Triennial Advisory Council Report
Certifying Compliance with the NIH Policy on Inclusion Guidelines

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Division of Extramural Research, NICHD
January 25, 2019
The Director of NIH shall:

• ensure that women and members of minorities and their subpopulations are included in all human subject research;

• for Phase III clinical trials, ensure that women and minorities and their subpopulations must be included such that valid analyses of differences in intervention effect can be accomplished;

• not allow cost as an acceptable reason for excluding these groups; and,

• initiate programs and support for outreach efforts to recruit these groups into clinical studies.

(Federal Register, 28 March 1994; 59 FR: 14508-14513)
Contents of the Report:

I. Background/Overview: NICHD Mission & Research Portfolio
II. Strategies for Ensuring Compliance
III. Enrollment Data
IV. Additional Information:
   • Inclusion policy changes related to the 21st Century Cures Act
   • Publications with analysis of gender/race/ethnicity
   • Projects specifically addressing inclusion of women and/or minority populations
   • Other highlighted information
Enrollment Data

- Total numbers of NICHD clinical research projects and Phase III trials
- Aggregate data showing total enrollment of women/men and racial/ethnic groups for:
  - Extramural
  - Intramural
  - Clinical research projects
  - Phase III trials
  - U.S. and non-U.S. enrollment
## Enrollment Overview

### NICHD Clinical Research Projects

<table>
<thead>
<tr>
<th>FY</th>
<th>Total</th>
<th>U.S. Site</th>
<th>Non-U.S. Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>1,070</td>
<td>896</td>
<td>108</td>
</tr>
<tr>
<td>2017</td>
<td>1,129</td>
<td>929</td>
<td>96</td>
</tr>
<tr>
<td>2018</td>
<td>1,121</td>
<td>862</td>
<td>109</td>
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</tbody>
</table>

### NICHD Phase III Clinical Trials

<table>
<thead>
<tr>
<th>FY</th>
<th>Total</th>
<th>U.S. Site</th>
<th>Non-U.S. Site</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>40</td>
<td>19</td>
<td>20</td>
</tr>
<tr>
<td>2017</td>
<td>45</td>
<td>31</td>
<td>12</td>
</tr>
<tr>
<td>2018</td>
<td>30</td>
<td>18</td>
<td>6</td>
</tr>
</tbody>
</table>
## Inclusion of Women

### Total Enrollment for All NICHD Extramural and Intramural Clinical Research Projects

<table>
<thead>
<tr>
<th>FY</th>
<th>Total Enrollment</th>
<th>Females</th>
<th>%</th>
<th>Males</th>
<th>%</th>
<th>Unknown</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016</td>
<td>2,784,689</td>
<td>1,882,262</td>
<td>67.6</td>
<td>856,033</td>
<td>30.7</td>
<td>46,394</td>
<td>1.7</td>
</tr>
<tr>
<td>2017</td>
<td>1,212,881</td>
<td>757,047</td>
<td>62.4</td>
<td>447,090</td>
<td>36.9</td>
<td>8,744</td>
<td>0.7</td>
</tr>
<tr>
<td>2018</td>
<td>1,293,100</td>
<td>778,357</td>
<td>60.2</td>
<td>503,448</td>
<td>38.9</td>
<td>11,295</td>
<td>0.9</td>
</tr>
</tbody>
</table>
## Total Enrollment for All NICHD Extramural and Intramural Clinical Research Projects
(2018 data, U.S. sites by race)

<table>
<thead>
<tr>
<th>Year</th>
<th>Sex Gender</th>
<th>American Indian Alaska Native</th>
<th>% American Indian Alaska Native</th>
<th>Asian</th>
<th>% Asian</th>
<th>Black African American</th>
<th>% Black African American</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018</td>
<td>Female</td>
<td>6,002</td>
<td>1.3</td>
<td>19,182</td>
<td>4.0</td>
<td>96,276</td>
<td>20.2</td>
</tr>
<tr>
<td>2018</td>
<td>Male</td>
<td>4,731</td>
<td>1.5</td>
<td>11,767</td>
<td>3.7</td>
<td>64,469</td>
<td>20.5</td>
</tr>
<tr>
<td>2018</td>
<td>Unknown</td>
<td>44</td>
<td>0.9</td>
<td>44</td>
<td>0.9</td>
<td>258</td>
<td>5.3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Native Hawaiian Pacific Islander</th>
<th>% Native Hawaiian Pacific Islander</th>
<th>White</th>
<th>% White</th>
<th>More Than One Race</th>
<th>% More Than One Race</th>
<th>Unknown Not Reported</th>
<th>% Unknown Not Reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>6,922</td>
<td>1.5</td>
<td>265,271</td>
<td>55.6</td>
<td>22,438</td>
<td>4.7</td>
<td>60,670</td>
<td>12.7</td>
</tr>
<tr>
<td>2,538</td>
<td>0.8</td>
<td>166,322</td>
<td>52.9</td>
<td>19,297</td>
<td>6.1</td>
<td>45,312</td>
<td>14.4</td>
</tr>
<tr>
<td>16</td>
<td>0.3</td>
<td>758</td>
<td>15.7</td>
<td>63</td>
<td>1.3</td>
<td>3,654</td>
<td>75.5</td>
</tr>
</tbody>
</table>
Total Enrollment for All NICHD Extramural and Intramural Clinical Research Projects (2018 data, U.S. sites by ethnicity)

<table>
<thead>
<tr>
<th>Year</th>
<th>Sex Gender</th>
<th>Not Hispanic</th>
<th>% Not Hispanic</th>
<th>Hispanic Latino</th>
<th>% Hispanic Latino</th>
<th>Unknown Not Reported</th>
<th>Unknown Not Reported</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>2018</td>
<td>Female</td>
<td>360,290</td>
<td>75.6</td>
<td>62,837</td>
<td>13.2</td>
<td>53,634</td>
<td>11.2</td>
<td></td>
</tr>
<tr>
<td>2018</td>
<td>Male</td>
<td>238,226</td>
<td>75.8</td>
<td>47,327</td>
<td>15.1</td>
<td>28,883</td>
<td>9.2</td>
<td></td>
</tr>
<tr>
<td>2018</td>
<td>Unknown</td>
<td>1,140</td>
<td>23.6</td>
<td>344</td>
<td>7.1</td>
<td>3,353</td>
<td>69.3</td>
<td></td>
</tr>
</tbody>
</table>
Highlighted areas of the report

• Inclusion policy changes related to the 21st Century Cures Act
• Research related to Intellectual and Developmental Disabilities (IDD)
• Research addressing Health Disparities
• Intramural research
• Projects & publications addressing sex/gender, racial and/or ethnic differences
Future trends

• Continued monitoring
• Attention to project milestones
• New tools for data analysis using RCDC terms
• Inclusion across the lifespan
Conclusions

- NICHD has working processes in place.
- Enrollment data show substantial inclusion of women and minorities across a broad spectrum of NICHD-supported research.
- **Focus of Inclusion Policy:**
  - Science driven
  - Ethical basis
  - Partnership
Acknowledgements

Sandra Delcore
LaShaun Thompson
Constantine Stratakis
Forbes Porter
Della Hann
Meredith Temple-O’Connor
Melissa Parisi
Rebecca Clark
Sarah Glavin
James Griffin
Lisa Kaeser
Charisee Lamar
Ronna Popkin
Numerous staff in NICHD, OER, ORWH
QUESTIONS?