NIH Inclusion Updates

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ACRWH
April 6, 2022
Inclusion of Women and Minorities in NIH Research

- Women and members of racial and ethnic minority groups must be included in all NIH-funded clinical research studies unless there is a compelling rationale for exclusion (NOT-OD-18-014)

- NIH-defined phase 3 clinical trials must be designed to permit analysis by sex/gender, race and ethnicity
  - Applicable NIH-defined phase 3 clinical trials must report results of analyses in Clinicaltrials.gov
• Individuals of all ages must be included in NIH human subjects research unless there are scientific or ethical reasons not to do so (NOT-OD-18-116)
  – Effective for applications submitted for due dates on or after January 25, 2019 (and for contract solicitations issued and intramural studies initiated after that date)

• Submission of individual-level data on participant sex/gender, race, ethnicity and age at enrollment in progress reports required
United States Government Accountability Office

Report to Congressional Requesters

October 2015

NATIONAL INSTITUTES OF HEALTH

Better Oversight Needed to Help Ensure Continued Progress Including Women in Health Research
1. Make IC-level enrollment data readily available through public means **CLOSED**

2. Examine approaches for aggregating more detailed enrollment data at the disease and condition level **CLOSED**

3. Ensure that program officers have a means of recording their monitoring of awardees' plans for and progress in conducting analysis of potential sex differences **CLOSED**

4. On a regular basis, systematically collect and analyze summary data regarding awardees' plans for analysis of potential sex differences **CLOSED**

5. Report on this summary data and analysis in its regular report to Congress on the inclusion of women in research **CLOSED**
Recurrent Themes

- Select **trial outcomes** that reflect participant concerns
- Limit use of unnecessary **inclusion/exclusion criteria**
- Adequately weigh **risks of excluding** groups—like pregnant women and children—with that of their participation
- **Minimize** participant and caregiver **burden**
- Consider the **diversity** of individuals within a given group (e.g. size, comorbidities, diet, cognitive status)
- Regularly **assess recruitment and retention** and make modifications as needed
Communications and Training

Some Thoughts Following the NIH Inclusion Across the Lifespan 2 Workshop

By Mike Leuer
Posted December 10, 2020

“The [NIH Inclusion Across the Lifespan] policy, and the review and reporting requirements associated with it, should help ensure that children and older adults are not inappropriately excluded from clinical studies. The policy also has the potential to provide a more robust understanding of the full spectrum of participants recruited into clinical studies.”

Together with my NIH colleagues Drs. Marie Bernard and Janine Clayton, we made this point in a 2018 JAMA opinion piece following the inaugural NIH Inclusion Across the Lifespan workshop. Fast forward, we revisited this issue at the NIH’s Inclusion Across the Lifespan 2 workshop held this past September. You can watch the videocast here. The report covering the event was posted today, and I wanted to share some of my takeaways.

Including appropriate participants in research leads to sound science that informs clinical practice. It also means that study results are more likely to be generalizable across populations. We remain committed to these inclusion principles, including as it comes to persons of different ages. The NIH Inclusion Across the Lifespan policy requires individuals of all ages be included in clinical research studies unless there are scientific or ethical reasons to exclude them. More on the policy can be found at


https://www.youtube.com/watch?v=fYoNnIt_f1o
NIH Clinical Research Enrollment by Sex or Gender, FY2019 – FY2021

FY 2019

- % Females: 3.1%
- % Males: 52.1%
- % Unknown/Not Reported: 44.8%

FY 2020

- % Females: 4.5%
- % Males: 55.1%
- % Unknown/Not Reported: 40.4%

FY 2021

- % Females: 2.5%
- % Males: 39.0%
- % Unknown/Not Reported: 58.5%
NIH-Defined Phase 3 Clinical Trial Enrollment by Sex or Gender, FY2019 – FY2021

FY 2019

- % Females: 61.4%
- % Males: 36.2%
- % Unknown/Not Reported: 2.4%

FY 2020

- % Females: 61.8%
- % Males: 36.6%
- % Unknown/Not Reported: 1.6%

FY 2021

- % Females: 61.2%
- % Males: 37.9%
- % Unknown/Not Reported: 0.9%
U.S.-Only NIH-Defined Phase 3 Clinical Trial Enrollment by Race, FY2019 – FY2021
NIH U.S.-Only Clinical Research Enrollment by Ethnicity, FY2019 – FY2021

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>% Not Hispanic/Latino</th>
<th>% Hispanic/Latino</th>
<th>% Unknown/Not Reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY 2019</td>
<td>79.5%</td>
<td>11.5%</td>
<td>9.0%</td>
</tr>
<tr>
<td>FY 2020</td>
<td>75.7%</td>
<td>13.4%</td>
<td>10.9%</td>
</tr>
<tr>
<td>FY 2021</td>
<td>77.7%</td>
<td>11.8%</td>
<td>10.5%</td>
</tr>
</tbody>
</table>
U.S.-Only NIH-Defined Phase 3 Enrollment by Ethnicity, FY2019 – FY2021

<table>
<thead>
<tr>
<th>Year</th>
<th>% Not Hispanic/Latino</th>
<th>% Hispanic/Latino</th>
<th>% Unknown/Not Reported</th>
</tr>
</thead>
<tbody>
<tr>
<td>FY 2019</td>
<td>88.4%</td>
<td>8.7%</td>
<td>2.9%</td>
</tr>
<tr>
<td>FY 2020</td>
<td>78.6%</td>
<td>17.3%</td>
<td>4.1%</td>
</tr>
<tr>
<td>FY 2021</td>
<td>57.1%</td>
<td>39.5%</td>
<td>3.4%</td>
</tr>
</tbody>
</table>
NIH Clinical Research Enrollment by Broad Age Groups, FY 2021

- Children (<18 years): 3%
- Adults (18-64 years): 20%
- Older Adults (65+ years): 58%
- Unknown or Not Reported: 19%
NIH Enrollment in Clinical Research by Narrow Age Groups, FY 2021

* Includes ages reported in weeks, months, or years that are equivalent to less than 1 year.
** Includes all individuals less than 1 year. Age reported in units from days to years.
**NIH Inclusion Data by Research, Condition, and Disease Categories**

This report displays the typical representation of participants in human subject studies enrolled in FY2018 projects associated with the listed research, condition, or disease category. Median percent participation is presented for each demographic variable.

Adjust the filters to view characteristics by race or ethnicity or to exclude single population studies. Drill down to explore more detailed statistics.

**Notes:** Research, condition, and disease categories are not mutually exclusive, so the same projects may appear in more than one category. All participants enrolled in a project’s studies are included in all categories associated with that project. Individual research projects can be included in multiple categories so amounts depicted within each column of this table do not add up to the total participants enrolled in NIH-funded research.

**Example:** R01 IC12345 enrolled 300 participants and is associated with the Basic Behavioral and Social Science and Prevention categories. All 300 participants will appear in both the Basic Behavioral and Social Science and Prevention category totals for that IC.

<table>
<thead>
<tr>
<th>RCDC Category</th>
<th>Median % Female Participants</th>
<th>Median % Male Participants</th>
<th>Median % Participants of Unknown or Unreported Sex/Gender</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALS</td>
<td>45%</td>
<td>55%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Acquired Cognitive Impairment</td>
<td>55%</td>
<td>44%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Acute Respiratory Distress Syndrome</td>
<td>45%</td>
<td>55%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Adolescent Sexual Activity</td>
<td>52%</td>
<td>49%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Agent Orange &amp; Dioxin</td>
<td>76%</td>
<td>24%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Aging</td>
<td>50%</td>
<td>43%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Alcoholism, Alcohol Use and Health</td>
<td>44%</td>
<td>54%</td>
<td>&lt;1%</td>
</tr>
<tr>
<td>Allergic Rhinitis (Hay Fever)</td>
<td>49%</td>
<td>50%</td>
<td>&lt;1%</td>
</tr>
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</table>
Improving the Representation of Women and Underrepresented Minorities in Clinical Trials and Research


Current Efforts

The underrepresentation of diverse populations in clinical trials creates knowledge gaps about the

https://ctti-clinicaltrials.org/our-work/quality/diversity/

NIH Community Engagement Alliance (CEAL)

https://covid19community.nih.gov/
RESOURCES

WEB
Inclusion of Women and Minorities
https://grants.nih.gov/grants/funding/women_min/women_min.htm

Inclusion Across the Lifespan
https://grants.nih.gov/grants/funding/lifespan/lifespan.htm

EMAIL
inclusion@mail.nih.gov