



Report to the Advisory Committee on Research on Women's Health: Preliminary Analysis of NIH Inclusion Data FY2013-2014

April 10, 2015

Meredith D. Temple-O'Connor, Ph.D.
NIH Inclusion Policy Officer
Office of Extramural Research
National Institutes of Health



NIH National Institutes of Health
Office of Extramural Research

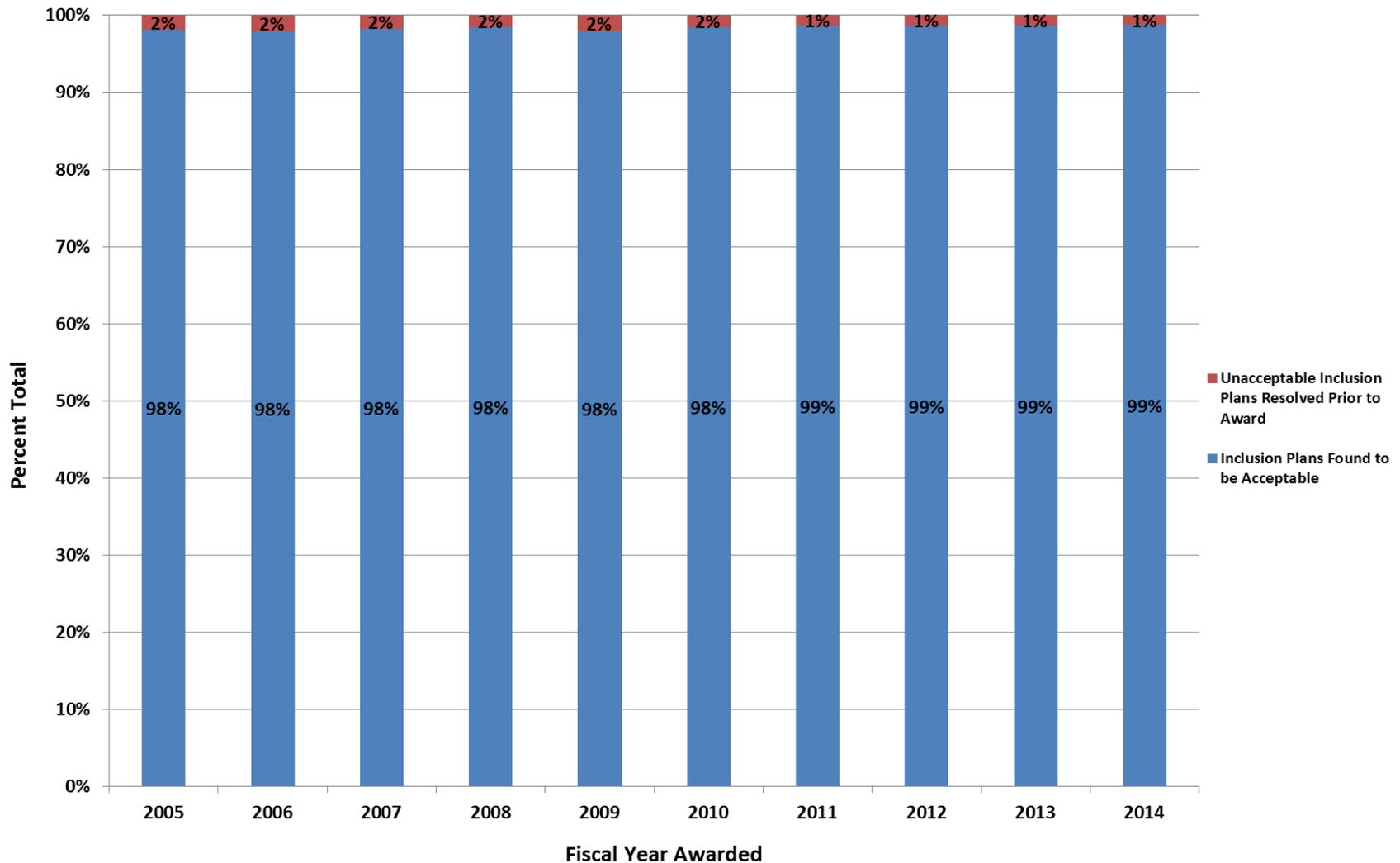
Outline for Presentation

- **Acceptability of inclusion plans for extramural research awards**
- **Aggregate Enrollment: Sex/Gender**
- **Aggregate Enrollment: Race and Ethnicity (US-based studies)**
- **Aggregate Enrollment: Race and Ethnicity by Sex/Gender (US-based studies)**
- **Updates on inclusion at NIH**

Some updates to data analysis and reporting

- **Minimal reporting on enrollment data records**
 - **Enrollment data records do not equal studies so can be misinterpreted**
 - **Using information on number of data records to give some context to distributions by sex/gender**
- **Expanded trend analyses**
- **Reorganized reporting of Race and Ethnicity by Sex/Gender**

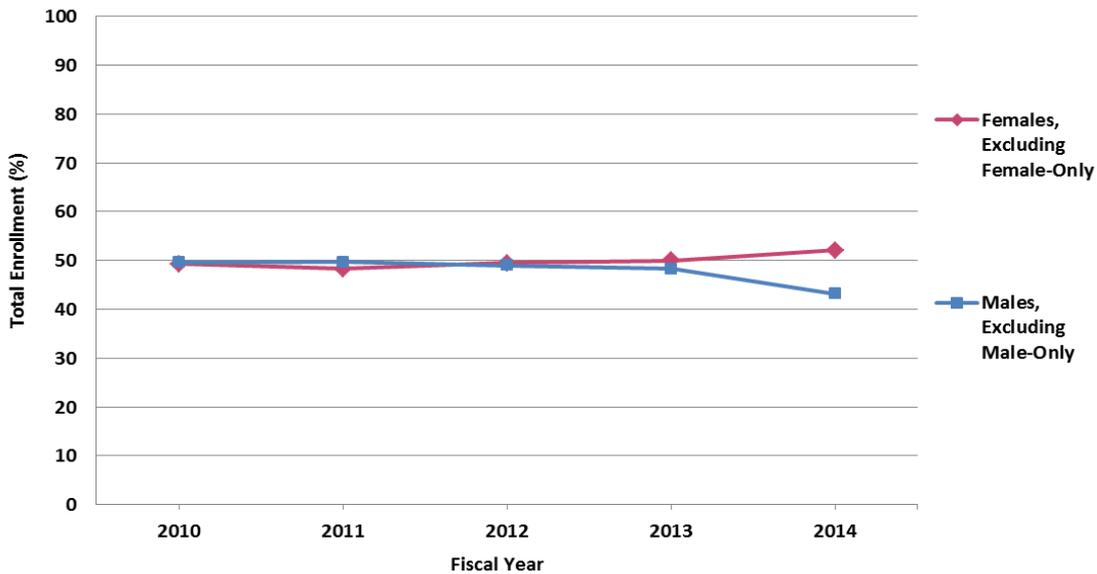
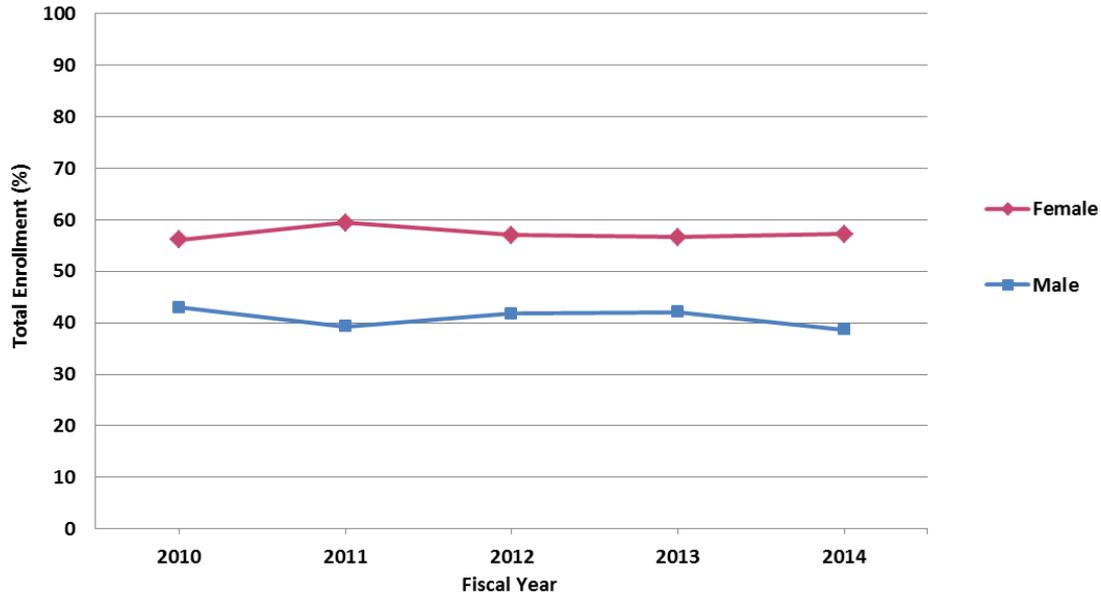
Competing Extramural Research Awards: Bars-to-Funding and Resolutions



Aggregate Enrollment: Sex/Gender



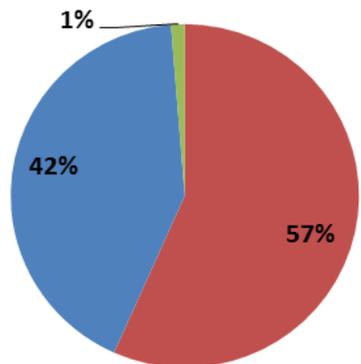
Long-Term Trend of Enrollment by Sex/Gender in NIH Clinical Research



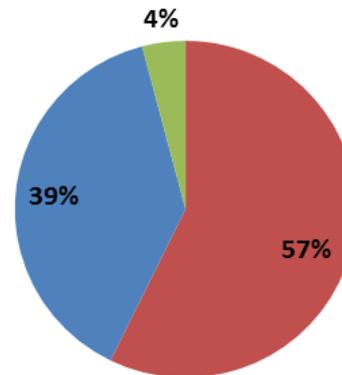
Enrollment by Sex/Gender for NIH Clinical Research

All Clinical Research

FY2013

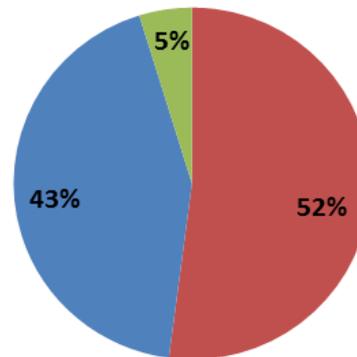
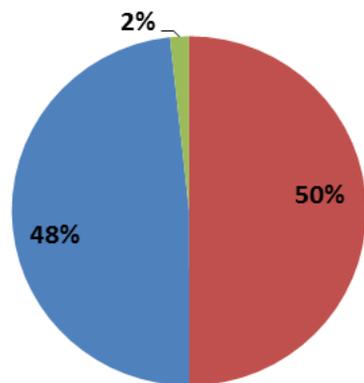


FY2014



■ Total Females
■ Total Males
■ Total Unknown

All Clinical Research Excluding Single-Sex Studies

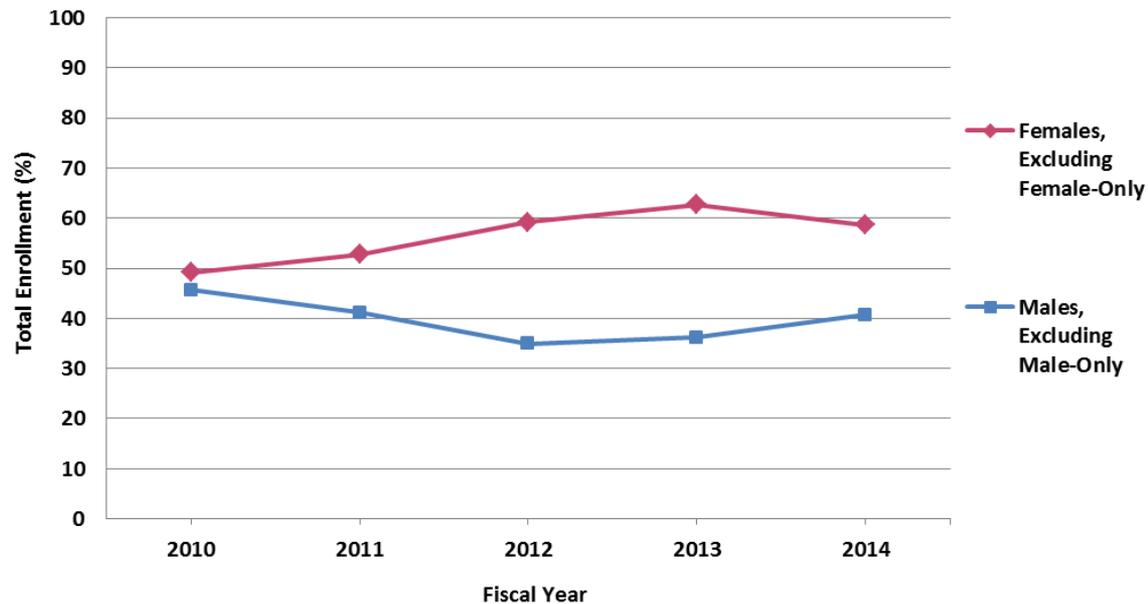
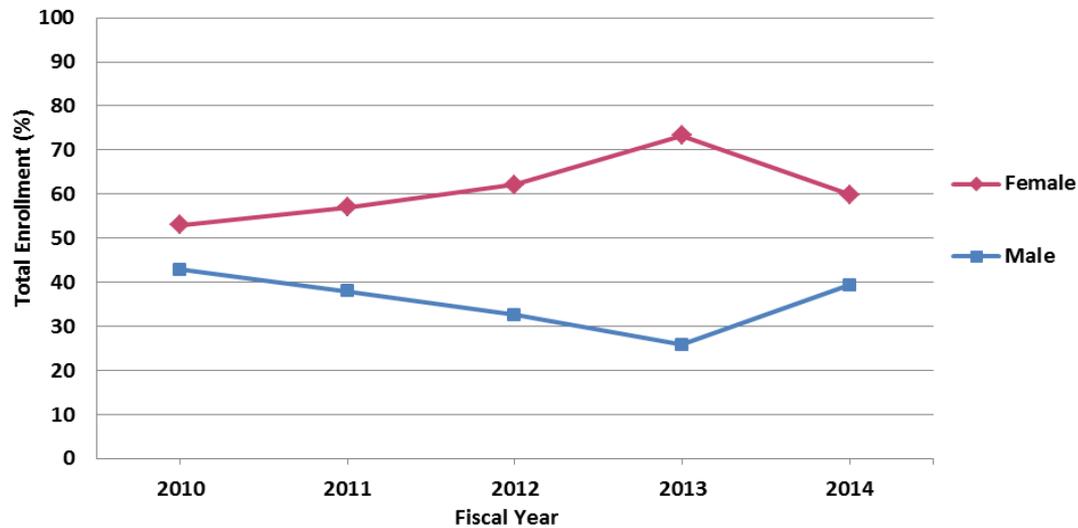


■ Females, Excluding Female-only
■ Males, Excluding Male-only
■ Total Unknown

Fiscal Year	Total IDRs	IDRs Without Enrollment	IDRs With Enrollment	Female Only IDRs	Male Only IDRs	IDRs Excluding Male-only and Female-only *
2013	15,017	4,425	10,592	1,206	614	8,772
2014	14,067	3,983	10,084	1,129	553	8,402

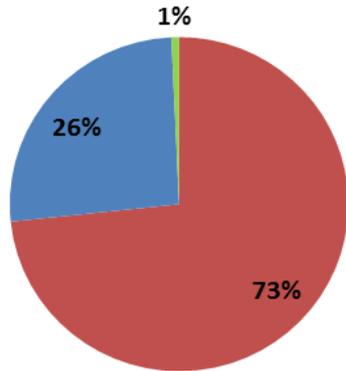


Long-Term Trend of Enrollment by Sex/Gender in NIH-Defined Phase III Clinical Trials

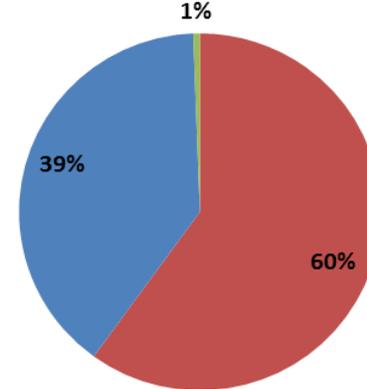


Percent Enrollment by Sex/Gender in NIH-Defined Phase III Clinical Trials

FY2013



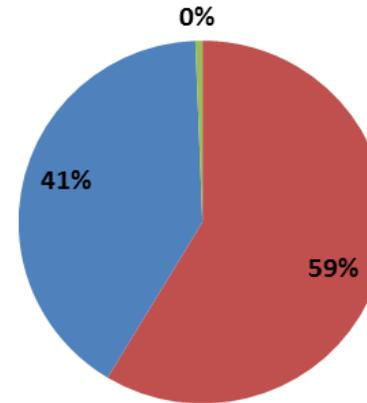
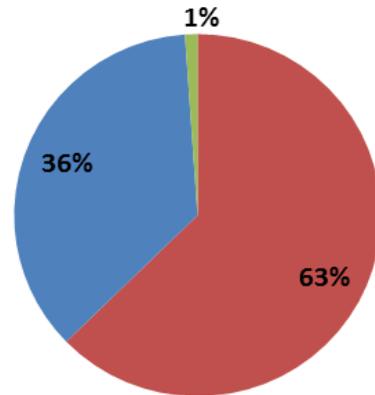
FY2014



All Phase III Trials

■ Total Females
■ Total Males
■ Total Unknown

Phase III Trials
Excluding
Single-Sex Studies



■ Females, Excluding Female-only
■ Males, Excluding Male-only
■ Total Unknown

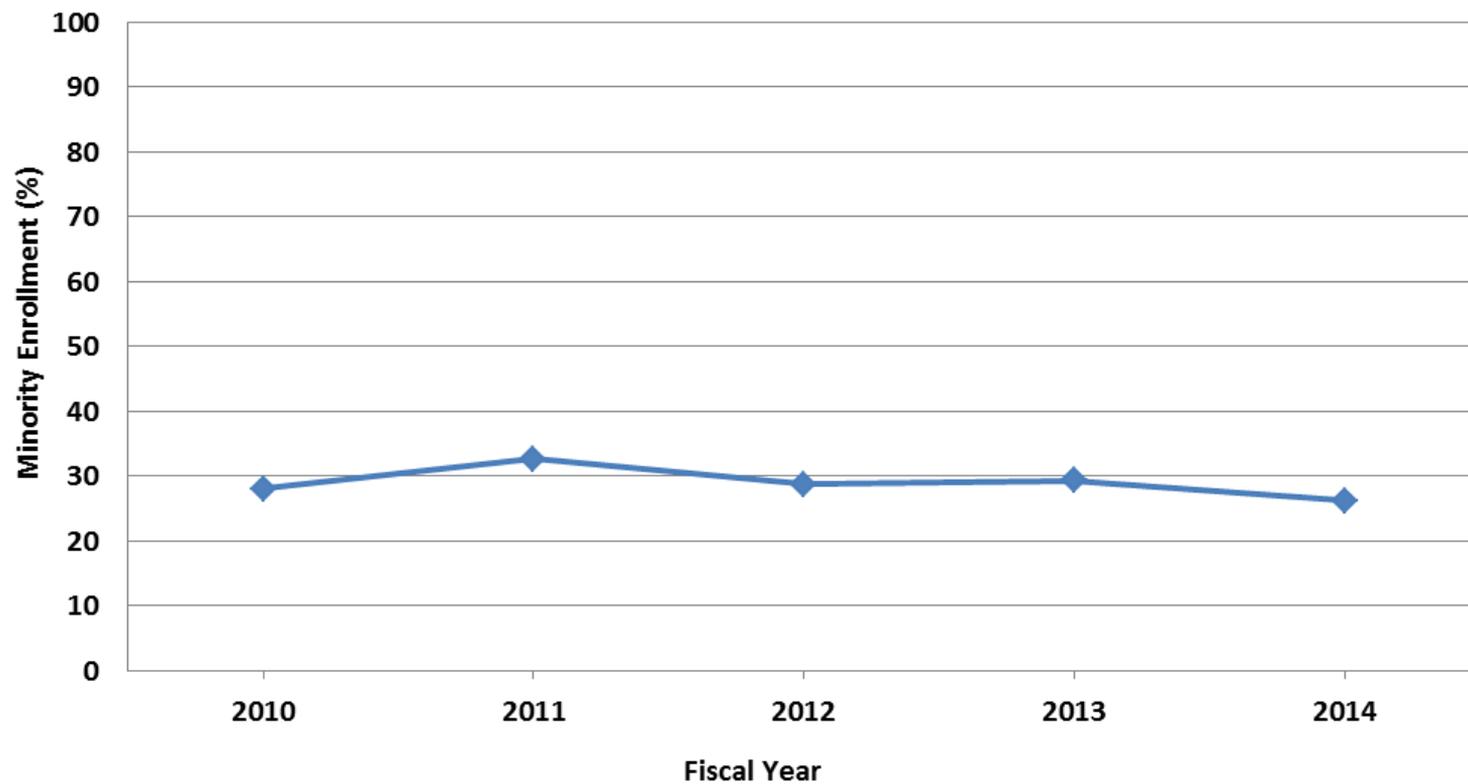
Fiscal Year	Total IDRs	IDRs Without Enrollment	IDRs With Enrollment	Female Only IDRs	Male Only IDRs	IDRs Excluding Male-only and Female-only *
2013	613	41	572	102	37	433
2014	576	50	526	73	29	424



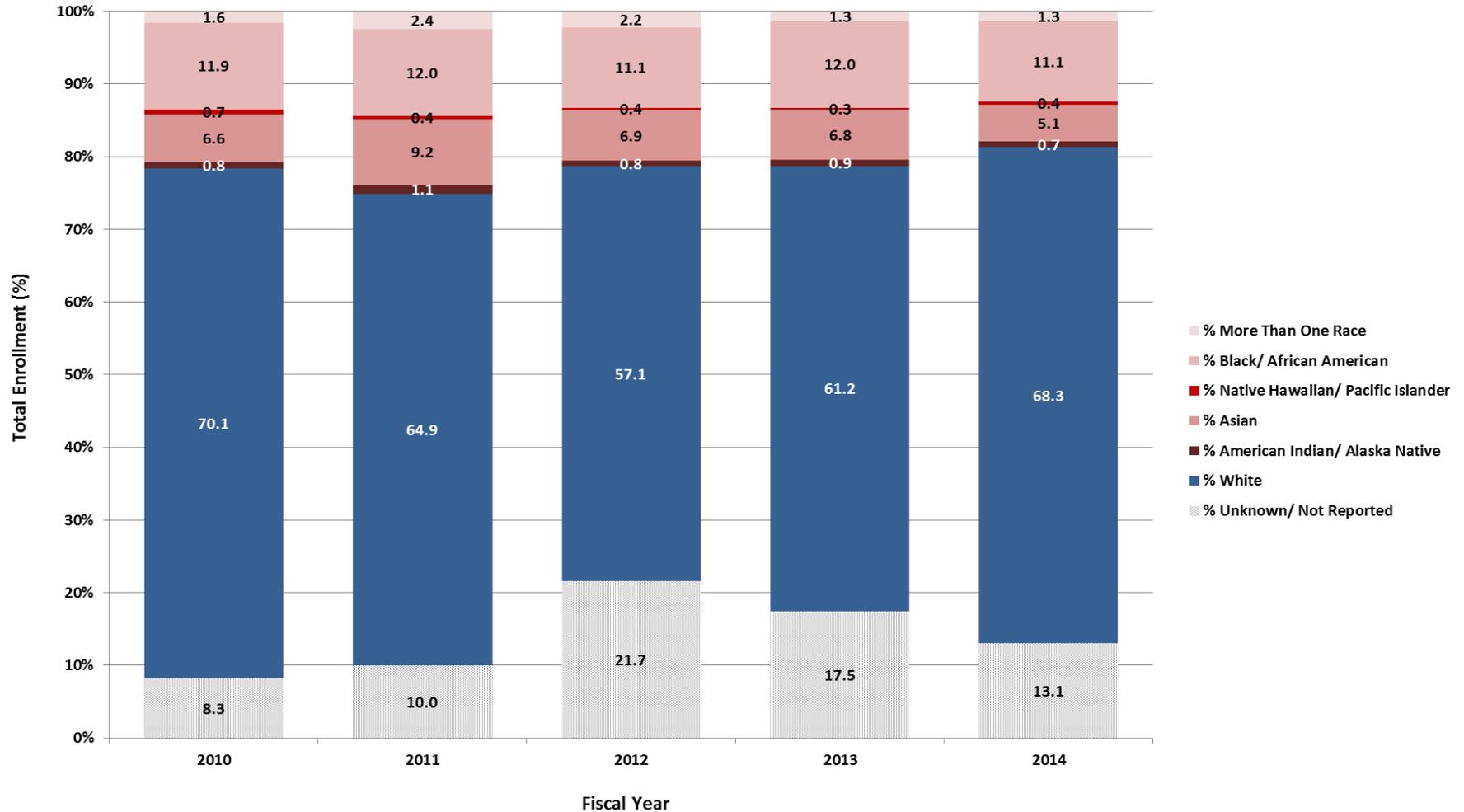
Aggregate Enrollment: Race and Ethnicity of US Based Studies



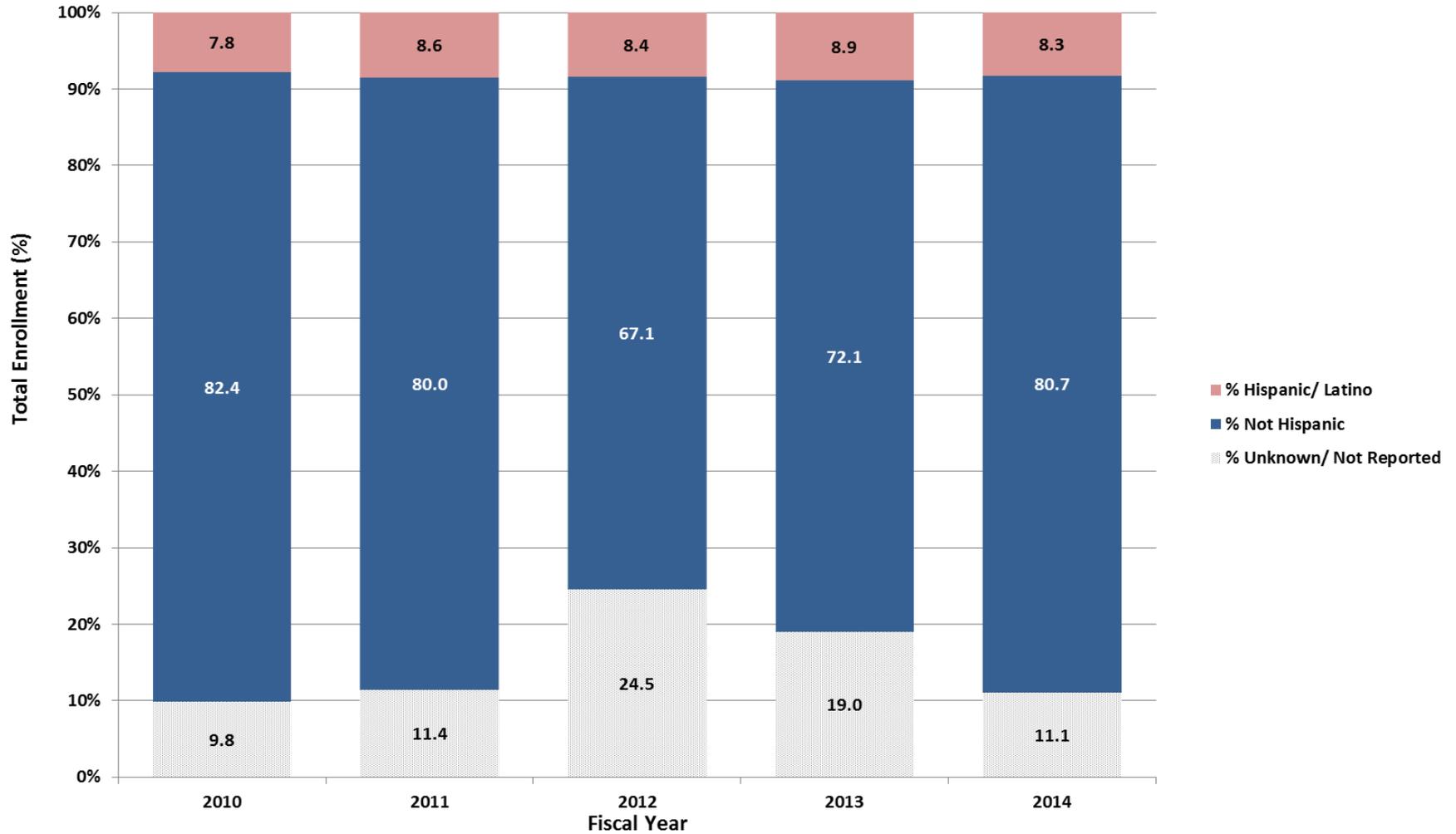
Minority Enrollment in NIH Clinical Research (US Populations Only)



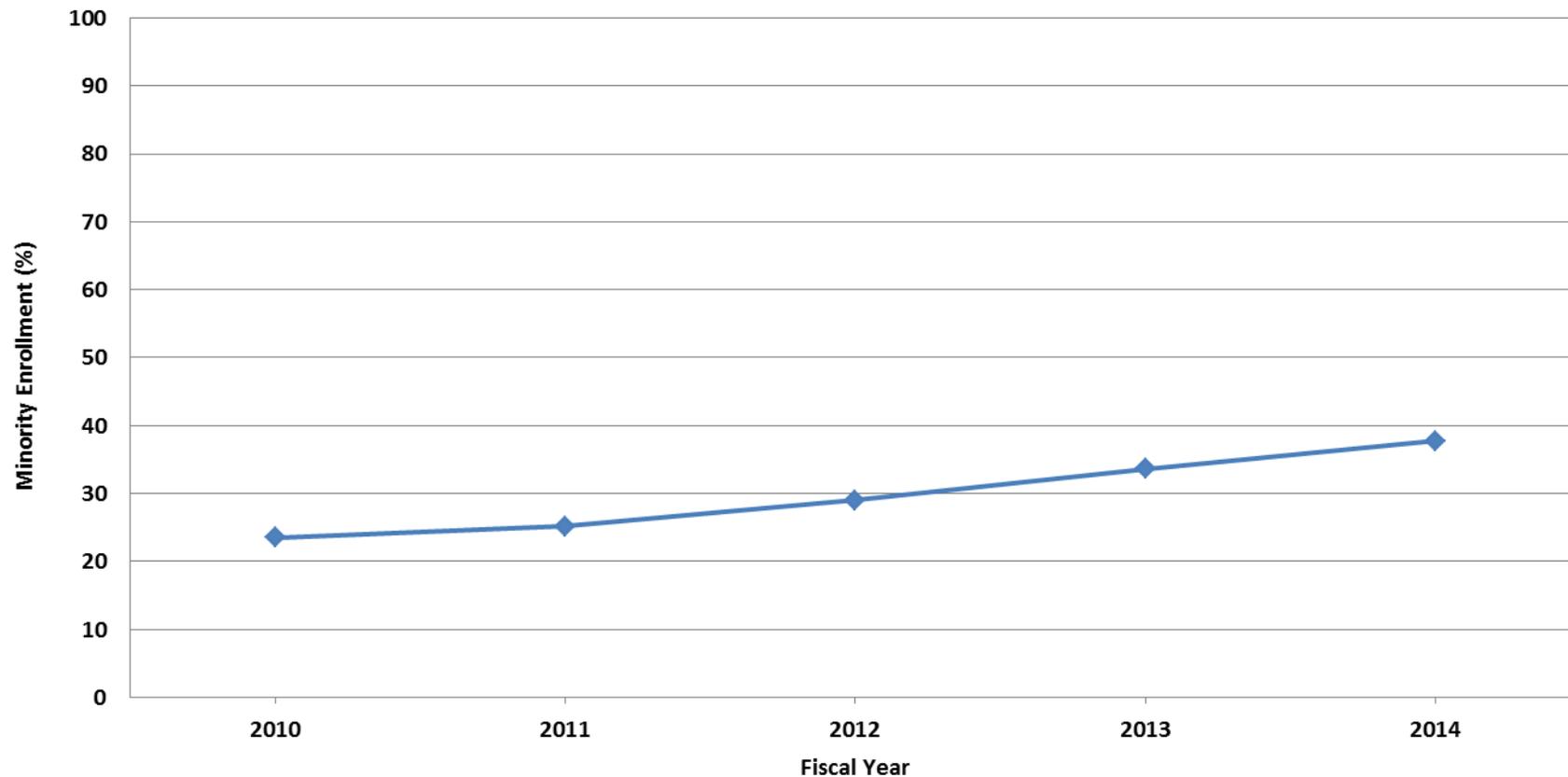
Enrollment in NIH Clinical Research: Racial Categories (US Populations Only)



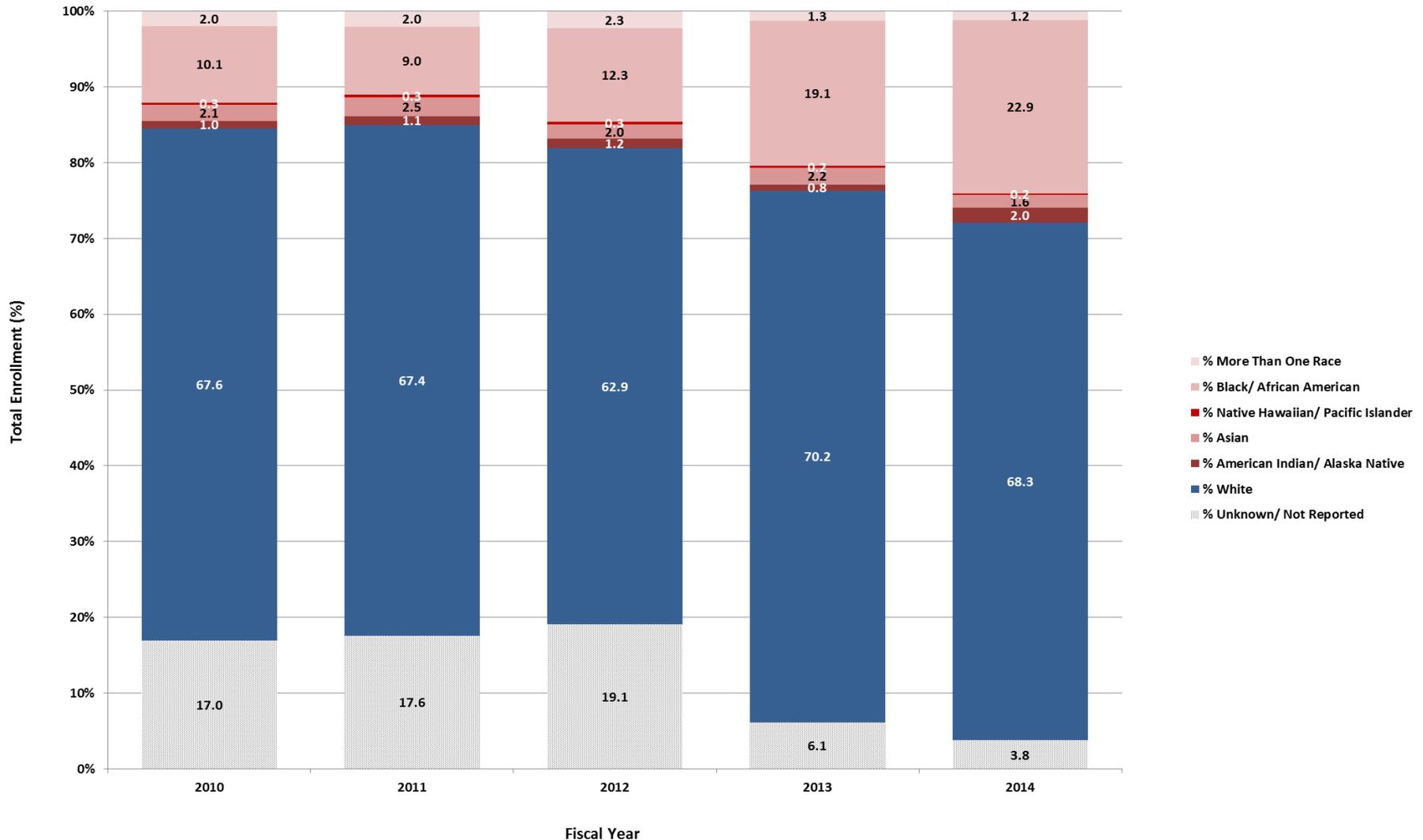
Enrollment in NIH Clinical Research: Ethnic Categories (US Populations Only)



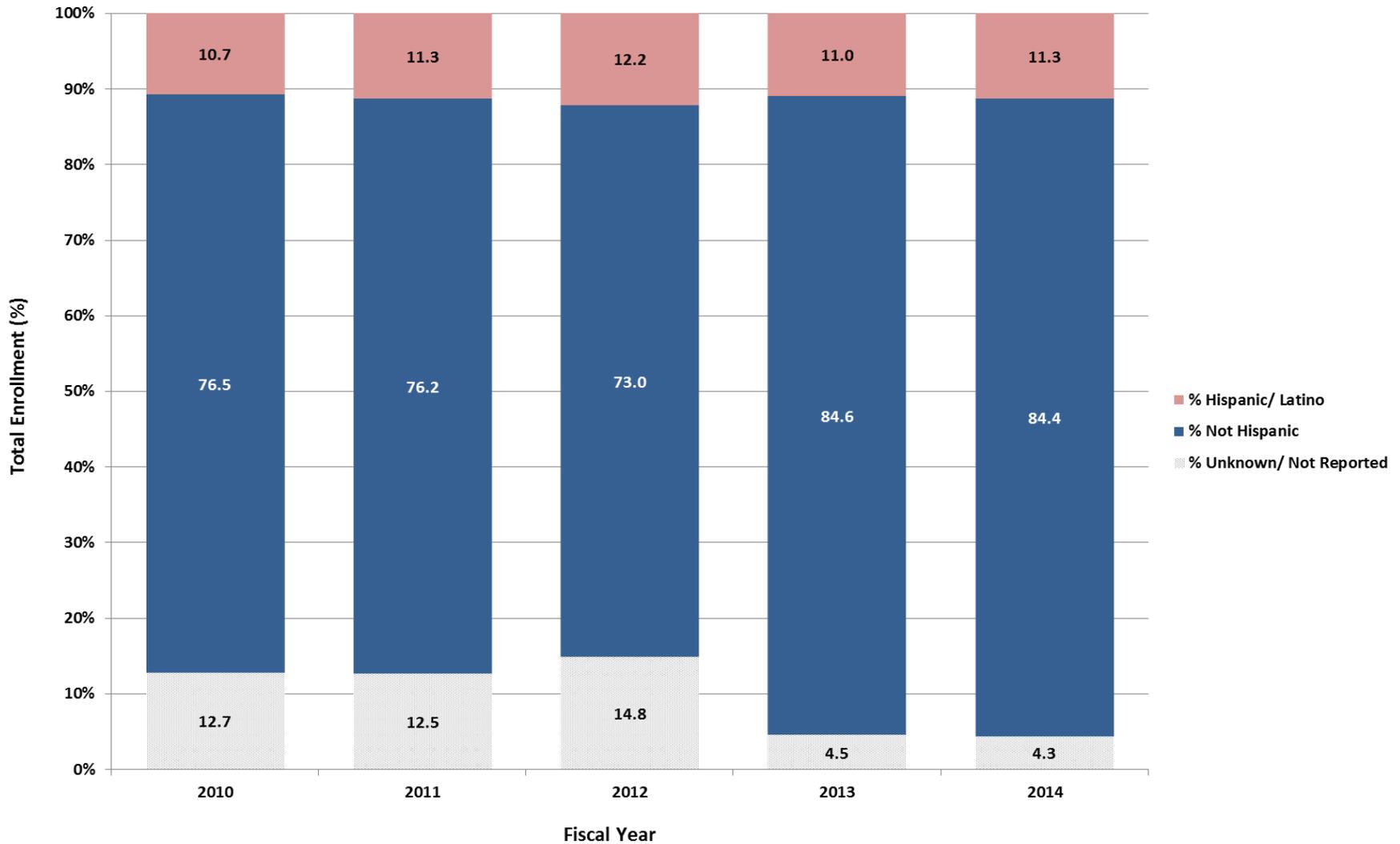
Minority Enrollment in NIH-Defined Phase III Clinical Trials (US Populations Only)



Enrollment in NIH-Defined Phase III Clinical Trials: Racial Categories (US Populations Only)



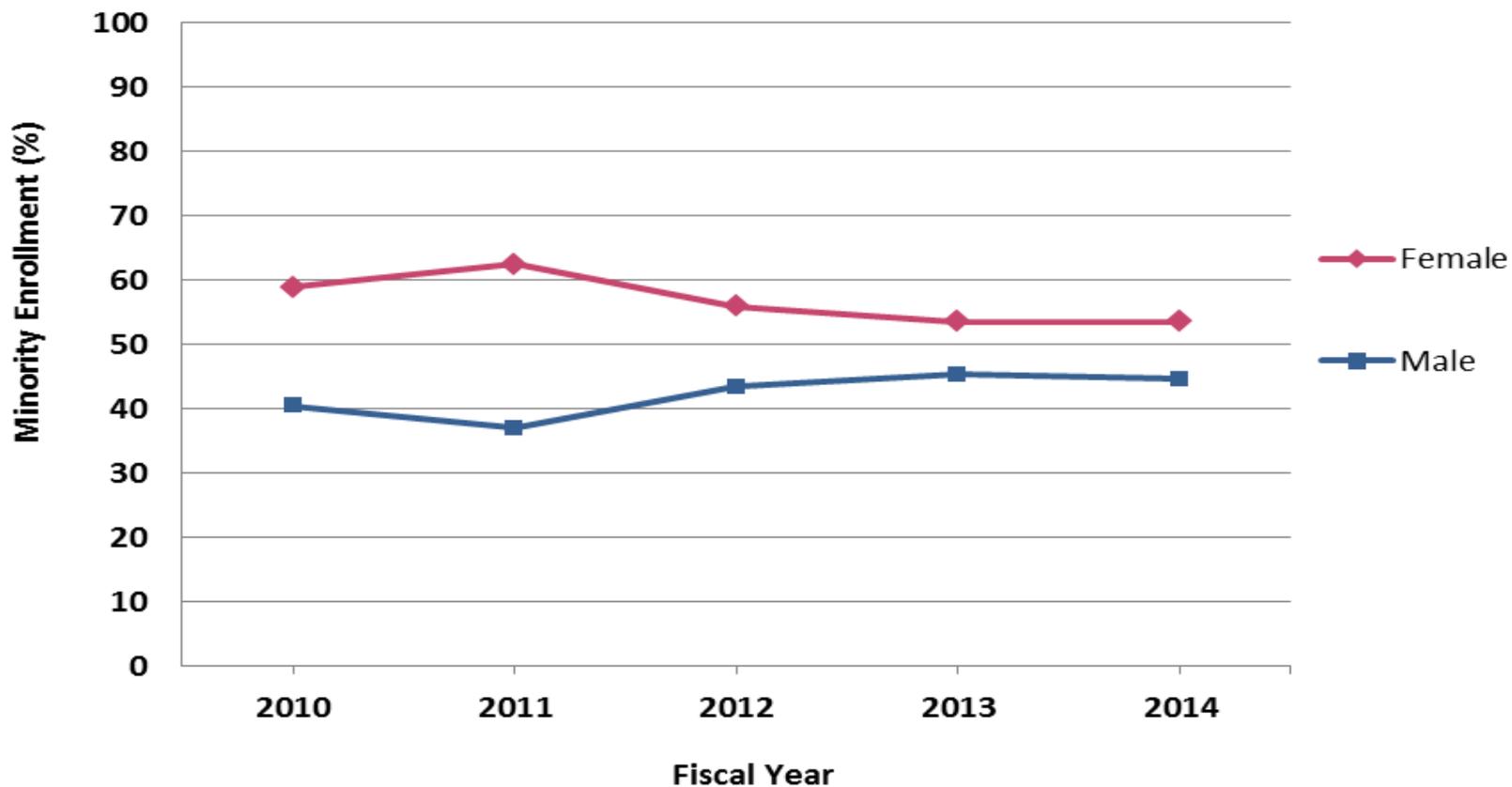
Enrollment in NIH-Defined Phase III Clinical Trials: Ethnic Categories (US Populations Only)



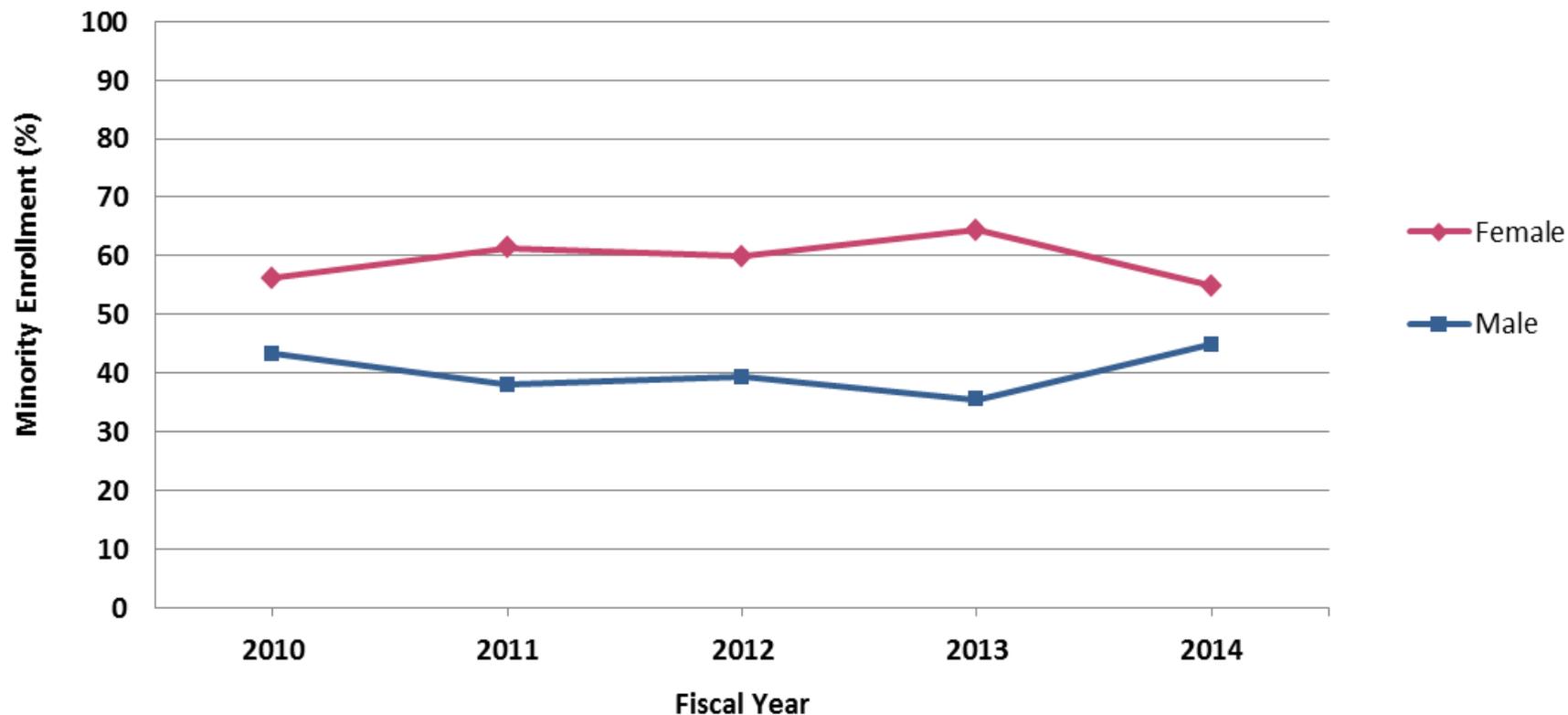
Aggregate Enrollment: Race and Ethnicity by Sex/Gender of US Populations



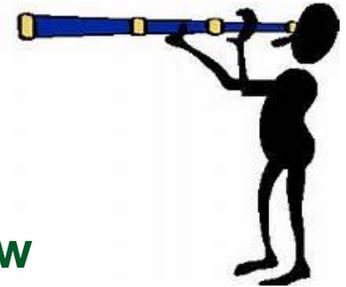
Minority Enrollment by Sex/Gender for NIH Clinical Research (US Populations Only)



Minority Enrollment by Sex/Gender for NIH-Defined Phase III Clinical Trials (US Populations Only)



Updates on Inclusion



- **Inclusion Management System:**
 - Staff and grantees are getting experience with the new process and enhanced integration with other systems
- **Reporting and Analysis:**
 - NIH will start thinking more about different ways to understand inclusion and analyze the data
 - Need to move beyond simply counting numbers and think about inclusion in the context of the science
 - Making efforts to standardize individual IC reports
- **Communications and Outreach:**
 - Continue to clarify expectations for different stakeholder groups (e.g., investigators, peer reviewers, staff in different roles, etc.)
 - Developing working group with FDA to tackle shared issues related to inclusion

Questions

