



# Report to the Advisory Committee on Research on Women's Health: NIH Inclusion Data FY2016-2017

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**NIH** National Institutes of Health  
Office of Extramural Research

# Outline for Presentation

- **Context for discussion of inclusion data**
- **Acceptability of inclusion plans for extramural research awards**
- **Overview of inclusion data**
- **Aggregate Enrollment: Sex/Gender**
- **Aggregate Enrollment: Race and Ethnicity (US-based studies)**

# Context for discussion of inclusion data

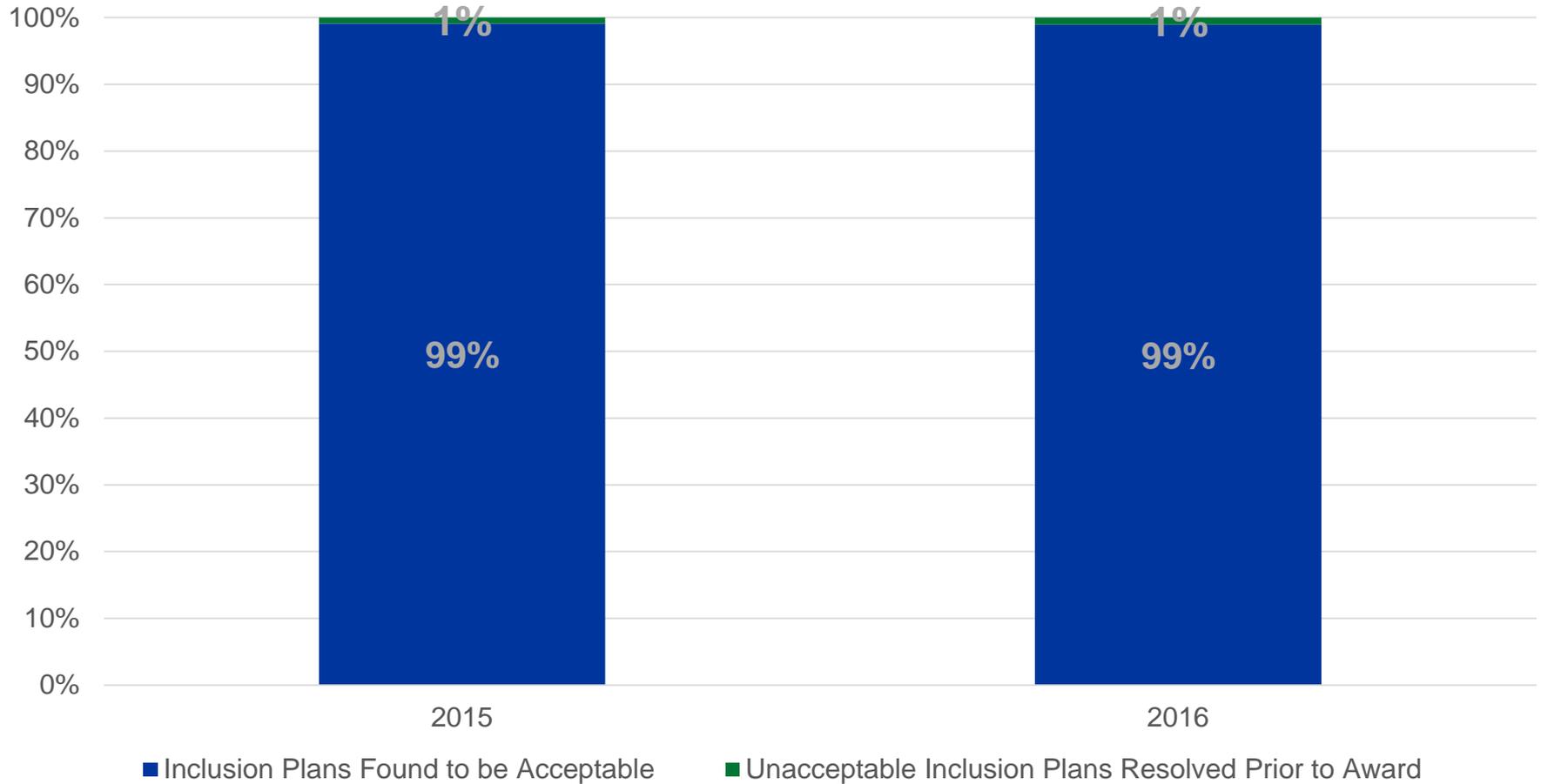
- **New system and procedures implemented in FY15**
  - **Data on existing datasets collected.**
    - **What is an existing dataset?**
      - **For the purposes of inclusion policy:**
        - **An existing dataset may be constructed of different types of data including but not limited to survey data, demographic information, health information, genomic information, etc. Also included would be data to be derived from existing samples of cells, tissues, or other types of materials that may have been previously collected for a different purpose or research question but will now be used to answer a new research question. In general, these will be studies meeting the NIH definition for clinical research with a prospective plan to analyze existing data and/or derive data from an existing resource and where no ongoing or future contact with participants is anticipated.**
        - **Must be considered human subjects' research**
    - **Additional funding mechanisms required to submit inclusion information (e.g. training grants, career development awards)**
    - **Most exceptions to inclusion monitoring discontinued**

# **Acceptability of Inclusion Plans for Extramural Research Awards**



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

Review of Inclusion Plans in Competing Clinical Research



# Overview of Inclusion Data



# FY15-16 Inclusion Data Overview

## Clinical Research

Fiscal Year	Total Inclusion Data Records (IDRs)	US Site IDRs	Non-US Site IDRs	Female Only IDRs	Male Only IDRs	IDRs Excluding Male-only and Female-only *
2015	11,082	9,058	867	1,005	548	8,372
2016	13,069	10,741	1,063	1,279	628	9,897

## Phase III Clinical Trials

Fiscal Year	Total IDRs	US Site IDRs	Non-US Site IDRs	Female Only IDRs	Male Only IDRs	IDRs Excluding Male-only and Female-only *
2015	498	355	112	61	22	384
2016	574	413	121	66	32	436

\* Inclusion Data Records (IDRs) excluding male-only and female-only include unknown sex/gender, and combination of unknown and any sex/gender(s).

7 Note: Records coded as existing datasets or resources excluded



# Aggregate Enrollment: Sex/Gender

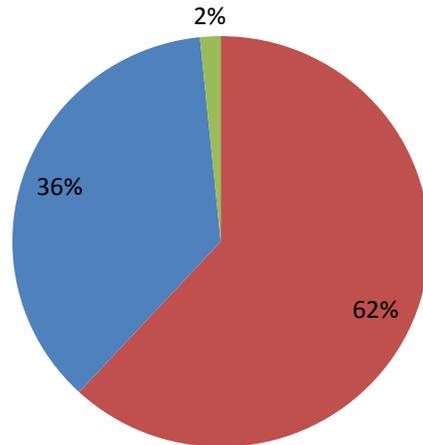


# Enrollment by Sex/Gender for NIH Clinical Research\*

FY2015

FY2016

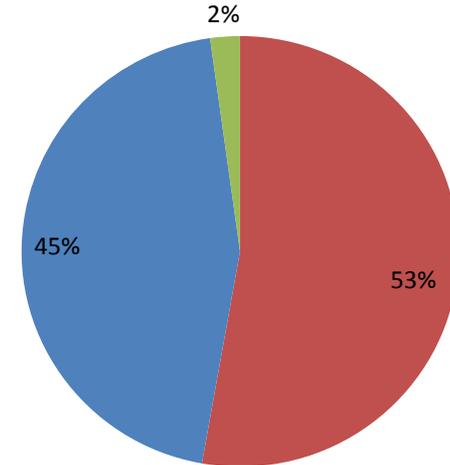
All Clinical Research



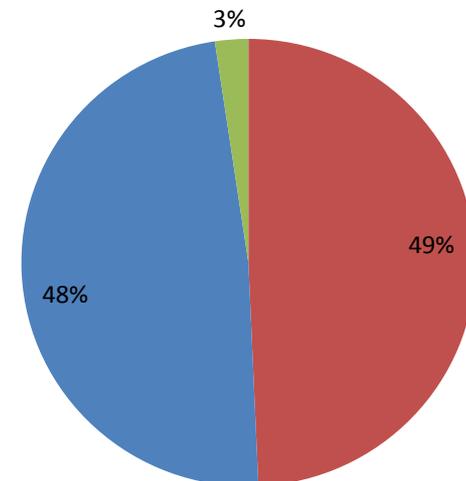
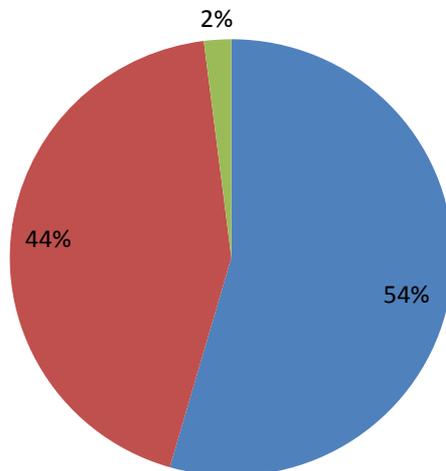
■ Females, Excluding Female-only

■ Males, Excluding Male-only

■ Total Unknown



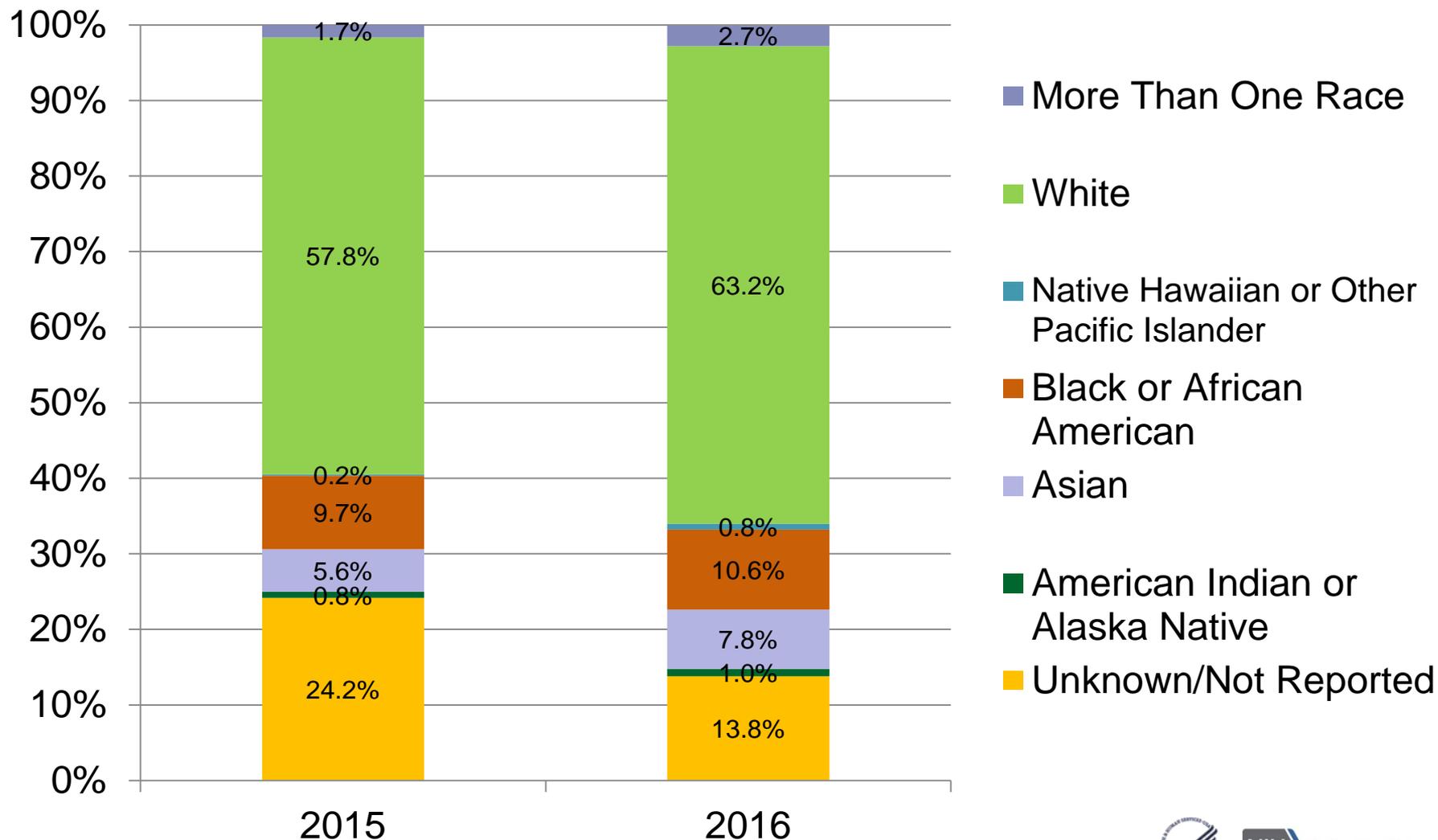
All Clinical Research Excluding Single-Sex Studies



# **Aggregate Enrollment: Race and Ethnicity of US Based Studies**



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

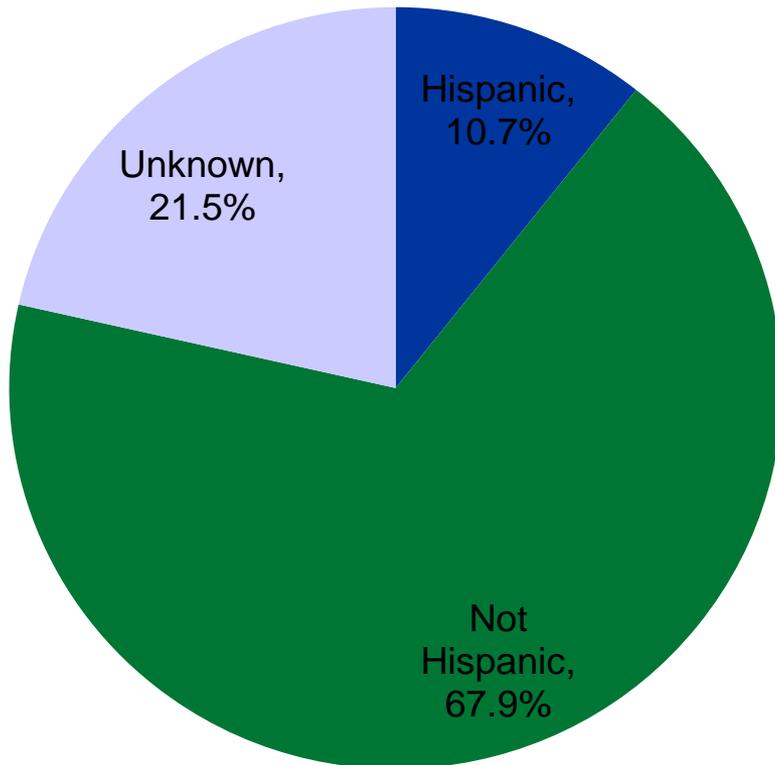


Note: Records coded as existing datasets or resources excluded

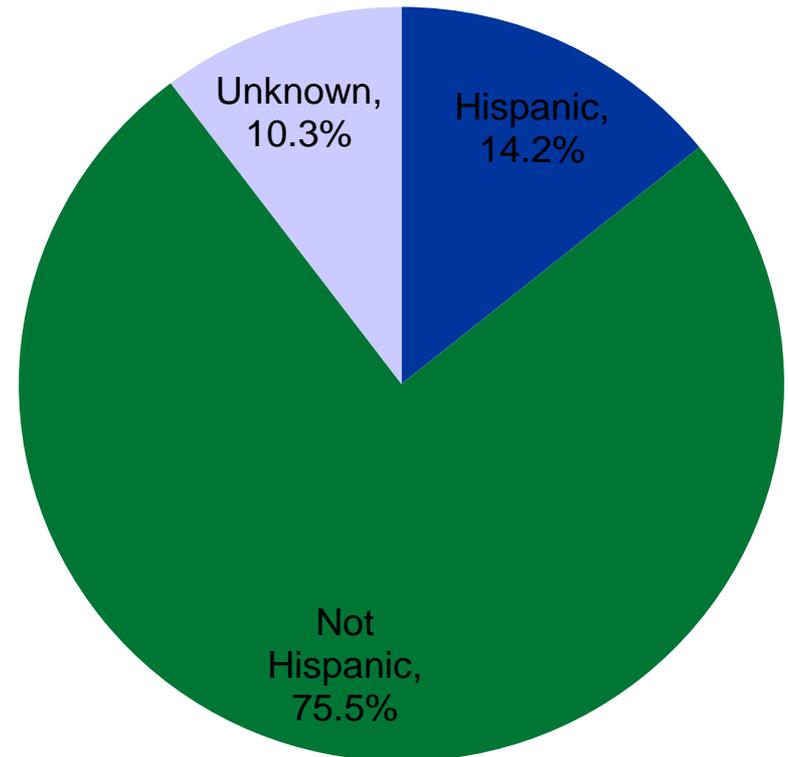


# Enrollment in NIH Clinical Research: Ethnic Categories (US Populations Only)

**FY 2015**



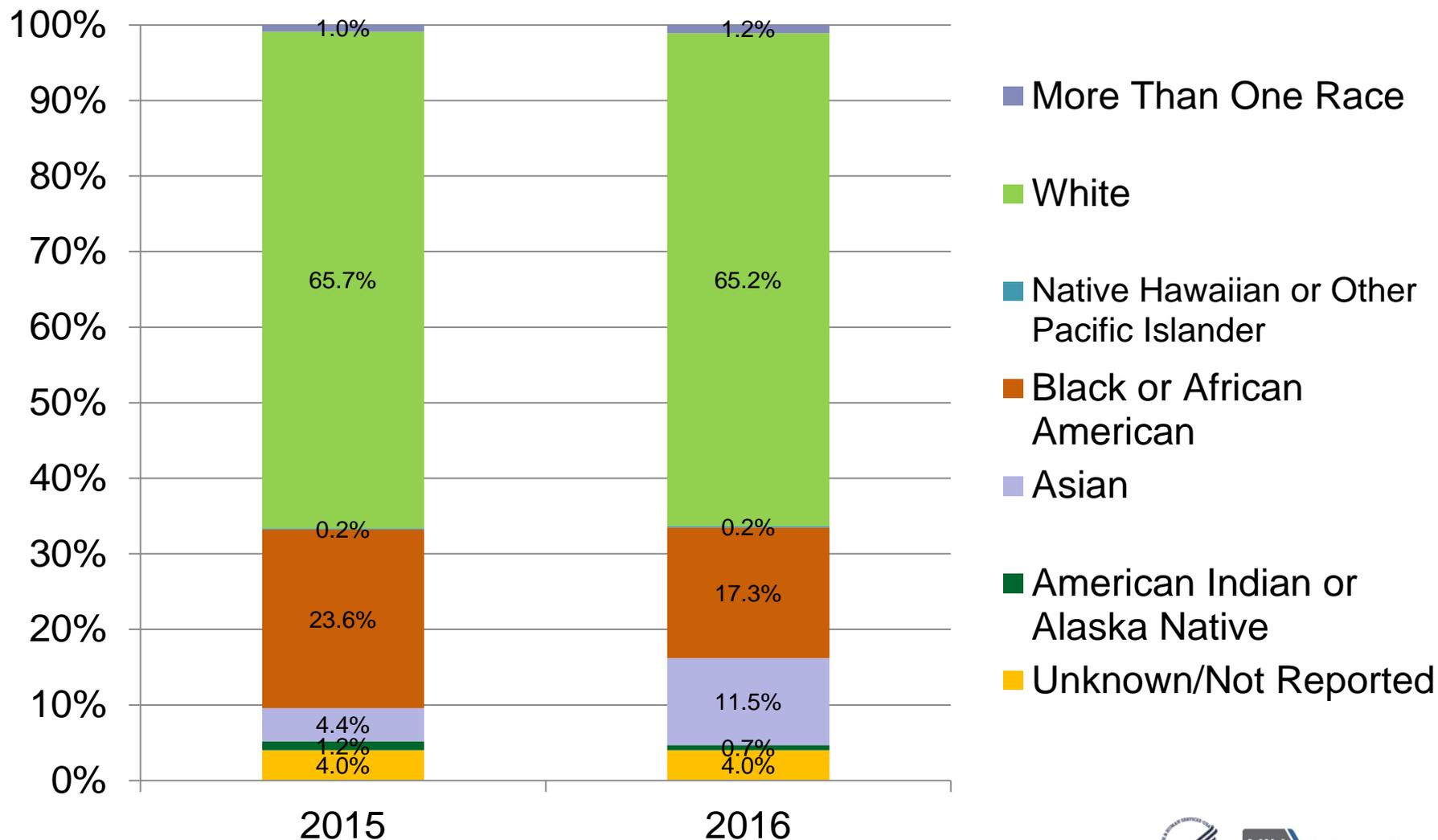
**FY 2016**



Note: Records coded as existing datasets or resources excluded

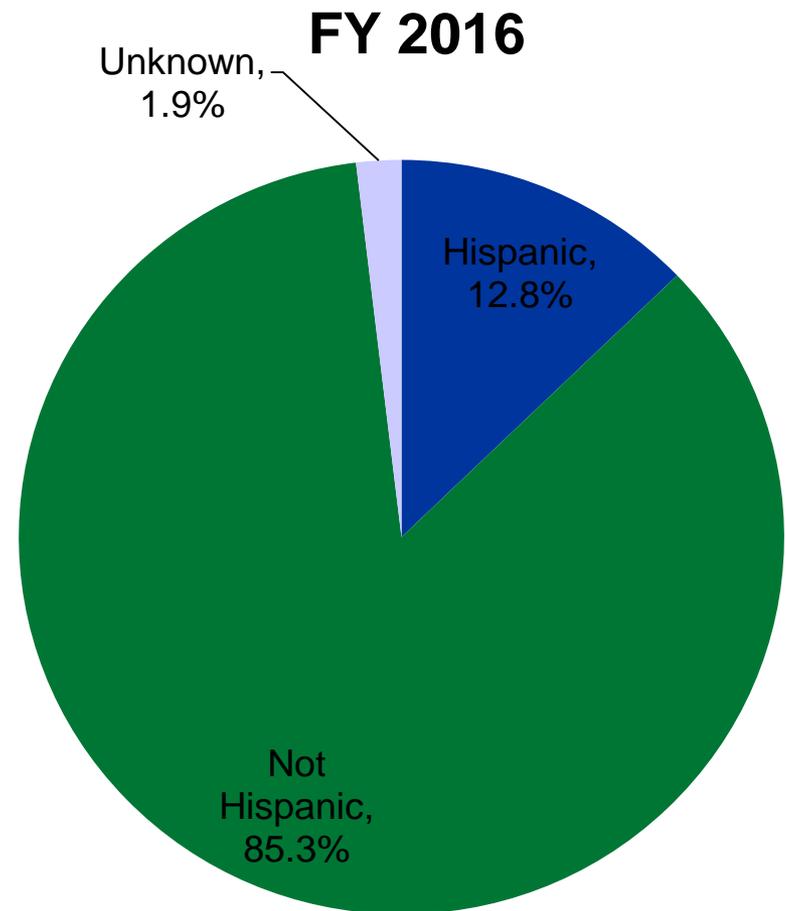
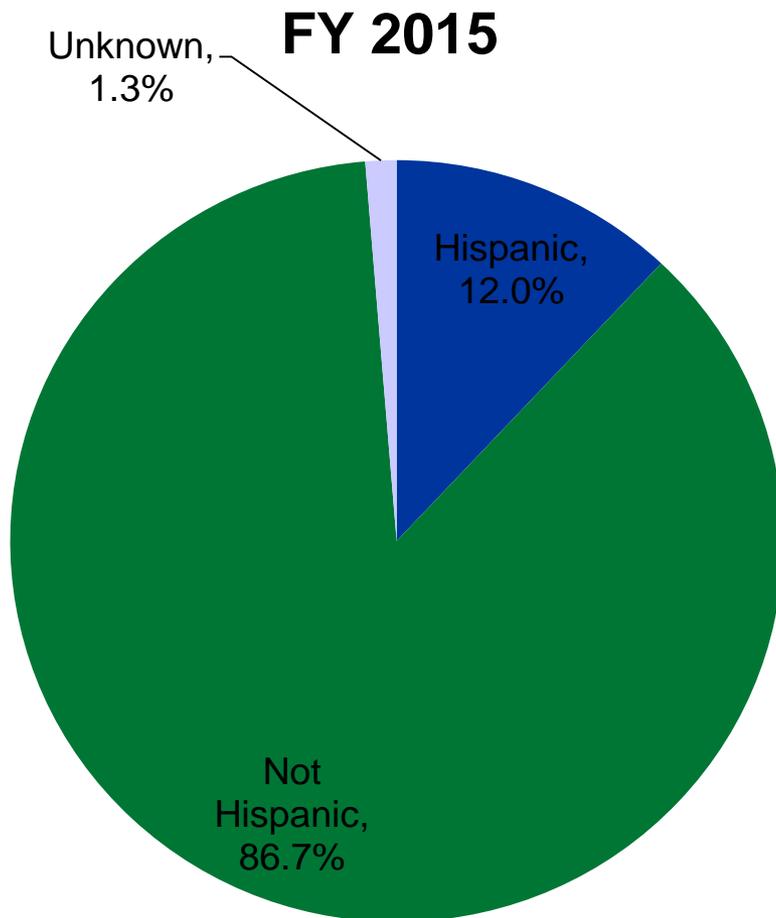


# Enrollment in NIH-Defined Phase III Clinical Trials: Racial Categories (US Populations Only)



Note: Records coded as using existing datasets or resources excluded

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



Note: Records coded as existing datasets or resources excluded



# Questions

