

# **NHLBI Compliance with the Congressional Mandate to Include Women and Minorities in Clinical Studies**

**March 2015**

## **I. Overview**

### ***NHLBI Mission Statement***

The National Heart, Lung, and Blood Institute (NHLBI) provides global leadership for a research, training, and education program to promote the prevention and treatment of heart, lung, and blood diseases and enhance the health of all individuals so that they can live longer and more fulfilling lives.

The NHLBI stimulates basic discoveries about the causes of disease, enables the translation of basic discoveries into clinical practice, fosters training and mentoring of emerging scientists and physicians, and communicates research advances to the public. It creates and supports a robust, collaborative research infrastructure in partnership with private and public organizations, including academic institutions, industry, and other government agencies. The Institute collaborates with patients, families, health care professionals, scientists, professional societies, patient advocacy groups, community organizations, and the media to promote the application of research results and leverage resources to address public health needs. The NHLBI also collaborates with international organizations to help reduce the burden of heart, lung, and blood diseases worldwide.

### ***History of Inclusion Policy***

The NIH Revitalization Act of 1993 (PL 103-43) directed the NIH to ensure that women and minorities are included as subjects in the clinical research it supports. The NIH policy on the inclusion of women and minorities as subjects in clinical research was published as a notice in the *Federal Register* on March 28, 1994, (Vol. 59, No. 59) and became effective in September 1994 for all grant applications and contract proposals submitted after June 1, 1994. As stated in the notice,

“It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH-supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research.”

The law also included the following provision:

“The advisory council of each national institute shall prepare biennial reports describing the manner in which the institute has complied with this section.”

The first of such reports was prepared for the NIH and its constituent Institutes and Centers (ICs) in 1997. Because recruitment data are only required to be provided to the NIH as part of noncompeting renewal applications, there is always a lag in the data presented. Thus, the data provided as part of this report reflect subjects enrolled in clinical research studies supported by the NHLBI in 2013, just as the

previous seven reports reflected subjects enrolled in clinical research studies supported by the NHLBI two years prior to the year of the report.

The categories in effect since January 10, 2002, are:

| <b>Race*</b>                              | <b>Ethnicity</b>   |                        |
|---|--------------------|------------------------|
| American Indian or Alaska Native          | Hispanic or Latino | Not Hispanic or Latino |
| Asian                                     |                    |                        |
| Black or African American                 |                    |                        |
| Native Hawaiian or Other Pacific Islander |                    |                        |
| White                                     |                    |                        |

\* Identification with more than one racial group permitted.

As it did in each of the previous report years, the NIH has elected to prepare centrally a summary report. The report, which is to be developed by the NIH Office of Extramural Research, will include statements related to each of the national advisory councils.

***National Heart, Lung, and Blood Advisory Council Review***

On February 10, 2015, the National Heart, Lung, and Blood Advisory Council (NHLBAC) reviewed:

- NHLBI’s procedures for implementation of the NIH policy for inclusion of women and minorities in clinical studies and
- The results of that implementation.

They determined that NHLBI is in compliance.

In 1997 and in each of the report years since then, the NHLBAC found that the NHLBI had complied with the policy mandate. Information and data are provided herein that can support a similar conclusion in 2013.

**II. Strategies for Ensuring Compliance**

***Peer Review***

Inclusion is addressed first for all applications by the initial review groups (IRGs), which are required to make a recommendation as to the acceptability of all study populations with respect to the policy. When the research involves human subjects, reviewers must evaluate the proposed plans for inclusion of women, minorities, and children as one of the review criteria that factor into the evaluation of scientific and technical merit. It is not expected that every study will include both sexes/genders, all racial and ethnic groups and subgroups, and children. Inclusion on the basis of sex/gender, race, and ethnicity, as well as the inclusion of children should be guided by the scientific aims of the study.

***NHLBI Procedures for Implementation of NIH Policy***

The NHLBI relies upon a four-step process involving its program officials (POs) for ensuring compliance with the NIH policy. Since the inception of the NIH policy, the NHLBI has scrutinized each project—even those that were rated acceptable for inclusion of women and minorities by the IRGs. The NHLBI procedure is to have:

- The POs evaluate all clinical research projects for appropriate representation of women and minorities.
- The POs discuss any concerns regarding the extent to which an application is in compliance with the policy with senior Institute staff.
- The POs discuss those issues needing further attention and their possible solution with the applicants.
- The POs release the projects for consideration by the National Heart, Lung, and Blood Advisory Council when all issues are resolved.

### ***NHLBI Training Approaches***

The NIH has developed numerous training documents, FAQs, and tools related to tracking study populations and addressing compliance with the Inclusion Policy. NHLBI Program Officers, Program Analysts, and other Program Staff have access to these resources. The NIH Office of Extramural Research (OER) provides access through their website to archived training sessions relevant to tracking study populations. Training sessions are available on video-cast or as a slide show. The NHLBI conducts training sessions as requested to address the needs of Program Staff. One-on-one training is always available.

## **III. Analysis and Interpretation of Data**

### ***All Clinical Research***

#### **A. Aggregate Planned Enrollee Distribution for NHLBI Clinical Research**

Planned enrollment of people from racial and ethnic minorities exceeded their corresponding representation in the 2010 census, except for those of more than one race (Table 1). Similarly, the proportion of women in NHLBI-supported studies active in 2013 was greater than their corresponding representation in the 2010 census and exceeded the percentage of men in every year reported, beginning in 2003 (Table 2). In 2011, the planned enrollee distribution for Hispanics fell short of the 2010 census. However, in 2013, planned enrollment of this population was increased to 15.8%—above that of the 2010 census (Table 3).

**Table 1. Aggregate Planned Enrollee Distribution by Sex and Race or Ethnicity for all NHLBI-supported Clinical Studies Active in FY2013**

|             | by Race                        |       |                        |                                  |       |          |               |       | by Ethnicity    |                     |       |
|-------------|--------------------------------|-------|------------------------|----------------------------------|-------|----------|---------------|-------|-----------------|---------------------|-------|
|             | American Indian/Alaskan Native | Asian | Black/African American | Native Hawaiian/Pacific Islander | White | > 1 Race | Other/Unknown | Total | Hispanic/Latino | Not Hispanic/Latino | Total |
| Female      | 0.7%                           | 5.5%  | 10.7%                  | 0.3%                             | 37.7% | 0%       | 0%            | 55%   | 8.4%            | 46.6%               | 55%   |
| Male        | 0.6%                           | 5.9%  | 8.6%                   | 0.2%                             | 29.6% | 0%       | 0%            | 45%   | 7.4%            | 37.6%               | 45%   |
| Total       | 1.3%                           | 11.4% | 19.3%                  | 0.5%                             | 67.4% | 0.1%     | 0%            | 100%  | 15.8%           | 84.2%               | 100%  |
| 2010 Census | 1.0%                           | 4.6%  | 12.9%                  | 0.2%                             | 79.6% | 1.7%     | 0%            | 100%  | 12.5%           | 87.5%               | 100%  |

| Sex    | 2003  | 2005  | 2007  | 2009  | 2011  | 2013  | 2010 Census |
|--------|-------|-------|-------|-------|-------|-------|-------------|
| Female | 60.4% | 56.3% | 57.1% | 61.7% | 58.8% | 55.0% | 50.7%       |
| Male   | 39.6% | 43.7% | 42.9% | 38.3% | 41.2% | 45.0% | 49.3%       |

| Race/Ethnicity                       | 2003  | 2005  | 2007  | 2009  | 2011  | 2013  | 2010 Census |
|--------------------------------------|-------|-------|-------|-------|-------|-------|-------------|
| American Indian/<br>Alaskan Native   | 1%    | 2.2%  | 2.1%  | 1.4%  | 1%    | 1.3%  | 1%          |
| Asian                                | 4.5%  | 5.3%  | 5.1%  | 8.7%  | 7.3%  | 11.4% | 4.6%        |
| Black/African<br>American            | 26.2% | 23.0% | 19.0% | 20.1% | 18.2% | 19.3% | 12.9%       |
| Native Hawaiian/<br>Pacific Islander | 0.5%  | 0.8%  | 0.8%  | 0.5%  | 0.4%  | 0.5%  | 0.2%        |
| White                                | 67.8% | 68.7% | 73.0% | 69.3% | 73.1% | 67.4% | 79.6%       |
| > 1 Race                             | 0%    | 0%    | 0%    | 0%    | 0%    | 0.1%  | 1.7%        |
| Other/Unknown                        | 0%    | 0%    | 0%    | 0%    | 0%    | 0%    | 0%          |
| Hispanic/Latino                      | 12.2% | 11.2% | 12.9% | 13.0% | 8.0%  | 15.8% | 12.5%       |
| Not<br>Hispanic/Latino               | 87.8% | 88.8% | 87.1% | 87.1% | 92.0% | 84.2% | 87.5%       |

## B. Aggregate Enrollment Data for NHLBI Clinical Research

The enrollment numbers and percent distribution of NHLBI-supported clinical research studies active in 2013 show that racial/ethnic minority participation exceeded their representation in the 2010 census (Table 4a and 4b). In addition, for all years from 2003 through 2013, the percent of women enrolled in NHLBI-supported clinical studies substantially exceeded that of the 2010 census (Table 5). Previous reports also illustrate a continuing trend of strong participation by all minority groups which, in most cases, exceeded the corresponding representation in the 2010 census (Table 6).

|             | American Indian/<br>Alaskan Native |      | Asian  |      | Black/ African American |       | Native Hawaiian/<br>Pacific Islander |      | White   |       | > 1 Race |      | Other/<br>Unknown |      | Total   |       |
|-------------|------------------------------------|------|--------|------|-------------------------|-------|--------------------------------------|------|---------|-------|----------|------|-------------------|------|---------|-------|
|             | #                                  | %    | #      | %    | #                       | %     | #                                    | %    | #       | %     | #        | %    | #                 | %    | #       | %     |
| Female      | 3,706                              | 0.7% | 27,907 | 5.4% | 53,401                  | 10.2% | 1,271                                | 0.2% | 199,181 | 38.2% | 6,293    | 1.2% | 20,719            | 4%   | 312,478 | 60%   |
| Male        | 2,479                              | 0.5% | 29,332 | 5.6% | 30,799                  | 5.9%  | 1,281                                | 0.2% | 123,871 | 23.8% | 4,927    | 0.9% | 13,710            | 2.6% | 206,399 | 39.6% |
| Unknown     |                                    | 0%   |        | 0%   |                         | 0%    |                                      | 0%   |         | 0%    |          | 0%   | 2,280             | 0.4% | 2,280   | 0.4%  |
| Totals      | 6,185                              | 1.2% | 57,239 | 11%  | 84,200                  | 16.2% | 2,552                                | 0.5% | 323,052 | 62%   | 11,220   | 2.2% | 36,709            | 7%   | 521,157 | 100%  |
| 2010 Census |                                    | 1.0% |        | 4.6% |                         | 12.9% |                                      | 0.2% |         | 79.6% |          | 1.7% |                   | 0%   |         | 100%  |

| Table 4b. Aggregate Enrollment by Sex and Ethnicity in all NHLBI-supported Clinical Studies Active in FY 2013 |                 |       |                      |       |                |    |         |       |
|---|-----------------|-------|----------------------|-------|----------------|----|---------|-------|
|   | Hispanic/Latino |       | Not Hispanic/ Latino |       | Other/ Unknown |    | Total   |       |
| Female  | 39,703          | 7.6%  | 272,775              | 52.3% | 0              | 0% | 312,478 | 60%   |
| Male  | 28,278          | 5.4%  | 178,121              | 34.2% | 0              | 0% | 206,399 | 39.6% |
| Unknown   | 0               | 0%    | 0                    | 0%    | 2,280          | 0% | 2,280   | 0.4%  |
| Total   | 67,981          | 13%   | 450,896              | 86.5% | 2,280          | 0% | 521,157 | 100%  |
| 2010 Census   |                 | 12.5% |                      | 87.5% |                | 0% |         | 100%  |

| Table 5. Aggregate Enrollment by Sex in All NHLBI-supported Clinical Studies (Active Studies, 2003-2013) |         |       |         |       |         |       |         |       |         |       |         |       |             |
|--|---------|-------|---------|-------|---------|-------|---------|-------|---------|-------|---------|-------|-------------|
|  | 2003    |       | 2005    |       | 2007    |       | 2009    |       | 2011    |       | 2013    |       | 2010 Census |
|  | #       | %     | #       | %     | #       | %     | #       | %     | #       | %     | #       | %     |             |
| Female   | 156,244 | 65%   | 307,879 | 62.8% | 280,254 | 61.4% | 476,360 | 65.7% | 547,523 | 64.8% | 312,478 | 60%   | 50.7%       |
| Male   | 83,589  | 34.7% | 182,345 | 37.2% | 176,018 | 38.6% | 249,199 | 34.3% | 297,828 | 35.2% | 206,399 | 39.6% | 49.3%       |
| Unknown  |         | 0.3%  | 741     | 0%    |         | 0%    |         | 0%    |         | 0%    | 2,280   | 0.4%  | 0%          |

| Table 6. Aggregate Enrollment by Race/Ethnicity in all NHLBI-supported Clinical Studies (Active Studies, 2007-2013) |         |       |         |       |         |       |         |       |             |
|---|---------|-------|---------|-------|---------|-------|---------|-------|-------------|
| Race/Ethnicity  | 2007    |       | 2009    |       | 2011    |       | 2013    |       | 2010 Census |
|   | #       | %     | #       | %     | #       | %     | #       | %     |             |
| American Indian/ Alaskan Native   | 8,330   | 1.8%  | 10,034  | 1.4%  | 3,018   | 0.4%  | 6,185   | 1.2%  | 1.0%        |
| Asian   | 14,918  | 3.2%  | 19,698  | 2.7%  | 68,246  | 8.1%  | 57,239  | 11.0% | 4.6%        |
| Black/ African American   | 70,874  | 15.4% | 107,118 | 14.8% | 213,247 | 25.2% | 84,200  | 16.2% | 12.9%       |
| Native Hawaiian/ Pacific Islander   | 1,380   | 0.3%  | 3,453   | 0.5%  | 1,155   | 0.1%  | 2,552   | 0.5%  | 0.2%        |
| White   | 331,339 | 72.2% | 548,660 | 75.6% | 507,845 | 60.1% | 323,052 | 62.0% | 79.6%       |
| > 1 Race  | 10,575  | 2.3%  | 6,328   | 0.9%  | 17,526  | 2.1%  | 11,220  | 2.2%  | 1.7%        |
| Other/ Unknown  | 21,650  | 4.7%  | 30,268  | 4.2%  | 34,314  | 4.1%  | 36,709  | 7.0%  | 0%          |
| Hispanic/ Latino  | 62,085  | 13.6% | 57,400  | 7.9%  | 73,587  | 8.7%  | 67,981  | 13.0% | 12.5%       |
| Not Hispanic/Latino   | 394,187 | 86.4% | 668,159 | 92.1% | 771,764 | 91.3% | 450,896 | 86.5% | 87.5%       |

### C. NIH-Defined Phase III Clinical Trials

**Aggregate Planned Enrollee Distribution for NHLBI-supported Phase III Clinical Trials**  
Individual investigators planned to enroll women in relatively high percentages in NHLBI-supported Phase III clinical trials, although slightly below that of the 2010 census (Table 7). However, the aggregate planned enrollee distribution for each individual racial/ethnic minority exceeded their corresponding representation in the 2010 census, except for those of more than one race (Table 7).

|             | American Indian/Alaskan Native | Asian | Black/African American | Native Hawaiian/Pacific Islander | White | > 1 Race | Other/Unknown | Total | Hispanic/Latino | Not Hispanic/Latino | Total | 2010 Census |
|-------------|--------------------------------|-------|------------------------|----------------------------------|-------|----------|---------------|-------|-----------------|---------------------|-------|-------------|
| Female      | 0.5%                           | 3.1%  | 8.9%                   | 0.1%                             | 35.8% | 0%       | 0%            | 48.4% | 7.8%            | 40.6%               | 48.4% | 50.7%       |
| Male        | 0.5%                           | 4.2%  | 8.8%                   | 0.1%                             | 37.8% | 0%       | 0%            | 51.6% | 7.7%            | 43.9%               | 51.6% | 49.3%       |
| Total       | 1.1%                           | 7.3%  | 17.7%                  | 0.3%                             | 73.6% | 0%       | 0%            | 100%  | 15.5%           | 84.5%               | 100%  | 100%        |
| 2010 Census | 1.0%                           | 4.6%  | 12.9%                  | 0.2%                             | 79.6% | 1.7%     | 0%            | 100%  | 12.5%           | 87.5%               | 100%  |             |

### Aggregate Enrollment Data for NHLBI-funded Phase III Clinical Trials

In 2013, the percent of women enrolled in active NHLBI-supported Phase III clinical trials was below the 2010 census (Tables 8a and 8b). Similarly, while enrollment of African Americans and Hispanics was well above census levels, enrollment of other minority groups was below the 2010 census. The Institute may need to encourage investigators to improve strategies for the recruitment of women and minorities in Phase III clinical trials.

|             | American Indian/Alaskan Native |      | Asian |      | Black/African American |       | Native Hawaiian/Pacific Islander |      | White  |       | > 1 Race |      | Other/Unknown |      | Total  |       | 2010 Census |
|-------------|--------------------------------|------|-------|------|------------------------|-------|----------------------------------|------|--------|-------|----------|------|---------------|------|--------|-------|-------------|
|             | #                              | %    | #     | %    | #                      | %     | #                                | %    | #      | %     | #        | %    | #             | %    | #      | %     |             |
| Female      | 275                            | 0.3% | 298   | 0.4% | 11,820                 | 14.7% | 26                               | 0%   | 22,761 | 28.2% | 178      | 0.2% | 1,289         | 1.6% | 36,647 | 45.4% | 50.7%       |
| Male        | 374                            | 0.5% | 453   | 0.6% | 10,624                 | 13.2% | 48                               | 0.1% | 31,132 | 38.6% | 200      | 0.2% | 1,177         | 1.5% | 44,008 | 54.6% | 49.3%       |
| Unknown     |                                | 0%   |       | 0%   |                        | 0%    |                                  | 0.0% |        | 0%    |          | 0%   | 4             | 0%   | 4      | 0%    |             |
| Totals      | 649                            | 0.8% | 751   | 0.9% | 22,444                 | 27.8% | 74                               | 0.1% | 53,893 | 66.8% | 378      | 0.5% | 2,470         | 3.1% | 80,659 | 100%  | 100%        |
| 2010 Census |                                | 1.0% |       | 4.6% |                        | 12.9% |                                  | 0.2% |        | 79.6% |          | 1.7% |               | 0%   |        | 100%  |             |

|             | Hispanic/Latino |       | Not Hispanic/Latino |       | Other/Unknown |    | Total  |       |
|-------------|-----------------|-------|---------------------|-------|---------------|----|--------|-------|
| Female      | 6,030           | 7.5%  | 30,617              | 38%   | 0             | 0% | 36,647 | 45.4% |
| Male        | 5,189           | 6.4%  | 38,819              | 48.1% | 0             | 0% | 44,008 | 54.6% |
| Unknown     | 0               | 0%    | 0                   | 0%    | 4             | 0% | 4      | 0%    |
| Total       | 11,219          | 13.9% | 69,436              | 86.1% | 4             | 0% | 80,659 | 100%  |
| 2010 Census |                 | 12.5% |                     | 87.5% |               | 0% |        | 100%  |

### *Intramural Research*

#### Aggregate Enrollment in Intramural Clinical Studies Active in FY13

NHLBI Intramural clinical studies active in 2013 included a high rate of African American participation (Tables 9a and 9b). However, the percent of women, Hispanics, American Indian/Alaska Natives, and Native Hawaiian/Pacific Islanders enrolled was below the 2010 census. This may be somewhat accounted for by the large percentage of people of unknown sex and unknown race/ethnicity.

**Table 9a. Aggregate Enrollment by Sex and Race in Intramural Clinical Studies Active in FY13**

|             | American Indian/Alaskan Native |      | Asian |      | Black/ African American |       | Native Hawaiian/ Pacific Islander |      | White  |        | > 1 Race |      | Other/ Unknown |       | Total  |        | 2010 Census |
|-------------|--------------------------------|------|-------|------|-------------------------|-------|-----------------------------------|------|--------|--------|----------|------|----------------|-------|--------|--------|-------------|
|             | #                              | %    | #     | %    | #                       | %     | #                                 | %    | #      | %      | #        | %    | #              | %     | #      | %      |             |
|             | Female                         | 30   | 0.1%  | 945  | 1.9%                    | 3,884 | 8.0%                              | 14   | 0%     | 14,906 | 30.7%    | 190  | 0.4%           | 1,764 | 3.6%   | 21,733 |             |
| Male        | 56                             | 0.1% | 1,125 | 2.3% | 3,216                   | 6.6%  | 27                                | 0.1% | 14,485 | 29.9%  | 134      | 0.3% | 1,879          | 3.9%  | 20,922 | 43.1%  | 49.3%       |
| Unknown     | 0                              | 0%   | 0     | 0%   | 1                       | 0%    | 0                                 | 0.0% | 3      | 0%     | 0        | 0%   | 5,828          | 12%   | 5,832  | 12.0%  |             |
| Totals      | 86                             | 0.2% | 2,070 | 4.3% | 7,101                   | 14.6% | 41                                | 0.1% | 29,394 | 60.6%  | 324      | 0.7% | 9,471          | 19.5% | 48,487 | 100%   | 100%        |
| 2010 Census |                                | 1.0% |       | 4.6% |                         | 12.9% |                                   | 0.2% |        | 79.6%  |          | 1.7% |                | 0%    |        | 100%   |             |

**Table 9b. Aggregate Enrollment by Sex and Ethnicity in all NHLBI-supported Phase III Clinical Studies Active in FY 2013**

|             | Hispanic/Latino |       | Not Hispanic/ Latino |        | Other/ Unknown |       | Total  |        |
|-------------|-----------------|-------|----------------------|--------|----------------|-------|--------|--------|
|             | #               | %     | #                    | %      | #              | %     | #      | %      |
|             | Female          | 1,674 | 3.5%                 | 14,602 | 30.1%          | 5,457 | 11.3%  | 21,733 |
| Male        | 1,836           | 3.8%  | 14,145               | 29.2%  | 4,941          | 10.2% | 20,922 | 43.1%  |
| Unknown     | 1               | 0%    | 4                    | 0%     | 5,827          | 12%   | 5,832  | 12%    |
| Total       | 3,511           | 7.2%  | 28,751               | 59.3%  | 16,225         | 33%   | 48,487 | 100%   |
| 2010 Census |                 | 12.5% |                      | 87.5%  |                | 0%    |        | 100%   |

## Conclusion

The mandate of the NIH Revitalization Act of 1993 was to ensure inclusion of both women and minorities in all NHLBI-supported clinical studies. The data demonstrate that the Institute has done far more than that minimal standard. Women, blacks, American Indian/Alaskan Natives, Asians, Native Hawaiians/Pacific Islanders, and Hispanics/Latinos are all represented in NHLBI-supported clinical studies at rates that are near or exceed their corresponding representation in the U.S. population according to the 2010 census.