NIH Inclusion Update

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

58th Meeting of the NIH Advisory Committee on Research on Women's Health
April 12, 2023

Timeline of NIH Inclusion Policies

1986
- NIH encourages inclusion of women

1994
- NIH requires inclusion of women and racial and ethnic minorities

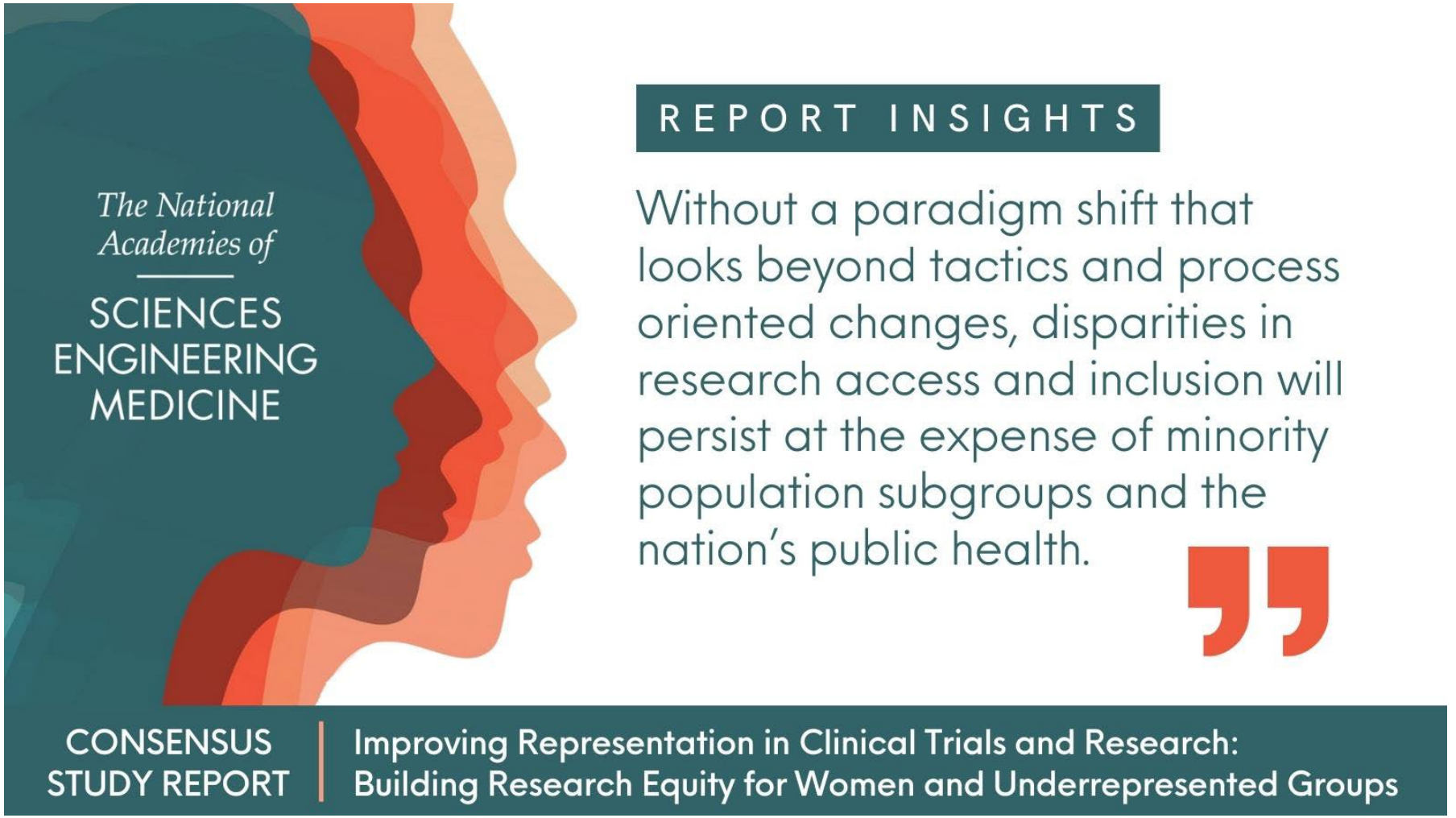
1998
- NIH requires inclusion of children

2017
- New phase 3 reporting requirements

2019
- NIH requires inclusion of individuals of all ages

2022
- NIH clarifies phase 3 project outcomes requirements

More To Be Done



Full report at https://nap.nationalacademies.org/read/26479/chapter/1

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

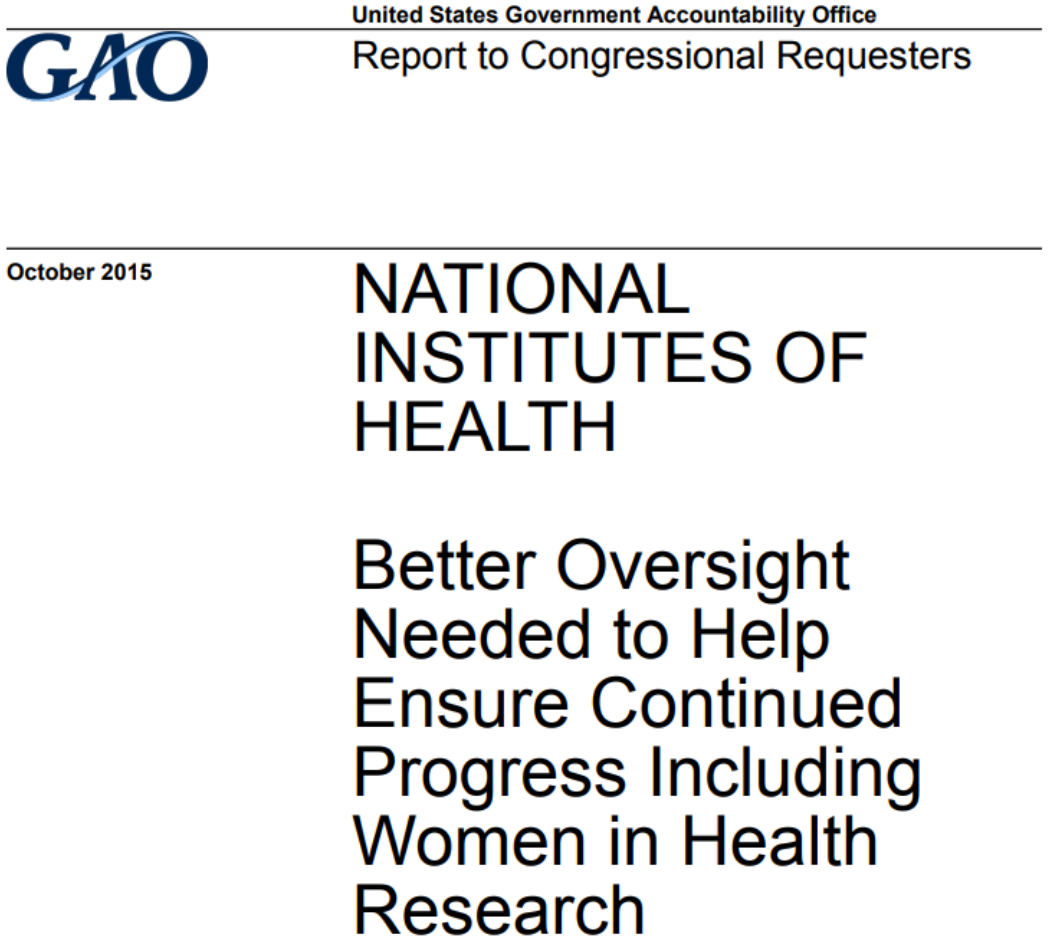
Policy Notice: NOT-OD-18-014

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

GAO Reports



United States Government Accountability Office

Report to Congressional Requesters

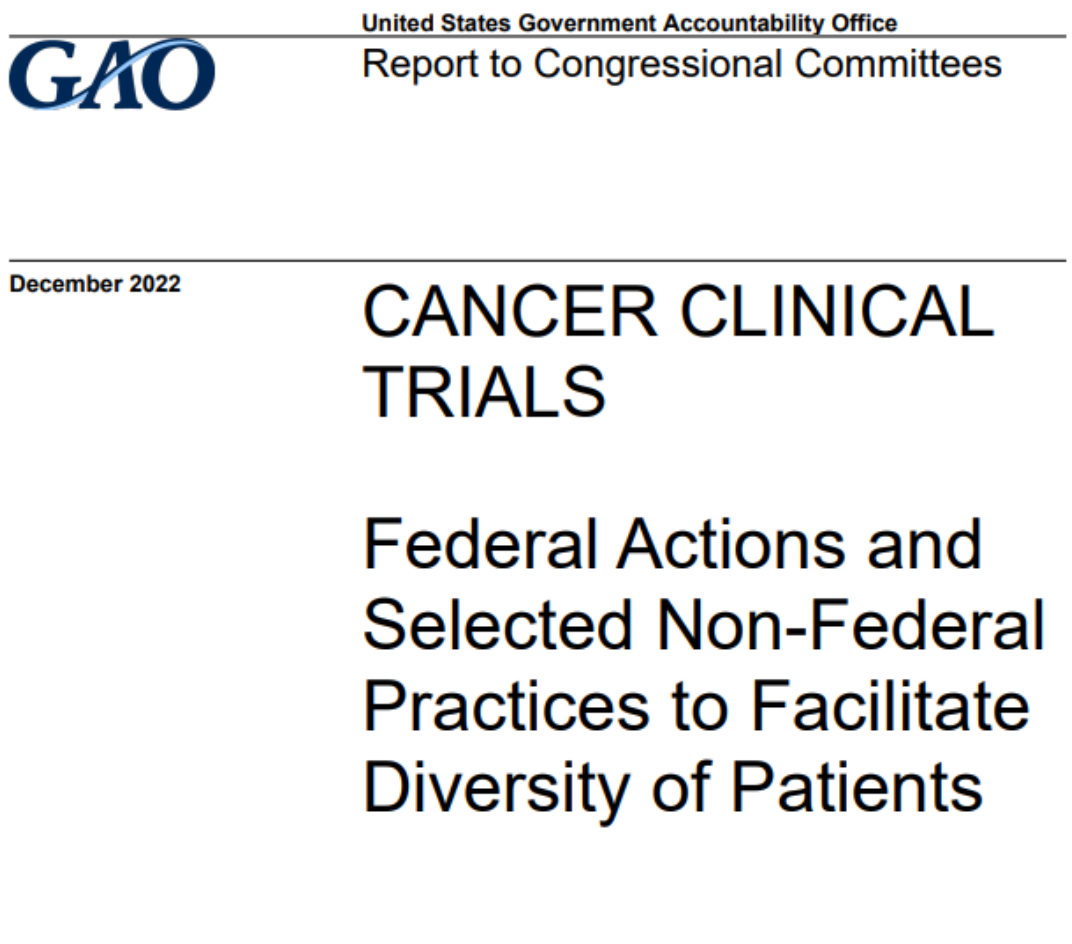
October 2015

NATIONAL INSTITUTES OF HEALTH

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

All Recommendations Closed

https://www.gao.gov/products/gao-16-13



United States Government Accountability Office

Report to Congressional Committees

December 2022

CANCER CLINICAL TRIALS

Federal Actions and Selected Non-Federal Practices to Facilitate Diversity of Patients

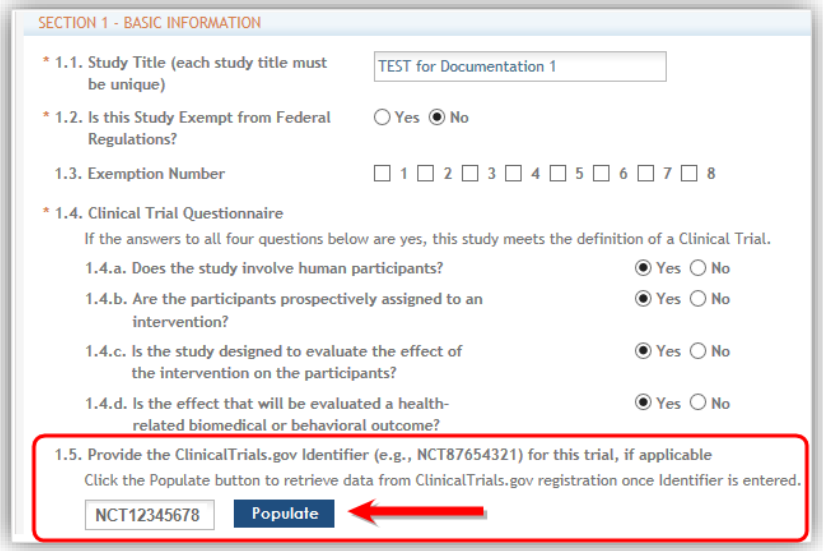
No Recommendations

https://www.gao.gov/products/gao-23-105245

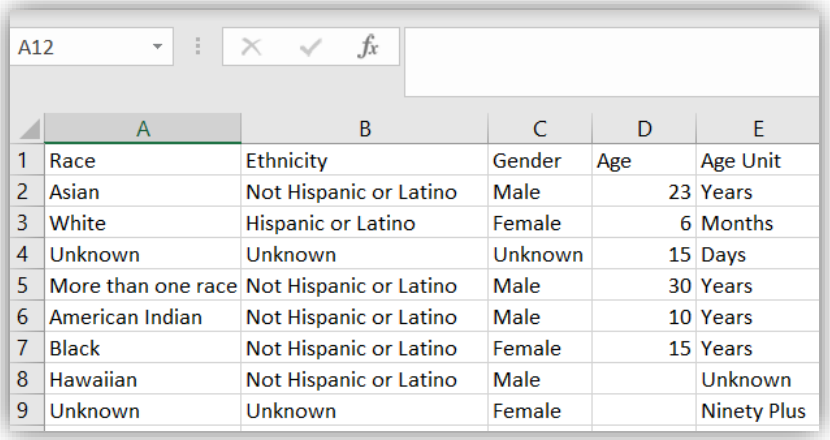
An NIH-wide Oversight System

HSS
Human Subjects System

Human subjects and trial information in one place



Synchronized with Clinicaltrials.gov

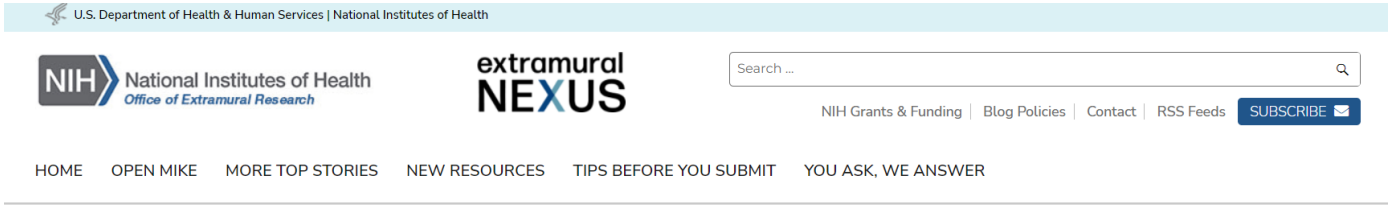


A12

	A	B	C	D	E
1	Race	Ethnicity	Gender	Age	Age Unit
2	Asian	Not Hispanic or Latino	Male	23	Years
3	White	Hispanic or Latino	Female	6	Months
4	Unknown	Unknown	Unknown	15	Days
5	More than one race	Not Hispanic or Latino	Male	30	Years
6	American Indian	Not Hispanic or Latino	Male	10	Years
7	Black	Not Hispanic or Latino	Female	15	Years
8	Hawaiian	Not Hispanic or Latino	Male		Unknown
9	Unknown	Unknown	Female		Ninety Plus

Accepts individual-level participant data

Enhanced Reporting



FY 2021 Data on Age at Enrollment in Clinical Research Now Available by RCDC Category

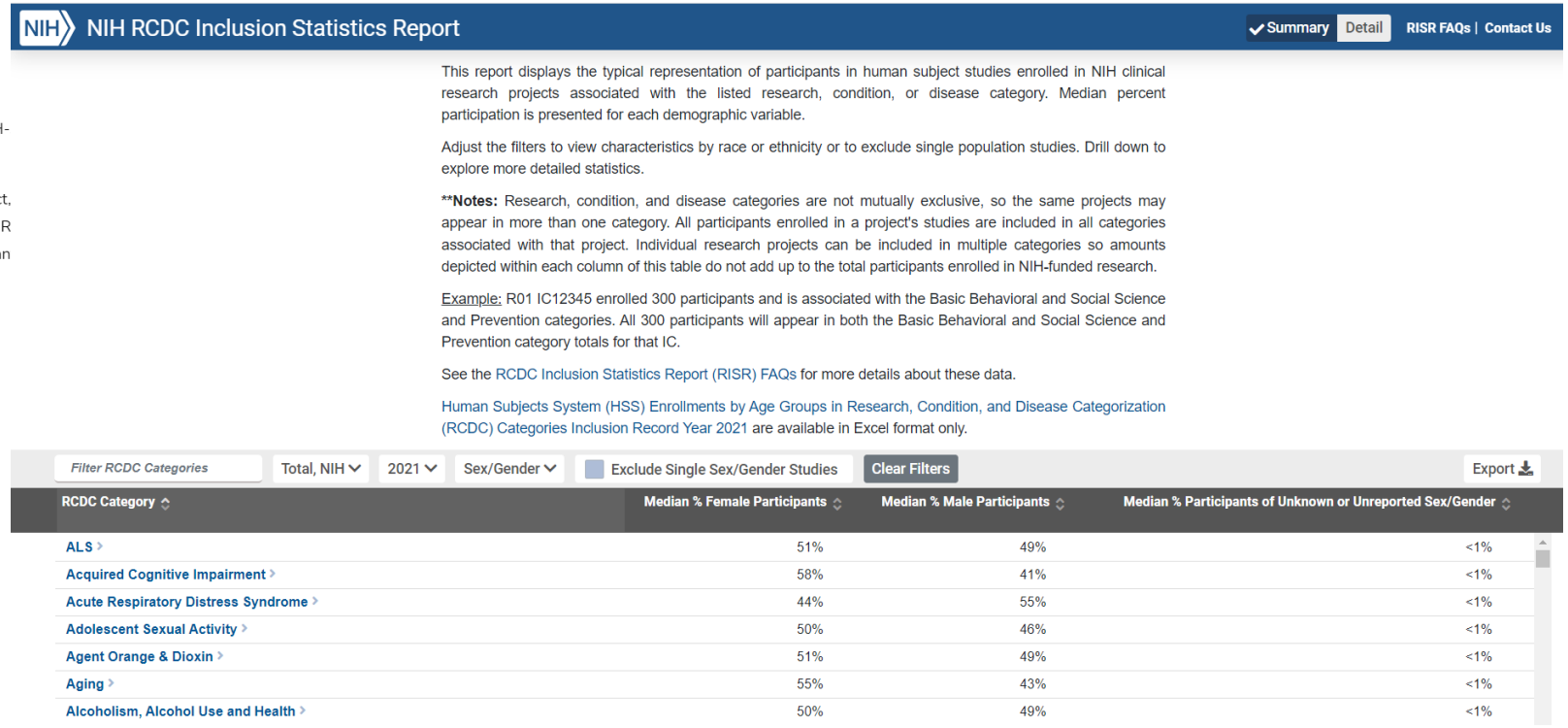
By Mike Lauer

Posted April 11, 2022

0 Comments

We are pleased to announce that for the first time, data are now available on the age of participants in NIH-on age adds to already reported data on participant sex or gender, race, and ethnicity.

The NIH Inclusion Across the Lifespan (IAL) policy, implemented in response to the 21st Century Cures Act, older adults) be included in our supported clinical research absent compelling scientific or ethical reasons. R submitting anonymized individual-level data on the sex or gender, race, ethnicity, and age of their participan these posts here for more).



https://report.nih.gov/research/inclusion-women-and-minorities-clinical-research#/

WHITE PAPER

Enhancing Diversity and Inclusion in Clinical Trials

Amy Corneli[1,2,3,*], Emily Hanlen-Rosado[1], Kevin McKenna[1], Richardae Araojo[4], Dawn Corbett[5], Kaveeta Vasisht[4], Bernadette Siddiqi[6], Tesheia Johnson[7], Luther T. Clark[8] and Sara B. Calvert[2,3]

Women and people from most racial and ethnic groups in the United States have historically been under-represented in clinical trials of investigational medical products. Inadequate representation of these groups may lead to an incomplete understanding of the safety and efficacy of new drugs, devices, biologics, and vaccines, and limit the generalizability of trial findings. As a result, new medical products may not be beneficial to all people who need them, and existing inequities in outcomes among various population groups may remain unchanged or worsen, or new disparities may arise. Although much work has focused on study-level strategies, research organizations must make systemic changes to how clinical trials are envisioned and implemented to achieve sustainable support for diversity and inclusion in clinical trials. The Clinical Trials Transformation Initiative (CTTI) conducted interviews with leaders at institutions that conduct clinical trials to explore perspectives on organizational-level practices that promote diversity and inclusion in clinical trials. Leaders described motivations, such as an ethical and moral imperative; organizational practices, such as staff investment and resource allocation; perceived return on investments, such as better science; and deterrents, such as cost and time. The CTTI also convened an expert meeting to discuss the interview findings and provide guidance. We present the interview findings and expert guidance in a framework that describes four key areas—commitment, partnerships, accountability, and resources—on sustaining organizational-level approaches for improving diversity and inclusion in clinical trials, with the ultimate goal of advancing health equity. Institutions who conduct and support clinical trials should implement organizational-level approaches to improve equitable access and diverse patient participation in clinical trials.

"Although much work has focused on study-level strategies, research organizations must make systemic changes to how clinical trials are envisioned and implemented to achieve sustainable support for diversity and inclusion in clinical trials"

Corneli A, Hanlen-Rosado E, McKenna K, Araojo R, Corbett D, Vasisht K, Siddiqi B, Johnson T, Clark LT, Calvert SB. Enhancing Diversity and Inclusion in Clinical Trials. Clin Pharmacol Ther. 2023 Mar;113(3):489-499. doi: 10.1002/cpt.2819. Epub 2023 Jan 11.

Continuing the Conversation

Event Page: https://www.nimhd.nih.gov/news-events/conferences-events/inclusive-participation-clinical-research-workshop.html

Enrollment in NIH Clinical Research

US and non-US Enrollment for All NIH Clinical Research

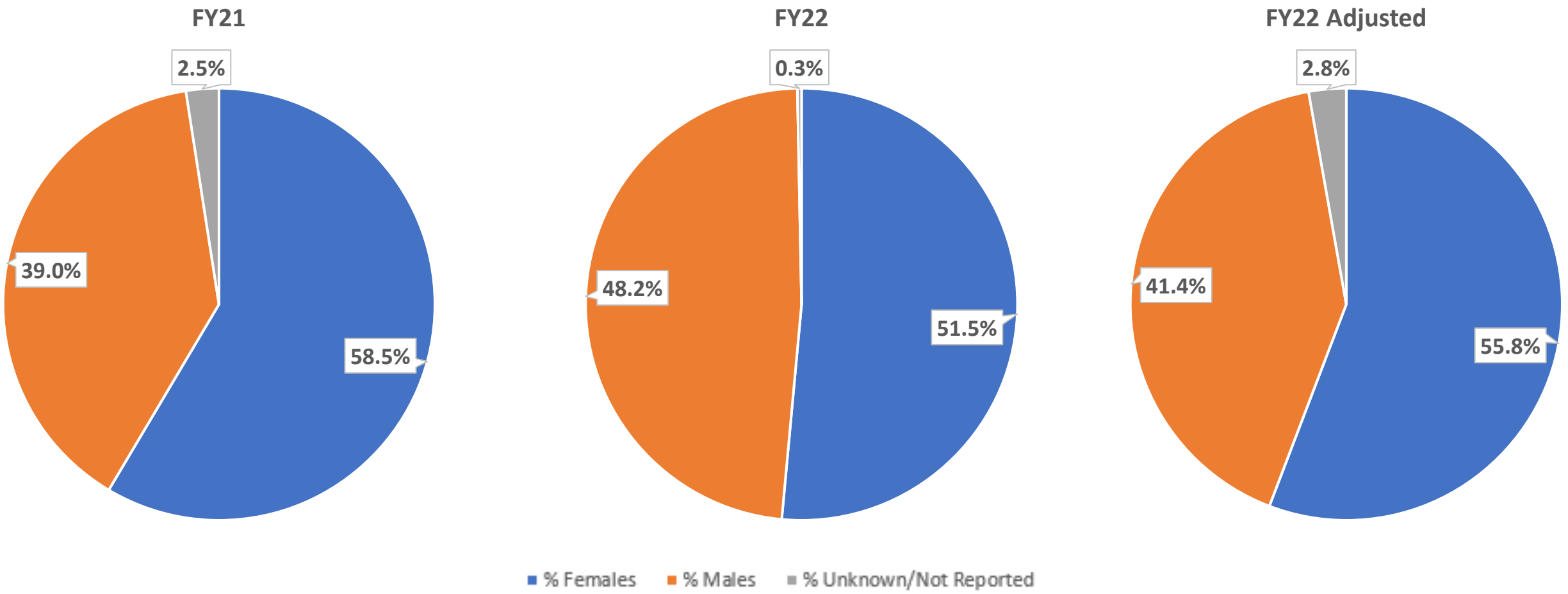
Fiscal Year	Total Enrollment	US Only	% US only	Foreign only	% Foreign only
2021	12,937,156	9,957,714	77.0%	2,979,442	23.0%
2022	97,162,052	95,165,832	97.9%	1,996,220	2.1%
2022 Adjusted*	10,751,975	8,755,755	81.4%	1,996,220	18.6%

US and non-US Enrollment for All NIH Phase 3 Clinical Trials

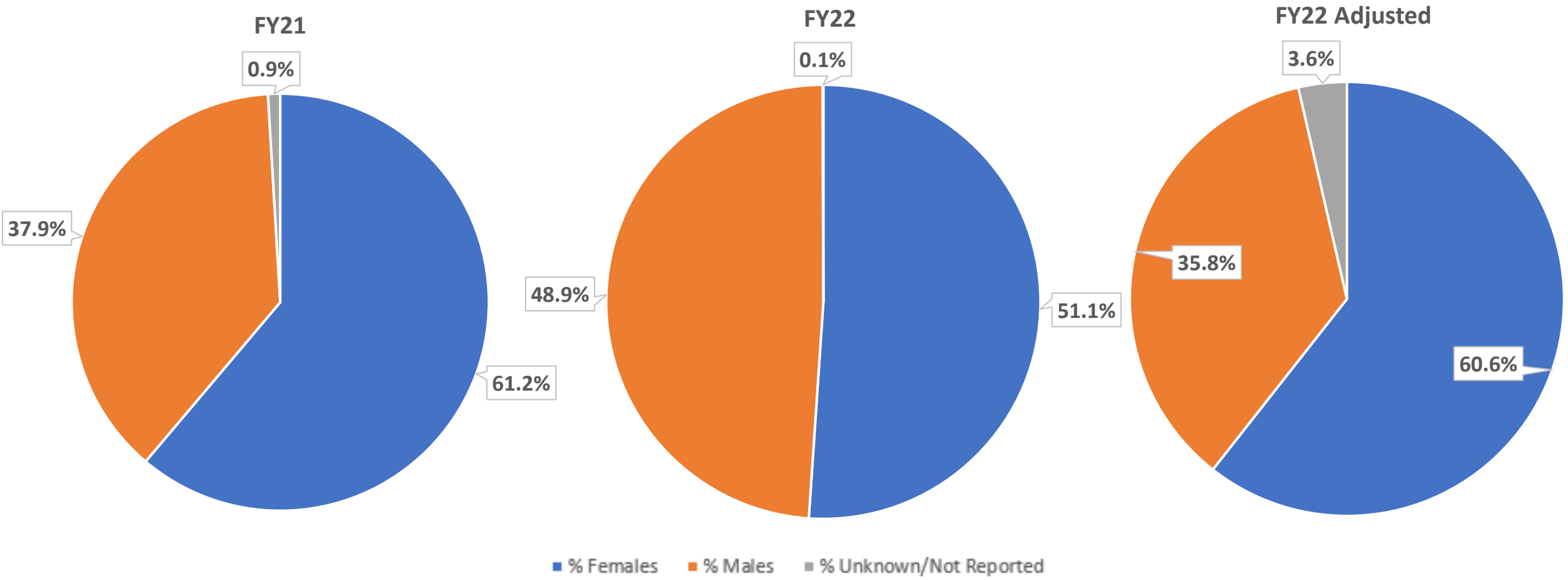
Fiscal Year	Total Enrollment	US Only	% US only	Foreign only	% Foreign only
2021	666,800	441,034	66.1%	225,766	33.9%
2022	87,647,554	87,418,025	99.7%	229,529	0.3%
2022 Adjusted*	1,237,477	1,007,948	81.5%	229,529	18.5%

*2022 Adjusted excludes one outlier, a large COVID-19 social media NIH-defined Phase 3 clinical trial with over 86,000,000 participants.

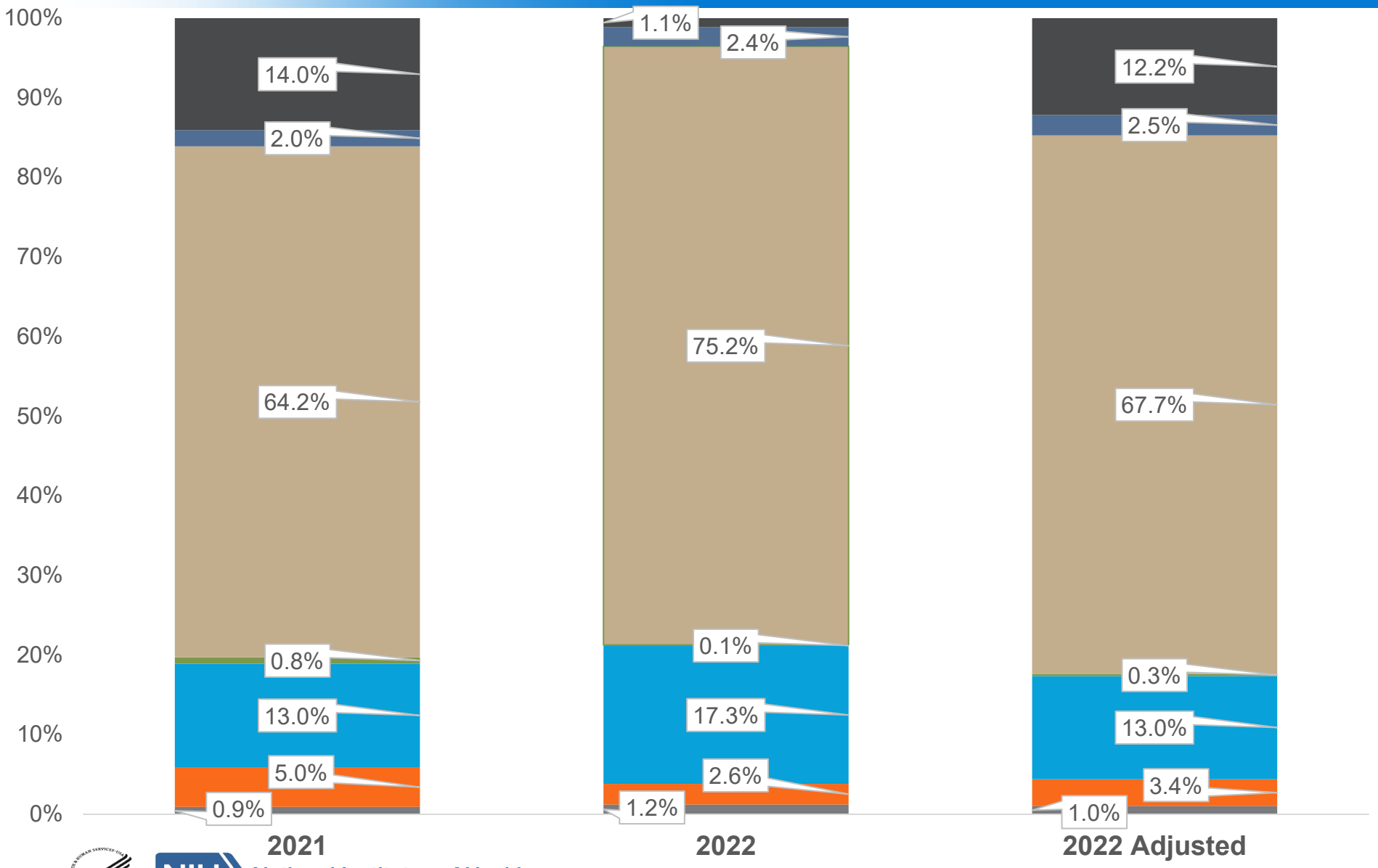
Sex or Gender Clinical Research Enrollment



Sex or Gender NIH-defined Phase 3 Trial Enrollment



Race U.S.-Only Clinical Research Enrollment



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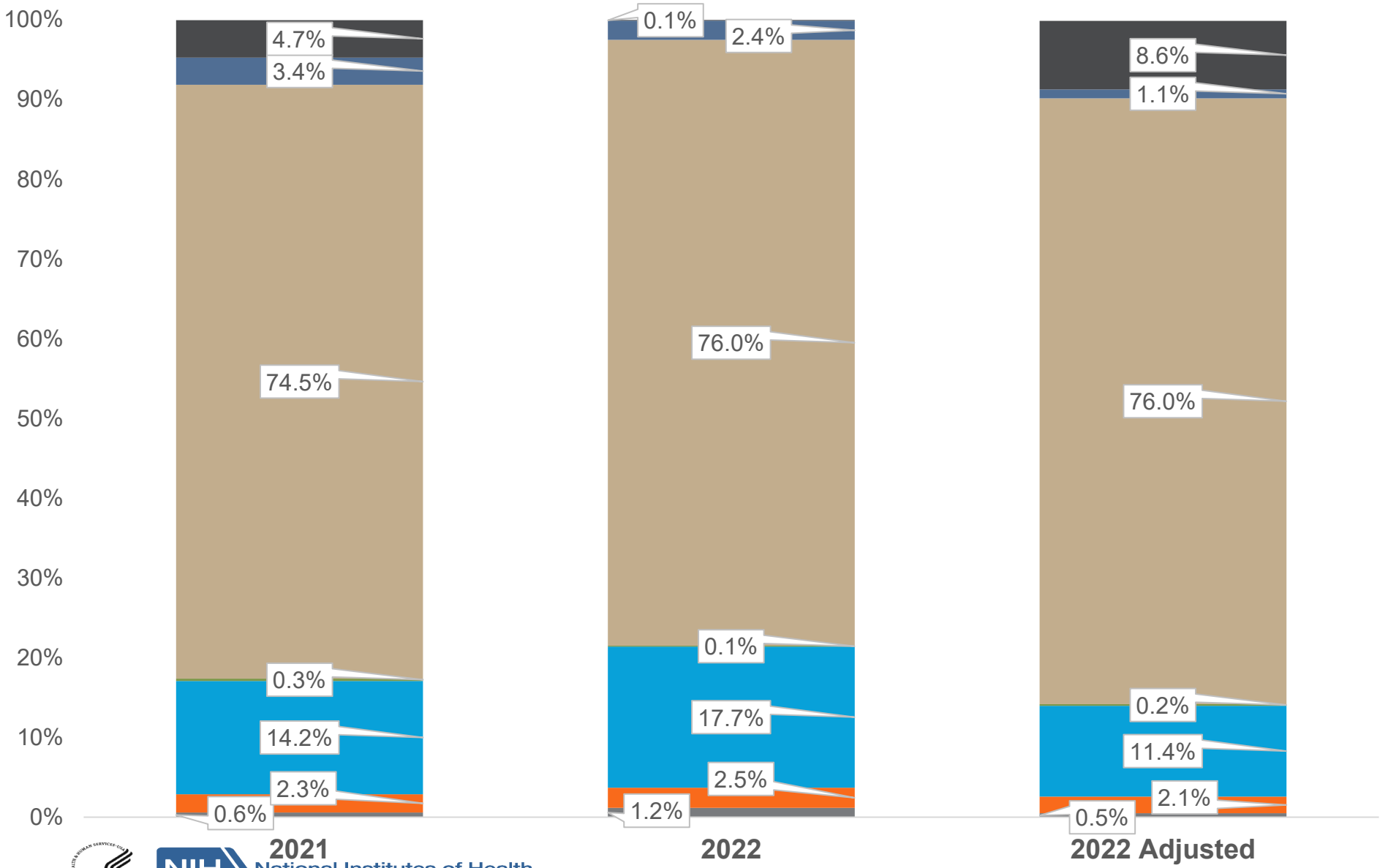
Race U.S.-Only NIH-defined Phase 3 Clinical Trial Enrollment



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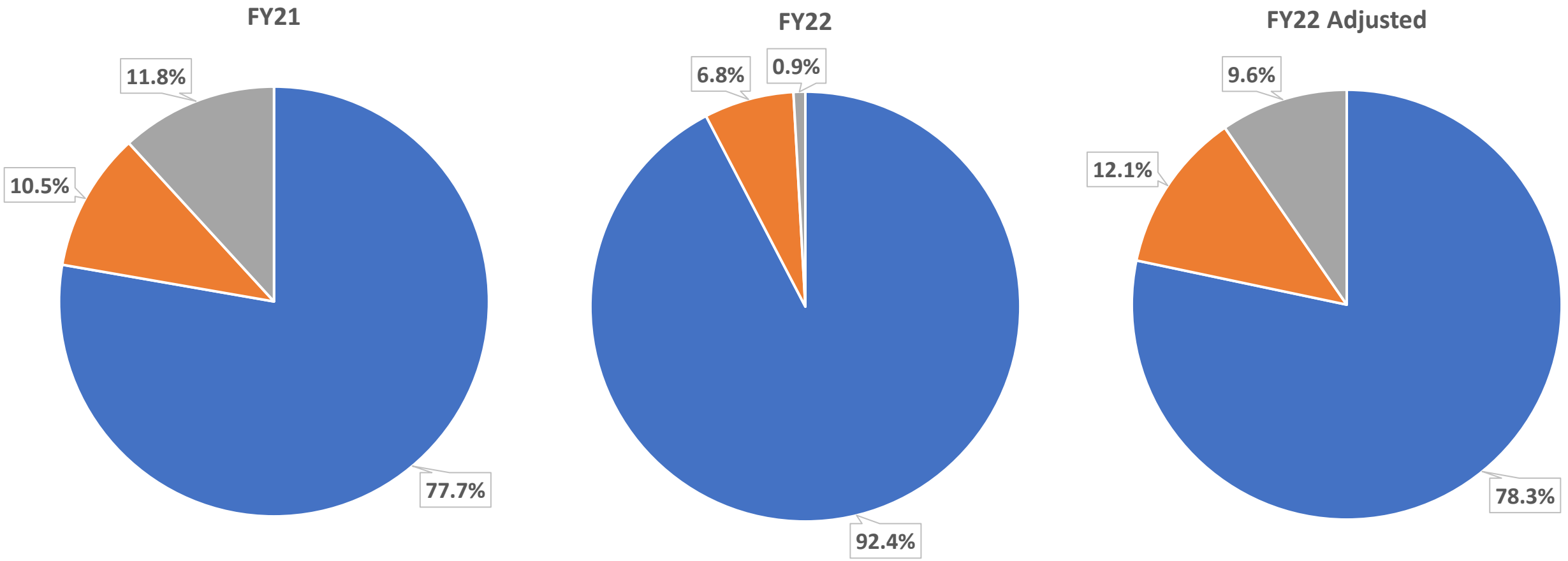
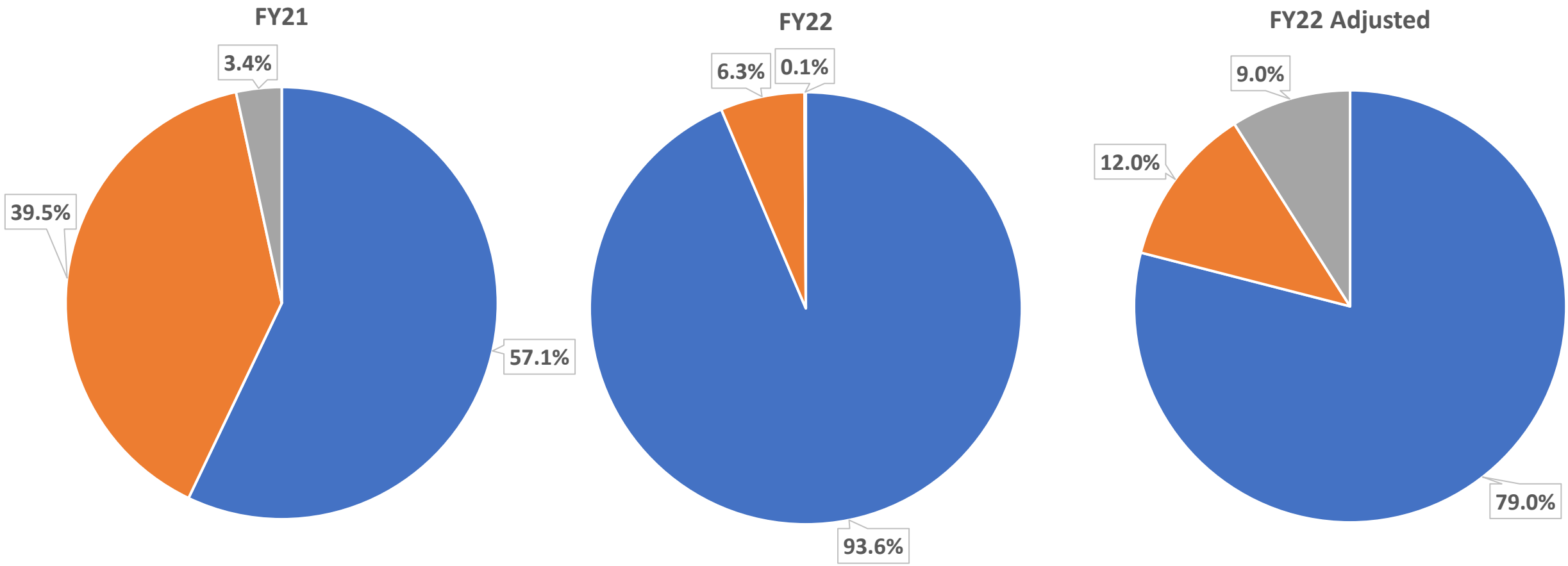
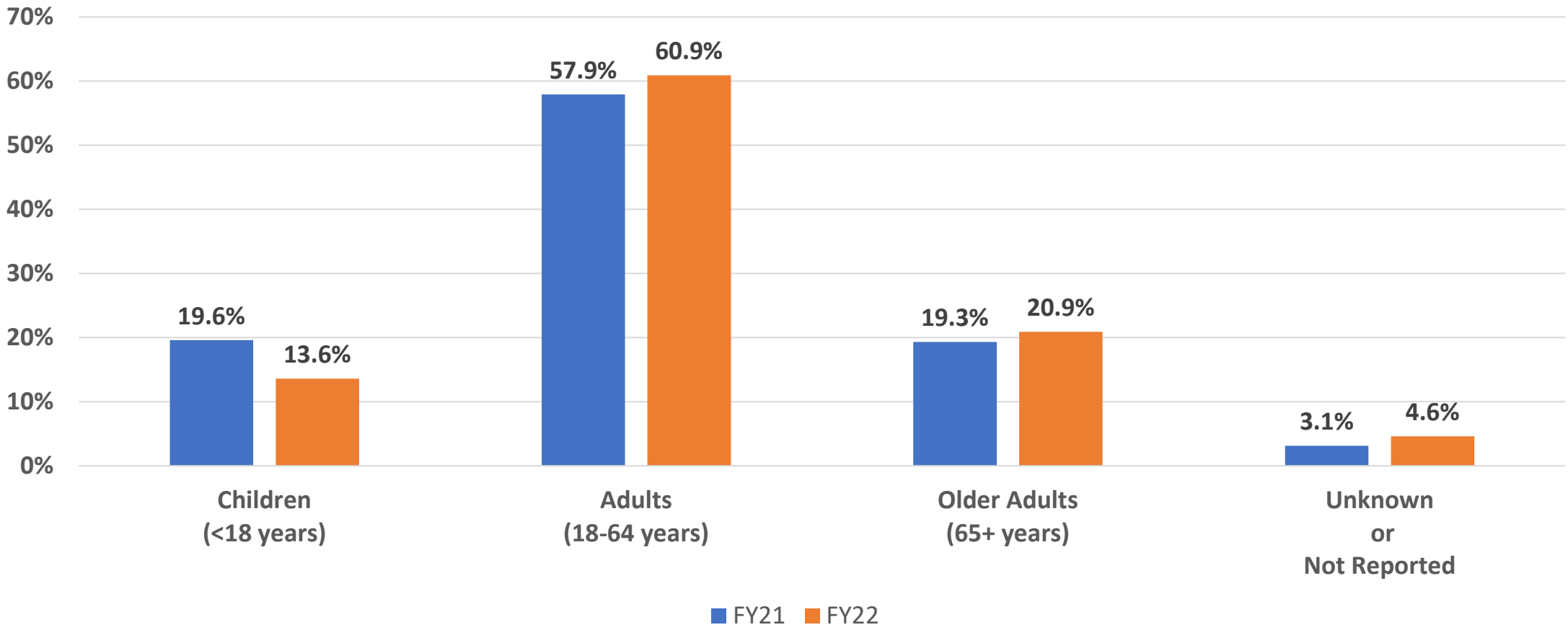
Ethnicity U.S.-Only Clinical Research Enrollment



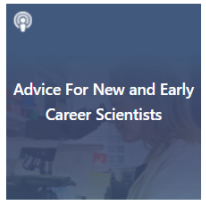
Ethnicity U.S.-Only NIH-defined Phase 3 Trial Enrollment



Age in Clinical Research Enrollment



Training and Resources



Inclusion Plans (Part 1): The Application

April 14, 2022

Inclusion plans. You have questions. We have answers. What exactly are they? How do they relate to NIH's policies requiring specific populations be included in NIH-supported clinical research? What do they mean for your application? And, what is an inclusion table anyway? In Part 1 of this NIH All About Grants podcast miniseries, NIH's Inclusion Policy Officer Dawn Corbett tells us how to consider inclusion plans when putting together your application. The good news is there's no page limit. So you can take the space that you need to describe inclusion of these populations in your research...in the inclusion of women and minorities plan, you'll be describing your inclusion based on sex or gender and race and ethnicity. And then in your inclusion of across the life span plan, you'll be describing distribution based on age and then you talk about the rationale. So why did you choose this population distribution? And this should really be based on science and ethics and you'll justify any exclusions. (Dawn Corbett) Part 2 covers inclusion plans during peer review and post-award. Interested in this topic? Learn more in our related podcasts on the Inclusion Across the Lifespan policy and valid/stratified analysis .

Dawn Corbett, M.P.H.

NIH's Inclusion Policy Officer

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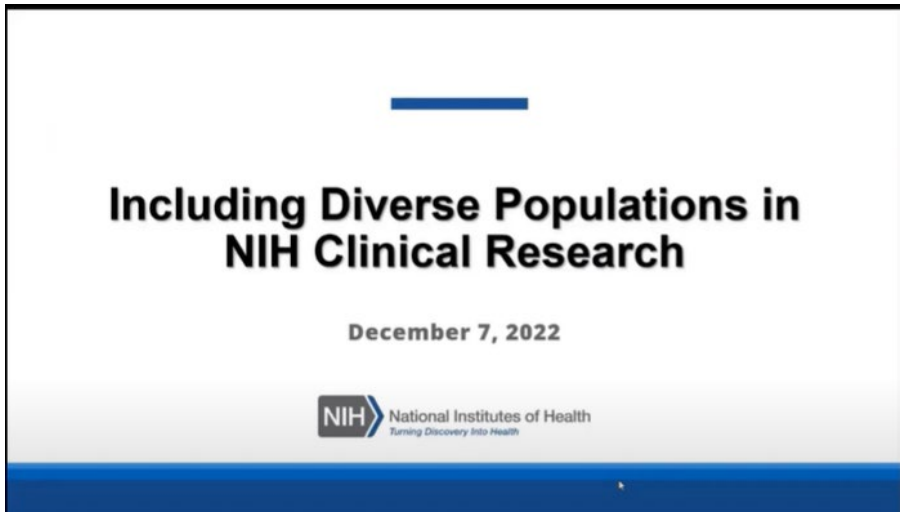

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Available Resources on the Recruitment and Retention of Women, Racial and Ethnic Minorities, and Individuals Across the Lifespan

Click on the resource title to open the item. You can also check out our FAQ on this topic.

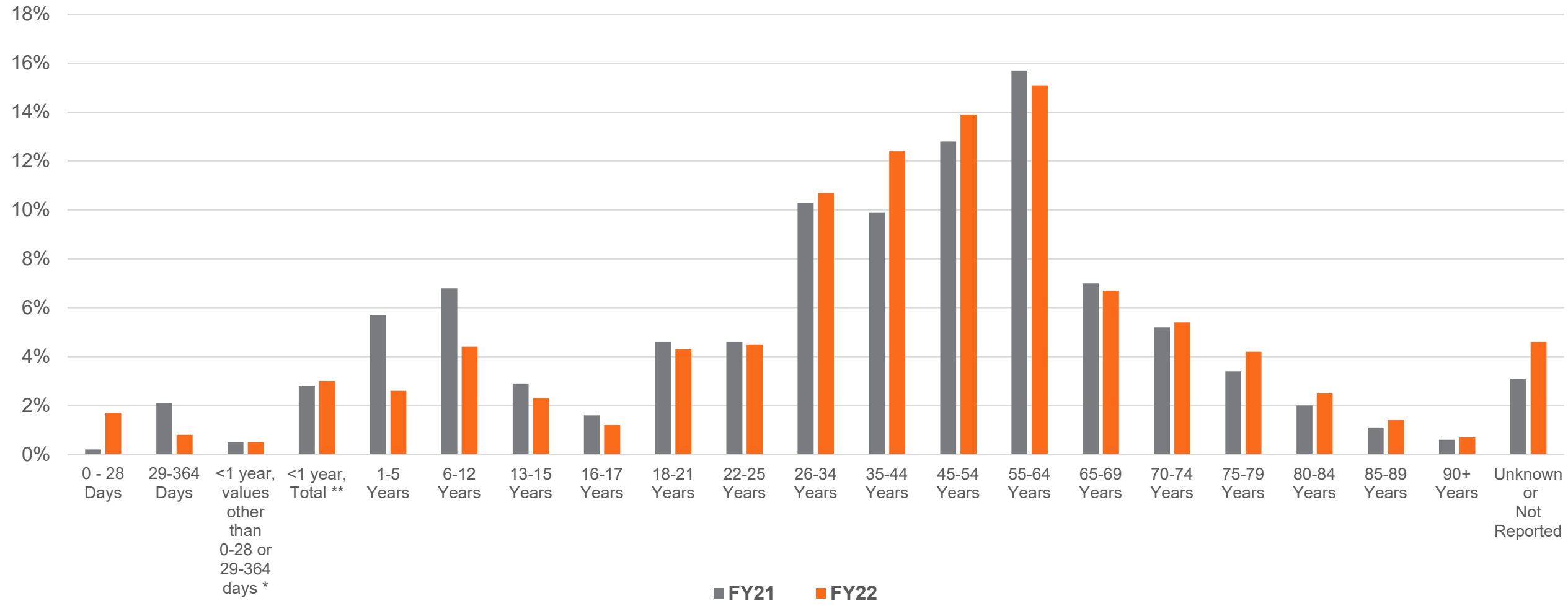
NIH Outreach Toolkit	Created by the NIH Office of Research on Women's Health (ORWH), this toolkit provides recruitment case studies and other important information regarding the recruitment and retention of women in research.
The National Institute on Aging (NIA) Recruiting Older Adults into Research (ROAR) Toolkit	Part of a collaborative project to encourage research participation among older adults and their caregivers, this toolkit provides recruitment steps and information for volunteers.
NIA Health Professionals Information website	Provides materials to assist healthcare professionals in communicating with older adults, including considerations for diverse populations. See also this featured research story on minority recruitment.
NIA OutreachPro	Resource from NIA that houses tools to help dementia researchers recruit and engage study participants.

https://grants.nih.gov/policy/inclusion.htm

Questions?

ADDITIONAL SLIDES

Age at Enrollment in NIH Clinical Research by Narrow Age Groups



* Includes ages reported in weeks, months, or years that are equivalent to less than 1 year.

**Includes all ages equivalent to less than one year, including all those reported in days, weeks, months and years.

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