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

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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

- Inclusion Plans Found to be Acceptable
- Unacceptable Inclusion Plans Resolved Prior to Award

2015: 99% Acceptable, 1% Unacceptable
2016: 99% Acceptable, 1% Unacceptable
Overview of Inclusion Data
## FY15-16 Inclusion Data Overview

### Clinical Research

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

### Phase III Clinical Trials

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Total IDRs</th>
<th>US Site IDRs</th>
<th>Non-US Site IDRs</th>
<th>Female Only IDRs</th>
<th>Male Only IDRs</th>
<th>IDRs Excluding Male-only and Female-only *</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>498</td>
<td>355</td>
<td>112</td>
<td>61</td>
<td>22</td>
<td>384</td>
</tr>
<tr>
<td>2016</td>
<td>574</td>
<td>413</td>
<td>121</td>
<td>66</td>
<td>32</td>
<td>436</td>
</tr>
</tbody>
</table>

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

Note: Records coded as existing datasets or resources excluded.
Aggregate Enrollment: Sex/Gender
Enrollment by Sex/Gender for NIH Clinical Research*

**FY2015**

- **All Clinical Research**
  - 36% Females, Excluding Female-only
  - 62% Males, Excluding Male-only
  - 2% Total Unknown

- **All Clinical Research Excluding Single-Sex Studies**
  - 44% Females, Excluding Female-only
  - 54% Males, Excluding Male-only
  - 2% Total Unknown

**FY2016**

- **All Clinical Research**
  - 45% Females, Excluding Female-only
  - 53% Males, Excluding Male-only
  - 2% Total Unknown

- **All Clinical Research Excluding Single-Sex Studies**
  - 48% Females, Excluding Female-only
  - 49% Males, Excluding Male-only
  - 3% Total Unknown

Note: Records coded as existing datasets or resources excluded.
Aggregate Enrollment: Race and Ethnicity of US Based Studies
Enrollment in NIH Clinical Research: Ethnic Categories (US Populations Only)

FY 2015
- Not Hispanic, 67.9%
- Hispanic, 10.7%
- Unknown, 21.5%

FY 2016
- Not Hispanic, 75.5%
- Hispanic, 14.2%
- Unknown, 10.3%

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)

FY 2015
- Hispanic, 12.0%
- Not Hispanic, 86.7%
- Unknown, 1.3%

FY 2016
- Hispanic, 12.8%
- Not Hispanic, 85.3%
- Unknown, 1.9%

Note: Records coded as existing datasets or resources excluded
Questions