

NIA Report of FY2013-2014 Inclusion Data

I. NIA Background and Mission

NIA, one of the 27 Institutes and Centers of NIH, leads the federal government in conducting and supporting research on aging and the health and well-being of older people. The Institute seeks to understand the nature of aging and the aging process, and diseases and conditions associated with growing older, in order to extend the healthy, active years of life.

In 1974, Congress granted authority to form NIA to provide leadership in aging research, training, health information dissemination, and other programs relevant to aging and older people. Subsequent amendments to this legislation designated NIA as the primary Federal agency on Alzheimer's disease research.

Mission

The Institute's mission is to:

- Support and conduct genetic, biological, clinical, behavioral, social, and economic research on aging.
- Foster the development of research and clinician scientists in aging.
- Provide research resources.
- Disseminate information about aging and advances in research to the public, health care professionals, and the scientific community, among a variety of audiences.

Programs

NIA sponsors research on aging through extramural and intramural programs. The extramural program funds research and training at universities, hospitals, medical centers, and other public and private organizations nationwide. The intramural program conducts basic and clinical research in Baltimore, MD, and on the NIH campus in Bethesda, MD.

II. Scientific Review Compliance

Table 1. Level of Compliance with Inclusion Policy in New Extramural Grant Applications as Assessed During Scientific Peer Review

NATIONAL INSTITUTE ON AGING

| Council Dates | | Jan-13 | May-13 | Aug-13 | Oct-13 | Jan-14 | May-14 | Aug-14 | Oct-14 |
|---|-----|--------|--------|--------|--------|--------|--------|--------|--------|
| Total Number of Applications Reviewed | (#) | 1,071 | 1,369 | 323 | 1,059 | 1,038 | 1,187 | 272 | 965 |
| Number of Applications with Human Subjects | (#) | 487 | 690 | 111 | 500 | 476 | 600 | 89 | 492 |
| Number (percent) of Applications approved by IRG as submitted | (#) | 482 | 682 | 110 | 492 | 469 | 593 | 89 | 478 |
| | (%) | 98.97% | 98.84% | 99.1% | 98.4% | 98.53% | 98.83% | 100% | 97.15% |
| Number (percent) of Applications with unacceptable minority-only inclusion | (#) | 2 | 4 | 1 | 4 | 4 | 2 | 0 | 9 |
| | (%) | 0.41% | 0.58% | 0.9% | 0.8% | 0.84% | 0.33% | 0% | 1.83% |
| Number (percent) of Applications with unacceptable sex/gender-only inclusion | (#) | 1 | 0 | 0 | 0 | 2 | 1 | 0 | 0 |
| | (%) | 0.21% | 0% | 0% | 0% | 0.42% | 0.17% | 0% | 0% |
| Number (percent) of Applications with both unacceptable minority AND sex/gender inclusion | (#) | 2 | 4 | 0 | 4 | 1 | 4 | 0 | 5 |
| | (%) | 0.41% | 0.58% | 0% | 0.8% | 0.21% | 0.67% | 0% | 1.02% |
| Total Number (percent) of Applications with unacceptable minority inclusion | (#) | 4 | 8 | 1 | 8 | 5 | 6 | 0 | 14 |
| | (%) | 0.82% | 1.16% | 0.9% | 1.6% | 1.05% | 1% | 0% | 2.85% |
| Total Number (percent) of Applications with unacceptable sex/gender inclusion | (#) | 3 | 4 | 0 | 4 | 3 | 5 | 0 | 5 |
| | (%) | 0.62% | 0.58% | 0% | 0.8% | 0.63% | 0.83% | 0% | 1.02% |
| Total Number (percent) of unacceptable Applications as submitted | (#) | 5 | 8 | 1 | 8 | 7 | 7 | 0 | 14 |
| | (%) | 1.03% | 1.16% | 0.9% | 1.6% | 1.47% | 1.17% | 0% | 2.85% |

Table 2. Extramural Research Awards: Bars-To-Funding and Resolutions

NATIONAL INSTITUTE ON AGING

| Council Dates | | Jan-13 | May-13 | Aug-13 | Oct-13 | Jan-14 | May-14 | Aug-14 | Oct-14 |
|--|-----|--------|--------|--------|--------|--------|--------|--------|--------|
| Total number of awards | (#) | 184 | 236 | 81 | 167 | 204 | 229 | 97 | 65 |
| Number of awards involving Human Subjects | (#) | 78 | 105 | 21 | 77 | 82 | 122 | 28 | 30 |
| Number (percent) of awards involving Human Subjects that met the inclusion requirements as submitted | (#) | 78 | 104 | 21 | 77 | 82 | 120 | 28 | 29 |
| | (%) | 100% | 99% | 100% | 100% | 100% | 98% | 100% | 97% |
| Number (percent) of awards where minority-only bar-to-funding was removed by program staff (M_U) | (#) | 0 | 1 | 0 | 0 | 0 | 0 | 0 | 1 |
| | (%) | 0% | 1% | 0% | 0% | 0% | 0% | 0% | 3% |
| Number (percent) of awards where sex/gender-only bar-to-funding was removed by program staff (G_U) | (#) | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| | (%) | 0% | 0% | 0% | 0% | 0% | 1% | 0% | 0% |
| Number (percent) of awards where both minority AND sex/gender bar-to-funding were removed by program staff | (#) | 0 | 0 | 0 | 0 | 0 | 1 | 0 | 0 |
| | (%) | 0% | 0% | 0% | 0% | 0% | 1% | 0% | 0% |
| Total Number (percent) of awards where minority bar-to-funding was removed by program staff | (#) | 0 | 1 | 0 | 0 | 0 | 1 | 0 | 1 |
| | (%) | 0% | 1% | 0% | 0% | 0% | 1% | 0% | 3% |
| Total Number (percent) of awards where sex/gender bar-to-funding was removed by program staff | (#) | 0 | 0 | 0 | 0 | 0 | 2 | 0 | 0 |
| | (%) | 0% | 0% | 0% | 0% | 0% | 2% | 0% | 0% |
| Total Number (percent) of awards where bar-to-funding was removed | (#) | 0 | 1 | 0 | 0 | 0 | 2 | 0 | 1 |
| | (%) | 0% | 1% | 0% | 0% | 0% | 2% | 0% | 3% |

III. Inclusion and Interpretation of Data

The National Institute on Aging (NIA) as a component of the National Institutes of Health is mandated by the U.S. Congress under the NIH Revitalization Act of 1993, Public Law 103-43, Section 492B(2)(f), to report on the inclusion of women and minorities in clinical research studies. This act requires that each clinical research trial be designed and carried out in a manner sufficient to provide for valid analysis of variables that may affect women or minority groups. Since interventions or therapies may affect women and /or men or members of minority groups and their subpopulations differently, it is, therefore, recognized that scientific evidence can be very important in leading to a change in health policy or standard of care. The NIA, consequently, pursues scientific evidence for these purposes and complies with NIH guidelines and other requirements of this law. This report provides a comparison of FY2013 and FY2014 inclusion of both genders and all racial and ethnic minority groups in clinical studies at NIA.

NIA's Aggregate Extramural Enrollment Data

The enrollment data for all Extramural Research Protocols for FY2013 was 726,695 with 441 protocols and FY2014 was 748,516 with 381 protocols. This is an increase in 21,821 participants. These numbers are shown in Tables 1 and 2 with totals of all subjects reported. In FY2014, sixteen of the 381 protocols (or studies) reported an enrollment of over 10,000 (see Table 3). This table shows the Principal investigators and enrollment totals of the sixteen NIA funded studies that had 10,000 participants or more in FY 2014. The NIA Population Distribution for NIH Tracked Data for FY2013 and FY2014 is provided in Table 4. The chart provides a comparison of the population distribution including totals and percentages of all participants in clinical studies by race and ethnicity.

Phase III Clinical Trial Studies Data

The Phase III clinical trial enrollment data for FY2013 involved four protocols with an aggregate total of 723 participants. In FY2014, the Phase III clinical trial enrollment data involved three protocols, Dr. Marco Pahor - 5U01AG022376-09 "The LIFE Study", Dr. Frederick E. Sieber, - 5R01AG033615-05 "A Strategy for Reduction of Postoperative Delirium in Elderly Patients and Dr. Kevin Volpp - 5R01AG045045-03 "A randomized trial of financial incentives for maintenance of weight loss" with an aggregate total of 720 participants. There was a decrease in enrollment in FY2014 by 3 participants. This information including all subjects by race and ethnicities is provided in Tables 5 and 6.

Table 3: FY 2013 Aggregate Enrollment Data for All Extramural Research Protocols

NATIONAL INSTITUTE ON AGING

Old Form: Total of All Subjects Reported Using the 1977 OMB Standards

Number of Protocols with Enrollment Data: 0

| | American Indian/ Alaska Native | Asian | Black or African American | * Hawaiian/ Pacific Islander | Hispanic | White | * More Than One Race | Unknown/ Other | Total |
|---------|--------------------------------|-------|---------------------------|------------------------------|----------|-------|----------------------|----------------|-------|
| Female | | | | | | | | | |
| Male | | | | | | | | | |
| Unknown | | | | | | | | | |
| Total | | | | | | | | | |

* Categories not in use in Old Forms, but are provided here for consistency with the 1997 OMB Standard.

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: 441

| | Total of All Subjects by Race | | | | | | | | Total of All Subjects by Ethnicities | | | |
|---------|--------------------------------|---------|---------------------------|----------------------------|---------|--------------------|-----------------------|---------|--------------------------------------|--------------------|-----------------------|---------|
| | American Indian/ Alaska Native | Asian | Black or African American | Hawaiian/ Pacific Islander | White | More Than One Race | Unknown/ Not Reported | Total | Not Hispanic | Hispanic or Latino | Unknown/ Not Reported | Total |
| Female | 6,322 | 136,471 | 32,971 | 558 | 177,980 | 6,481 | 25,964 | 386,747 | 330,008 | 39,199 | 17,540 | 386,747 |
| | 1.63% | 35.29% | 8.53% | 0.14% | 46.02% | 1.68% | 6.71% | 53.22% | 85.33% | 10.14% | 4.54% | 53.22% |
| Male | 6,287 | 127,089 | 22,193 | 454 | 146,133 | 3,870 | 22,625 | 328,651 | 284,434 | 29,600 | 14,617 | 328,651 |
| | 1.91% | 38.67% | 6.75% | 0.14% | 44.46% | 1.18% | 6.88% | 45.23% | 86.55% | 9.01% | 4.45% | 45.23% |
| Unknown | 1 | 11 | 13 | 1 | 76 | 2 | 11,193 | 11,297 | 96 | 4,190 | 7,011 | 11,297 |
| | 0.01% | 0.1% | 0.12% | 0.01% | 0.67% | 0.02% | 99.08% | 1.55% | 0.85% | 37.09% | 62.06% | 1.55% |
| Total | 12,610 | 263,571 | 55,177 | 1,013 | 324,189 | 10,353 | 59,782 | 726,695 | 614,538 | 72,989 | 39,168 | 726,695 |
| | 1.74% | 36.27% | 7.59% | 0.14% | 44.61% | 1.42% | 8.23% | 100% | 84.57% | 10.04% | 5.39% | 100% |

Table 4: FY 2014 Aggregate Enrollment Data for All Extramural Research Protocols

NATIONAL INSTITUTE ON AGING

Old Form: Total of All Subjects Reported Using the 1977 OMB Standards

Number of Protocols with Enrollment Data: 1

| | American Indian/ Alaska Native | Asian | Black or African American | * Hawaiian/ Pacific Islander | Hispanic | White | * More Than One Race | Unknown/ Other | Total |
|---------|--------------------------------|--------|---------------------------|------------------------------|----------|--------|----------------------|----------------|--------|
| Female | 0 | 270 | 0 | | 8 | 62 | | 17 | 357 |
| | 0% | 75.63% | 0% | | 2.24% | 17.37% | | 4.76% | 52.12% |
| Male | 0 | 253 | 0 | | 9 | 45 | | 21 | 319 |
| | 0% | 79.31% | 0% | | 2.82% | 14.11% | | 6.58% | 46.57% |
| Unknown | 0 | 0 | 0 | | 0 | 0 | | 0 | 0 |
| | | | | | | | | | 0% |
| Total | 0 | 523 | 0 | | 17 | 107 | | 38 | 685 |
| | 0% | 76.35% | 0% | | 2.48% | 15.62% | | 5.55% | 100% |

* Categories not in use in Old Forms, but are provided here for consistency with the 1997 OMB Standard.

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: 381

| | Total of All Subjects by Race | | | | | | | | Total of All Subjects by Ethnicities | | | |
|---------|--------------------------------|---------|---------------------------|----------------------------|---------|--------------------|-----------------------|---------|--------------------------------------|--------------------|-----------------------|---------|
| | American Indian/ Alaska Native | Asian | Black or African American | Hawaiian/ Pacific Islander | White | More Than One Race | Unknown/ Not Reported | Total | Not Hispanic | Hispanic or Latino | Unknown/ Not Reported | Total |
| Female | 7,301 | 148,233 | 38,210 | 316 | 180,181 | 4,266 | 28,313 | 406,820 | 356,946 | 31,172 | 18,702 | 406,820 |
| | 1.79% | 36.44% | 9.39% | 0.08% | 44.29% | 1.05% | 6.96% | 54.35% | 87.74% | 7.66% | 4.6% | 54.35% |
| Male | 7,342 | 136,695 | 23,945 | 196 | 136,500 | 3,012 | 22,442 | 330,132 | 291,726 | 22,586 | 15,820 | 330,132 |
| | 2.22% | 41.41% | 7.25% | 0.06% | 41.35% | 0.91% | 6.8% | 44.1% | 88.37% | 6.84% | 4.79% | 44.1% |
| Unknown | 0 | 14 | 3 | 0 | 249 | 0 | 11,298 | 11,564 | 250 | 4,186 | 7,128 | 11,564 |
| | 0% | 0.12% | 0.03% | 0% | 2.15% | 0% | 97.7% | 1.54% | 2.16% | 36.2% | 61.64% | 1.54% |
| Total | 14,643 | 284,942 | 62,158 | 512 | 316,930 | 7,278 | 62,053 | 748,516 | 648,922 | 57,944 | 41,650 | 748,516 |
| | 1.96% | 38.07% | 8.3% | 0.07% | 42.34% | 0.97% | 8.29% | 100% | 86.69% | 7.74% | 5.56% | 100% |

Table 5
NIA Studies in FY2014 with Enrollment over 10,000
(2014 data for these studies are all included in Table 2 – New Form Totals)

| PROJECT # | PRINCIPAL INVESTIGATOR | INSTITUTION | INSTITUTION LOCATION | 2014 ENROLLMENT | NAME OF STUDY | |
|-----------|------------------------|--------------------------|--|-------------------|---------------|---|
| 1 | 5R01AG023627-10 | ZENG, YI | DUKE UNIVERSITY | DURHAM , NC | 87,037 | Demographic Analysis on Determinants of Healthy Longevity in China |
| 2 | 5R01AG026676-07 | STRAUSS, JOHN A | RAND CORPORATION | SANTA MONICA, CA | 53,043 | Twenty Years On The Fifth Indonesia Family Survey of Aging |
| 3 | 5R01AG031266-07 | FRANKENBERG, ELIZABETH A | DUKE UNIVERSITY | DURHAM , NC | 45,862 | The Evolution of Well-Being among Older Adults after a Disaster |
| 4 | 5P01AG005842-28 | WISE, DAVID A | NATIONAL BUREAU OF ECONOMIC | CAMBRIDGE, MA | 39,623 | Economics of Health, Wealth, and Well-Being |
| 5 | 5U01AG009740-25 | WEIR, DAVID R. | UNIVERSITY OF MICHIGAN | ANN ARBOR, MI | 37,815 | Health and Retirement Study Yrs 23-28 |
| 6 | 5R01AG042340-03 | DIMICK, JUSTIN BRIGHAM | UNIVERSITY OF MICHIGAN | ANN ARBOR, MI | 31,799 | Understanding Variation in Failure to Rescue in the Elderly |
| 7 | 5R01AG033713-05 | MENKEN, JANE A | UNIVERSITY OF COLORADO | BOULDER, COLORAD | 26,845 | Long-term Effects of Health and Development Interventions in Rural Bangladesh |
| 8 | 5R01AG034151-04 | BAICKER, KATHERINE | NATIONAL BUREAU OF ECONOMIC | CAMBRIDGE , MA | 23,780 | What Does Health Insurance Do? Evidence from the Oregon Health |
| 9 | 5R01AG018016-09 | WONG, REBECA | UNIVERSITY OF TEXAS MEDICAL BR | GALVESTON, TX | 21,458 | The Mexican Health and Aging Study - II |
| 10 | 5P01AG029409-07 | FREEDMAN, VICKI A | UNIVERSITY OF MICHIGAN | ANN ARBOR, MI | 14,077 | Economic Status, Health, & Well-Being Over the Life Course and Across |
| 11 | 5R01AG040213-04 | FREEDMAN, VICKI A. | UNIVERSITY OF MICHIGAN | ANN ARBOR, MI | 13,745 | Health, Wealth, and Wellbeing over the Life Course and Across Generations |
| 12 | 5R01AG024119-10 | GURVEN, MICHAEL DOUGLAS | UNIVERSITY OF CALIFORNIA SANTA BARBARA | SANTA BARBARA, CA | 12,300 | The Human Life Course and the Biodemography of Aging |
| 13 | 5R01AG033035-05 | WOLINSKY, FREDRIC D | UNIVERSITY OF IOWA | IOWA CITY | 11,737 | A Patient Activation Intervention to Enhance Bone Health |
| 14 | 5R01AG041776-03 | MILLEN, AMY ELIZABETH | STATE UNIVERSITY OF NEW YORK AT | BUFFALO , NY | 11,489 | The Role of Vitamin D in Retinal Diseases in Aging |
| 15 | 5R01AG042582-02 | CHAPMAN, BENJAMIN P | UNIVERSITY OF | ROCHESTER, NY | 11,288 | Personality-Epidemiologic Research on Inequalities in Longevity |
| 16 | 5R01AG038651-04 | KRYSCIO, RICHARD J | UNIVERSITY OF KENTUCKY | LEXINGTON , KY | 10,585 | Role of impaired cognitive states & risk factors in conversion to mixed dementias |

Table 6
A Comparison of Population Distribution for NIH Tracked Data FY 2013 and FY 2014 (New Form)
Totals and percentages of all Participants in Clinical Studies by race/Ethnicity

| # of Protocols | Fiscal Year | Total of All Subjects by | | | | | | | | Total of All Subjects by Ethnicities | | | |
|----------------|-------------|------------------------------------|---------|---------------------------|-------------------------------|---------|--------------------|--------------------------|---------|--------------------------------------|--------------------|--------------------------|---------|
| | | American Indian/ Alaskan Native | Asian | Black or African American | Hawaiian/ Pacific Islander | White | More than One Race | Unknown/ Not Reported | Total | Not Hispanic | Hispanic or Latino | Unknown/ Not Reported | Total |
| 441 | 2013 | 12,610 | 263,571 | 55,177 | 1,013 | 324,189 | 10,353 | 59,782 | 726,695 | 614,538 | 72,989 | 39,168 | 726,695 |
| | | 1.74% | 36.27% | 7.59% | 0.14% | 44.61% | 1.42% | 8.23% | 100% | 84.57% | 10.04% | 5.39% | 100% |
| 381 | 2014 | 14,643 | 284,942 | 62,158 | 512 | 316,930 | 7,278 | 62,053 | 748,516 | 648,922 | 57,944 | 41,650 | 748,516 |
| | | 1.96% | 38.07% | 8.3% | 0.07% | 42.34% | 0.97% | 8.29% | 100% | 86.69% | 7.74% | 5.56% | 100% |

Table 7: FY 2013 Aggregate Enrollment Data for Extramural Phase III Research Protocols

NATIONAL INSTITUTE ON AGING

Old Form: Total of All Subjects Reported Using the 1977 OMB Standards

Number of Protocols with Enrollment Data: 0

| | American Indian/ Alaska Native | Asian | Black or African American | * Hawaiian/ Pacific Islander | Hispanic | White | * More Than One Race | Unknown/ Other | Total |
|---------|--------------------------------|-------|---------------------------|------------------------------|----------|-------|----------------------|----------------|-------|
| Female | | | | | | | | | |
| Male | | | | | | | | | |
| Unknown | | | | | | | | | |
| Total | | | | | | | | | |

* Categories not in use in Old Forms, but are provided here for consistency with the 1997 OMB Standard.

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: 3

| | Total of All Subjects by Race | | | | | | | | Total of All Subjects by Ethnicities | | | |
|---------|--------------------------------|-------|---------------------------|----------------------------|--------|--------------------|-----------------------|--------|--------------------------------------|--------------------|-----------------------|--------|
| | American Indian/ Alaska Native | Asian | Black or African American | Hawaiian/ Pacific Islander | White | More Than One Race | Unknown/ Not Reported | Total | Not Hispanic | Hispanic or Latino | Unknown/ Not Reported | Total |
| Female | 4 | 0 | 64 | 0 | 283 | 12 | 2 | 365 | 340 | 24 | 1 | 365 |
| | 1.1% | 0% | 17.53% | 0% | 77.53% | 3.29% | 0.55% | 68.74% | 93.15% | 6.58% | 0.27% | 68.74% |
| Male | 1 | 4 | 16 | 1 | 140 | 4 | 0 | 166 | 158 | 7 | 1 | 166 |
| | 0.6% | 2.41% | 9.64% | 0.6% | 84.34% | 2.41% | 0% | 31.26% | 95.18% | 4.22% | 0.6% | 31.26% |
| Unknown | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | | | | | | 0% | | | | 0% |
| Total | 5 | 4 | 80 | 1 | 423 | 16 | 2 | 531 | 498 | 31 | 2 | 531 |
| | 0.94% | 0.75% | 15.07% | 0.19% | 79.66% | 3.01% | 0.38% | 100% | 93.79% | 5.84% | 0.38% | 100% |

Table 8: FY 2014 Aggregate Enrollment Data for Extramural Phase III Research Protocols
NATIONAL INSTITUTE ON AGING

Old Form: Total of All Subjects Reported Using the 1977 OMB Standards

Number of Protocols with Enrollment Data: 0

| | American Indian/ Alaska Native | Asian | Black or African American | * Hawaiian/ Pacific Islander | Hispanic | White | * More Than One Race | Unknown/ Other | Total |
|---------|--------------------------------|-------|---------------------------|------------------------------|----------|-------|----------------------|----------------|-------|
| Female | | | | | | | | | |
| Male | | | | | | | | | |
| Unknown | | | | | | | | | |
| Total | | | | | | | | | |

* Categories not in use in Old Forms, but are provided here for consistency with the 1997 OMB Standard.

New Form: Total of All Subjects Reported Using the 1997 OMB Standards

Number of Protocols with Enrollment Data: 3

| | Total of All Subjects by Race | | | | | | | | Total of All Subjects by Ethnicities | | | |
|---------|--------------------------------|-------|---------------------------|----------------------------|--------|--------------------|-----------------------|--------|--------------------------------------|--------------------|-------------------|--------|
| | American Indian/ Alaska Native | Asian | Black or African American | Hawaiian/ Pacific Islander | White | More Than One Race | Unknown/ Not Reported | Total | Not Hispanic | Hispanic or Latino | Unknown/ Reported | Total |
| Female | 5 | 0 | 72 | 0 | 441 | 19 | 4 | 541 | 518 | 22 | 1 | 541 |
| | 0.92% | 0% | 13.31% | 0% | 81.52% | 3.51% | 0.74% | 75.14% | 95.75% | 4.07% | 0.18% | 75.14% |
| Male | 1 | 3 | 16 | 1 | 152 | 4 | 2 | 179 | 171 | 7 | 1 | 179 |
| | 0.56% | 1.68% | 8.94% | 0.56% | 84.92% | 2.23% | 1.12% | 24.86% | 95.53% | 3.91% | 0.56% | 24.86% |
| Unknown | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| | | | | | | | | 0% | | | | 0% |
| Total | 6 | 3 | 88 | 1 | 593 | 23 | 6 | 720 | 689 | 29 | 2 | 720 |
| | 0.83% | 0.42% | 12.22% | 0.14% | 82.36% | 3.19% | 0.83% | 100% | 95.69% | 4.03% | 0.28% | 100% |

Table 9. Distribution of Human Subjects by Sex and Race in All Research Studies Receiving Funding in FY 2013
NATIONAL INSTITUTE ON AGING

| | Extramural Studies | | Intramural Studies | |
|---|--------------------|---------------------------|--------------------|----------|
| | Phase III trials* | Other Clinical research** | On-Site | Off-Site |
| Protocols reporting women only | 0 | 26 | 0 | 6 |
| Protocols reporting men only | 0 | 21 | 0 | 4 |
| Protocols reporting both women and men | 3 | 354 | 0 | 32 |
| Protocols reporting men, women and unknown*** | 0 | 31 | 0 | 3 |
| Protocols reporting sex composition as unknown only | 0 | 2 | 0 | 4 |
| Protocols reporting men and unknown | 0 | 0 | 0 | 0 |
| Protocols reporting women and unknown | 0 | 0 | 0 | 0 |
| Early Stage studies where enrollment data has not yet submitted | 1 | 176 | 0 | 3 |
| Totals | 4 | 610 | 0 | 52 |

* According to the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Phase III clinical investigations usually involve several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with standard or control intervention or comparing two or more existing treatments.

** Human subject studies that are not Phase III trials.

*** Many studies may be generic.

Table 10. Distribution of Human Subjects by Sex and Race in All Research Studies Receiving Funding in FY 2014
NATIONAL INSTITUTE ON AGING

| | Extramural Studies | | Intramural Studies | |
|---|--------------------|-------------------------|--------------------|-----------|
| | Phase III trials* | Other Clinical trials** | On-Site | Off-Site |
| Protocols reporting women only | 0 | 24 | 0 | 3 |
| Protocols reporting men only | 0 | 15 | 0 | 4 |
| Protocols reporting both women and men | 3 | 308 | 0 | 24 |
| Protocols reporting men, women and unknown*** | 0 | 30 | 0 | 2 |
| Protocols reporting sex composition as unknown only | 0 | 3 | 0 | 3 |
| Protocols reporting men and unknown | 0 | 0 | 0 | 0 |
| Protocols reporting women and unknown | 0 | 0 | 0 | 0 |
| Early Stage studies where enrollment data has not yet submitted | 2 | 228 | 0 | 2 |
| Totals | 5 | 608 | 0 | 38 |

* According to the NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Phase III clinical investigations usually involve several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with standard or control intervention or comparing two or more existing treatments.

**Human subject studies that are not Phase III trials.

***Many studies may be generic.

IV. Additional information

The Aggregate enrollment data for 2013 show that over 36% of the research participants were Asian. In 2014 a little over 38% of the participants were Asian. Table 5 (FY 2014 studies with enrollment over 10,000) shows the reason for these high proportions. The award with the largest number of participants (87,037) is a study-based in China. The award with the second largest number of participants (53,043) is based in Indonesia. Also the award with the seventh largest number of participants (26,845) is based in Bangladesh. The participants from these three studies total a little under 60% of the total Asian sample across all 381 protocols in the FY 2014 data. In short the Asian numbers are particularly distorted by the presence of three large epidemiological/demographic studies based in Asia. The FY 2013 data show a similar pattern of distortion.