

NIH Inclusion Update

Dawn Corbett, MPH
NIH Inclusion Policy Officer
Office of Extramural Research
National Institutes of Health

60th Meeting of the NIH Advisory Committee on Research on Women's Health
April 9, 2024



Inclusion of Women and Members of Racial and Ethnic Groups

- 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
- Additional requirements for NIH-defined phase 3 clinical trials
 - Analysis of primary outcome by sex or gender, race and ethnicity
 - Status/results reported in progress reports/RPPR Project Outcomes
 - If applicable clinical trial (ACT) must report results of analyses in [Clinicaltrials.gov](https://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
- Requires submission of individual-level participant data in progress reports
 - Sex or Gender
 - Race
 - Ethnicity
 - Age at Enrollment



NIH 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 NIH clinical research 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.

See the [RCDC Inclusion Statistics Report \(RISR\) FAQs](#) for more details about these data.

[Human Subjects System \(HSS\) Enrollments by Age Groups in Research, Condition, and Disease Categorization \(RCDC\) Categories Inclusion Record Year 2021](#) are available in Excel format only.

Filter RCDC Categories	Total, NIH	2021	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	51%	49%	<1%			
Acquired Cognitive Impairment	58%	41%	<1%			
Acute Respiratory Distress Syndrome	44%	55%	<1%			
Adolescent Sexual Activity	50%	46%	<1%			
Agent Orange & Dioxin	51%	49%	<1%			
Aging	55%	43%	<1%			
Alcoholism, Alcohol Use and Health	50%	49%	<1%			





Inclusion Across the Lifespan Case Studies

The Inclusion Across the Lifespan Policy requires research supported by the NIH to include individuals of all ages, unless there is a scientific or ethical reason not to include a specific age group. The case studies below provide examples that can help investigators examine whether their plans for age-specific exclusion criteria are justifiable according to NIH policy. See also the “Policy” section of the guide notice announcing the Inclusion Across the Lifespan policy, [NOT-OD-18-116](#).

Case #1:

An investigator is planning a study analyzing stress and anxiety levels in children involved in caregiving responsibilities for parents or younger siblings with cancer. The investigator will include standardized measures of stress and anxiety, observations of behavior, and review of the medical records for both the children and the family member with cancer.

The investigator plans to exclude individuals 60 years of age and over because the goal is to focus on parent/sibling relationships rather than grandparents. The investigator anticipates that most individuals under 18 will have parents below the excluded age range.

Considerations	Response
Is there a scientific reason for excluding specific age groups?	No
Is there an ethical reason for excluding specific age groups?	No

Take away: Age should only be used as an exclusion criterion when necessary. Rather than using age as exclusion criteria, the investigator can specify the types of relationships that allow individuals to be eligible for the study.

<https://grants.nih.gov/sites/default/files/IAL-Case-studies-for-Extramural-community.pdf>



Allowable Costs Related to Participant Inclusion Activities

See [NIH GPS 7.9.1 Selected Items of Cost](#) for more details on allowable and unallowable costs

Item	Examples
Advertising and Public Relations	Advertising: community activities to communicate the grant-supported research activities, such as creating/distributing flyers to advertise a clinical research study. Public relations: townhalls, press interviews, or other meetings to discuss grant-supported research activities and their results.
Child Care Costs	Providing childcare at the research site or reimbursing expenses which are necessary for childcare.
Incentive Costs	A gift card to volunteers or patients participating in an NIH-funded clinical trial.
Meals	Providing meals to compensate participants for time spent on grant-supported research activities.
Nursery Items	Providing toys, books, and other items to make waiting rooms/waiting times more conducive to children of research participants. <i>Note:</i> Recipients should consider utilizing this item in conjunction with allowable childcare costs (see the item above).
Pre-Award (Pre-Agreement) Costs	Recipients at their own risk may consider if pre-award costs may be appropriate to initiate research planning activities prior to receiving the Notice of Award (NoA), such as fostering community relationships or establishing scientific, advisory, and other committees.
Publication and Printing Costs	Creating participant and/or community media outreach, such as brochures or newsletters, to provide research updates and opportunities for participation.
Research Patient Care	Clinical services that are included in the research activities or protocol, such as blood draws or imaging.
Travel/Research Patients	Reimbursing participants for transportation costs to the site of the research study (e.g., a hospital where the patient will undergo diagnostic testing as part of the grant-supported research). Setting up a system to transport study participants for grant-supported research visits.

NIH Office of the Director
Office of Extramural Research (OER)/Division of Human Subjects Research (DHSR)
Last modified 11/29/2023

<https://grants.nih.gov/sites/default/files/Allowable-costs-related-to-participant-inclusion-activities.pdf>

- This maturity model's purpose is to guide research organizations to assess their current infrastructure for improving equitable access to, and diverse participation in, clinical trials and to identify their desired future state.
- Organizations can choose how to use the model; not all rows will apply to every organization and desired levels of development may vary.

COMMITMENT

» Leadership

» Culture

PARTNERSHIPS

» Bi-directional Community

» Patient and Patient Groups

RESOURCES

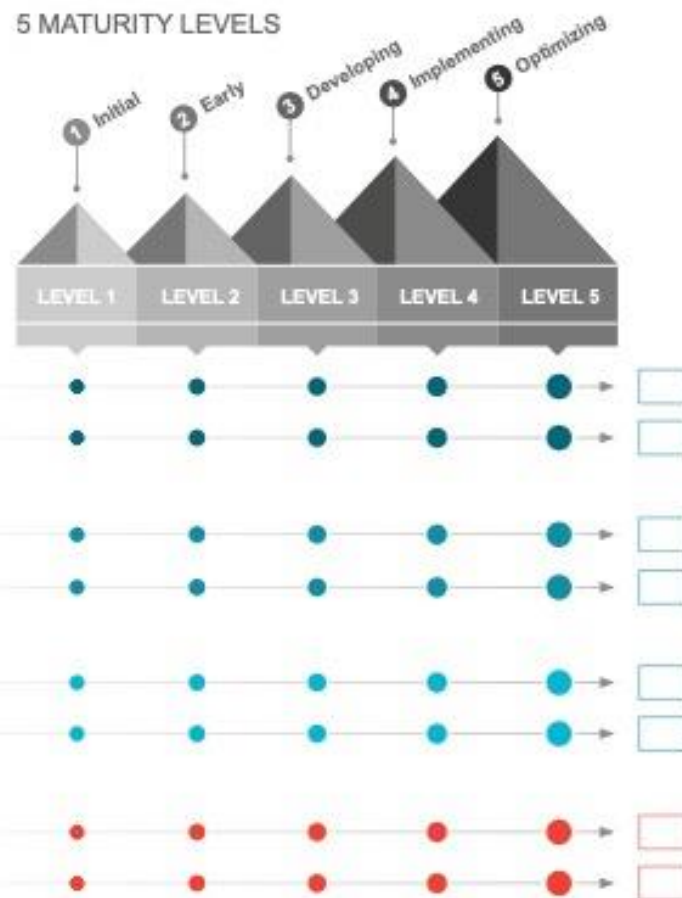
» Dedicated Personnel

» Sufficient Investments

ACCOUNTABILITY

» Data Driven Strategies

» Continuous Improvement



CTTI's Diversity Maturity Model Purpose:

Provide a guide for research organizations to:

- Assess their current organizational infrastructure for increasing diversity in clinical trials, and
- Identify a desired future state – desired levels of development may vary

Total Inclusion Enrollment Reports (IERs)

Fiscal Year	Total IERs	IERs Without Enrollment	IERs With Enrollment	US Site IERs	Non-US Site IERs	Female Only IERs	Male Only IERs	IERs Excluding Male only and Female only*
2021	25,941	11,320	14,621	13,129	1,492	1,616	693	12,312
2022	27,971	11,879	16,092	14,507	1,585	1,737	794	13,561
2023	28,167	11,719	16,448	14,772	1,676	1,821	757	13,870

Total Phase 3 Inclusion Enrollment Reports (IERs)

Fiscal Year	Total IERs	IERs Without Enrollment	IERs With Enrollment	US Site IERs	Non-US Site IERs	Female Only IERs	Male Only IERs	IERs Excluding Male only and Female only*	IERs requiring valid analysis
2021	1,010	416	594	464	130	101	33	460	961
2022	1,166	424	742	591	151	113	39	590	1138
2023	1,187	395	792	616	176	121	40	631	1124

U.S. Only vs. Non-U.S. Enrollment

U.S. and Non-U.S. Enrollment in Clinical Research

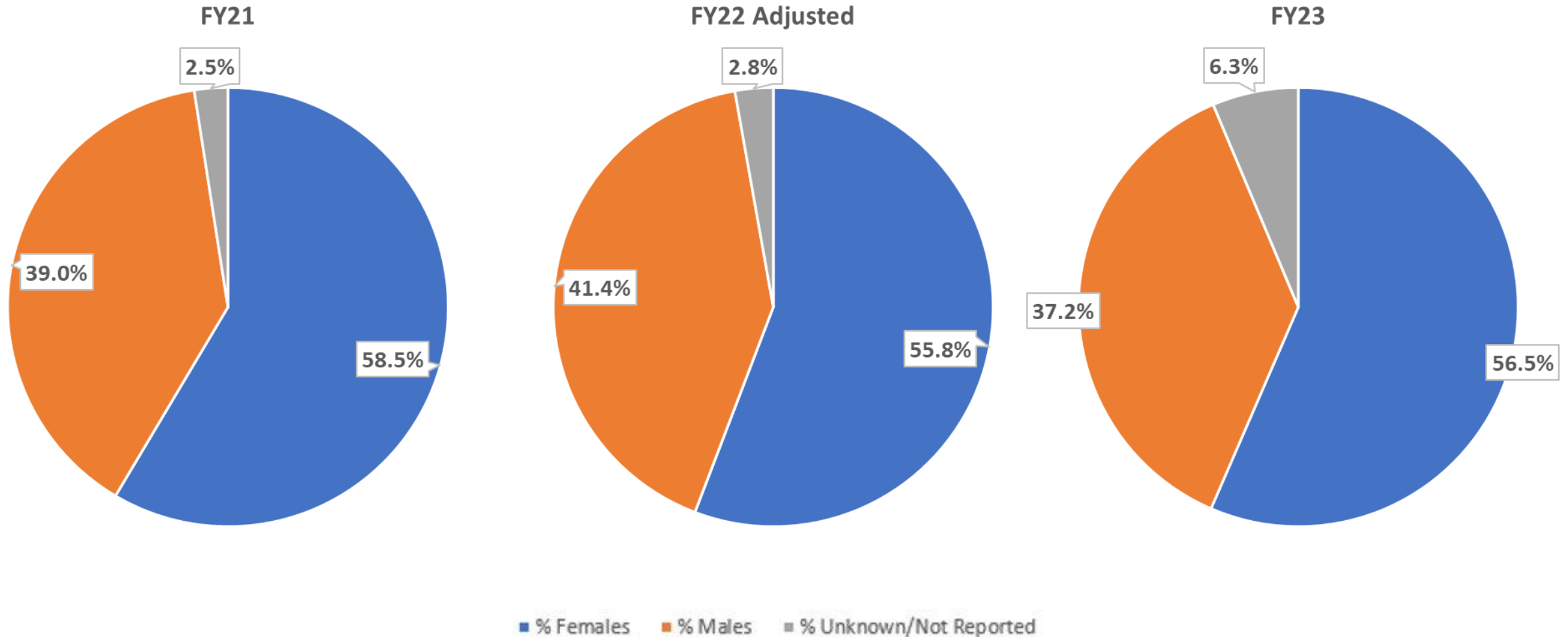
Fiscal Year	Total Enrollment	U.S. only Enrollment	% U.S only	Non-U.S. only Enrollment	% Non-U.S. only
2021	12,937,156	9,957,714	77.0%	2,979,442	23.0%
2022	97,162,052	95,165,832	97.9%	1,996,220	2.1%
2022 Adjusted*	10,751,975	8,755,755	81.4%	1,996,220	18.6%
2023	12,258,841	9,247,082	75.4%	3,011,759	24.6%

U.S. and Non-U.S. Enrollment in NIH-Defined Phase 3 CTs

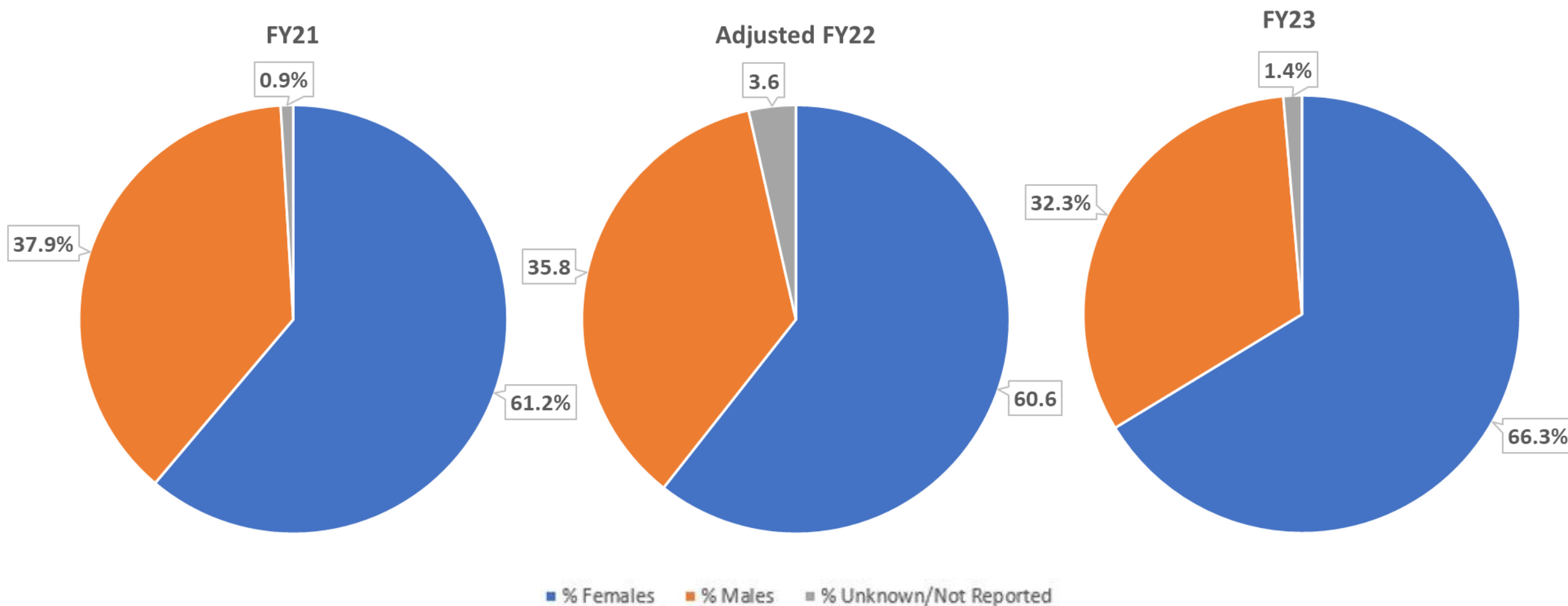
Fiscal Year	Total Enrollment	US Only	% US only	Non-U.S. only	% Non-U.S. only
2021	666,800	441,034	66.1%	225,766	33.9%
2022	87,647,554	87,418,025	99.7%	229,529	0.3%
2022 Adjusted*	1,237,477	1,007,948	81.5%	229,529	18.5%
2023	832,222	516,750	62.1%	315,472	37.9%



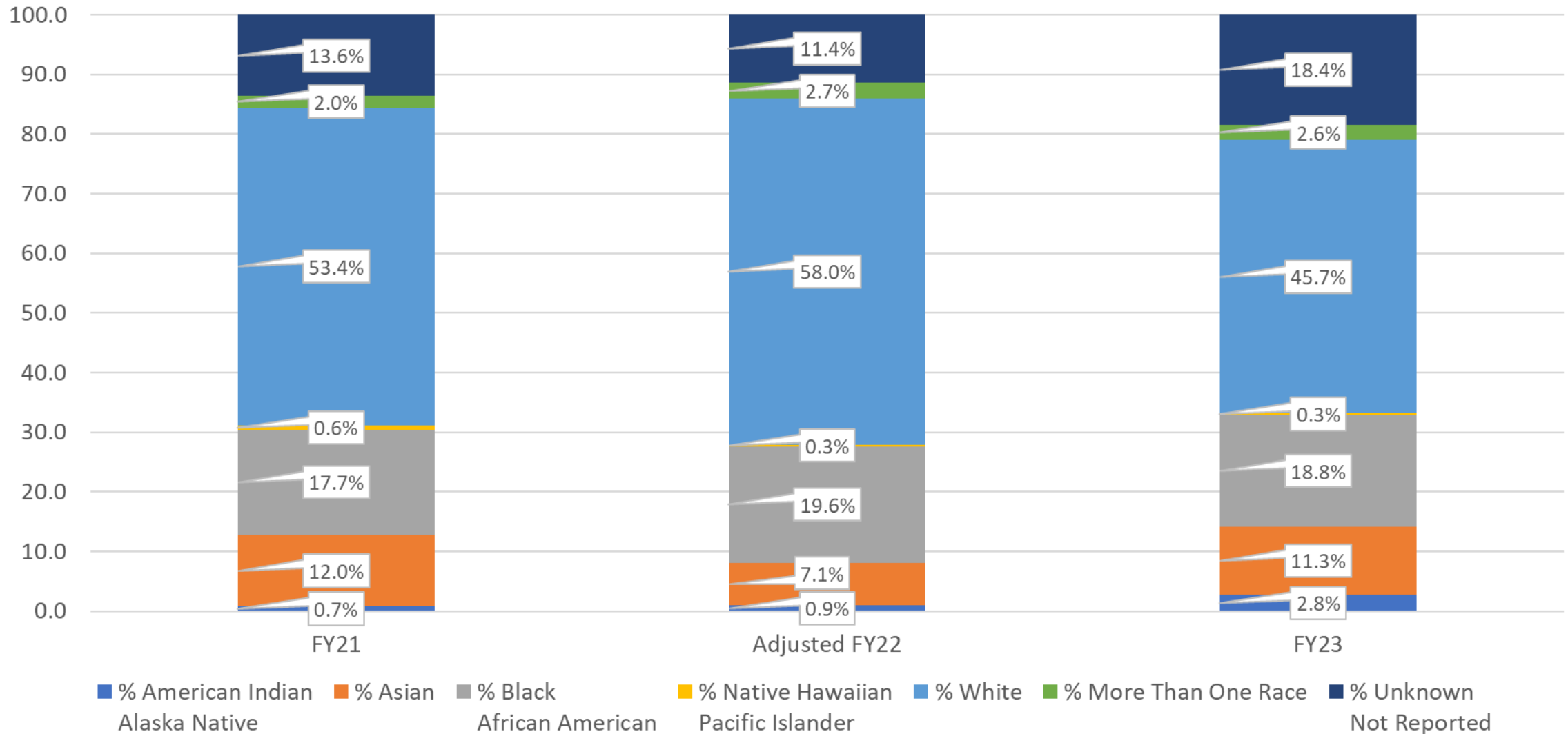
NIH Clinical Research Enrollment by Sex or Gender



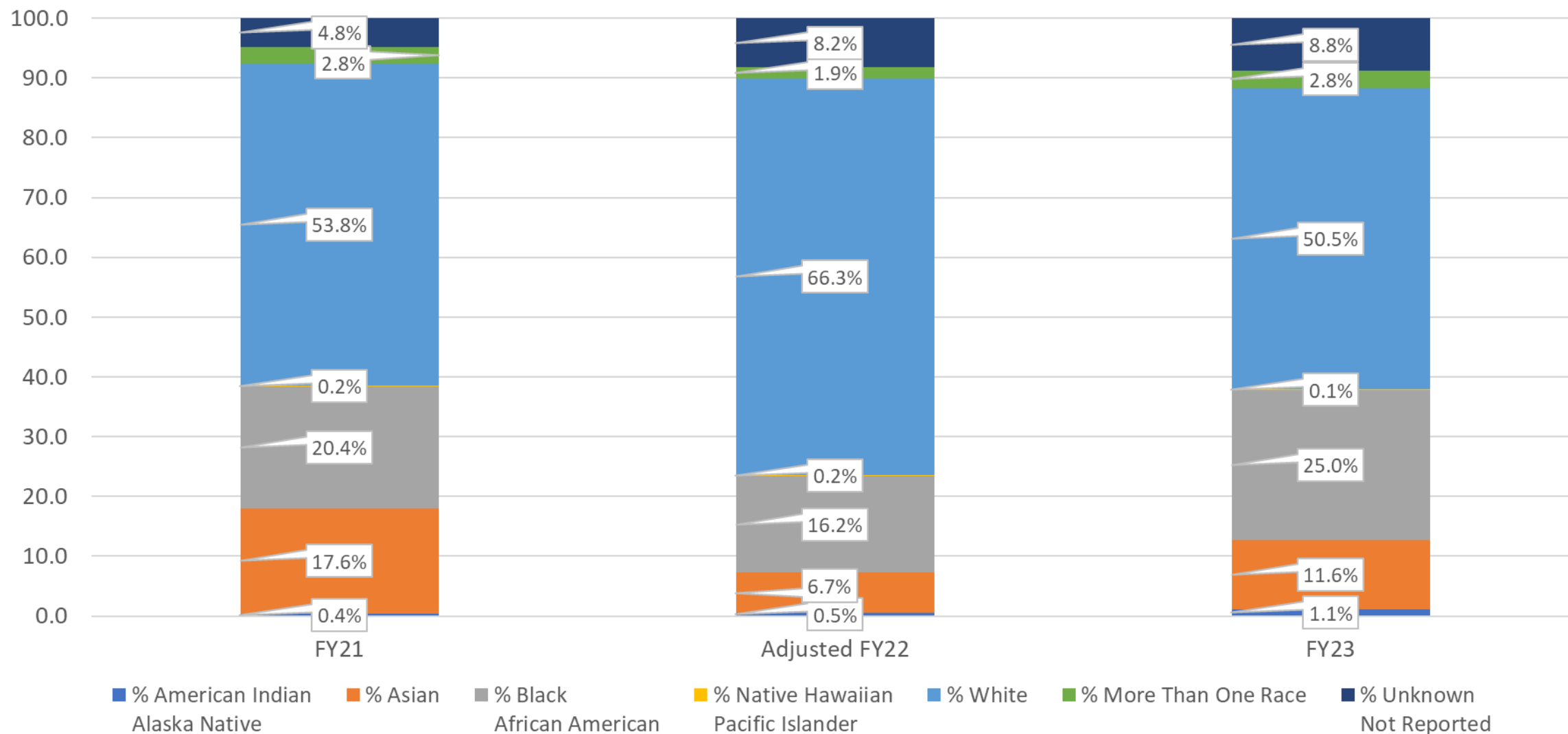
NIH-Defined Phase 3 Enrollment by Sex or Gender



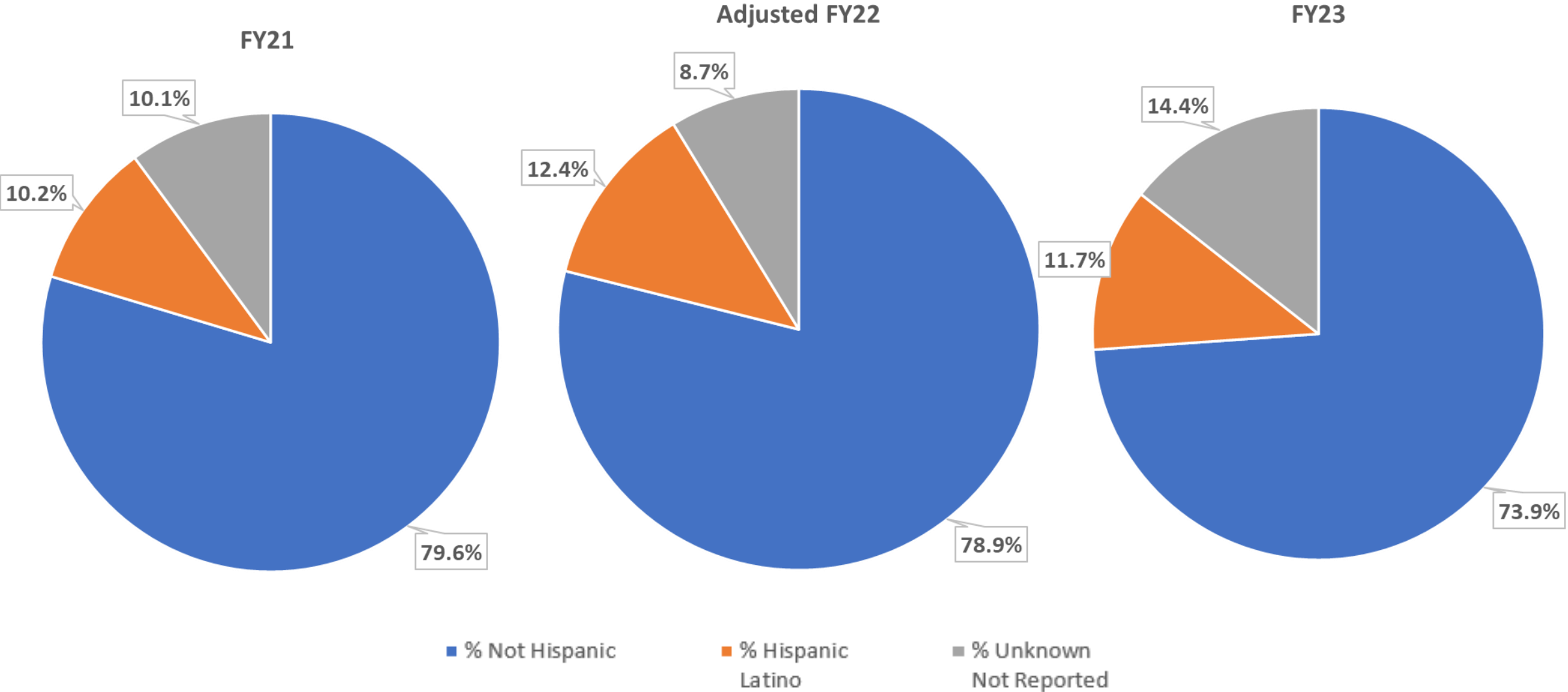
Enrollment in NIH Clinical Research by Race



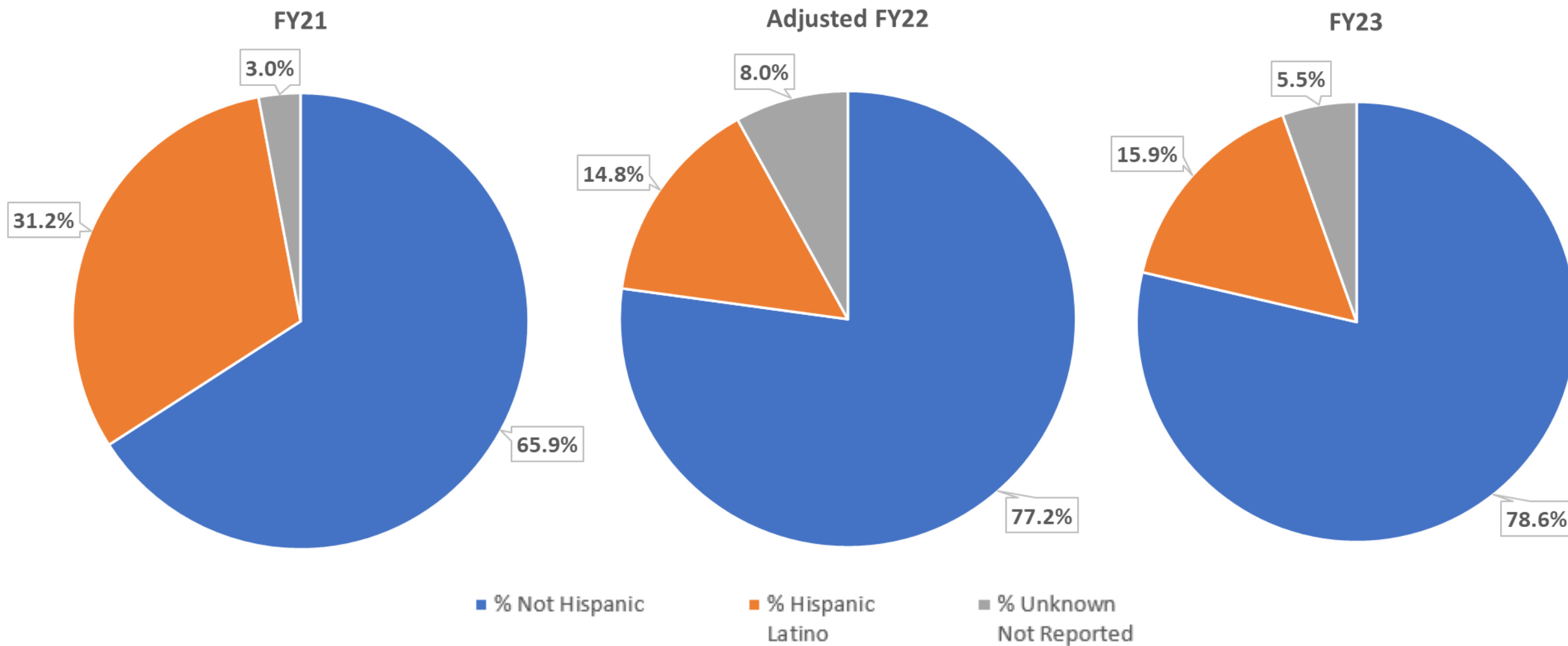
Enrollment in NIH-Defined Phase 3s by Race



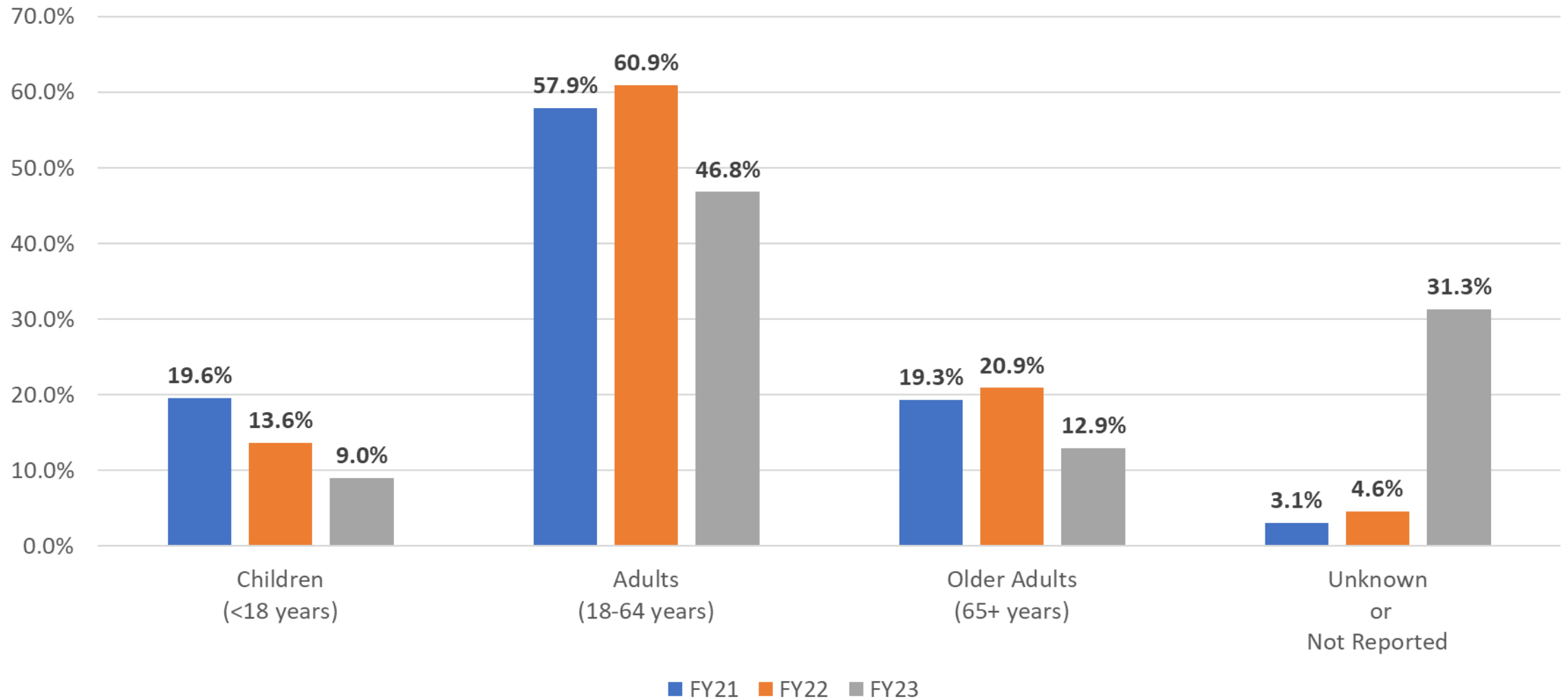
NIH Clinical Research Enrollment by Ethnicity



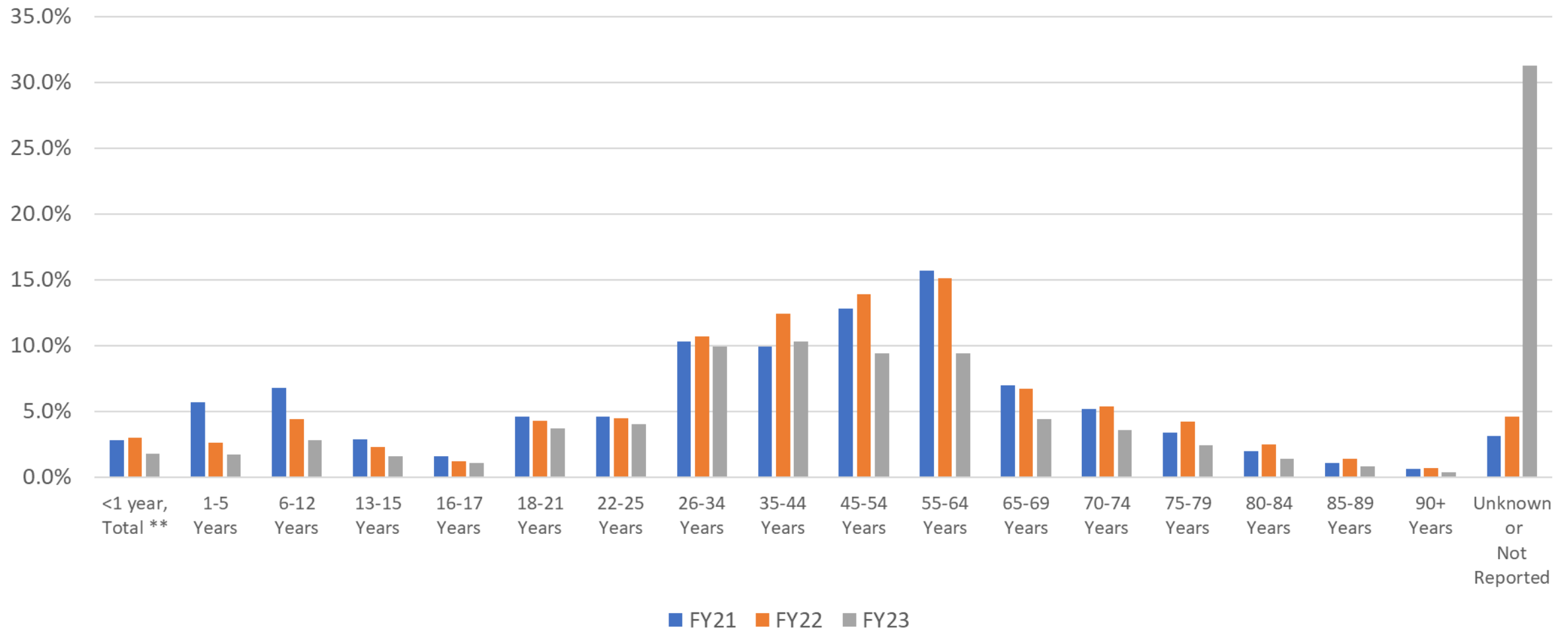
NIH-Defined Phase 3 Clinical Trial Enrollment by Ethnicity



NIH Clinical Research Enrollment by Broad Age Groups



Clinical Research Enrollment by Narrow Age Groups



Questions?

