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*
<table>
<thead>
<tr>
<th>Ethnic Category</th>
<th>Females (F)</th>
<th>Males (M)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hispanic or Latino (Hisp)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not Hispanic or Latino (Not Hisp)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unknown (Not reporting ethnicity) (Unk)</td>
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<table>
<thead>
<tr>
<th>Racial Categories</th>
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</thead>
<tbody>
<tr>
<td>American Indian/Alaska Native (AI/AN)</td>
</tr>
<tr>
<td>Asian</td>
</tr>
<tr>
<td>Native Hawaiian or Other Pacific Islander (Haw/Pac)</td>
</tr>
<tr>
<td>Black or African American (BI/AA)</td>
</tr>
<tr>
<td>White</td>
</tr>
<tr>
<td>More Than One Race (&gt;1 Race)</td>
</tr>
<tr>
<td>Unknown or Not Reported (Unk)</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th></th>
<th>ERP*</th>
<th>IRP</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of Protocols</strong></td>
<td>50</td>
<td>94</td>
<td>144</td>
</tr>
<tr>
<td><strong>Number of Participants</strong></td>
<td>238,273</td>
<td>64,717</td>
<td>302,990</td>
</tr>
</tbody>
</table>

*ERP data excluding 23andMe*
FY13-14 Size of Funded Protocols

*ERP data excluding 23andMe
FY13-14 NHGRI Actual Enrollment Data by Race

ERP* (n=238,273)

- White: 56.7%
- BI/AA: 20.4%
- Asian: 7.3%
- Am Ind: 8.6%
- Haw/Pac: 1.6%
- Unk: 1.5%
- >1 Race: 3.8%

IRP (n=64,717)

- White: 70.9%
- BI/AA: 20.5%
- Asian: 4.4%
- Am Ind: 0.6%
- Haw/Pac: 3.5%
- Unk: 0.1%
- >1 Race: 0.1%

*ERP data excluding 23andMe
FY13-14 NHGRI Actual Enrollment Data by Ethnicity

ERP* (n=238,273)
- Not Hisp: 80.1%
- Hisp: 3.9%
- Unk: 16.0%

IRP (n=64,717)
- Not Hisp: 95.4%
- Hisp: 2.6%
- Unk: 2.0%

*ERP data excluding 23andMe
FY13-14 NHGRI Actual Enrollment Data by Gender

ERP* (n=238,273)

- Female: 61.9%
- Male: 37.6%
- Unk: 0.5%

IRP (n=64,717)

- Female: 43.7%
- Male: 51.5%
- Unk: 4.9%

*ERP data excluding 23andMe
FY13-14 23andMe Actual Enrollment Data by Race

23andMe (n=583,266)

- White: 58.1%
- BI/AA: 4.9%
- Asian: 4.4%
- Hawaiian Pacific: 30.4%
- Am Ind: 2.2%
- Am Ind: 0%
- Am Ind: 0%
- >1 Race: 0%

ERP* (n=238,273)

- White: 56.7%
- BI/AA: 20.4%
- Hawaiian Pacific: 7.3%
- Am Ind: 3.8%
- Am Ind: 1.6%
- Unk: 1.5%
- >1 Race: 8.6%

*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%

*ERP data excluding 23andMe
FY13-14 23andMe Actual Enrollment Data by Gender

23andMe (n=583,266)
- Female: 48.6%
- Male: 51.4%
- Unk: 0.5%

ERP* (n=238,273)
- Female: 61.9%
- Male: 37.6%
- Unk: 0.5%

*ERP data excluding 23andMe
Time Trends in Major Race Categories, NHGRI 2010-2014 and US Census

Percent Enrolled (%)

Racial Categories

White
BI/AA
Asian
Unk

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 Ethnic Categories, NHGRI 2010-2014 and US Census

Not Hisp

Hisp

Unk

Percent Enrolled (%)

NHGRI 2010
n=245,563

NHGRI 2011-12
n=375,551

NHGRI 2013-14*

US Census 2010
n=886,256

*ERP data excluding 23andMe
Time Trends in Major Gender Categories, NHGRI 2010-2014 and US Census

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.
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