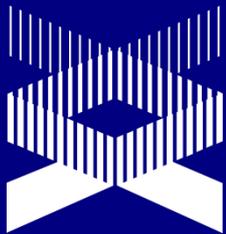




**U.S. Department  
of Health and  
Human Services**



**National Institutes  
of Health**



**National Human  
Genome Research  
Institute**

# **Inclusion of Women and Minorities in NHGRI Clinical Studies FY 2011-2012**

**Rongling Li, MD, PhD**

NHGRI Advisory Council Meeting (February 11, 2013)

# 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 data reported in FY 2011 and FY2012**

\* **Former Division of Extramural Research and Office of Population Genomics, reorganized on Oct 1, 2012.**

# Tracking Data

**Proposed or “Target” data** are based on applicants’ proposed numbers of participants in their grant/study applications

**Actual or “Enrollment” data** are based on participants actually recruited and examined as described in annual progress reports

# Tracking Required

- **All human subjects research must report gender and minority inclusion unless exempted under 45 CFR part 46.101(b) (4)**
- **Exemptions include:**
  - Not clinical research
  - Duplication of reporting
  - Early stage technology development, etc.
  - Small sample size
  - Secondary analysis
- **Target data and enrollment data for Phase III clinical trials must be reported**
- **No Phase III clinical trials were supported by NHGRI**

# Tracking and Monitoring Adherence to Inclusion Guidelines

- Extramural monitoring occurs at the review, program, and grants management levels
  - **IRG** reviews applications for inclusion and can raise concerns that must be addressed prior to funding
  - **Program officers** review applications and progress reports and contact PI to resolve target or actual enrollment issues
  - **Grants Management** releases funds for new or continuing grants only when Program Officer indicates inclusion is appropriate
- Intramural monitoring occurs through the Intramural IRB protocol review and monitoring process

# Demographic Information Tracked

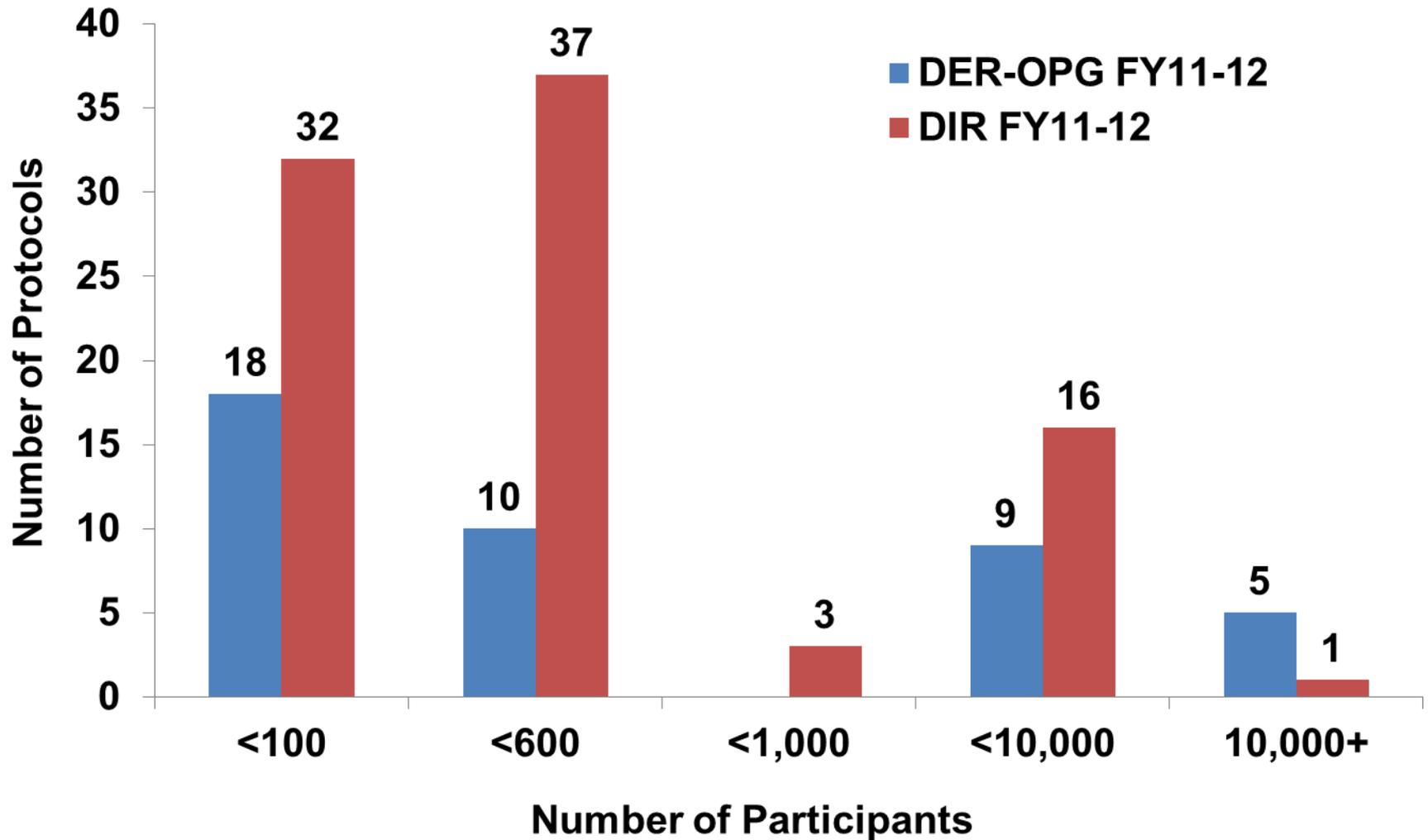
- **Race**
  - American Indian/Alaska Native (AI/AN)
  - Asian
  - Hawaiian/Pacific Islander (Haw/Pac)
  - Black/African American (BI/AA)
  - White
  - More than 1 Race (> 1 Race)
  - Unknown (Unk)
- **Ethnicity – Hispanic/Latino, Not Hispanic, Unknown**
- **Gender – Male, Female, Unknown**

# NHGRI Number of Protocols and Actual Enrollment During FY11-FY12

	<b>DER-OPG*</b>	<b>DIR</b>	<b>Total</b>
<b>Number of Protocols</b>	<b>42</b>	<b>89</b>	<b>131</b>
<b>Number of Participants</b>	<b>270,061</b>	<b>105,490</b>	<b>375,551</b>

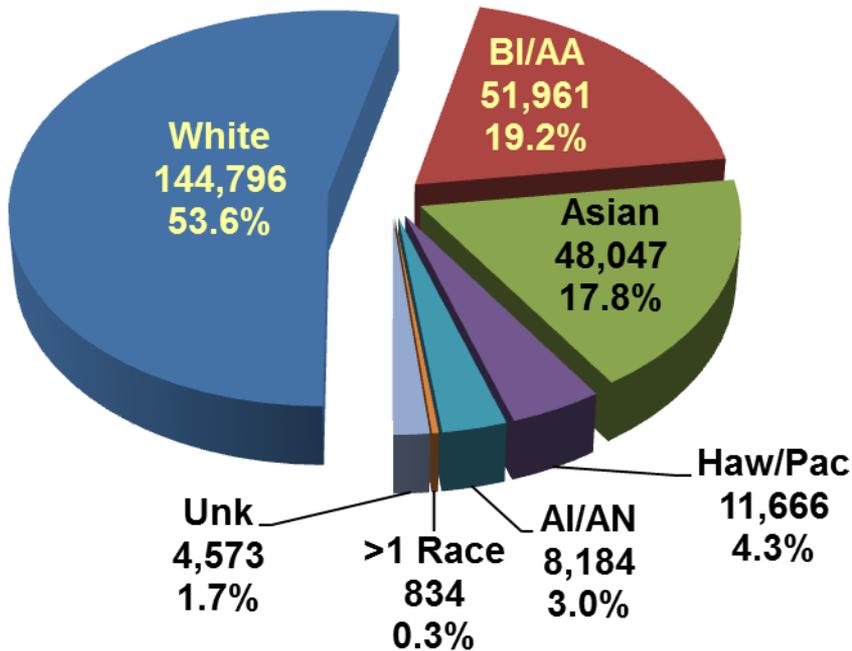
\* Former Division of Extramural Research and Office of Population Genomics

# Size of Enrollment

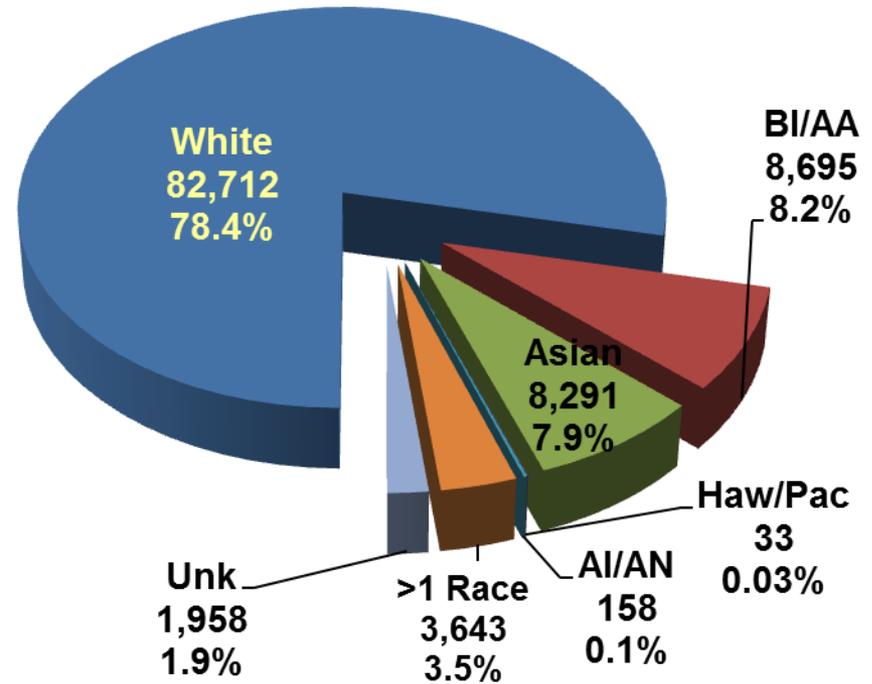


# 2011-2012 NHGRI Actual Enrollment Data by Race

DER-OPG (n=270,061)

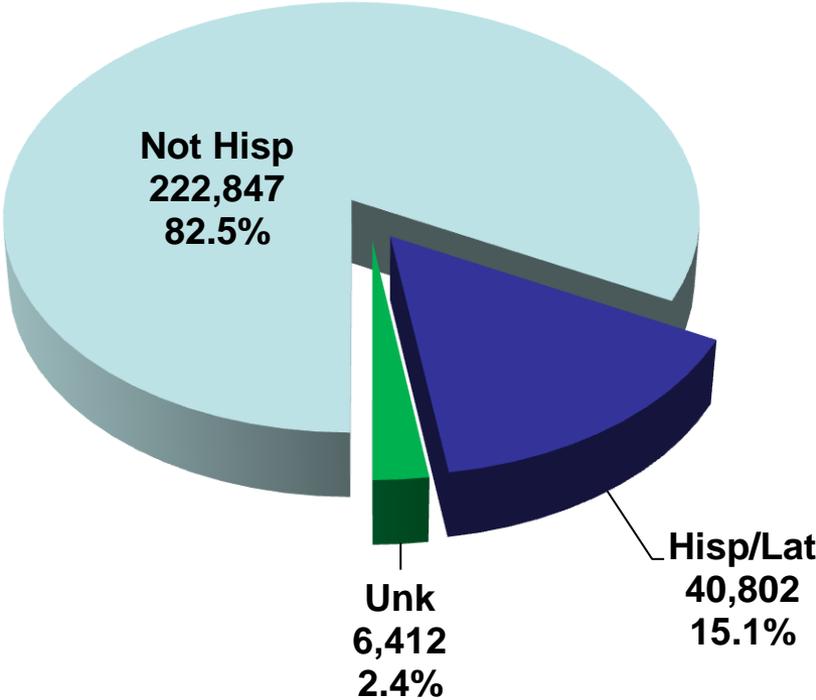


DIR (n=105,490)

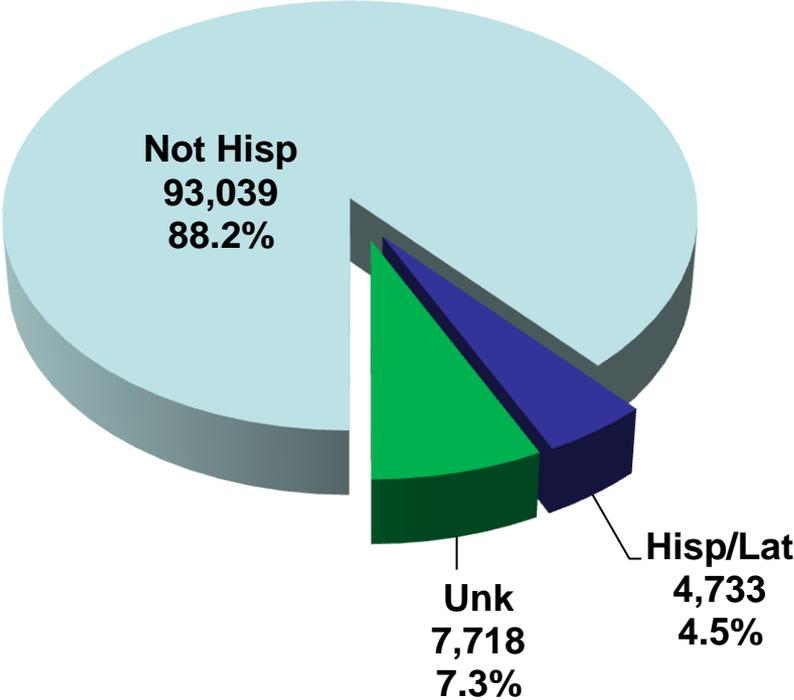


# 2011-2012 NHGRI Actual Enrollment Data by Ethnicity

DER-OPG (n=270,061)

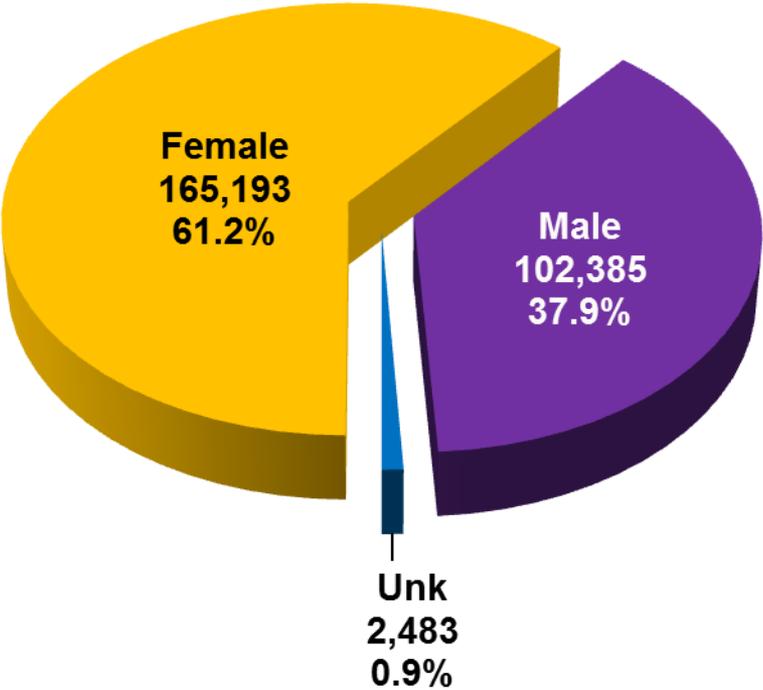


DIR (n=105,490)

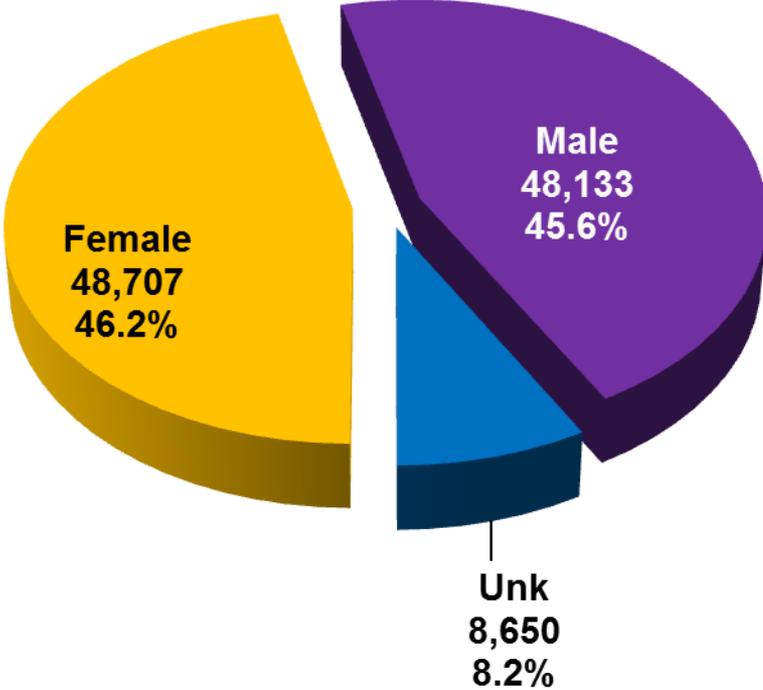


# 2011-2012 NHGRI Actual Enrollment Data by Gender

DER-OPG (n=270,061)



DIR (n=105,490)



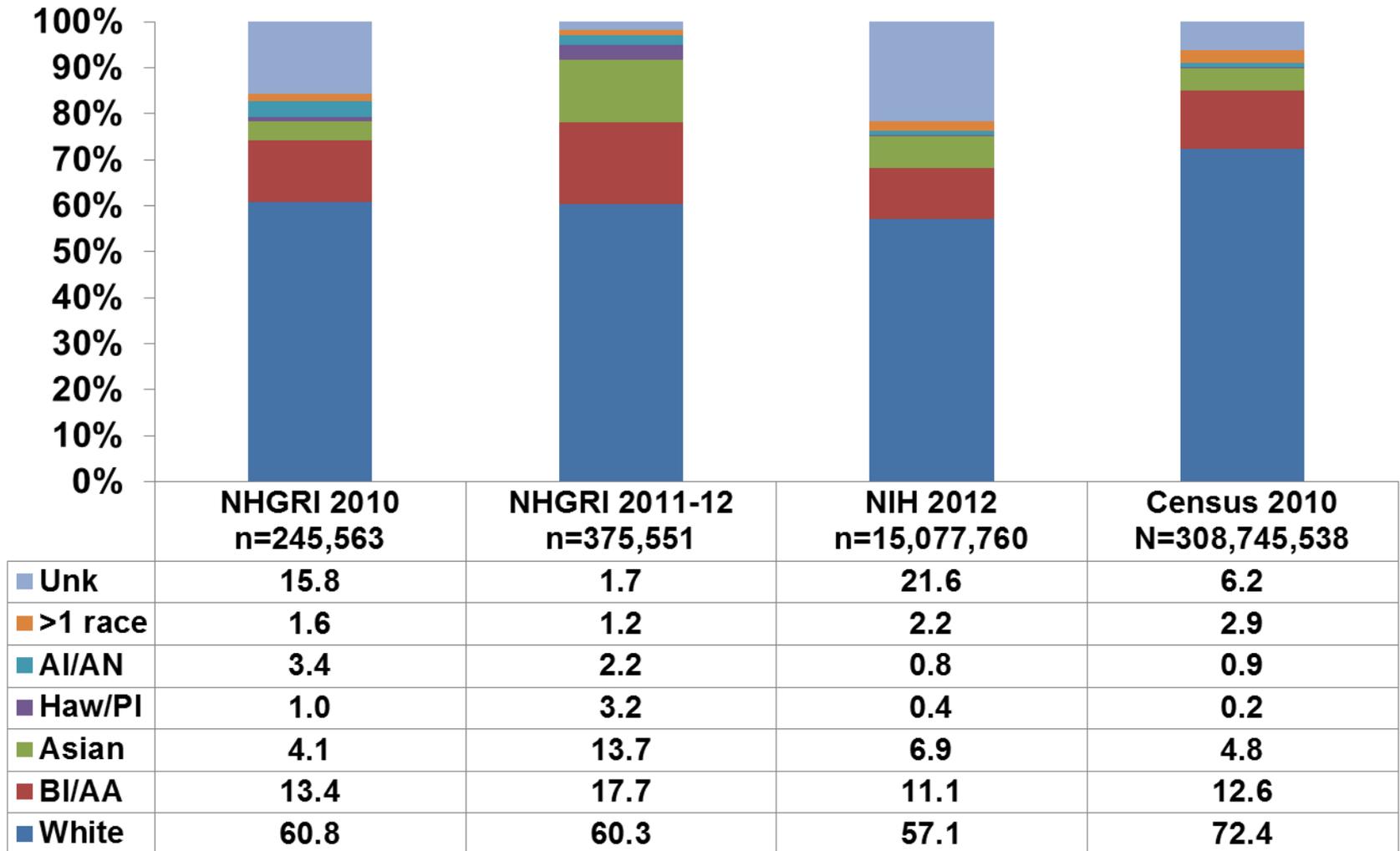
# NHGRI Extramural Research

- **42 protocols in FY2011 and FY2012**
- **Sample size ranges from 5 to 67,124**
- **A large number of enrolled participants come from OPG and are association studies using existing cohorts or patients with biorepository samples**
- **Protocols with small sample size target discrete populations with limited demographic diversity (e.g. health/research professionals or individuals that have already undergone genetic testing)**
- **Small number of protocols with big sample size lead to large shifts in demographic data**

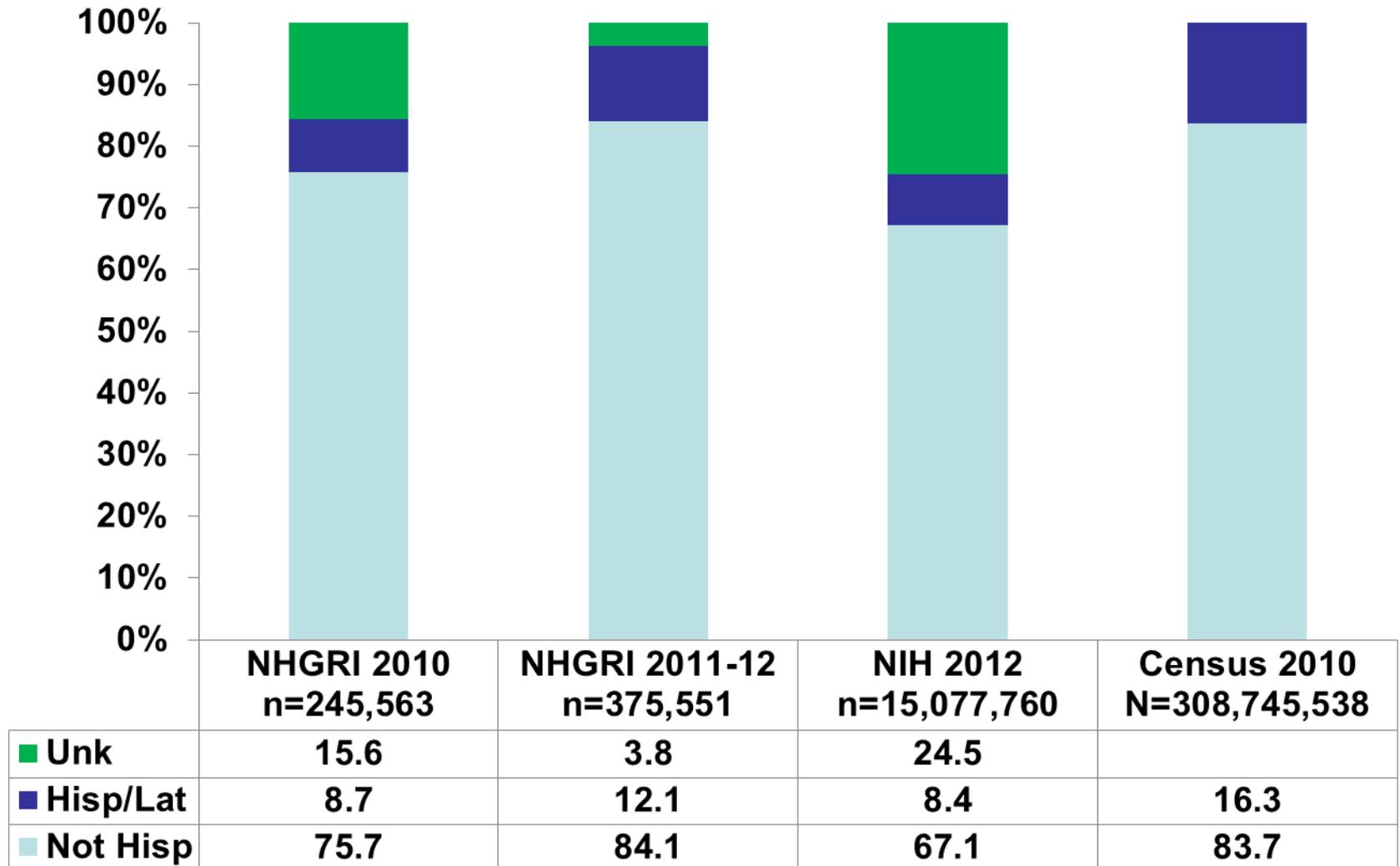
# NHGRI Intramural Research

- **89 protocols in FY2011-FY2012**
- **Sample size range from 1 to 32,367; 36% (32/89) protocols with sample size less than 100 and 78% (69/89) less than 600**
- **Types of studies include social science protocols, prospective linkage/gene identification studies, genotype-phenotype studies, and pilot and early phase intervention studies**

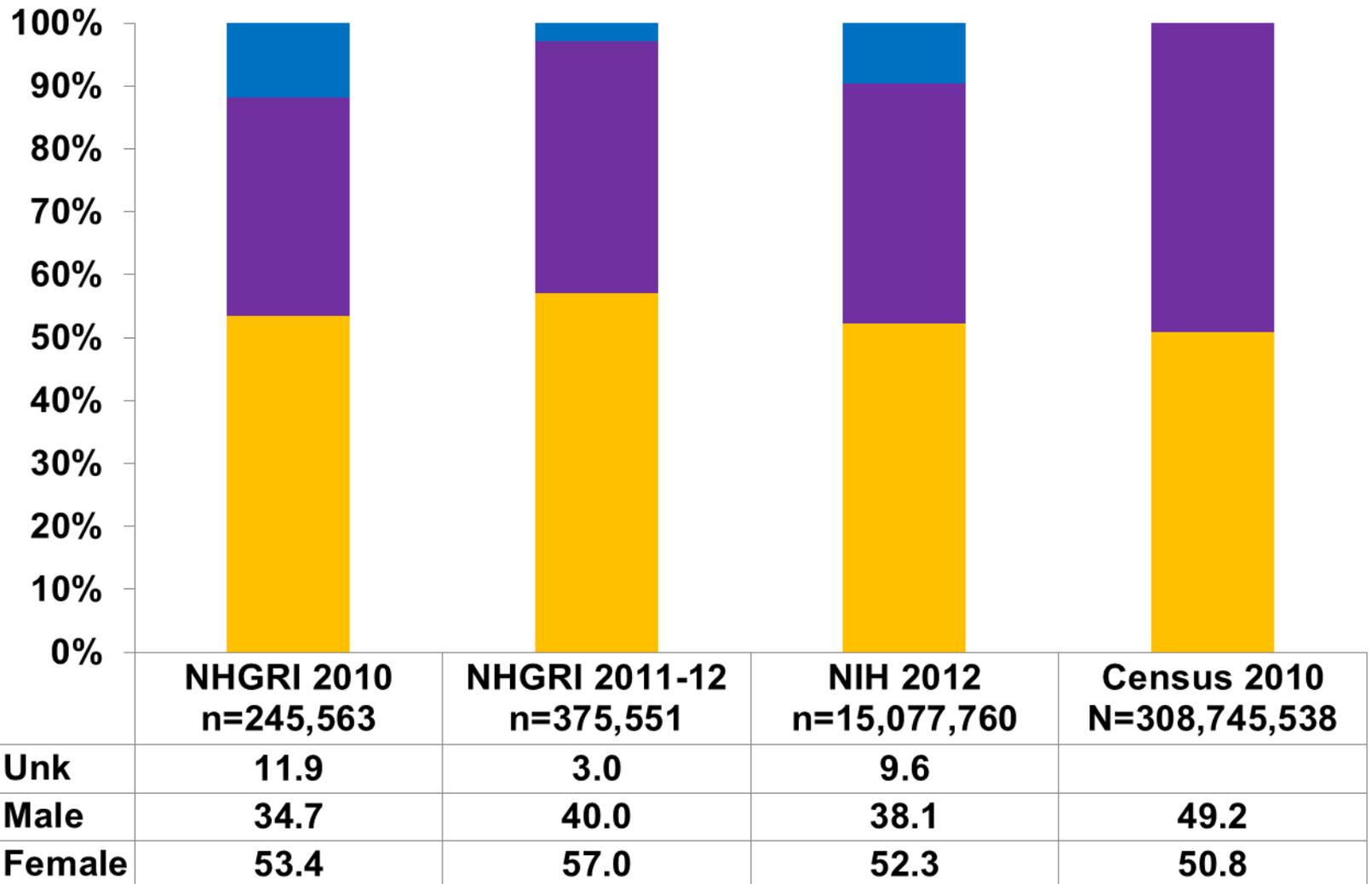
# Racial Distribution between Actual Enrollment Data and US Census Data



# Ethnic Distribution between Actual Enrollment Data and US Census Data



# Gender Distribution between Actual Enrollment Data and US Census Data



# Summary

- **NHGRI improved enrollment of minority and female participants in FY11-FY12 compared with FY10**
- **NHGRI had higher proportions of minority and female participants and lower proportion of unknown race, ethnicity, and gender compared with NIH in FY11-FY12**
- **NHGRI had a more diverse group of enrolled research participants compared with the 2010 US census**

# Acknowledgements

- **Peer reviewers, program officials, and grants management specialists**
- **Joy Boyer, Division of Genomics and Society**
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- **Carolyn Taylor, Division of Extramural Operations**