

Appendices

Appendix D: Monitoring Adherence to the NIH Policy on the Inclusion of Women and Minorities as Subjects in Clinical Research (excerpt)

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Department of Health and Human Services
National Institutes of Health

MONITORING ADHERENCE TO THE
NIH POLICY ON THE INCLUSION
OF WOMEN AND MINORITIES
AS SUBJECTS IN CLINICAL RESEARCH

Comprehensive Report: Tracking of Human Subjects Research
As Reported in Fiscal Year 2007 and Fiscal Year 2008

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Preface

To demonstrate effective implementation of Public Law 103-43 and implementation of NIH policies on the tracking and inclusion of women and minorities in clinical research, the Office of Research of Women's Health (ORWH), in collaboration with the Office of Extramural Research (OER) and the Office of Intramural Research (OIR), has led monitoring efforts for compliance including convening a trans-NIH Tracking and Inclusion Committee. Monitoring efforts have included the documentation of the numbers of males and females by race and ethnicity enrolled in clinical studies funded by NIH, as well as biennial statements from each Institute and Center (IC) Advisory Councils to confirm compliance with NIH policies. These and other efforts serve to ensure that NIH procedures comply with the NIH policy on the inclusion of women and minorities in clinical studies.

Data monitoring for the magnitude and diversity of clinical studies funded by NIH is not a simple task. There has been an extensive and dedicated effort to provide accurate and reproducible data. However, transitions in information system software at the NIH have introduced the need for modifications for monitoring inclusion and data collection.

The Acting Director of NIH has now established a task force to be co-chaired by the Director of ORWH, the Director of the National Center for Minority Health and Health Disparities (NCMHD), and an IC Director to examine the entire process for evaluating and monitoring the inclusion of women and minorities in clinical research funded by NIH; and the results of the deliberations of this task force should be reflected in the next biennial report. However, the FY2007 and FY2008 data in this document reflect the data reporting and current trends of the inclusion of participants in NIH clinical research.

This report would not be possible without the efforts of the members of the NIH Tracking and Inclusion Committee and the eRA Population Tracking User Group (ePTUG) who have each provided many hours addressing a multiplicity of issues related to data entry, reconciliation of grants, contracts and cooperative agreements, and other related issues or concerns.

**Monitoring Adherence to the NIH Policy on the Inclusion
of Women and Minorities as Subjects in Clinical Research
Summary Report of NIH Inclusion Data**

NIH AGGREGATE POPULATION DATA REPORTED IN FY2007 and FY2008

Because new clinical research studies begin each year while other studies may be ending, the inclusion figures will vary from year to year due to the scientific topics under study and the prevalence of those conditions within each individual study. These data help to establish trends on the inclusion of women and minorities as subjects in clinical research. Data on inclusion are tabulated from human subject populations in NIH-defined Phase III clinical trials and other human subject research studies and are based on self identification by the participants. NIH clinical research studies are determined in accordance with the NIH definition of clinical research to include, for example, non-intervention clinical research, non Phase III clinical trials, epidemiological studies, behavioral studies, and database studies.

Analysis of aggregate NIH data on inclusion for FY2007 and FY2008 documents participants of all ages, that substantial numbers of women and men, non-minority men, and minorities of all ages have been included as research subjects in NIH clinical trials and other human subject research studies during these fiscal years. However, caution should be utilized to avoid over-interpreting the figures that are provided. The NIH Tracking and Inclusion Committee have provided for the reader's interest conclusions that can be reasonably drawn from the data.

Previous inclusion reports and aggregate enrollment figures for women, men and minority groups for FY1994 to the present can be found on the ORWH website at <http://orwh.od.nih.gov/inclusion.html>.

NIH CLINICAL RESEARCH: Fiscal Years 2007 and 2008

In FY2007 there were 15,567 extramural and intramural clinical research protocols, including Phase III and other clinical studies, of which 10,914 protocols reported human subject participation as noted in this report's trend summary tables (*Table 1A*). Of these, 95.9% were domestic protocols and 4.1% were foreign protocols. (*Table 1E*) Approximately 17.4 million participants were enrolled in extramural and intramural research protocols of which 92.7% were domestic participants and 7.3% were foreign participants. Of the 17.4 million participants, 58.2% were women, 39.5% were men and 2.3% did not provide sex identification. (*Table 1A*) Further, 29.9% of the total participants, and 26.5% of the Domestic-only participants, were reported as minorities following the current OMB categories for race and ethnicity. (*Table 1F and 2C*)

Correspondingly, in FY2008 there were 15,598 extramural and intramural clinical research protocols, including Phase III and other clinical studies, of which 11,045 protocols reported human subject participation as noted in this report's trend summary tables. (*Table 1A*) Of these, 95.5% were domestic protocols and 4.5% were foreign protocols. (*Table 1E*) Approximately 15.4 million participants were enrolled in extramural and intramural research protocols of which 91.7% were domestic participants and 8.3% were foreign participants. Of the 15.4 million participants, 60.0% were women, 38.9% were men and 1.1% did not provide sex identification. (*Table 1A*) Further 28.6% of the total participants, and 24.9% of the Domestic-protocol participants, were reported as minorities following the current OMB categories for race and ethnicity. (*Table 1F & Table 3C*)

While the number of participants in all extramural and intramural clinical research decreased (17.4M in FY2007 and 15.4M in FY2008), there was no significant change in the proportion of women and men (58.2%F and 39.5%M in FY2007; and 60.0%F and 38.9%M in FY2008). (Table 1A)

NIH Defined Phase III Clinical Research: FY2007 and FY2008

In FY2007 there were 749 extramural and intramural Phase III clinical research protocols, of which 653 protocols reported human subject participation as noted in this report's trend summary tables. (Tables 4A and 5A) Of these, 93.3% were domestic protocols and 6.7% were foreign protocols. Clinical studies not included in this analysis are those studies that have just begun and have not reported enrollment data or have not begun recruiting patients. (Table 4E) A total of 591,159 participants were enrolled in extramural and intramural Phase III research protocols of which 72.5% were domestic participants and 27.5% were foreign participants. Of the 591,159 participants, 54.9% were women, 42.2% were men and 2.8% did not provide sex identification. (Table 4A) Further, 41.4% of the total participants, and 20.6% of Domestic-protocol participants, in Phase III clinical research were reported as minorities following the current OMB categories for race and ethnicity. (Table 5C)

Of the 197 extramural and intramural Phase III research protocols that report following the former OMB standards in FY2007, minority representation was highest for Blacks (not Hispanic) at 10.3% and lowest for American Indian/Alaska Natives at 0.4%. Hispanics represented approximately 4.5%, Asian/Pacific Islanders were 1.9% and Whites (not Hispanic) 81.0% of the participants. The categories *Hawaiian/Pacific Islander* and *More Than One Race* were not designations with the former OMB standards. (Table 4B)

Moreover, in FY 2007, there were 424 extramural and intramural Phase III research protocols reporting data following the current OMB standards for reporting by both race and ethnicity. Accordingly, minority representation by race was highest for Blacks at 22.1% and lowest for Hawaiian/Pacific Islanders 0.1%. Asians represented 12.4%, American Indian/Alaska Natives 2.5% and Whites 34.9% of participants. Participants identifying as *More Than One Race* were 1.1% of the total number of participants. In addition, 26.9% did not identify a race category. (Table 4C) Of the 424 extramural and intramural Phase III research protocols designating an ethnicity in FY2007, 66.8 % of total participants identified as "Not Hispanic", 18.8 % of the total participants identified as "Hispanic or Latino", and 14.5% of the total participants did not identify an ethnicity category. The racial distribution of the "Hispanic or Latino" participants is also provided separately. (Table 4D)

Correspondingly, in FY2008 there were 726 extramural and intramural Phase III clinical research protocols, of which 639 protocols reported human subject participation as noted in this report's trend summary tables. (Tables 4A and 6A) Of these, 91.5% were domestic protocols and 8.5% were foreign protocols. Clinical studies not included in this analysis are those studies that have just begun and have not reported enrollment data or have not begun recruiting patients. A total of 792,578 participants were enrolled in extramural and intramural Phase III research protocols of which 74.6% were domestic participants and 25.4% were foreign participants. (Table 4E) Of the 792,578 participants, 57.5% were women, 40.3% were men and 2.2% did not provide sex identification. (Table 4A) Further, 38.9% of the total participants, and 20.2% of Domestic-only participants, in Phase III clinical research were reported as minorities following the current OMB categories for race and ethnicity. (Table 6C)

Of the 164 extramural and intramural Phase III research protocols that report following the former OMB standards in FY2008, minority representation was highest for Blacks (not Hispanic) at 9.7% and lowest for American Indian/Alaska Natives at 0.4%. Hispanics represented approximately 4.1%, Asian/Pacific Islanders were 2.0% and Whites (not Hispanic) 82.0% of the participants. The categories *Hawaiian/Pacific Islander* and *More Than One Race* were not designations with the former OMB standards. (Table 4B)

Moreover, in FY 2008, there were 475 extramural and intramural Phase III research protocols reporting data following the current OMB standards for reporting by both race and ethnicity. Accordingly, minority representation by race was highest for Blacks at 18.4% and lowest for Hawaiian/Pacific Islanders 0.1%. Asians represented 17%, American Indian/Alaska Natives 2.7% and Whites 50.2% of participants. Participants identifying as *More Than One Race* were 2.2% of the total number of participants. In addition, 9.4% did not identify a race category. Of the 475 extramural and intramural Phase III research protocols designating an ethnicity in FY2008, 82.3 % of total participants identified as “Not Hispanic”, 11.5 % of the total participants identified as “Hispanic or Latino”, and 6.2% of the total participants did not identify an ethnicity category. The racial distribution of the “Hispanic or Latino” participants is also provided separately. (Table 4C)

While the number of participants in Phase III extramural and intramural clinical research increased (591,159 in FY2007 and 792,578 in FY2008), there was a slight change in the proportions of women and men (54.9%F and 42.2% in FY2007 and 57.5%F and 40.3%M in FY2008). (Table 4A)

The following sections provide data on extramural research and intramural research separately.

EXTRAMURAL CLINICAL RESEARCH: Fiscal Years 2007 and 2008

In FY2007, there were 13,719 extramural clinical research protocols, including Phase III and other clinical studies, of which 9,362 protocols reported human subject participation. Of these, 82.3% were domestic protocols and 3.5% were foreign protocols. (Table 7A) Approximately 13.9 million participants were enrolled in extramural research protocols of which 92.8% of the total enrollment is domestic participants and 7.2% of the total enrollment is foreign participants. (Table 7B) Of the 13.9 million participants, 61.80% were women, 35.54% were men and 2.62% did not provide sex identification. Further, 31.44% of the total participants were reported as minorities following the current OMB categories for race and ethnicity. (Table 8A)

Correspondingly, in FY2008, there were 11,045 extramural clinical research protocols, including Phase III and other clinical studies, of which 9,381 protocols reported human subject participation. Of these, 81.2% were domestic protocols and 3.7% were foreign protocols. (Table 9A) Approximately 12.6 million participants were enrolled in extramural research protocols of which 91.7% of the total enrollment is domestic participants and 8.3% of the total enrollment is foreign participants. (Table 9B) Of the 12.6 million participants, 63.84% were women, 35.04% were men and 1.12% did not provide sex identification. Further, 29.4% of the total participants were reported as minorities following the current OMB categories for race and ethnicity. (Table 10A)

While the number of participants in extramural clinical research protocols decreased (13.9 million in FY2007 and 12.6 million in FY2008), there was no significant change in the proportions of women and men (61.8%F and 35.5%M in FY2007 and 63.8%F and 35.0%M in FY2008). (Table 8A and Table 10A) However, when sex-specific studies were excluded, the proportions of women and men in all extramural clinical research reported in FY2008 were similar to the proportions in the general population reported in FY2009 (from 46.5% to 45.61% for females and 49.8% to 52.6% for males. (Table 11A and Table 12A)

NIH Defined Phase III Extramural Clinical Research: FY2007 and FY2008

In FY2007 there were 71 extramural Phase III clinical research protocols, of which 617 protocols reported human subject participation. (Table 13A) A total of 547,687 participants were enrolled in extramural Phase III research protocols of which 55.10% were women, 41.83% were men and 3.07% did not provide sex identification. (Table 14A)

In FY2007 there were 399 extramural Phase III research protocols reporting data following the current OMB standards for reporting race and ethnicity. Minority representation by race was highest for Blacks at 23.21% and lowest for Hawaiian/Pacific Islanders 0.13%. Asians represented 13.09%, American Indian/Alaska Natives 2.59% and Whites 34.29% of participants. Participants identifying as *More Than One Race* were 1.02% of the total number of participants. In addition, 25.7 % did not identify a race category. Of the 399 extramural Phase III research protocols designating an ethnicity in FY 2007, 67.77 % of total participants identified as “Not Hispanic”, 17.78% of the total participants identified as “Hispanic or Latino”, and 14.44 % of the total participants did not identify an ethnicity category. The racial distribution of the “Hispanic or Latino” participants is also provided separately. (Table 14B)

In FY2008 there were 696 extramural Phase III clinical research protocols, of which 602 protocols reported human subject participation. (Table 15A) A total of 776,034 participants were enrolled in extramural Phase III research protocols of which 57.22% were women, 40.58% were men and 2.2% did not provide sex identification. (Table 16A)

Correspondingly in FY2008, there were 452 extramural Phase III research protocols reporting data following the current OMB standards for reporting race and ethnicity. Minority representation by race was highest for Blacks at 18.68% and lowest for Hawaiian/Pacific Islanders 0.12%. Asians represented 17.41%, American Indian/Alaska Natives 2.74% and Whites 51.22% of participants. Participants identifying as *More Than One Race* were 2.22% of the total number of participants. In addition, 7.62 % did not identify a race category. Of the 452 extramural Phase III research protocols designating an ethnicity in FY 2008, 83.84 % of total participants identified as “Not Hispanic”, 10.38% of the total participants identified as “Hispanic or Latino”, and 5.78 % of the total participants did not identify an ethnicity category. The racial distribution of the “Hispanic or Latino” participants is also provided separately. (Table 16B)

While the number of extramural Phase III clinical research protocols decreased (711 in FY2007 and 696 in FY2008) (Table 13A and Table 15A), there was a slight increase in the proportion of women (55.1 %F and 41.8%M in FY2007 and 57.2%F and 40.6%M in FY2008). (Tables 14A and 16A)

INTRAMURAL CLINICAL RESEARCH: Fiscal Years 2007 and 2008

In FY2007 there were 1,848 intramural clinical research protocols, including Phase III and other clinical studies, of which 1,552 protocols reported human subject participation. (Table 7A) Approximately 3.5 million participants were enrolled in intramural research protocols of which 43.39% were women, 55.42% were men and 1.20% did not provide sex identification. (Table 16A)

In FY2007, approximately 3.5 million participants were reported in all intramural research including Phase III clinical trials, and other clinical studies. Of the 449 intramural research protocols that report data following the former OMB standards, minority representation was highest for Blacks (not-Hispanic) at 17.6% and lowest for American Indian/Alaska Natives at 0.2%. Asian/Pacific Islanders represented 3.65%, Hispanics 4.31%; and Whites (not Hispanic) 73.16% of the intramural research study population. The categories *Hawaiian/Pacific Islander* and *More Than One Race* were not designations with the former OMB standards. (Table 17C)

For the 1,103 intramural clinical research studies that reported data following the current OMB standards in FY 2007, the largest racial minority group was Blacks at 9.72 % and the smallest racial minority group was Hawaiian/Pacific Islanders at 0.16%. Asian represented 7.66%, American Indian/Alaska Natives 0.89% and Whites 69.85% of participants in all intramural clinical research. Approximately 0.56% of participants reported *More Than One Race* as their racial category. In addition, 11.16 % did not identify a

race category. Of the 1,103 intramural research protocols following the current OMB standards designating an ethnicity in FY2007, 85.50 % of total participants identified as “Not Hispanic”, 4.19 % of the total participants identified as “Hispanic or Latino”, and 10.31 % of the total participants did not identify an ethnicity category. The racial distribution of the “Hispanic or Latino” participants is also provided separately. (Table 17B)

Correspondingly, in FY2008 there were 1,873 intramural clinical research protocols, including Phase III and other clinical studies, of which 1,664 protocols reported human subject participation. (Table 9A) Approximately 2.8 million participants were enrolled in intramural research protocols of which 42.82% were women, 55.93% were men and 1.25% did not provide sex identification. (Table 18A)

In FY 2008, approximately 2.8 million participants were reported in all intramural research including Phase III clinical trials, and other clinical studies. Of the 413 intramural research protocols that report data following the former OMB standards, minority representation was highest for Blacks (not-Hispanic) at 30.34% and lowest for American Indian/Alaska Natives at 0.15%. Asian/Pacific Islanders represented 3.38%, Hispanics 4.0%; and Whites (not Hispanic) 60.73% of the intramural research study population. The categories *Hawaiian/Pacific Islander* and *More Than One Race* were not designations with the former OMB standards. (Table 18C)

For the 1,251 intramural clinical research studies that reported data following the current OMB standards in FY 2008, the largest racial minority group was Asians at 9.8 % and the smallest racial minority group was Hawaiian/Pacific Islanders at 0.2%. Blacks represented 9.4%, American Indian/Alaska Natives 0.81% and Whites 67.92% of participants in all intramural clinical research. Approximately 0.61% of participants reported *More Than One Race* as their racial category. In addition, 11.30 % did not identify a race category. Of the 1,251 intramural research protocols following the current OMB standards designating an ethnicity in FY2008, 85.30 % of total participants identified as “Not Hispanic”, 4.07% of the total participants identified as “Hispanic or Latino”, and 10.62 % of the total participants did not identify an ethnicity category. The racial distribution of the “Hispanic or Latino” participants is also provided separately. (Table 18B)

While the number of participants specifically in Phase III intramural clinical research protocols significantly decreased (3.5M in FY2007 and 2.8M in FY2008), there was no substantive change in the proportions of women and men (43.4%F and 55.4% M in FY2007 and 42.8%F and 55.9%M in FY2008). (Tables 17A and Table 18A)

NIH Defined Phase III Intramural Clinical Research: FY2007 and FY2008

In FY2007 there were 38 intramural Phase III clinical research protocols, of which 36 protocols reported human subject participation. Of these, 88.8%, of the total number of protocols are domestic and 11.1% of the total number of protocols is foreign. (Table 13A) A total of 43,472 participants were enrolled in intramural Phase III research protocols of which 77.1 are domestic participants and 22.9% are foreign participants. (Table 13B) Of the 43,472 participants, 52.8% were women, 47.2% were men and 0% did not provide sex identification. (Table 19A) Further, 27.3% of total participants in Phase III intramural clinical research protocols were reported as minorities following the current OMB categories for race and ethnicity. (Table 13C)

Correspondingly, in FY2008 there were 39 intramural Phase III clinical research protocols, of which 37 protocols reported human subject participation. Of these, 89.1% of the total number of protocols is domestic and 10.8% of the total number of protocols is foreign. (Table 15A) A total of 16,544 participants were enrolled in intramural Phase III research protocols of which 36.7% of the total enrollment is

domestic participants and 63.2% are foreign participants. *(Table 15B)* Of the 16,544 participants, 69.71% were women, 28.92% were men and 1.37% did not provide sex identification. Further, 56.67% of total participants in Phase III clinical research protocols were reported as minorities following the current OMB categories for race and ethnicity. *(Table 20A)*

While the number of participants specifically in Phase III intramural clinical research protocols significantly decreased (43,472 in FY2007 and 16,544 in FY2008), there was a substantial increase in the proportions of women (52.8%F and 47.2% M in FY2007 and 69.7%F and 28.9%M in FY2008). *(Tables 19A and Table 20A)*

TREND REPORT ON NIH AGGREGATE POPULATION DATA: FY1995 – FY2008

Trend data vary over time because the data for each year represent the net total of data resulting from: (1) studies continuing from the prior year; (2) the addition of new studies reported; and (3) the subtraction of studies that are no longer reported.

Table 21 is a fourteen year summary report showing a steady increase in the number of protocols and enrollment. The number of protocols with enrollment increased from 3,188 in FY1995 to 11,045 in FY2008 – a 3.5 fold increase. Reported enrollment increased from approximately 1.0 million (FY1995) to 15.4 million (FY2008) – a 15.1 fold increase; minority enrollment increased from approximately 0.4 million (FY1995) to 4.3 million (FY2008) – an 11.7 fold increase in minority representation in NIH clinical research. (*Table 21A*) The total number of protocols reported with enrollment data has increased such that, since FY2003 the number is in excess of 10,000 protocols per year. (*Table 21B*)

With the deployment of an updated population tracking system in 2002 and the OMB requirement to report data using the current format, NIH was able to report domestic and foreign data in a better way. Thus, trend data are available for domestic and foreign protocols and participation beginning in FY2002. Domestic enrollment increased from 10.2 million (FY2002) to 14.1 million (FY2008) – a 1.4 fold increase. Foreign enrollment increased from 0.9 million (FY2002) to 1.3 million (FY2008) – a 1.4 fold increase. (*Table 21A*) Overall, the total enrollment has increased with domestic participation ranging between 75.9-92.7% and foreign participation ranging between 7.3-24.1%. In FY2008, domestic and foreign enrollment was 91.7% and 8.3% respectively. (*Table 21C*)

Table 1 is a summary report of all extramural and intramural clinical research by sex/gender and minority representation following the old and new data formats for domestic and foreign studies. The report demonstrates that female participation in all extramural and intramural research generally ranged between 51.7% and 63.9%, male participation in all extramural and intramural research ranged between 34.0% and 45.0%. (*Table 1A*) Overall minority participation in all extramural and intramural clinical research ranged between 28.6% and 43.1%. (*Tables 1B-D*) *Table 1E* provides a comparison of domestic and foreign participation between FY2002 and FY2008. The vast majority of protocols are domestic (~94%-96%) of the total clinical research protocols. While the number of foreign protocols has increased, they incorporate only about 4%-6% of the total clinical research protocols with enrollment. *Table 1F* shows domestic and foreign enrollment for the seven-year period. Domestic minority enrollment varied between 24.1% and 28.9% of total domestic participation, while foreign minority enrollment varied between 67.7% and 90.9% of total foreign participation.

Table 4 is a summary of NIH-funded Phase III extramural and intramural clinical research by sex/gender and minority enrollment following the old and new data reporting formats for domestic and foreign studies. This table demonstrates that female participation in NIH funded Phase III extramural and intramural clinical research generally ranged between 54.1% and 74.8% and male participation in NIH-funded Phase III extramural and intramural clinical research ranged between 24.3% and 44.6%. (*Table 4A*) Overall minority participation in NIH-funded Phase III extramural and intramural clinical research ranged from 26.9% to 41.4%. (*Tables 4B-D*) *Table 4E* provides a comparison of domestic and foreign participation between FY2002 and FY2008. The vast majority of protocols are domestic, ranging from 75.5% and 95.8% of the total clinical research protocols. While the number of foreign protocols has decreased, they incorporate only about 4.2%-9.6% of the total clinical research protocols with enrollment in the last seven years. *Table 4F* shows domestic and foreign enrollment for the seven-year period. Domestic minority enrollment varied between 20.2% and 25.4% of total domestic participation, while foreign minority enrollment in NIH-funded Phase III clinical research varied between 48.4% and 96.2% of total foreign participation. In comparing both domestic and foreign Phase III enrollment over the seven

year period shows that the small percentage of foreign protocols in FY2008 account for a significant proportion of the total foreign enrollment.

Tables 22-25 summarize domestic and foreign participation for NIH funded clinical research and NIH-funded Phase III clinical research. For extramural and intramural clinical research, domestic participants enrolled in domestic protocols, female participation ranged between 58.1% and 67.3% while male participation ranged between 31.2 and 39.5%. (Table 22A) For NIH-funded Phase III extramural and intramural clinical research, domestic participants enrolled in domestic protocols, female participation ranged between 53.3 and 64.6% while male participation ranged between 34.4 and 44.8%. (Table 23A) For all extramural and intramural clinical research, foreign participants enrolled in foreign protocols, female participation varied from 39.2% to 59.5% while male participation varied from 39.3% to 60.4%. (Table 24A) For NIH-funded Phase III extramural and intramural clinical research, foreign participants enrolled in foreign protocols, female participation varied from 47.4% to 59.2% while male participation varied from 40.4% to 52.5%. (Table 25A)