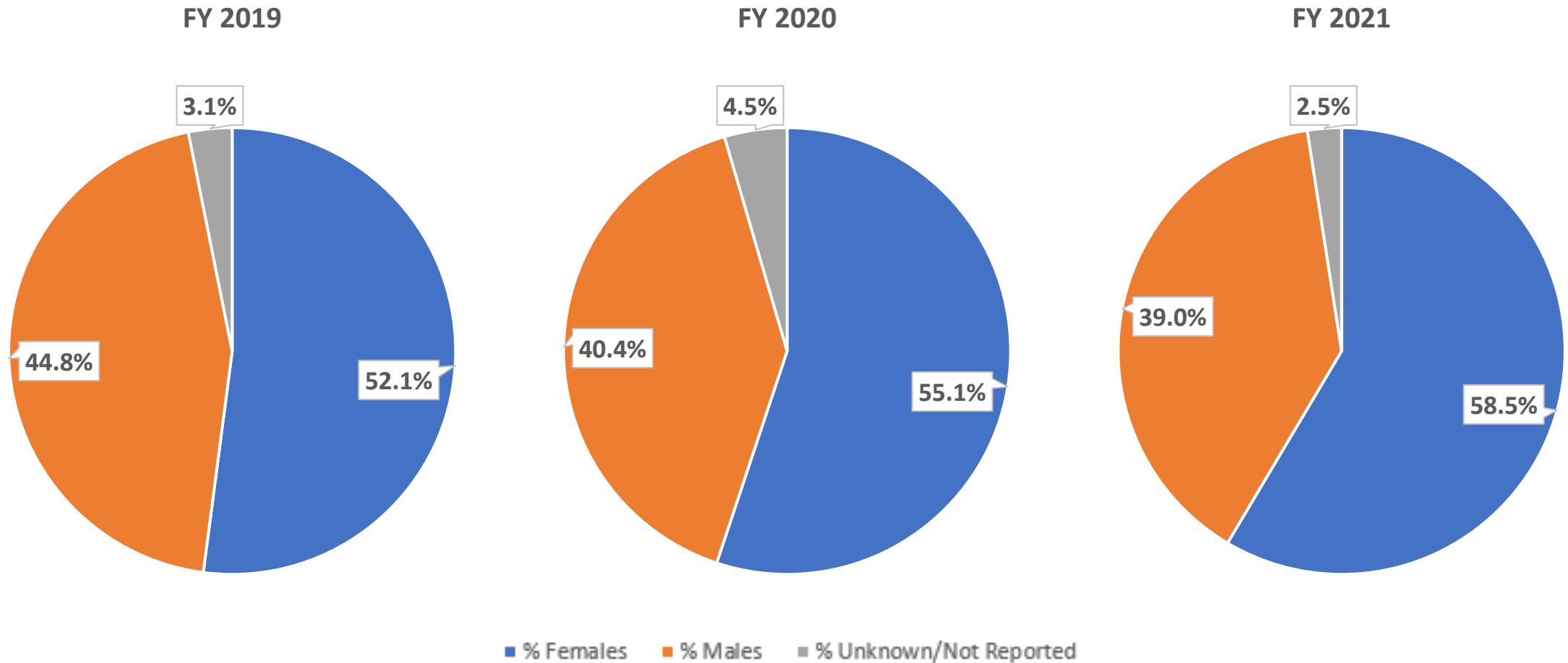
<https://nexus.od.nih.gov/all/2020/12/10/some-thoughts-following-the-nih-inclusion-across-the-lifespan-2-workshop/>



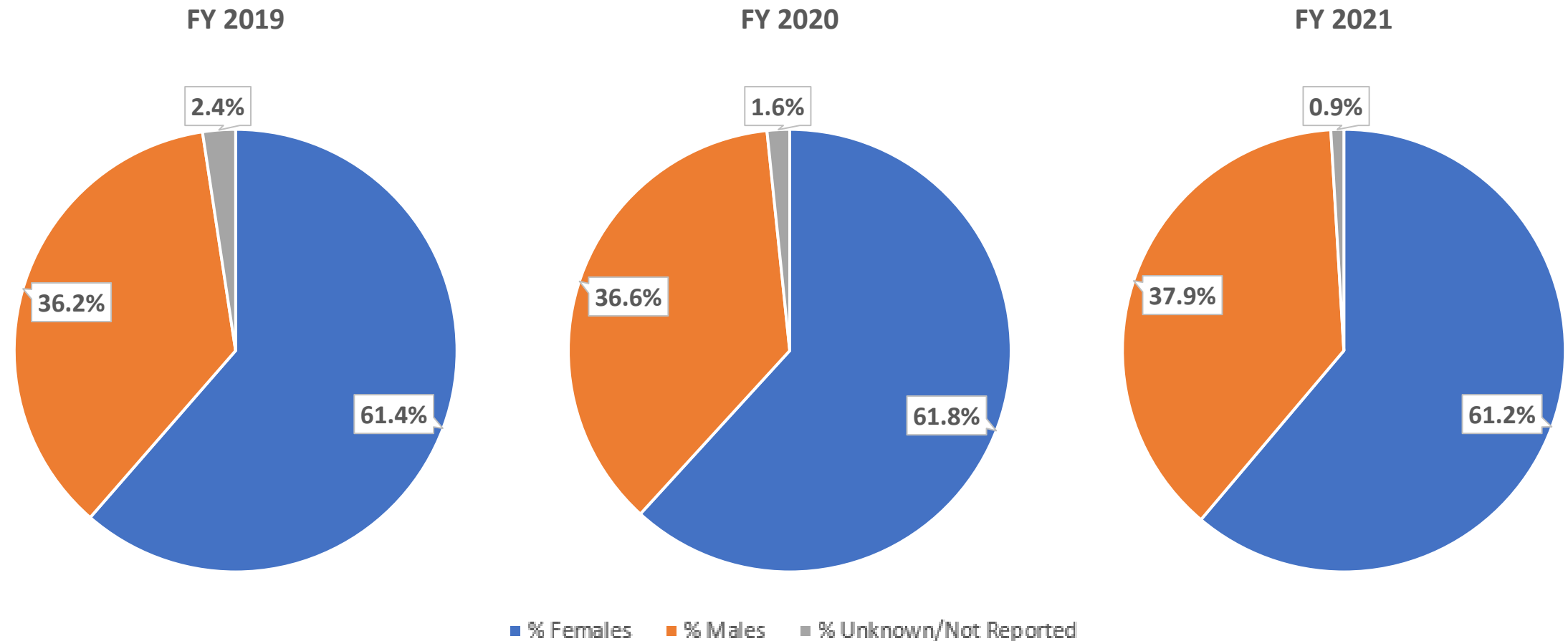
https://www.youtube.com/watch?v=fYoNnlt_f1o



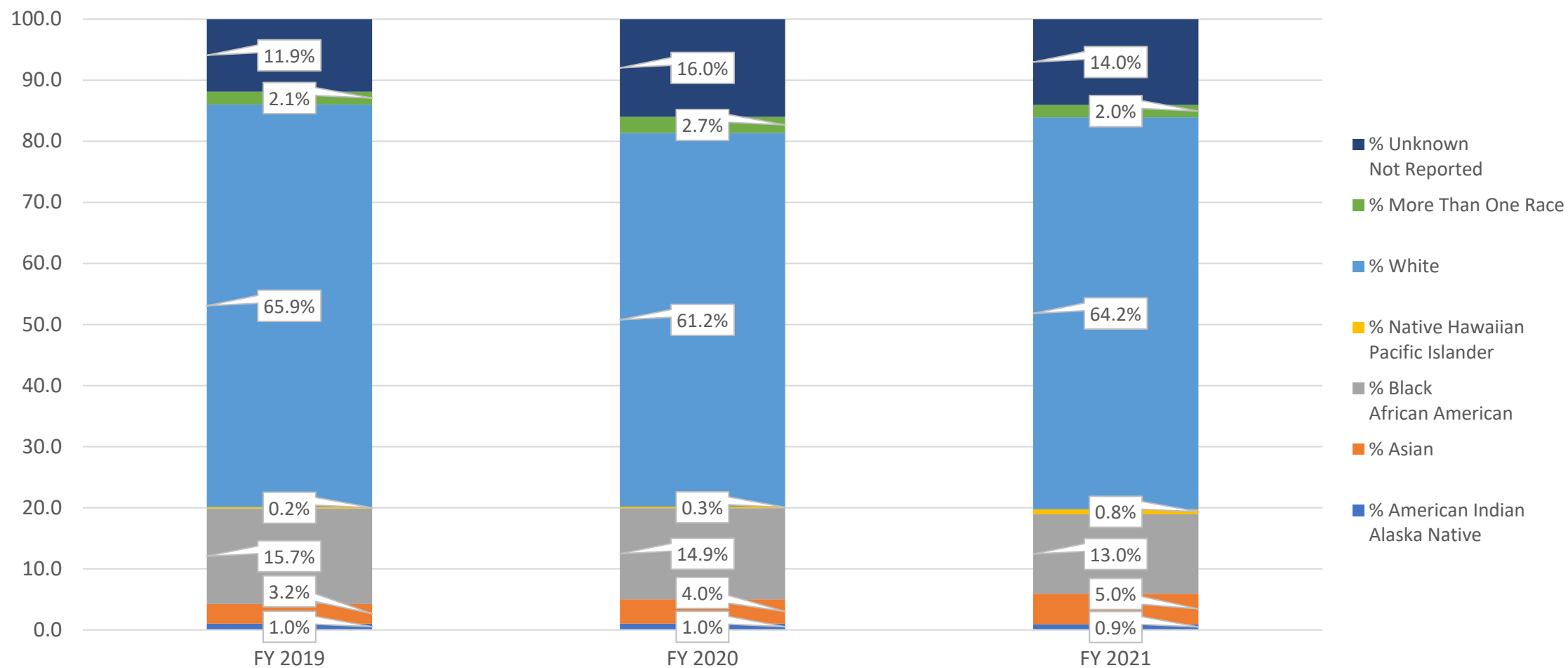
NIH Clinical Research Enrollment by Sex or Gender, FY2019 – FY2021



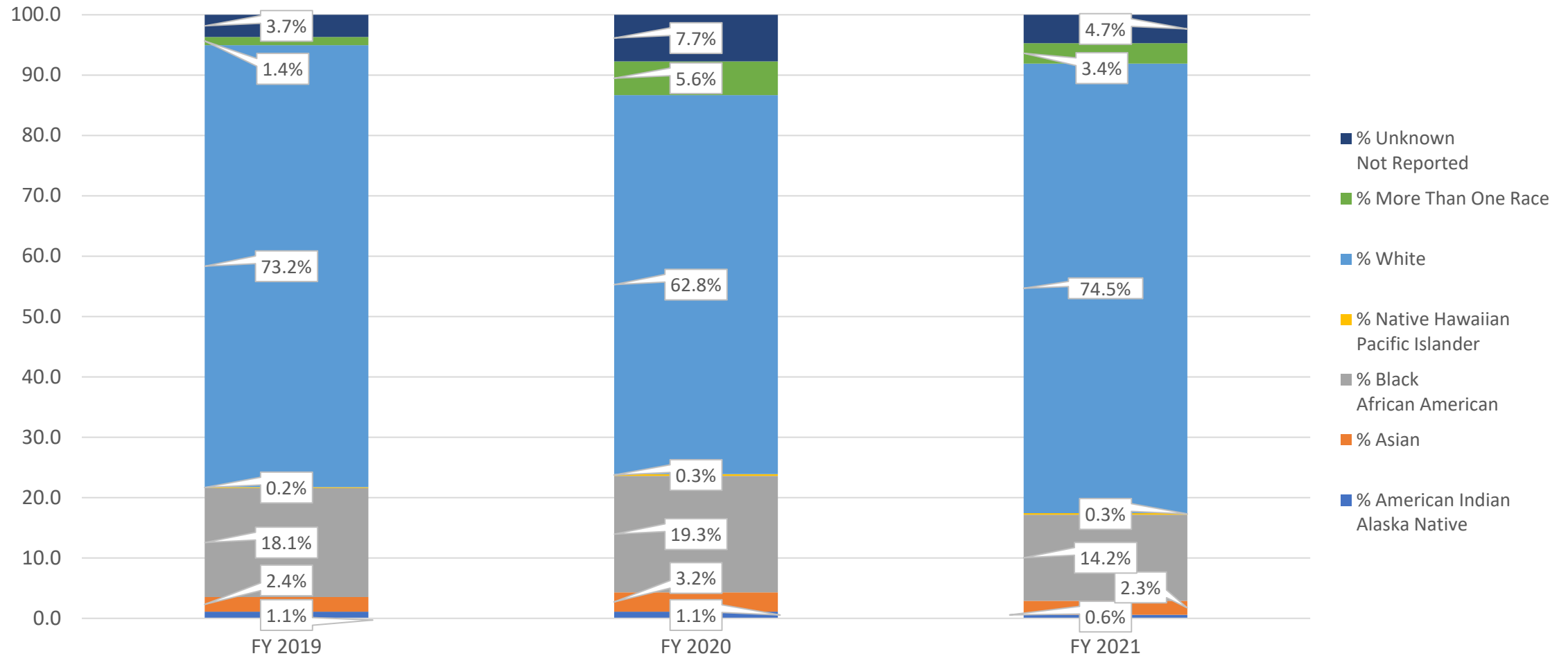
NIH-Defined Phase 3 Clinical Trial Enrollment by Sex or Gender, FY2019 – FY2021



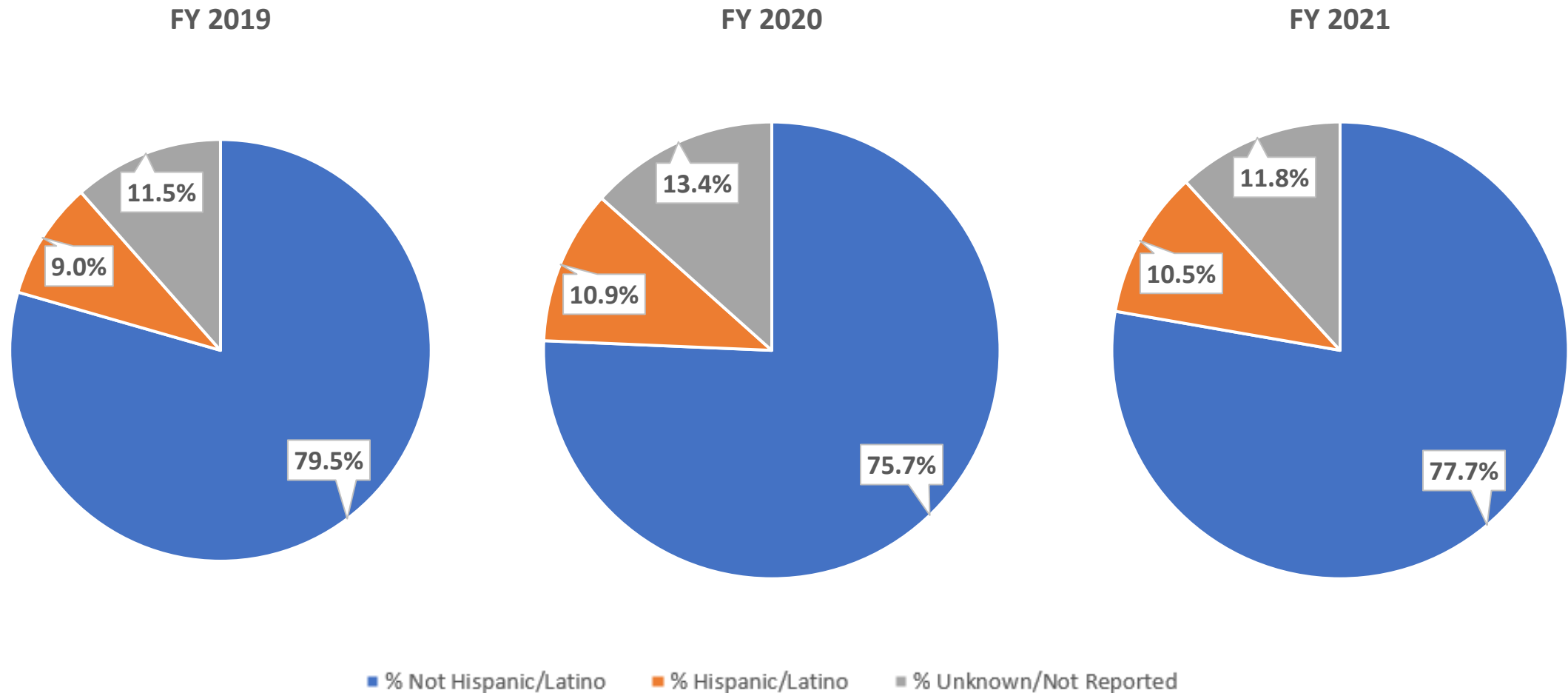
NIH U.S.-Only Clinical Research Enrollment, FY2019 – FY2021



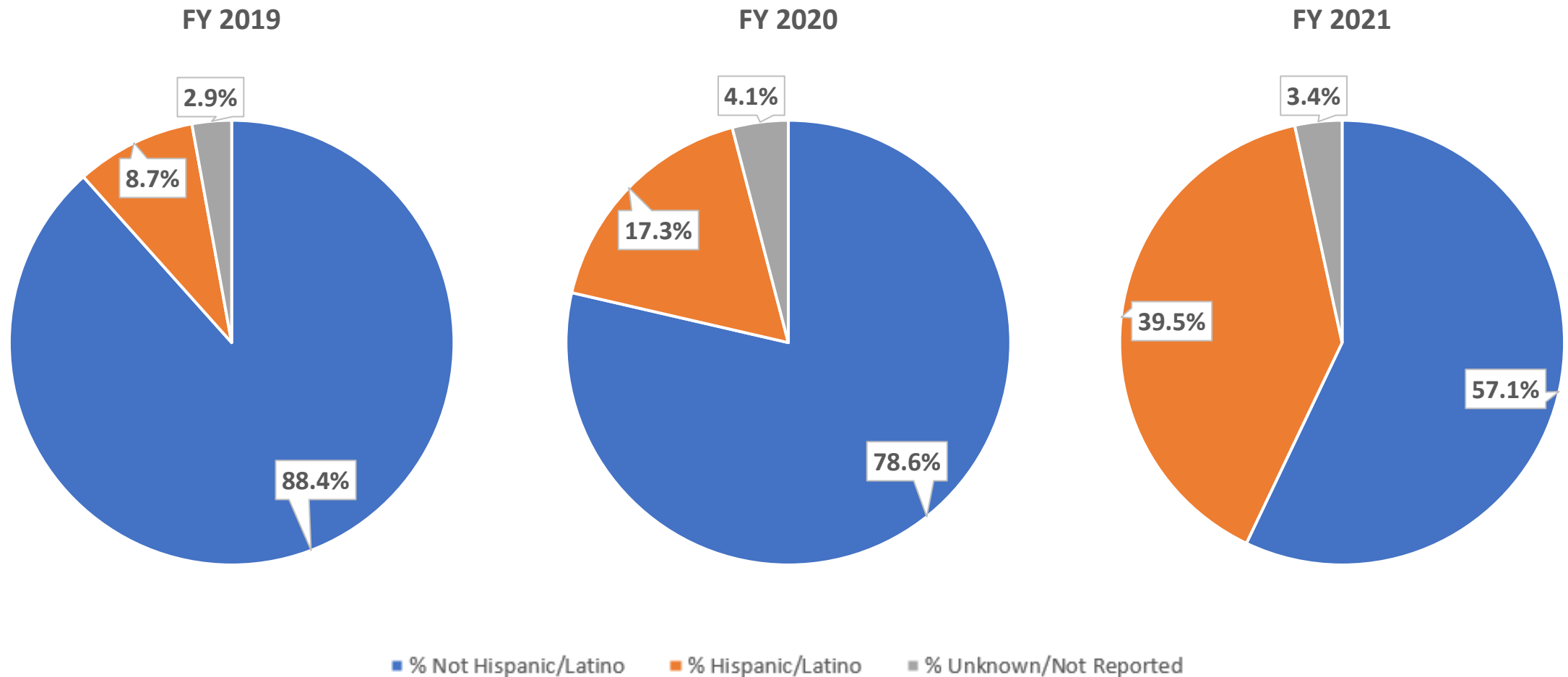
U.S.-Only NIH-Defined Phase 3 Clinical Trial Enrollment by Race, FY2019 – FY2021



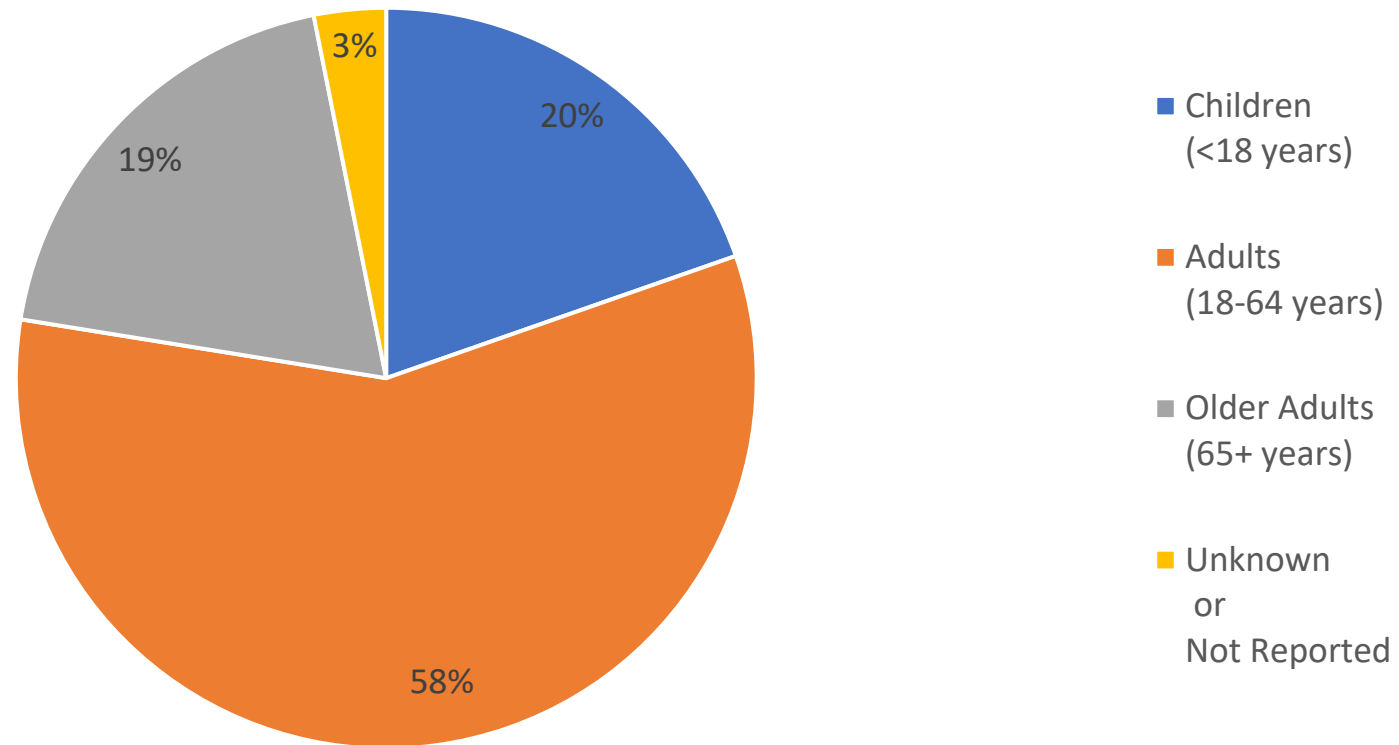
NIH U.S.-Only Clinical Research Enrollment by Ethnicity, FY2019 – FY2021



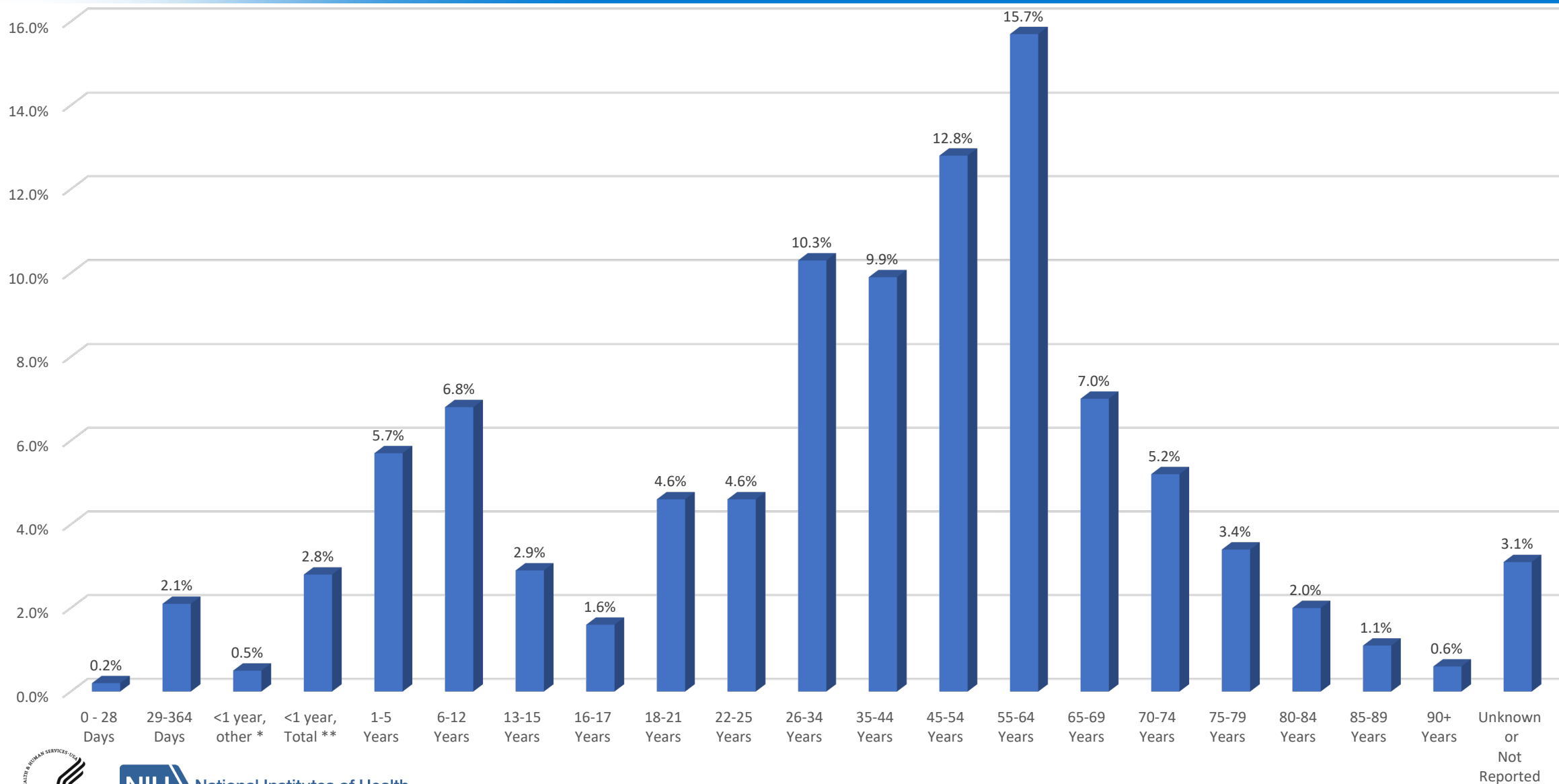
U.S.-Only NIH-Defined Phase 3 Enrollment by Ethnicity, FY2019 – FY2021



NIH Clinical Research Enrollment by Broad Age Groups, FY 2021



NIH Enrollment in Clinical Research by Narrow Age Groups, FY 2021



NIH Inclusion Data by Research, Condition, and Disease Categories

NIH RCDC Inclusion Statistics Report

Summary Detail RISR FAQs | Contact Us

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.

Filter RCDC Categories	Total, NIH	Sex/Gender	Exclude Single Sex/Gender Studies	Clear Filters	Export
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%		



Improving the Representation of Women and Underrepresented Minorities in Clinical Trials and Research

SHARE f t in x

IMPROVING THE
REPRESENTATION OF WOMEN
AND UNDERREPRESENTED
MINORITIES IN CLINICAL TRIALS
AND RESEARCH

<https://www.nationalacademies.org/our-work/improving-the-representation-of-women-and-underrepresented-minorities-in-clinical-trials-and-research>



WHO V

DIVERSITY

HOME - OUR WORK - QUALITY - Diversity

OVERVIEW

The underrepresentation of diverse populations in clinical trials creates knowledge gaps about the <https://ctti-clinicaltrials.org/our-work/quality/diversity/>



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NIH Community Engagement Alliance (CEAL)

The Community Engagement Alliance (CEAL) Against COVID-19 Disparities **works closely with the communities hit hardest**

<https://covid19community.nih.gov/>

Explore CEAL Topics



RESOURCES

WEB

Inclusion of Women and Minorities

https://grants.nih.gov/grants/funding/women_min/women_min.htm

Inclusion Across the Lifespan

<https://grants.nih.gov/grants/funding/lifespan/lifespan.htm>

EMAIL

inclusion@mail.nih.gov



National Institutes of Health
Office of Extramural Research