NIH Inclusion Update

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National Institutes of Health

58th Meeting of the NIH Advisory Committee on Research on Women’s Health
April 12, 2023
Timeline of NIH Inclusion Policies

1986
• NIH encourages inclusion of women

1994
• NIH requires inclusion of women and racial and ethnic minorities

1998
• NIH requires inclusion of children

2017
• New phase 3 reporting requirements

2019
• NIH requires inclusion of individuals of all ages

2022
• NIH clarifies phase 3 project outcomes requirements
Without a paradigm shift that looks beyond tactics and process oriented changes, disparities in research access and inclusion will persist at the expense of minority population subgroups and the nation’s public health.

Full report at https://nap.nationalacademies.org/read/26479/chapter/1
Inclusion of Women and Members of Racial and Ethnic Groups

- 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.

- Additional requirements for NIH-defined phase 3 clinical trials:
  - Analysis of primary outcome by sex or gender, race and ethnicity
    - Status/results reported in progress reports/RPPR Project Outcomes
    - If applicable clinical trial (ACT) must report results of analyses in Clinicaltrials.gov

Policy Notice: NOT-OD-18-014
• Individuals of **all ages** must be included in NIH human subjects research unless there are scientific or ethical reasons not to do so

• Requires submission of individual-level participant data in progress reports
  – Sex or Gender
  – Race
  – Ethnicity
  – Age at Enrollment
GAO Reports

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

All Recommendations Closed


United States Government Accountability Office

Report to Congressional Committees

December 2022

CANCER CLINICAL TRIALS

Federal Actions and Selected Non-Federal Practices to Facilitate Diversity of Patients

No Recommendations

An NIH-wide Oversight System

Human subjects and trial information in one place

Synchronized with Clinicaltrials.gov

Accepts individual-level participant data
FY 2021 Data on Age at Enrollment in Clinical Research Now Available by RCDC Category

By Mike Lauer  
Posted April 11, 2022

We are pleased to announce that for the first time, data are now available on the age of participants in NIH-on age adds to already reported data on participant sex or gender, race, and ethnicity.

The NIH Inclusion Across the Lifespan (IAL) policy, implemented in response to the 21st Century Cures Act, older adults be included in our supported clinical research absent compelling scientific or ethical reasons. If submitting anonymized individual-level data on the sex or gender, race, ethnicity, and age of their participants, please see here for more.

https://report.nih.gov/research/inclusion-women-and-minorities-clinical-research#/

Enhanced Reporting
Although much work has focused on study-level strategies, research organizations must make systemic changes to how clinical trials are envisioned and implemented to achieve sustainable support for diversity and inclusion in clinical trials.

Workshop on Inclusive Participation in Clinical Research

March 30 – March 31, 2023
11:00 a.m. – 5:00 p.m. ET

## Enrollment in NIH Clinical Research

### US and non-US Enrollment for All NIH Clinical Research

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Total Enrollment</th>
<th>US Only</th>
<th>% US only</th>
<th>Foreign only</th>
<th>% Foreign only</th>
</tr>
</thead>
<tbody>
<tr>
<td>2021</td>
<td>12,937,156</td>
<td>9,957,714</td>
<td>77.0%</td>
<td>2,979,442</td>
<td>23.0%</td>
</tr>
<tr>
<td>2022</td>
<td>97,162,052</td>
<td>95,165,832</td>
<td>97.9%</td>
<td>1,996,220</td>
<td>2.1%</td>
</tr>
<tr>
<td>2022 Adjusted*</td>
<td>10,751,975</td>
<td>8,755,755</td>
<td>81.4%</td>
<td>1,996,220</td>
<td>18.6%</td>
</tr>
</tbody>
</table>

*2022 Adjusted excludes one outlier, a large COVID-19 social media NIH-defined Phase 3 clinical trial with over 86,000,000 participants.

### US and non-US Enrollment for All NIH Phase 3 Clinical Trials

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Total Enrollment</th>
<th>US Only</th>
<th>% US only</th>
<th>Foreign only</th>
<th>% Foreign only</th>
</tr>
</thead>
<tbody>
<tr>
<td>2021</td>
<td>666,800</td>
<td>441,034</td>
<td>66.1%</td>
<td>225,766</td>
<td>33.9%</td>
</tr>
<tr>
<td>2022</td>
<td>87,647,554</td>
<td>87,418,025</td>
<td>99.7%</td>
<td>229,529</td>
<td>0.3%</td>
</tr>
<tr>
<td>2022 Adjusted*</td>
<td>1,237,477</td>
<td>1,007,948</td>
<td>81.5%</td>
<td>229,529</td>
<td>18.5%</td>
</tr>
</tbody>
</table>
Sex or Gender Clinical Research Enrollment

FY21
- % Females: 39.0%
- % Males: 58.5%
- % Unknown/Not Reported: 2.5%

FY22
- % Females: 48.2%
- % Males: 51.5%
- % Unknown/Not Reported: 0.3%

FY22 Adjusted
- % Females: 41.4%
- % Males: 55.8%
- % Unknown/Not Reported: 2.8%
Sex or Gender NIH-defined Phase 3 Trial Enrollment

- **FY21**
  - Females: 37.9%
  - Males: 61.2%
  - Unknown/Not Reported: 0.9%

- **FY22**
  - Females: 48.9%
  - Males: 51.1%
  - Unknown/Not Reported: 0.1%

- **FY22 Adjusted**
  - Females: 35.8%
  - Males: 60.6%
  - Unknown/Not Reported: 3.6%
Race U.S.-Only NIH-defined Phase 3 Clinical Trial Enrollment

- 2021:
  - Unknown/Not Reported: 4.7%
  - >1 Race: 0.3%
  - White: 74.5%
  - Native Hawaiian or Other Pacific Islander: 0.6%
  - Black or African American: 14.2%
  - Asian: 2.3%
  - American Indian/Alaska Native: 0.6%

- 2022:
  - Unknown/Not Reported: 0.1%
  - >1 Race: 2.4%
  - White: 76.0%
  - Native Hawaiian or Other Pacific Islander: 1.2%
  - Black or African American: 17.7%
  - Asian: 2.5%
  - American Indian/Alaska Native: 0.1%

- 2022 Adjusted:
  - Unknown/Not Reported: 8.6%
  - >1 Race: 1.1%
  - White: 76.0%
  - Native Hawaiian or Other Pacific Islander: 0.2%
  - Black or African American: 11.4%
  - Asian: 2.1%
  - American Indian/Alaska Native: 0.5%
Ethnicity U.S.-Only NIH-defined Phase 3 Trial Enrollment

FY21:
- 39.5% Not Hispanic or Latino
- 57.1% Hispanic or Latino
- 3.4% Unknown/Not Reported

FY22:
- 93.6% Not Hispanic or Latino
- 6.3% Hispanic or Latino
- 0.1% Unknown/Not Reported

FY22 Adjusted:
- 79.0% Not Hispanic or Latino
- 12.0% Hispanic or Latino
- 9.0% Unknown/Not Reported
Age in Clinical Research Enrollment

- **Children (<18 years)**: FY21 (19.6%) vs. FY22 (13.6%)
- **Adults (18-64 years)**: FY21 (57.9%) vs. FY22 (60.9%)
- **Older Adults (65+ years)**: FY21 (19.3%) vs. FY22 (20.9%)
- **Unknown or Not Reported**: FY21 (3.1%) vs. FY22 (4.6%)
Inclusion Plans (Part 1): The Application

Inclusion plans. You have questions. We have answers. What exactly are they? How do they relate to NIH’s policies requiring specific populations be included in NIH-supported clinical research? What do they mean for your application? And, what is an inclusion table anyway? In Part 1 of this NIH All About Grants podcast miniseries, NIH’s Inclusion Policy Officer Dawn Corbett tells us how to consider inclusion plans when putting together your application. The good news is there’s no page limit. So you can take the space that you need to describe inclusion of these populations in your research. In the inclusion of women and minorities plan, you’ll be describing your inclusion based on sex or gender and race and ethnicity. And then in your inclusion of across the life span plan, you’ll be describing distribution based on age and then you talk about the rationale. So why did you choose this population distribution? And this should really be based on science and ethics and you’ll justify any exclusions. (Dawn Corbett) Part 2 covers inclusion plans during peer review and post-award. Interested in this topic? Learn more in our related podcasts on the Inclusion Across the Lifespan policy and validated analysis.

Dawn Corbett, M.P.H.
NIH Inclusion Policy Officer

Available Resources on the Recruitment and Retention of Women, Racial and Ethnic Minorities, and Individuals Across the Lifespan

Click on the resource title to open the item. You can also check out our FAQ on this topic.

- NIH Outreach Toolkit
  Created by the NIH Office of Research on Women’s Health (ORWH), this toolkit provides recruitment case studies and other important information regarding the recruitment and retention of women in research.

- The National Institute on Aging (NIA) Recruiting Older Adults into Research (ROAR) Toolkit
  Part of a collaborative project to encourage research participation among older adults and their caregivers, this toolkit provides recruitment steps and information for volunteers.

- NIA Health Professionals Information website
  Provides materials to assist healthcare professionals in communicating with older adults, including considerations for diverse populations. See also this featured research story on minority recruitment.

- NIA OutreachPro
  Resource from NIA that houses tools to help dementia researchers recruit and engage study participants.

https://grants.nih.gov/policy/inclusion.htm
Questions?
ADDITIONAL SLIDES
Age at Enrollment in NIH Clinical Research by Narrow Age Groups

* Includes ages reported in weeks, months, or years that are equivalent to less than 1 year.

** Includes all ages equivalent to less than one year, including all those reported in days, weeks, months and years.