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FY2016-FY2018 Triennial Council Report Certifying Compliance with the NIH Policy on Inclusion Guidelines

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NHGRI Advisory Council Meeting

February 11, 2019



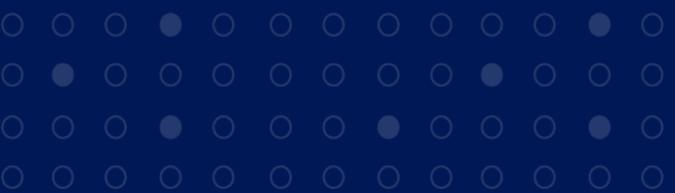
National Human Genome
Research Institute

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Overview

- Background of Inclusion Reporting Requirements
- Definitions
- FY16-FY18 Data Analysis
- Summary



Background

- NIH is mandated by the Public Health Service Act to ensure inclusion of women and minority groups that is appropriate to scientific question under study
- NIH has examined and reported inclusion enrollment data for clinical research since FY1994
- Biennial reports for each NIH IC are publicly available at NIH RePORT
(https://report.nih.gov/recovery/inclusion_research.aspx)
- Because of changes related to the 21st Century Cures Act, reporting is now on triennial basis

Definitions

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- **Clinical research** is research that is:
 - Patient-oriented – conducted with human subjects or with materials of human origin for which an investigator/colleague directly interacts with human subjects
 - Epidemiological/behavioral studies
 - Outcomes and health services research
- **Minority groups** includes all races except White and Unknown Race, plus Hispanic ethnicity

Inclusion Enrollment Report (IER)

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PHS Inclusion Enrollment Report

This report format should NOT be used for collecting data from study participants.

OMB Number: 0925-0001
Expiration Date: 3/31/2020

*Study Title (must be unique):

* Delayed Onset Study? Yes No

If study is not delayed onset, the following selections are required:

Enrollment Type Planned Cumulative (Actual)

Using an Existing Dataset or Resource Yes No

Enrollment Location Domestic Foreign

Clinical Trial Yes No

NIH-Defined Phase III Clinical Trial Yes No

Comments:

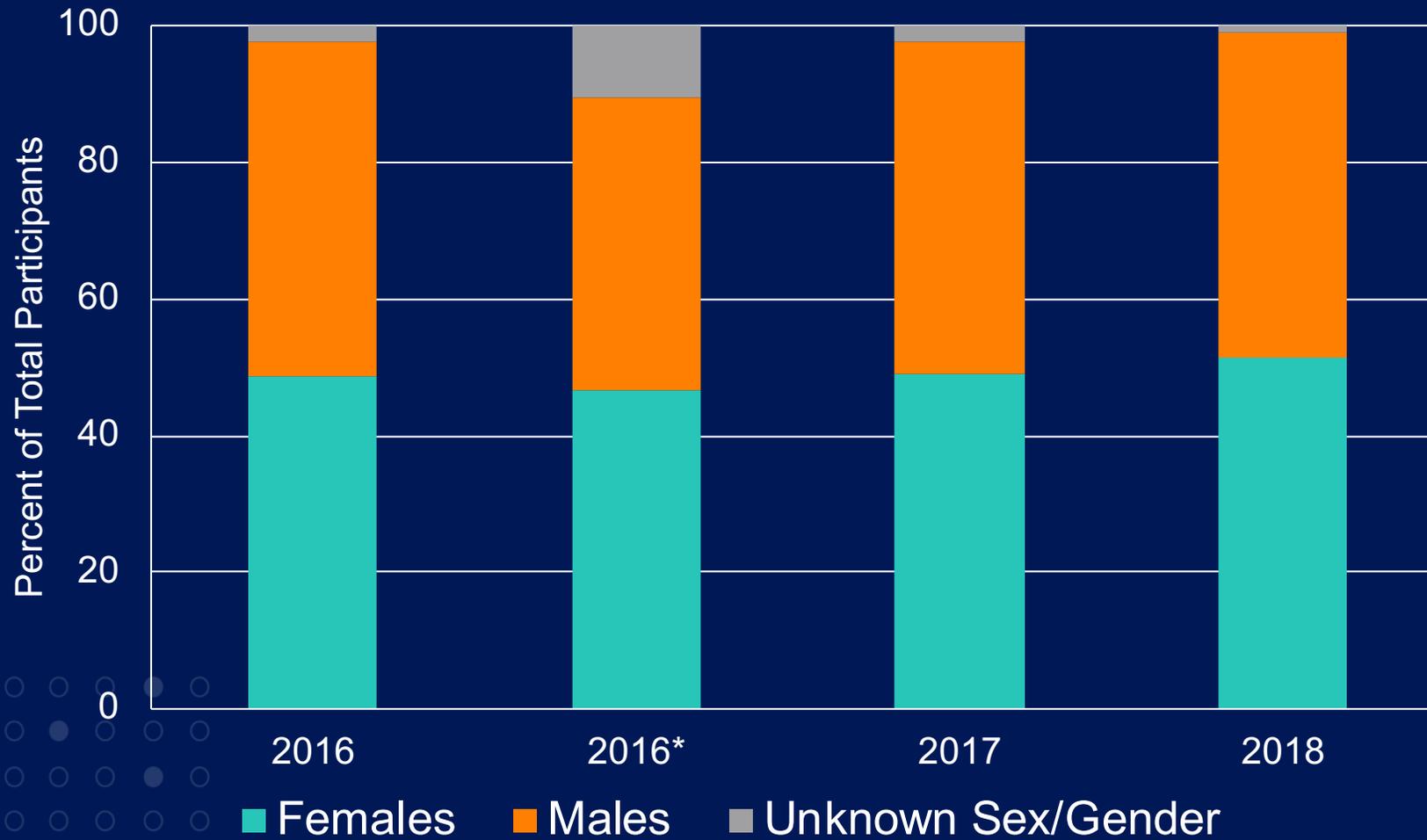
Racial Categories	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			Total
	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	Female	Male	Unknown/Not Reported	
American Indian/Alaska Native	0	0	0	0	0	0	0	0	0	0
Asian	0	0	0	0	0	0	0	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0	0	0	0	0	0	0	0
Black or African American	0	0	0	0	0	0	0	0	0	0
White	0	0	0	0	0	0	0	0	0	0
More than One Race	0	0	0	0	0	0	0	0	0	0
Unknown or Not Reported	0	0	0	0	0	0	0	0	0	0
Total	0	0	0	0	0	0	0	0	0	0

Overall Enrollment

Fiscal Year	Total		Extramural		Intramural	
	Enrolled Participants	No. of IERs	Enrolled Participants	No. of IERs	Enrolled Participants	No. of IERs
2016	1,545,412	175	1,445,917	68	99,495	107
2016*	262,271	174	162,776	67	99,495	107
2017	258,605	178	173,244	69	85,361	109
2018	192,255	102	157,767	93	34,505	9

* Extramural data excluding one outlier grant with >1 million participants

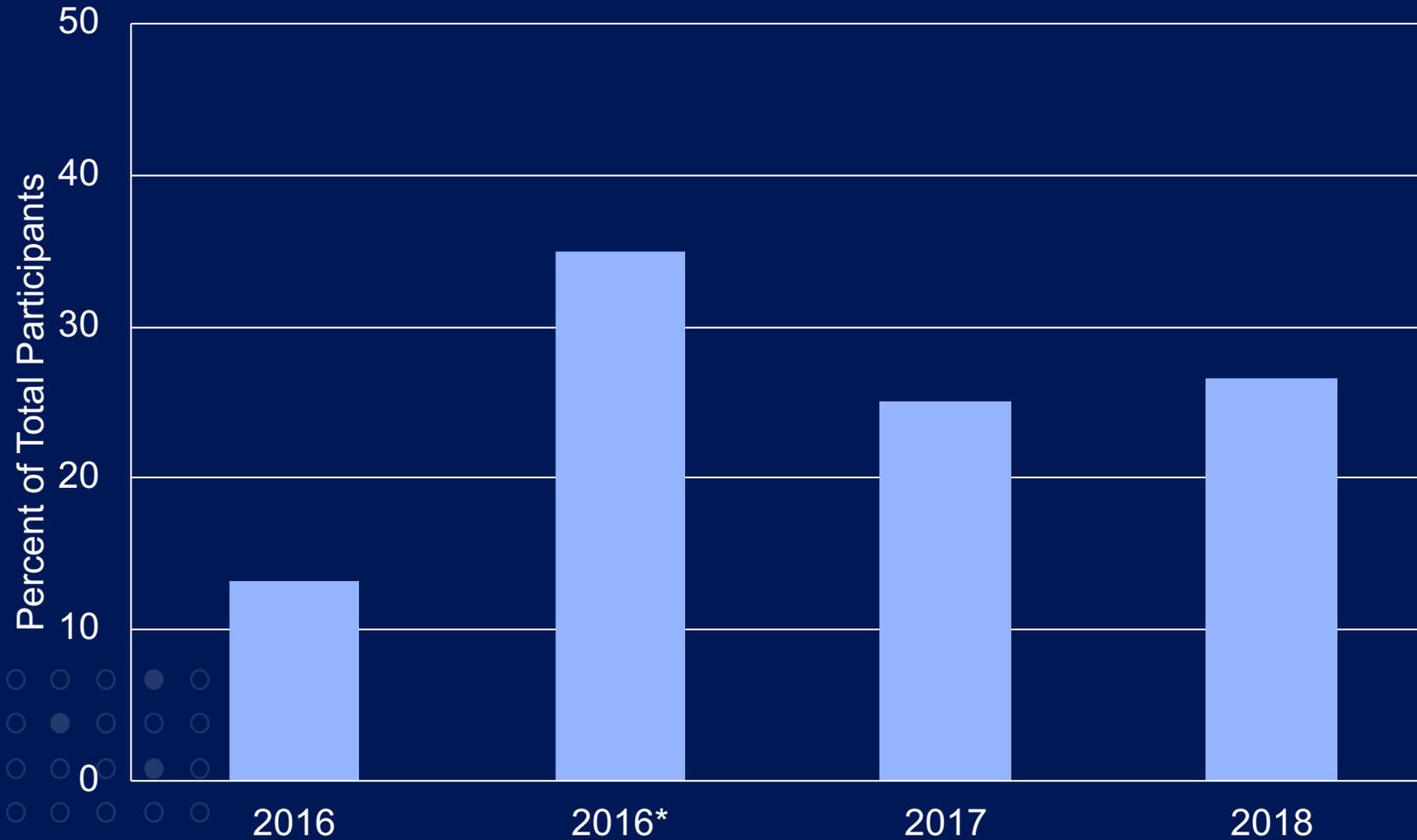
By Sex/Gender



* Extramural data excluding one outlier grant with >1 million participants

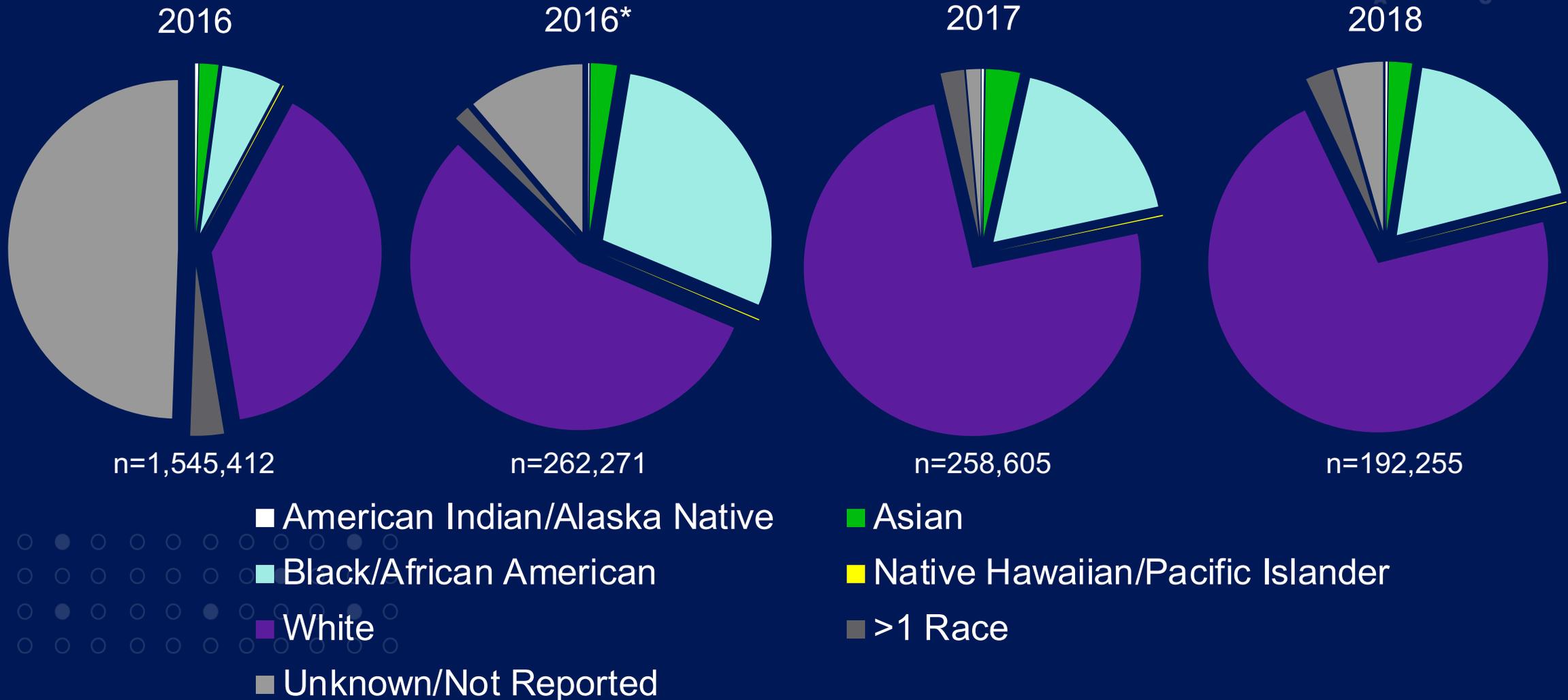
By Minority

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* Extramural data excluding one outlier grant with >1 million participants

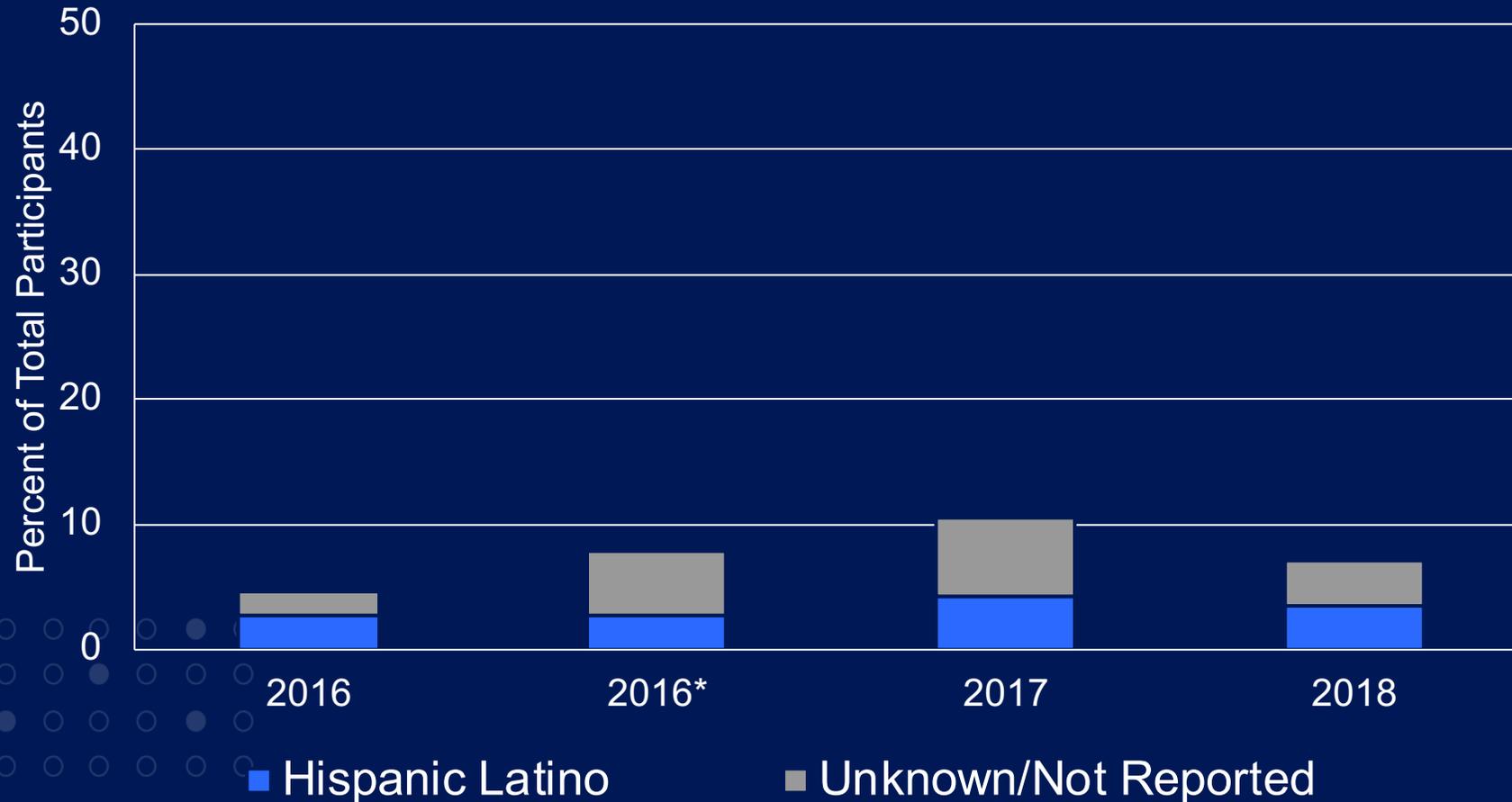
By Race



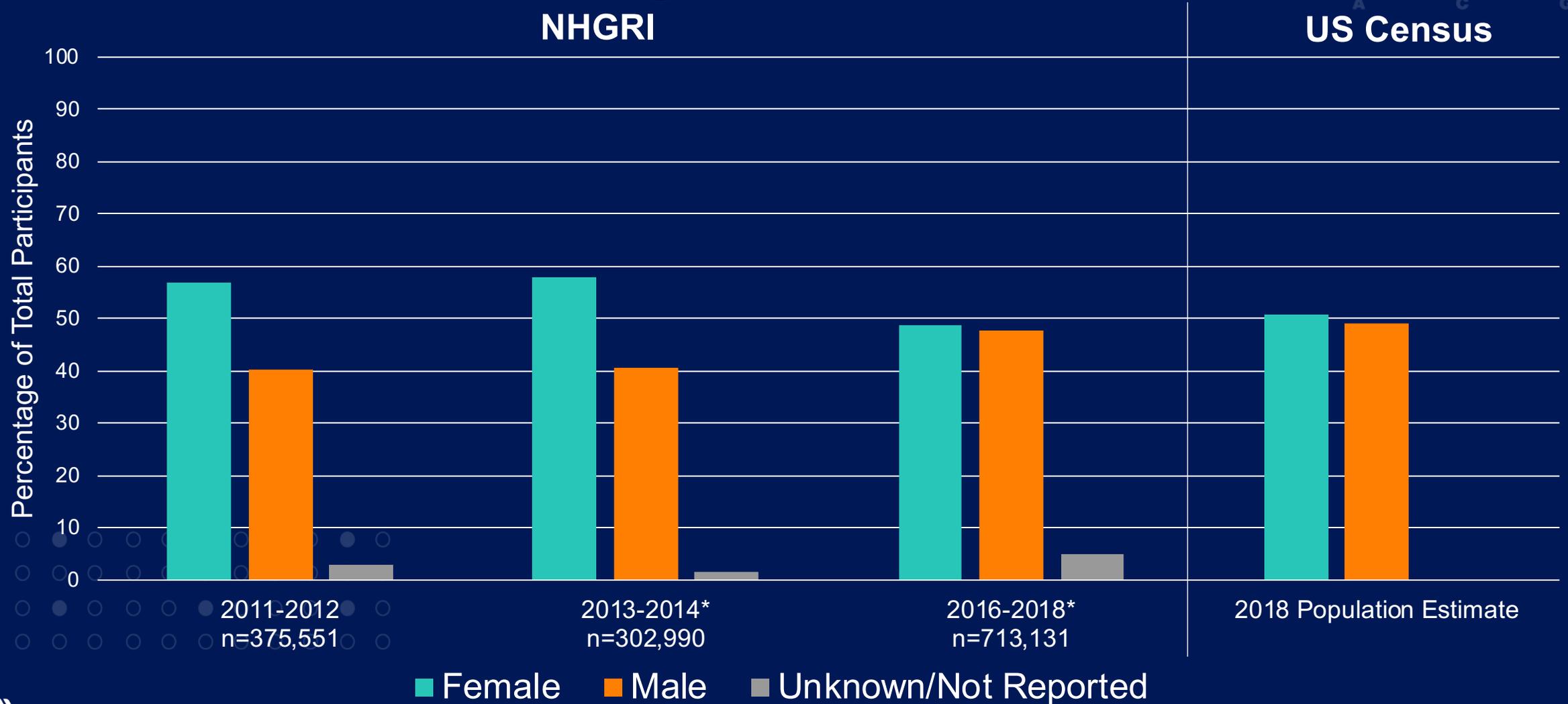
* Extramural data excluding one outlier grant with >1 million participants

By Ethnicity

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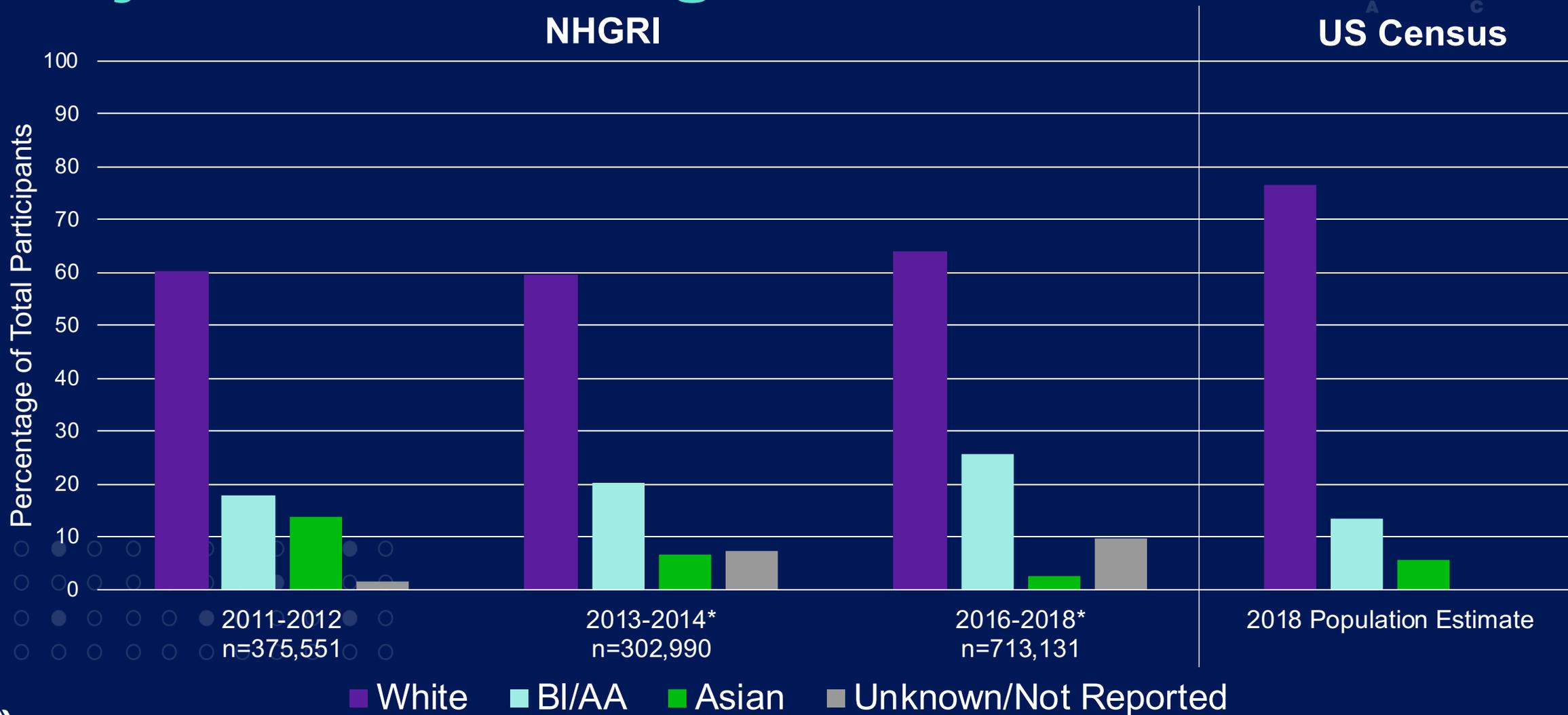


Sex/Gender Categories FY2011-2018



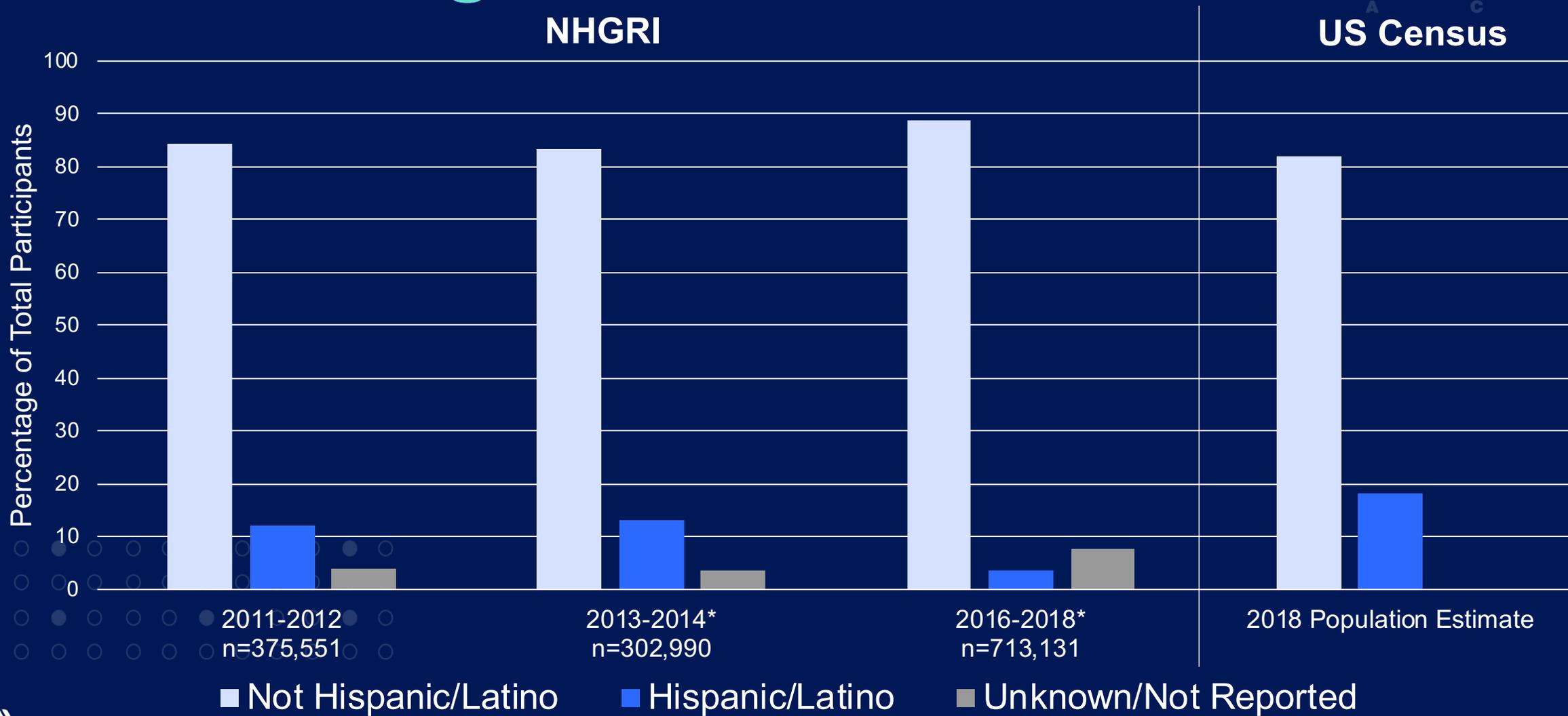
* Extramural data excluding one outlier grant with >1 million participants

Major Racial Categories FY2011-2018



* Extramural data excluding one outlier grant with >1 million participants

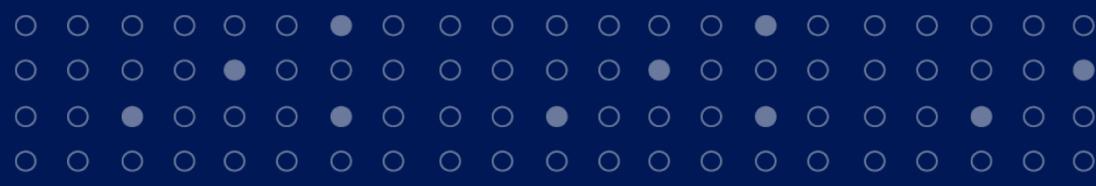
Ethnic Categories FY2011-2018



* Extramural data excluding one outlier grant with >1 million participants

Summary

- Since FY2012, the proportion of Black/African-American enrollment has increased, while Asian and Hispanic/Latino enrollment has decreased
- Programs such as H3A, CSER, and IGNITE focus on increasing minority enrollment
- Other efforts to include diversity include diversity supplements and diversity action plans in training
- The change in Intramural data for FY18 is due to data cleaning and centralization in the tracking/reporting system



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Questions and Comments?



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Largest Extramural Studies

1. A NEW REFERENCE PANEL TO BOOST AFRICAN AMERICAN GENOTYPE IMPUTATION - 1,283,141
2. BETTER OUTCOMES FOR CHILDREN: PROMOTING EXCELLENCE IN HEALTHCARE GENOMICS TO INFORM POLICY – 91,791
3. INTEGRATED, INDIVIDUALIZED, INTELLIGENT PRESCRIBING (I3P) – 21,669

Largest Intramural Studies

1. Mapping Genes for Type 2 (Non-Insulin Dependent) Diabetes Mellitus – 32,329
2. Advanced Genetic Analyses of dbGaP Datasets for the Study of Complex Diseases – 19,172
3. Genetics of Type 2 Diabetes in Diverse Populations – 6,727

H3Africa accounts for 32,462 (35%) of all minority enrollment (FY16* without 23andme)