U.S. Department of Health and Human Services

National Human Genome Research Institute

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Inclusion of Women and Minorities in NHGRI Clinical Studies
FY2013-FY2014

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NHGRI Advisory Council Meeting
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Overview

- **History of NIH Requirement to Report Enrollment**

- **Definitions**

- **Exclusion of 23andMe Enrollment Data**

- **Report of NHGRI FY13-FY14 Enrollment Data**

- **Comparisons and Analysis**

- **Summary**

Background

- **Inclusion of women and minorities in clinical research is scientifically important**

- **Biennial report is required by the NIH Revitalization Act of 1993**

- **Ensures NHGRI is in compliance with NIH mandate to include women and minorities in clinical research**

- **Covers Extramural and Intramural enrollment data reported in FY2013 and FY2014**

- **All human subjects research must report gender and minority inclusion unless exempted**

Population Tracking Definitions

- A **minority group*** is a readily identifiable subset of the U.S. population distinguished by racial, ethnic, and/or cultural heritage.

- A **significant difference*** is a difference that is of clinical or public health importance, based on substantial scientific data.

- A **protocol** is a single grant or IRB-approved project.

*As defined in the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research

Enrollment Tables from PIs

Ethnic Category	Females (F)	Males (M)
Hispanic or Latino (**Hisp**)		
Not Hispanic or Latino (**Not Hisp**)		
Unknown (Not reporting ethnicity) (**Unk**)		
Racial Categories		
American Indian/Alaska Native (**AI/AN**)		
Asian		
Native Hawaiian or Other Pacific Islander (**Haw/Pac**)		
Black or African American (**Bl/AA**)		
White		
More Than One Race (**>1 Race**)		
Unknown or Not Reported (**Unk**)		

23andMe and the FY2013-FY2014 NHGRI Data

- **ERP funds 23andMe study of >580K participants; data collected differently:**
  - Data are collected online
  - Participants not identifying as Hisp assumed to be Not Hisp
  - Gender determined by genetic data; not self-reported
- **The high proportion of unknown race significantly skewed the proportions unknown for NHGRI as a whole**
- **Subsequent analyses generally exclude 23andMe data or report them separately**

NHGRI Number of Protocols and Actual Enrollment During FY13-FY14

	ERP*	IRP	Total
Number of Protocols	50	94	144
Number of Participants	238,273	64,717	302,990

*ERP data excluding 23andMe

FY13-14 Size of Funded Protocols
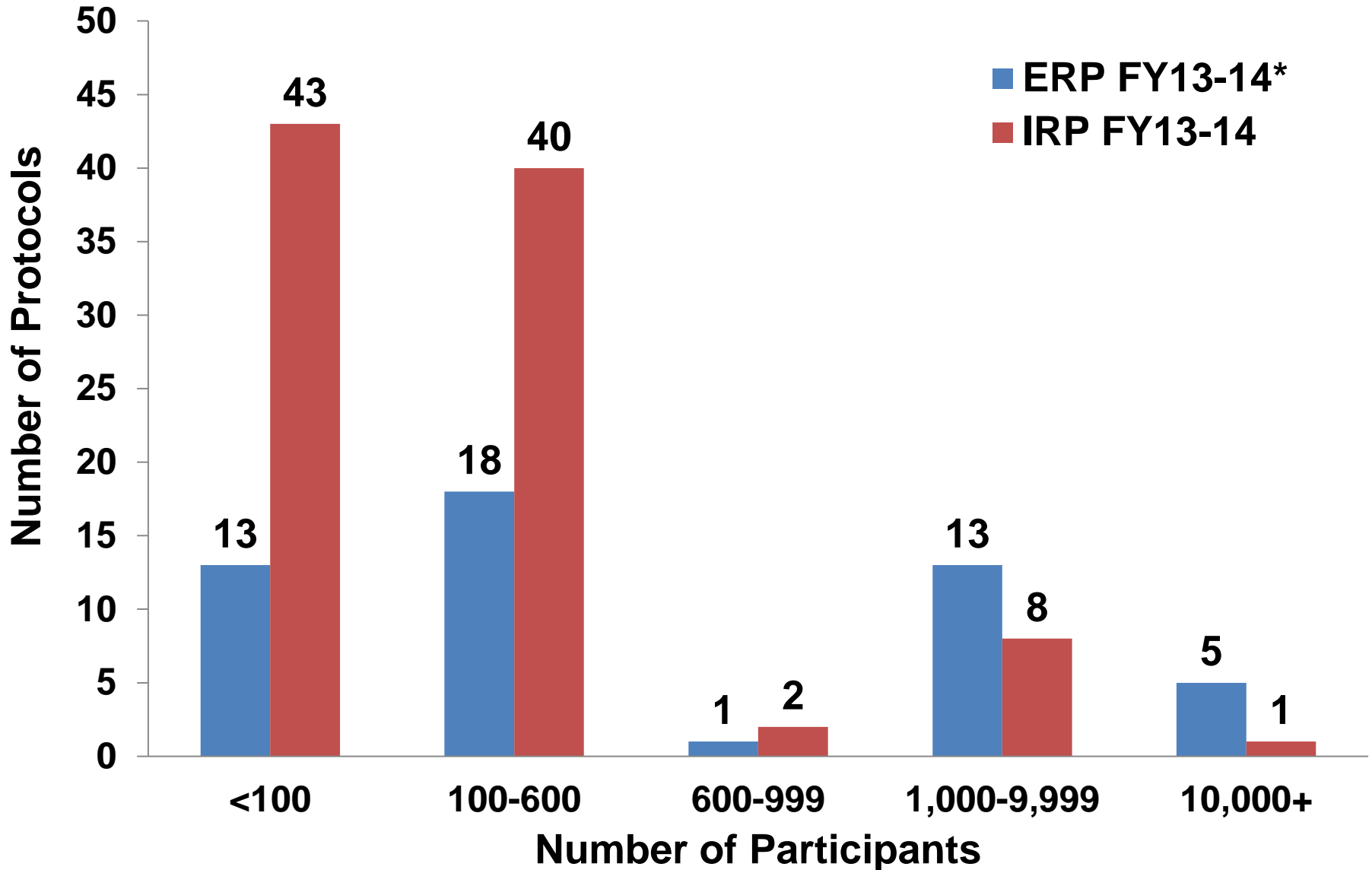
FY13-14 NHGRI Actual Enrollment Data by Race

ERP* (n=238,273)
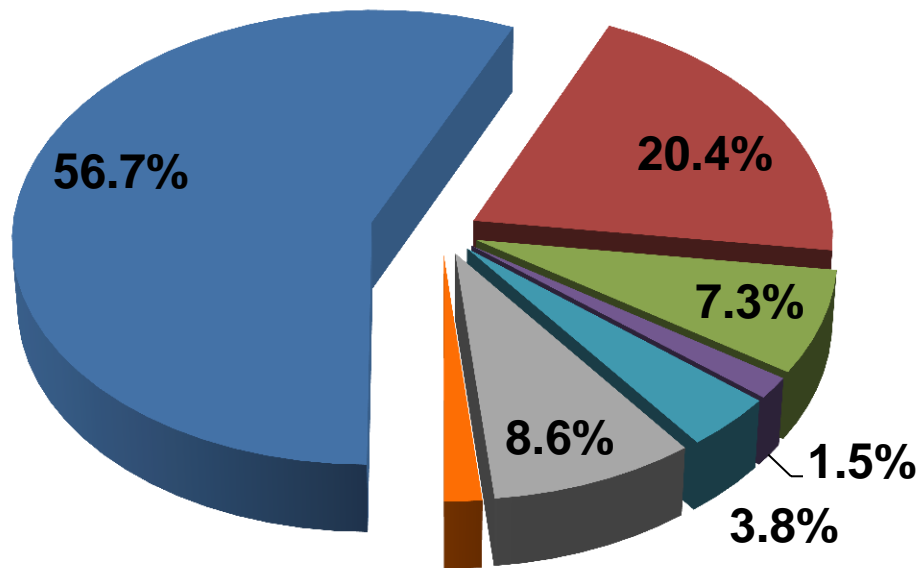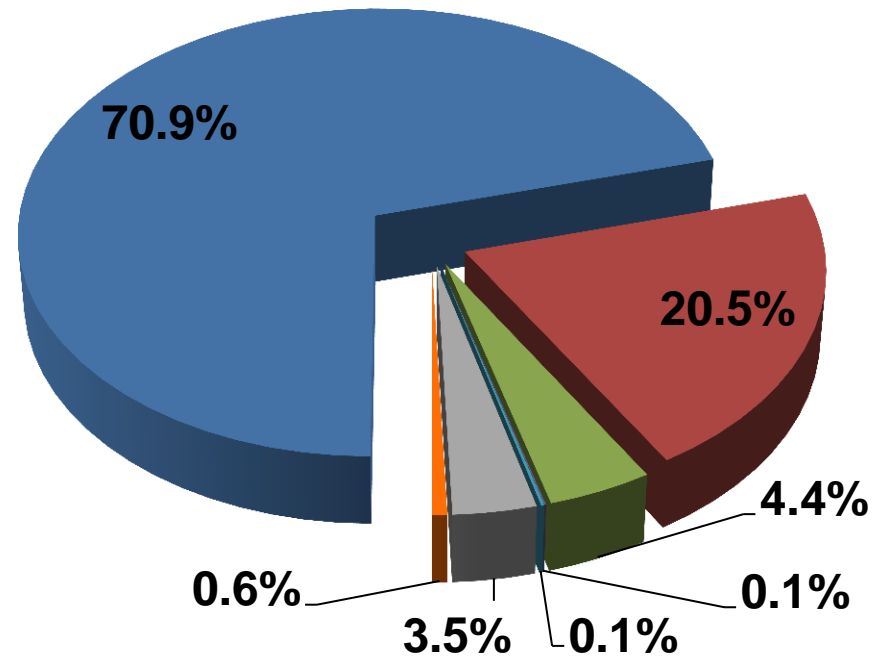
56.7%
20.4%
7.3%
1.5%
3.8%
8.6%
1.6%

IRP (n=64,717)

70.9%
20.5%
4.4%
0.1%
0.1%
3.5%
0.6%

■ White   ■ Bl/AA   ■ Asian
■ Haw/Pac   ■ Am Ind   ■ Unk
■ >1 Race

*ERP data excluding 23andMe

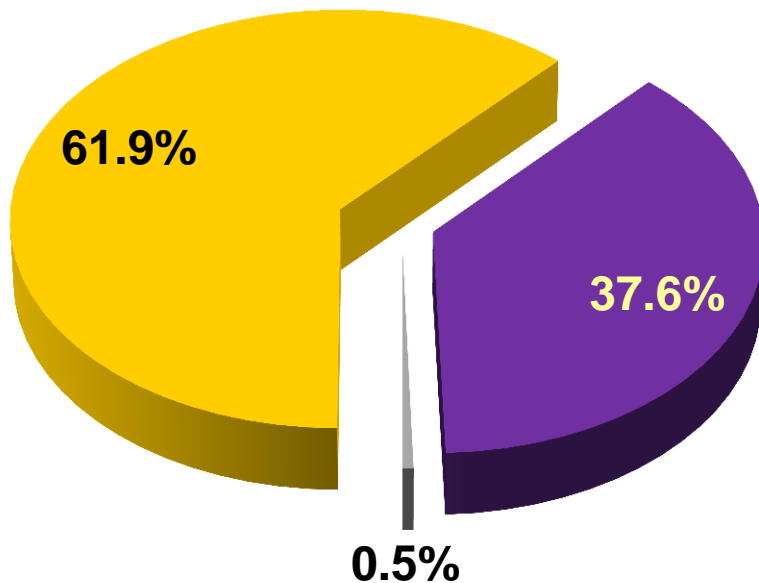# FY13-14 NHGRI Actual Enrollment Data by Ethnicity

ERP* (n=238,273)
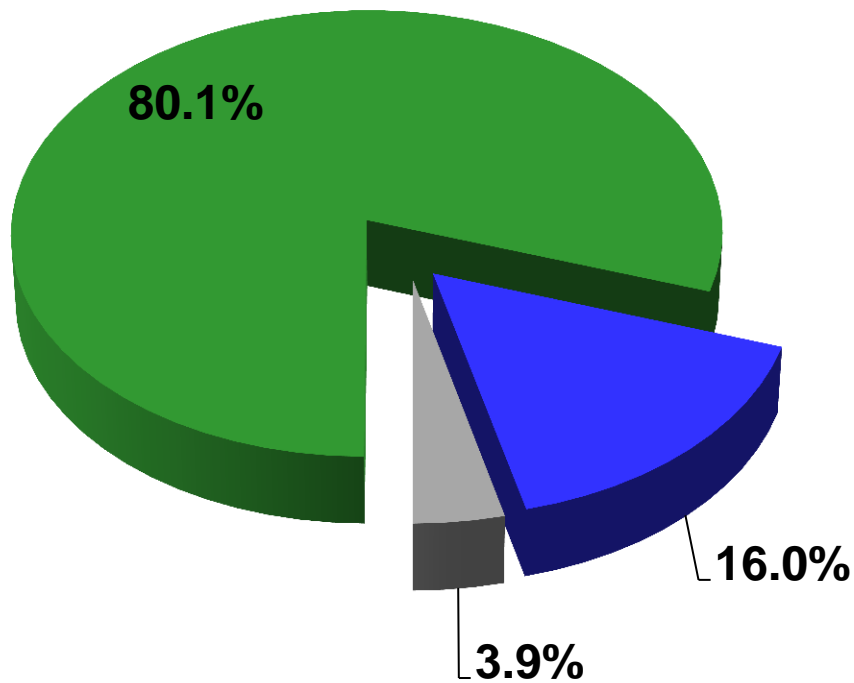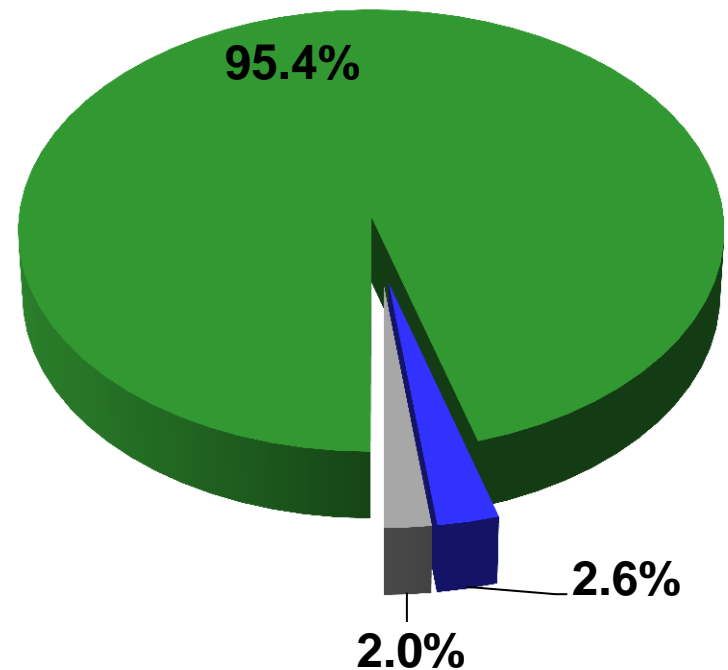
80.1%

16.0%

3.9%

IRP (n=64,717)

95.4%

2.6%

2.0%

■ Not Hisp ■ Hisp ■ Unk

*ERP data excluding 23andMe

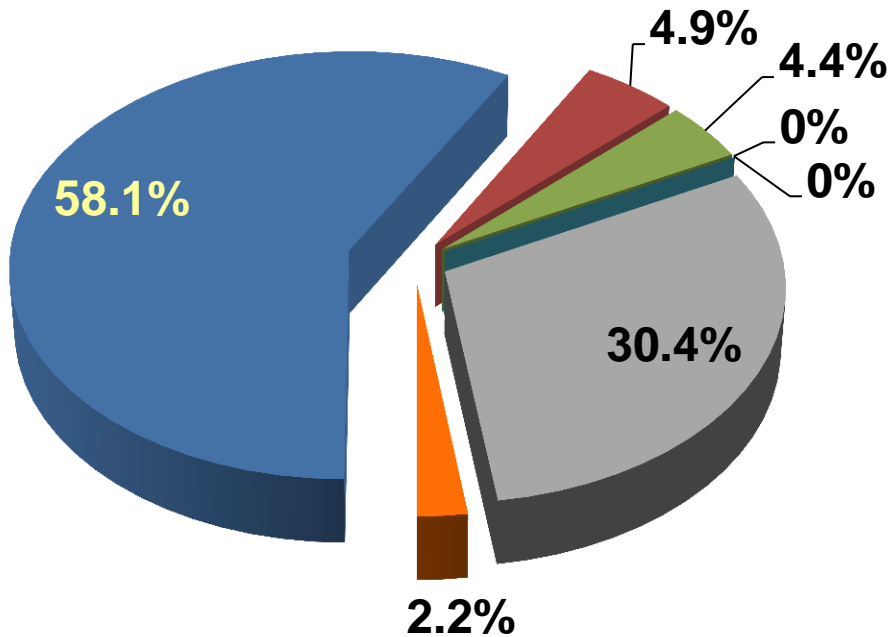# FY13-14 NHGRI Actual Enrollment Data by Gender
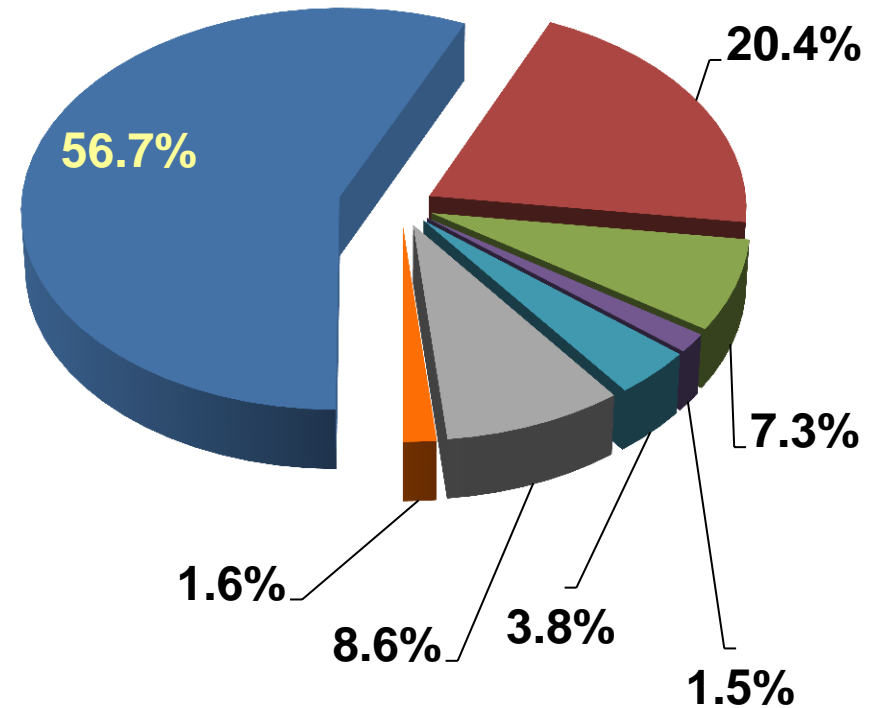
ERP* (n=238,273)

61.9%

37.6%

0.5%

IRP (n=64,717)

43.7%

51.5%

4.9%
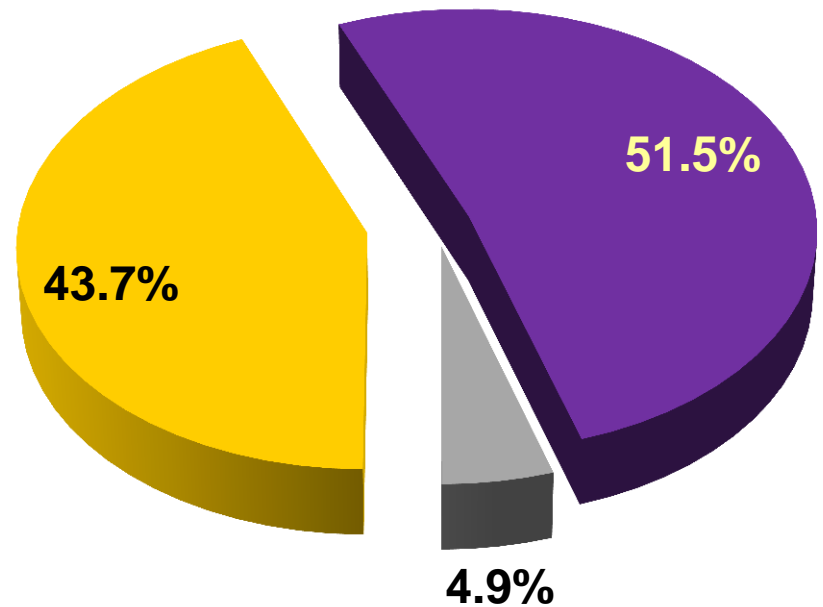
■ Female ■ Male ■ Unk

*ERP data excluding 23andMe

FY13-14 23andMe Actual Enrollment Data by Race

23andMe (n=583,266)

58.1%
4.9%
4.4%
0%
0%
30.4%
2.2%

ERP* (n=238,273)

56.7%
20.4%
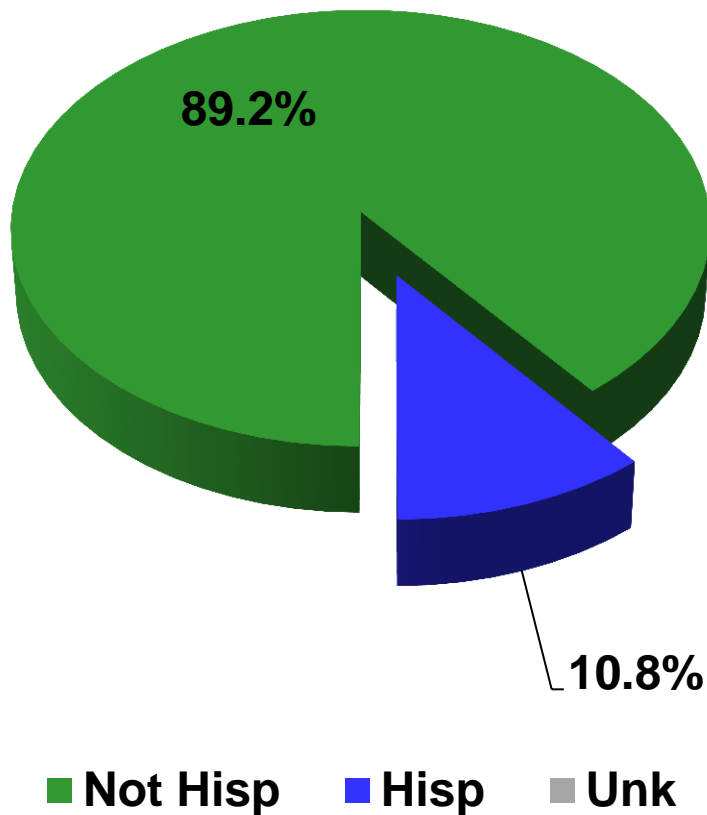7.3%
1.5%
3.8%
8.6%
1.6%

Legend:
- ■ White
- ■ Bl/AA
- ■ Asian
- ■ Haw Pac
- ■ Am Ind
- ■ Unk
- ■ >1 Race

*ERP data excluding 23andMe

FY13-14 23andMe Actual Enrollment Data by Ethnicity
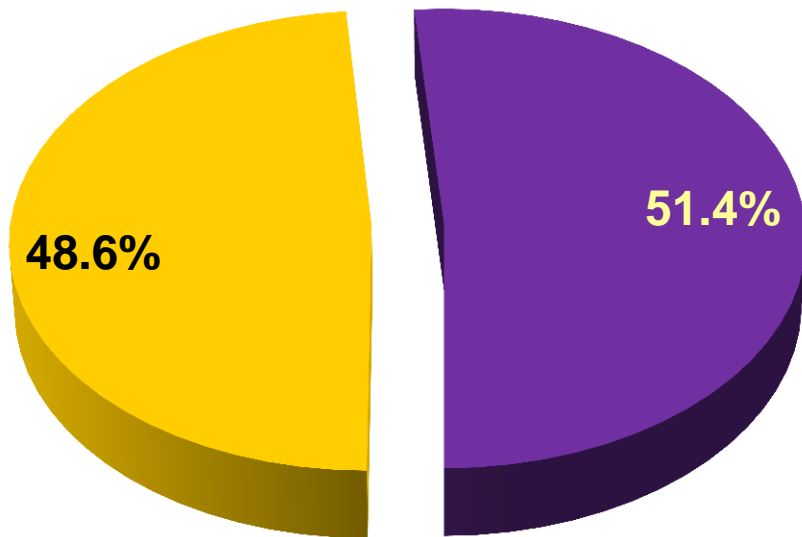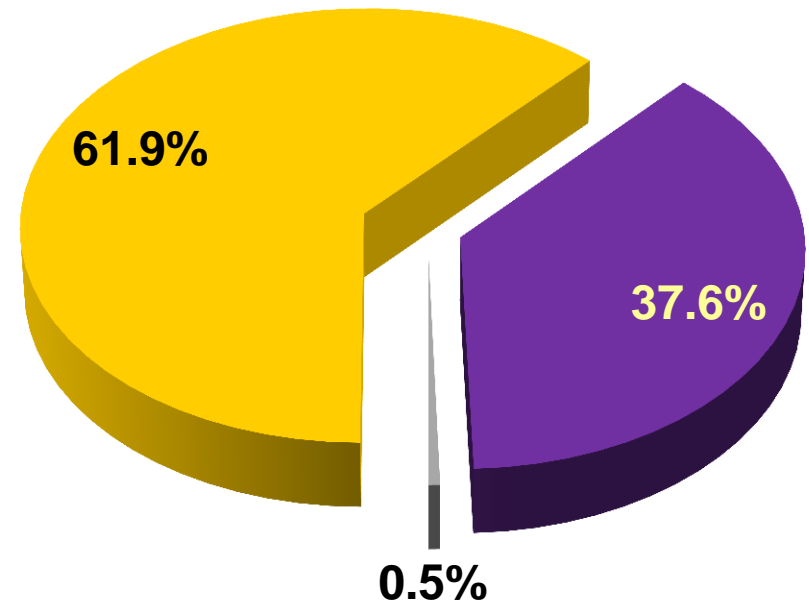
23andMe (n=583,266)

89.2%

10.8%

ERP* (n=238,273)

80.1%

3.9%

16.0%

■ Not Hisp ■ Hisp ■ Unk
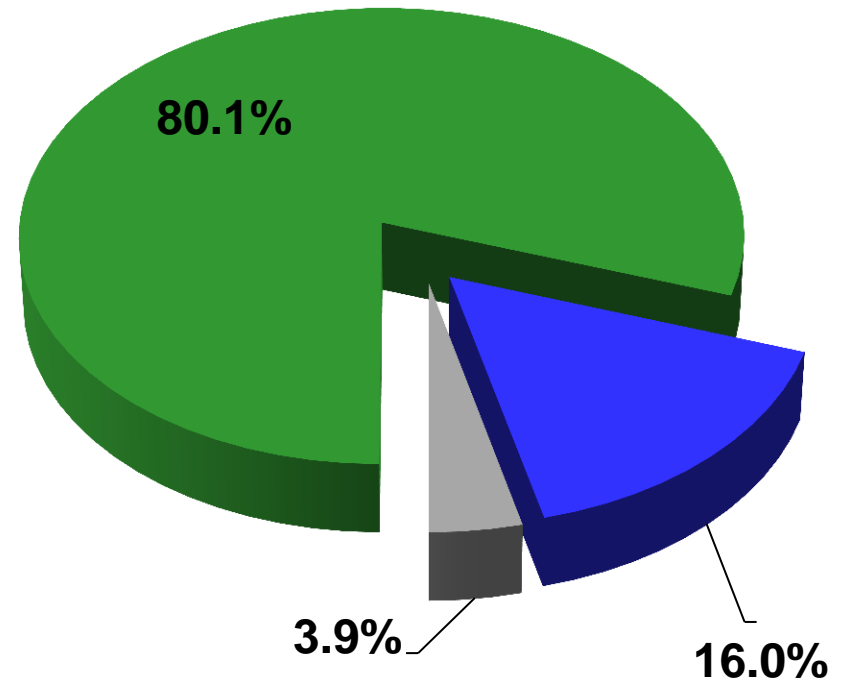
*ERP data excluding 23andMe

FY13-14 23andMe Actual Enrollment Data by Gender

23andMe (n=583,266)

48.6%

51.4%

ERP* (n=238,273)

61.9%

37.6%

0.5%

■ **Female** ■ **Male** ■ **Unk**

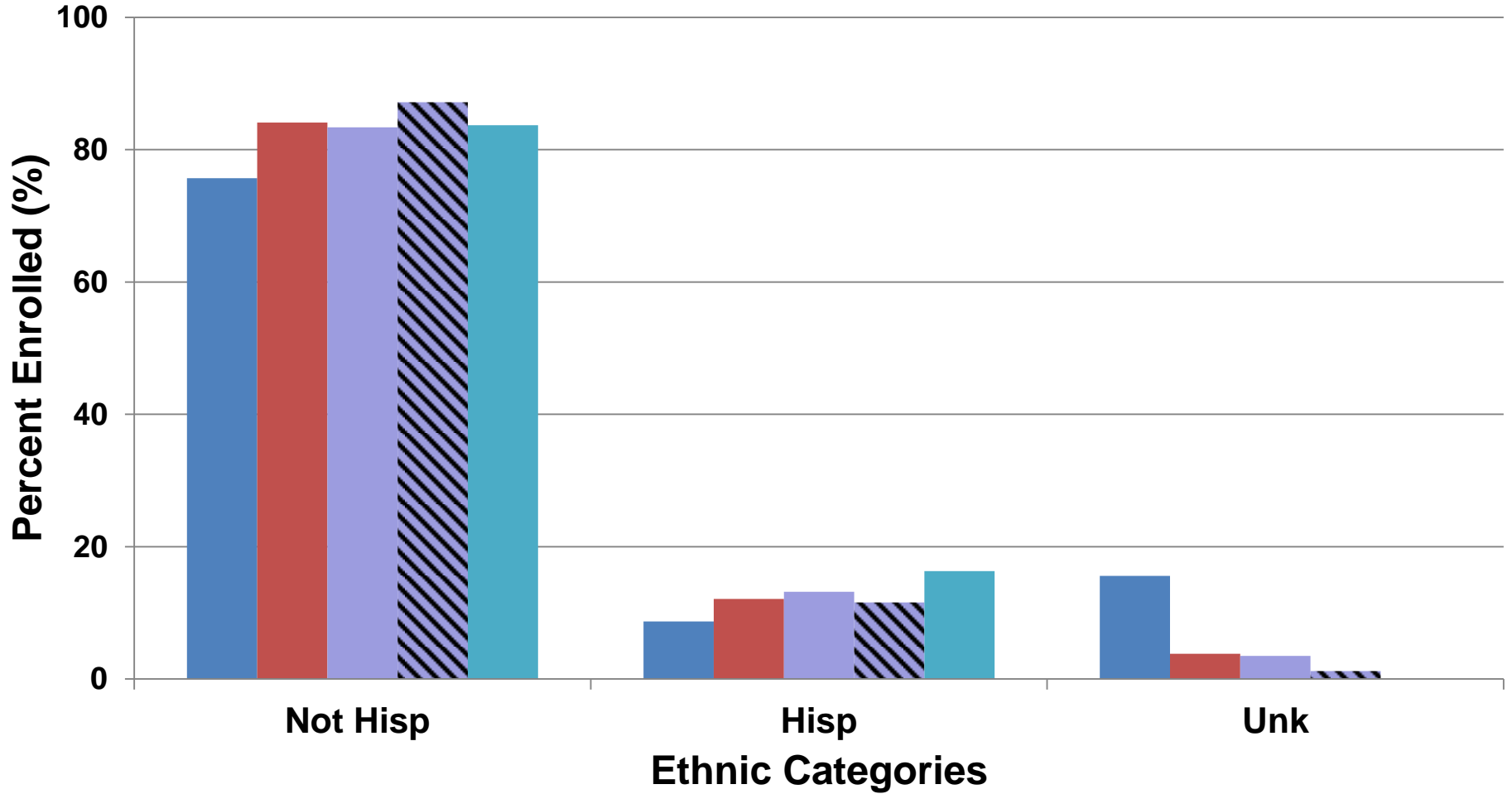***ERP data excluding 23andMe**

Time Trends in Major Race Categories, NHGRI 2010-2014 and US Census
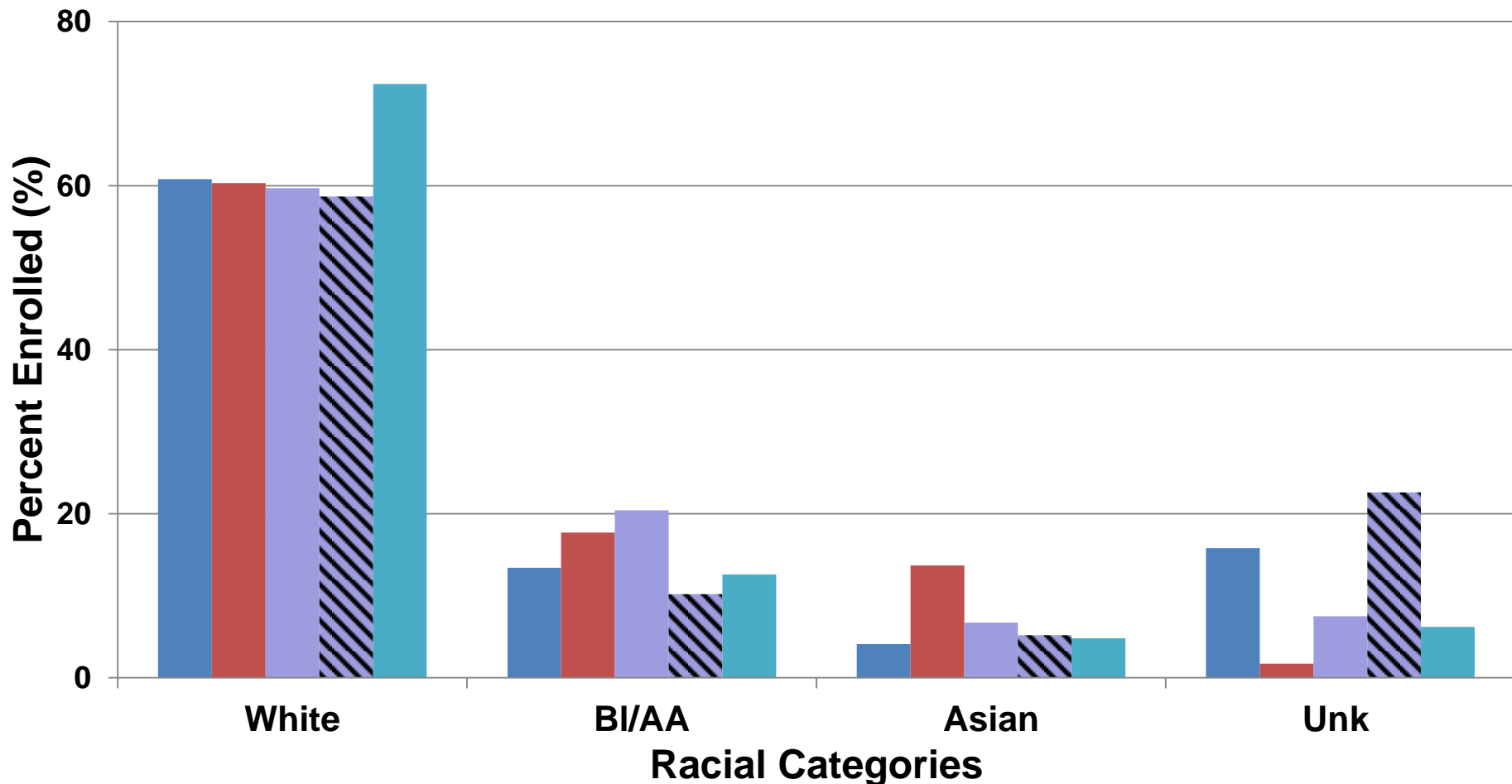
Legend:
- NHGRI 2010 n=245,563
- NHGRI 2011-12 n=375,551
- NHGRI 2013-14* n=302,990
- NHGRI 2013-14 n=886,256
- US Census 2010

*ERP data excluding 23andMe

Racial Categories: White, Bl/AA, Asian, Unk

Y-axis: Percent Enrolled (%)

Time Trends in Major Ethnic Categories, NHGRI 2010-2014 and US Census

Ethnic Categories (x-axis): Not Hisp, Hisp, Unk

Percent Enrolled (%) (y-axis)

Legend:
- NHGRI 2010 n=245,563
- NHGRI 2011-12 n=375,551
- NHGRI 2013-14* n=302,990
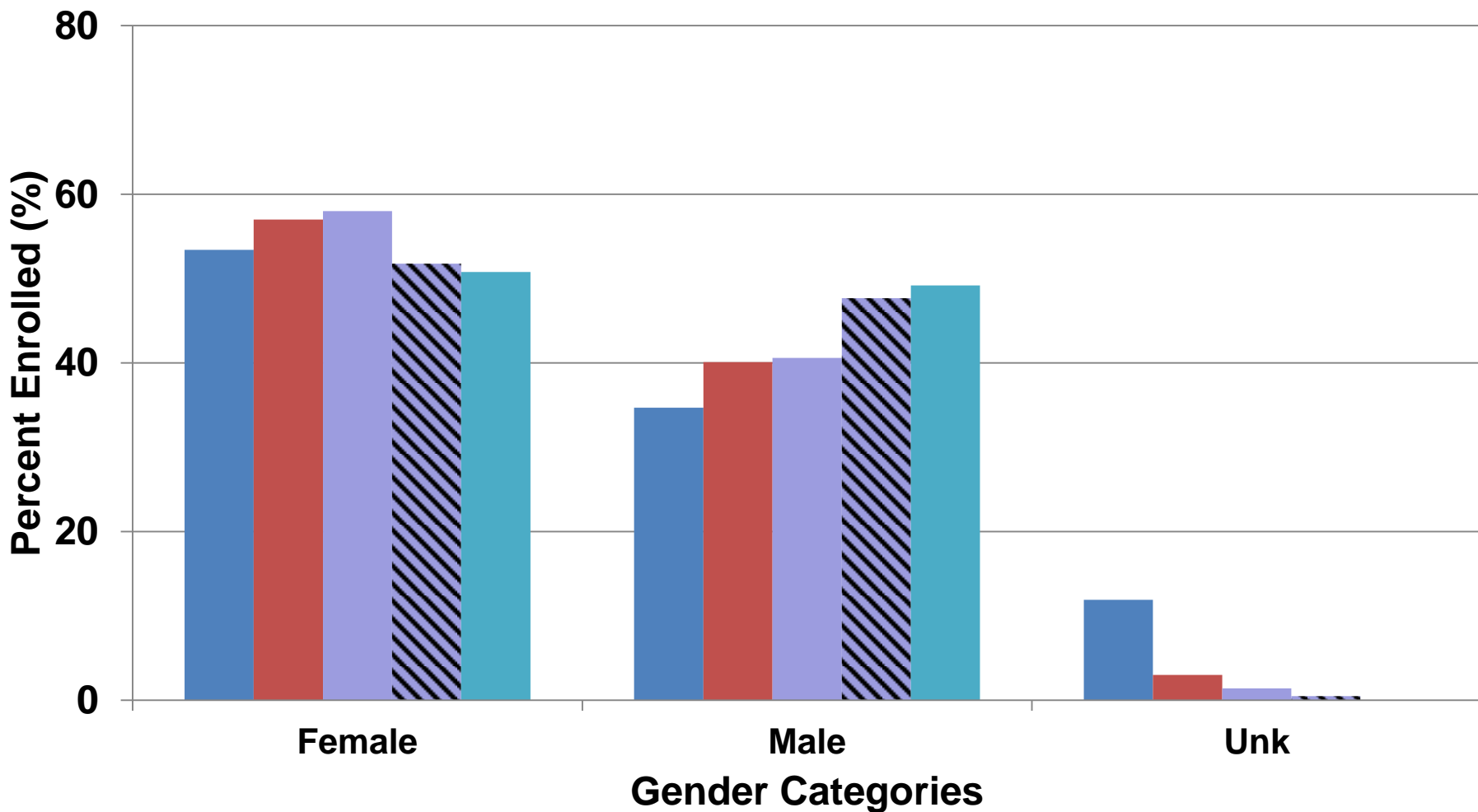- NHGRI 2013-14 n=886,256
- US Census 2010

*ERP data excluding 23andMe

Time Trends in Major Gender Categories, NHGRI 2010-2014 and US Census

Gender Categories

Percent Enrolled (%)

Female — Male — Unk

- NHGRI 2010 n=245,563
- NHGRI 2011-12 n=375,551
- NHGRI 2013-14* n=302,990
- NHGRI 2013-14 n=886,256
- NIH 2014

*ERP data excluding 23andMe

Summary

- **NHGRI improved enrollment of minority and female participants in FY2013-FY2014.**

- **NHGRI had a more diverse group of enrolled participants compared with the 2010 census.**

- **The high proportion of unknown race in 23andMe skewed the proportions unknown for NHGRI as a whole.**

- **The high proportion of unknown race for ERP is due to collecting race and ethnicity in a single item or Hisp participants declining to report race.**

Acknowledgements

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